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Department of Health and Human Services

Health Care Financing Administration

42 CFR Part 400, et al.

Medicaid Program; Medicaid Managed Care; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

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

[HCFA–2001–FC]

RIN 0938–AI70

Medicaid Program; Medicaid Managed Care

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

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period amends the Medicaid regulations to implement provisions of the Balanced Budget Act of 1997 (BBA) that allow the States greater flexibility by permitting them to amend their State plan to require certain categories of Medicaid beneficiaries to enroll in managed care entities without obtaining waivers if beneficiary choice is provided; establish new beneficiary protections in areas such as quality assurance, grievance rights, and coverage of emergency services; eliminate certain requirements viewed by State agencies as impediments to the growth of managed care programs, such as the enrollment composition requirement, the right to disenroll without cause at any time, and the prohibition against enrollee cost-sharing. In addition, this final rule expands on regulatory beneficiary protections provided to enrollees of prepaid health plans (PHPs) by requiring that PHPs comply with specified BBA requirements that would not otherwise apply to PHPs.

DATES: Effective Date: These regulations are effective on April 19, 2001. Provisions that must be implemented thorough contracts with managed care organizations, prepaid health plans, health insuring organizations, or enrollment brokers are effective with respect to contracts that are up for renewal or renegotiation on or after April 19, 2001, but no longer than April 19, 2002.

Comment Date: We will consider comments on the upper payment limits in § 438.(c) if we receive them at the appropriate address, as provided below, no later than 5 p.m. on March 20, 2001.

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–FC, P.O. Box 8010, Baltimore, MD 21244–8010 .

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

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses: Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5–16–03, 7500 Security Boulevard, Baltimore, MD 21244–8010.

Comments mailed to the above addresses may be delayed and received too late for us to consider them.

Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–2001–FC. 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 office at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 to 5 p.m. (phone: (202) 690–7890).

FOR FURTHER INFORMATION CONTACT:

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I. Background

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 with ''beneficiary'').

Increasingly, however, State agencies have provided Medicaid coverage through managed care contracts, under which a managed care organization (MCO) 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 these 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), State agencies were required to obtain a waiver of a statutory ''freedom of choice requirement'' in order to operate these mandatory managed care programs. No such waiver was required for arrangements involving voluntary enrollment in managed care.

The Balanced Budget Act of 1997

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 final rule with comment period implements 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. It also strengthens existing regulatory requirements that apply to prepaid health plans (PHPs) by applying to PHPs certain requirements that the BBA imposes on MCOs.

Several principles guided the development of the final rule. First, the rule was developed with a clear emphasis on consumer protections. 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.

Second, 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 recognized that uniform, national standards were not always appropriate in all instances and tried to identify areas where States needed flexibility to develop their own standards, unless an overriding beneficiary interest needed to be taken into account. The regulations were also 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 final rule attempt to provide State agencies with the tools needed to become better purchasers.

Third, wherever we determined it was appropriate to develop Medicaid regulatory language that is parallel to the language used in the final Medicare+Choice (M+C) regulations published on June 9, 2000 (65 FR 40170), we did so. The latter M+C final rule implements Medicare managed care provisions in the BBA, many of which are similar to the Medicaid provisions implemented in this final rule.

Fourth, with respect to the quality-related provisions, we opted to take a more conservative approach and not impose greater regulatory burden without a strong evidence base.

Finally, the BBA directed the Secretary of the Department of Health and Human Services to:

> conduct a study concerning the safeguards (if any) that may be needed to ensure that the health care needs of individuals with special health care needs and chronic conditions who are enrolled with Medicaid managed care organizations are adequately met. (Section 4705(c)(2) of the Balanced Budget Act of 1997.)

In response to this charge from the Congress, during October 1998 to August 1999, HCFA conducted a study of existing research, data, and other information in a variety of areas related to the needs of special populations. HCFA has already taken steps to address many of these recommendations through revisions to the 1915(b) waiver process and provision of technical assistance and training activities to States. HCFA's responses in this final rule with comment period to comments on the proposed rule pertaining to safeguards for populations with special health care needs have been informed by our analysis of information gathered for the report to Congress. The final rule reflects revisions in response to comments based on this analysis.

This final rule with comment period creates a new part 438 in title 42 of the Code of Federal Regulations. 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 appear in the new part 438. By creating this new part, we are attempting to help users of the regulations to better comprehend the overall regulatory framework for Medicaid managed care. More detailed discussions of the content of each of the subparts of this final rule are found at the beginning of the section of the preamble discussing each subpart.

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 under that section and contracting MCOs comply with applicable requirements in new section 1932. 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 waiver authority under sections 1915(b) or 1115 of the Act. Under the law prior to the BBA, a State agency was required to request Federal waiver authority under section 1915(b) or pursuant to a demonstration authority under section 1115 in order to restrict beneficiaries' Medicaid 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 meeting a new definition in section 1905(t) of the Act; establishes new requirements for managed care enrollment and choice of coverage; and requires MCOs, primary care case managers (PCCMs), 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 and must be covered; 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.

Proposed Rule

On September 29, 1998, we published a proposed rule setting forth proposed regulations implementing the above statutory provisions, as well as proposing to strengthen regulatory PHP requirements by incorporating by regulation requirements that would otherwise apply only to MCOs. (63 FR 52022) A summary of the specific provisions of the proposed regulations upon which we received public comments is set forth at the beginning of the discussion below of the comments we received. For a fuller discussion of our basis and purpose for the approach taken in the September 29, 1998 proposed rule, see the preamble to that document, at 63 FR 52022 through 52074.

We received 305 comments on the September 29, 1998 proposed rule. The comments were extensive and generally pertained to all the sections contained in the proposed rule. We carefully reviewed all of the comments and revisited the policies contained in the proposed rule that related to the comments.

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

A. General Provisions of the Proposed Rule (Subpart A)

1. Basis and Scope (Proposed § 438.1)

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

2. Definitions (Proposed §§ 438.2, 430.5)

Section 438.2 of the proposed rule included definitions of terms that would apply for purposes of proposed part 438. The proposed definitions and relevant comments and our responses are provided below. 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 carry out 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.

We also received comments on definitions of ''comprehensive risk contract'' in § 430.5, which defines a ''Comprehensive risk contract'' as a 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; and (9) home health services. We have moved this definition, along with the following other managed care-related definitions, from part 430 to § 438.2. In addition, we have clarified the definition of health insuring organization so that it does not appear to require that the health insuring organization's (HIO's) providers be capitated.

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

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

Health insuring organization means an entity that, in exchange for capitation payments, covers services for recipients—

(1) Through payments to, or arrangements with, providers;

(2) Under a risk contract.

Nonrisk contract means a contract under which the contractor—

(1) Is not at financial risk for changes in utilization or for costs incurred under the contract that do not exceed the upper payment limits specified in § 447.362 of this chapter; and

(2) May be reimbursed by the State at the end of the contract period on the basis of the incurred costs, subject to the specified limits.

Comments on Definitions

Comment: Several commenters believe that we should delete the reference to 20 CFR part 404, subpart R in the definition of authorized representative. The commenters believe that these rules, which generally govern representative payees for Social Security programs, have little, if any, relevance to the Medicaid program and that these requirements would limit assistance to beneficiaries in the Medicaid managed care enrollment process. They indicated that current rules recognize that beneficiaries may require assistance in a variety of circumstances and provide that applicants and recipients may obtain that assistance from a variety of sources. For example, commenters pointed out that in formal proceedings such as fair hearings, Medicaid beneficiaries enjoy the right to ''represent themselves, use legal counsel, a relative, friend or other spokesman.'' (§ 431.206.) If the applicant is incompetent or incapacitated, anyone acting responsibly for the applicant can make application on the applicant's behalf (§ 435.907). People with disabilities who are incompetent or incapacitated can currently be represented by anyone acting responsibly on their behalf. Commenters indicated that State law is available and is used to step in when a person cannot make medical decisions on his or her behalf.

Response: We concur with the commenters and have deleted the reference to 20 CFR part 404. We have also deleted the reference to ''authorized,'' using only the term ''representative'' to allow for a broad range of representatives, consistent with existing policies and practices. The definition, which has been moved to § 430.5, now reads ''Representative has the meaning given the term by each State consistent with its laws, regulations, and policies.''

We agree with the commenters that the appropriateness of a representative depends on the significance of the activity for which he or she is acting as representative, so that States should have the flexibility to determine who may represent the beneficiary in various activities. The State may establish various criteria depending upon the situation (for example, disenrollment requests, choice of health plans, receiving notices, filing grievance and appeals (including requests for expedited review, being included as a party to the appeal and the State fair hearing, receiving marketing materials, being provided opportunity to review records, etc.) In determining who may represent beneficiaries, we anticipate that States will provide special consideration for individuals with cognitive impairments, who are unable to appoint their own representatives but who may be especially vulnerable and require assistance in accessing the protections offered in these regulations.

Comment: One commenter found the definition of PHP to be too vague. Specifically, the commenter was not aware of what was meant by ''comprehensive'' and that it was confusing to use the words ''capitation'' and ''fee'' to describe a capitation payment. The commenter recommended that we not use the word ''fee'' in conjunction with capitation and that we define ''comprehensive.''

Another commenter believes the proposed regulations should include a new definition of a prepaid health plan (PHP) to include primary care case managers that are paid on a capitated basis for primary care services only. A commenter recommended that any entity meeting the definition of primary care case manager in section 1905(t) of the Act should be treated the same, whether capitated or paid on a fee-for-service (FFS) basis under State plan payment rates.

Response: Normally, we use the phrase ''capitation payment'' or ''capitation rate'' to describe the capitation method of payment rather than use ''capitation fee.'' As such, we agree with the commenter that the word ''fee,'' which is associated with ''fee-for-service'' payment, does not fit well with the word ''capitation.'' We therefore are revising the definition of PHP by replacing the word ''fee'' with the word ''payment'' after ''capitation.''

With respect to the commenter's request that ''comprehensive'' be defined, the September 29, 1998 proposed regulations contained a definition of ''comprehensive risk contract'' that would apply for purposes of the definition of PHP. In the September 29, 1998 proposed rule, it was proposed that this definition be included in § 430.5. Since the commenter apparently did not see this definition, and was not aware that it pertains only to part 438, we are moving the definition of ''comprehensive risk contract'' from § 430.5 to § 438.2.

We disagree that a primary care case manager paid on a capitation basis should be treated the same as one paid on a fee-for-service basis based on State plan payment rates. The definition of primary care case manager in section 1905(t)(2) of the Act does not preclude payment on a capitation basis. Thus, an entity that meets this definition is subject to the rules and requirements that apply to a primary care case manager, whether the entity is paid on a fee-for-service basis, a risk capitation basis, or some other basis. To the extent that a primary care case manager is paid on a capitation basis for providing less than a comprehensive array of services, it would also meet the definition of a PHP and be subject to the requirements in § 438.8. In this case, the primary care case manager would be both a PHP and a PCCM. When the MCO rules that apply to PHPs are stricter than the rules that apply to all primary care case managers, a primary care case manager paid on a capitation basis would have to follow the MCO rules by virtue of its status as a PHP.

Comment: One commenter noted that the proposed definition of primary care refers to service customarily furnished by various types of physicians but does not mention nurse midwives, nurse practitioners, and physician assistants. The commenter asked us to define primary care to describe the functions of a primary care provider to allow inclusion of those classes of providers who are permitted under State law to practice as primary care providers. A second commenter requested that nurse practitioners and certified nurse midwives be expressly referenced in the definition of primary care.

A few commenters asked us to specifically include Federally qualified health centers (FQHCs) and rural health centers (RHCs) within the definition of primary care case manager, which the commenters appear to believe would be necessary in order for FQHCs and RHCs to have the option of serving as a primary care case manager (and as a result be eligible for automatic reenrollment). One commenter noted that the rule failed to identify obstetricians and gynecologists (Ob-

Gyns) as primary care case managers and recommended their inclusion in that definition of primary care case manager.

One commenter urged that the definitions of primary care and primary care case manager include licensure or certification imposed by tribal governments in the case of individuals, groups, or entities that deliver health care services on a reservation. This commenter believes that this would be needed in order for some Tribes to implement tribal MCOs or PCCMs. A second commenter also noted that the definition of primary care case manager assumed State licensure and noted that the concept of tribal sovereignty generally precludes State licensing and certification of tribally operated programs. In order to implement an Indian Health Services (IHS) or tribally operated MCE, this commenter asked that language be added exempting tribes and the IHS from State license or certification requirements.

Finally, one commenter requested that the definitions of primary care and primary care case manager be more clear in order to distinguish between a PCCM system and a capitated program. The commenter urged that the language make clear that States have the option of offering a PCCM option as a form of noncapitated managed care. This commenter urged HCFA to require the PCCM option as an element of mandatory managed care at least for people with severe disabilities.

Response: Our definitions of primary care and primary care case manager mirror the statutory language in section 1905(t) of the Act. We believe that the Congress intended to limit the kinds of health care and laboratory services considered to be primary care to those ''customarily provided'' by the providers listed in the statute (and in the September 29, 1998 proposed rule). Contrary to the apparent belief of the first commenter discussed above, we believe this approach does focus on the ''functions'' performed, not on who is performing these functions. If the definition had been intended to limit primary care to services actually furnished by the physicians referenced, it would have said services ''provided by'' these providers, not services that are ''customarily provided by'' these providers. We thus believe the intent of the definition of primary care is to specify the health care and laboratory services considered to be ''primary care.'' This means that under the proposed rule, the types of practitioners mentioned by the commenters could provide ''primary care services'' if they are ''provided in accordance with State licensure and certification laws and regulations.''

The definition of primary care case manager specifies those practitioners who may provide primary care case management services (for example, locating, coordinating and monitoring health care), which may also include the provision of ''primary care'' if permitted under State law. Nurse practitioners, certified nurse midwives, and physician assistants are included in that definition at State option. Ob-Gyns are already included in the term ''physicians'' as individuals who the statute specifies may be primary care case managers, and a separate mention is not necessary (particularly since Ob-Gyns are specifically mentioned in the definition of primary care. In addition, the definition of primary care case manager allows for ''an entity employing or having other arrangements with physicians to . . .'' serve as a primary care case manager. This would include both RHC and FQHCs, which thus similarly do not need to be mentioned by name. This policy is consistent with what we have allowed under the section 1915(b) of the Act waiver authority.

From the comments received, it is clear that there was confusion between the definition for ''primary care case manager'' and that for ''provider.'' There is also confusion over the term PCCM, which has been used both to identify a managed care system established by the State and type of provider who participates in that system. We are using PCCM to mean ''primary care case manager''—a specific term used to describe those providers who qualify to provide primary care case management services. Conversely, the term ''provider'' is a general term we use in this rule to identify health care professionals who meet the definition; this includes but is not limited to primary care case managers.

The definition of ''provider'' as published in our September 29, 1998 proposed rule, mirrors the definition of provider published in the June 29, 2000 M+C regulation. However, to further clarify the definition and to be consistent with the definition of ''physician'' used in section 1861(r)(1) of the Act, we are revising the definition of ''provider'' (which we are moving to § 400.203 in this final rule) to be ''any individual or entity that is engaged in the delivery of health care services in a State and is legally authorized by the State to engage in that activity in the State.'' We have substituted the words ''licensed or certified'' with ''legally authorized.'' The revised definition allows States, at their option, to include licensure or certification requirements imposed by Tribal governments. It also provides States the flexibility to determine what State requirements any provider must meet (for example, licensure and certification requirements) in order to provide services under managed care arrangements.

In response to the comments about the provision of primary care by providers certified by Tribes, we believe that a change to the definition of primary care incorporating the above language used in the definition of provider would permit states to allow Tribal-certified providers to furnish primary care as primary care case managers. Accordingly, in response to these comments, in the definition of ''primary care,'' we are changing ''in accordance with State licensure and certification laws and regulations'' to ''to the extent the provision of these services is legally authorized in the State in which they are provided.'' As in the case of our definition of ''provider,'' we believe that this change is consistent with the Congress' intent that States have the discretion to regulate and authorize these services, while permitting the State flexibility in the approach it uses to do so. We disagree with the commenters that the definition of ''primary care case manager'' necessarily assumes certification by the State and therefore believe that no changes to this definition are necessary in order for States to permit Tribe-certified providers to serve as primary care case managers.

The primary care and primary care case management definitions do not address the type of payment provided for these services. As stated previously, the definitions related to primary care case manager services generally mirror section 1905(t) of the Act, which does not address payment for these services. These services are usually reimbursed on a fee-for-service (FFS) basis. However, some States do contract with providers or entities on a capitated basis for primary care services. Our definition allows for this practice to continue.

States now have more flexibility to offer Medicaid beneficiaries access to primary care case management services; section 1915(b) of the Act and section 1115 of the Act waiver authority are no longer the only options for States. Section 4702 of the BBA not only provides the definition of primary care case management services in section 1905(t) of the Act (along with definitions of ''primary care case manager,'' ''primary care case management contract'' and ''primary care'') and sets forth the contracting

requirements for providing these services, it also allows States to add primary care case management services as an optional State plan service. Moreover, section 4701 of the BBA allows States to enroll specified beneficiaries into a PCCM program under a mandatory managed care program without the need to obtain a waiver authority. The BBA does not, however, require States to have PCCM as an option when implementing mandatory managed care programs. As specified in § 438.52 of the September 29, 1998 proposed rule, the final rule continues to require States to provide a choice of at least two MCOs, PHPs, or PCCMs to beneficiaries required to enroll in a managed care program; but States can choose whether to offer a PCCM program or simply offer a choice of two or more MCOs.

Comment: One commenter believes the definition of ''comprehensive risk contract'' (now in § 438.2) should include language that makes explicit HCFA's longstanding interpretation that contracts covering specialty care only, such as behavior health contracts, are not comprehensive risk contracts. The commenter suggested that we include this clarification in the definition of comprehensive risk contract. In addition, the commenter suggested that MCO and MCE be defined in § 430.5 because the terms are used several times throughout the Medicaid regulations set forth in subchapter C before they are fully defined in § 438.2.

Response: We do not believe it is necessary to include language expressly reflecting our longstanding position that the provision of only a limited package of inpatient services related to behavioral health problems (or other similarly narrow area) does not constitute the coverage of ''inpatient services'' as used in the introductory clause in section 1903(m)(2)(A) of the Act, and in the definition of ''comprehensive risk contract'' that implements this statutory language. Under this interpretation, the reference to ''inpatient'' services is to coverage of the full range of these services, not a narrow subset. There does not appear to be any confusion regarding this interpretation, and we do not believe that any change in regulations text is justified.

We agree with the commenter that the terms MCO and MCE are used in part 430 before they are defined in § 438.2. Therefore, we are moving all of the relevant managed care definitions from § 430.5 to § 438.2, which will place all managed care definitions in one section. This will also eliminate duplicate definitions (such as PHP) in both sections.

Comment: One commenter believes that ''partial'' risk arrangements (for example, withhold or bonus arrangements that involve risk without traditional capitation) are not addressed in the definitions of nonrisk contract, PHP, and risk contract. This commenter also found that these arrangements are omitted in the reference in the parenthetical in proposed § 438.50(a) to ''whether fee-for-service or capitation'' payment will be used. The commenter recommended that to allow for States to adopt partial risk-sharing arrangements, the regulations should specify the regulatory requirements that apply if the State chooses to enter into partial risk arrangements.

Response: To the extent a partial risk arrangement puts an entity at ''financial risk for changes in utilization,'' it would not qualify as a ''nonrisk contract'' under our definition. It would, however, fall within the definition of ''risk contract'' since the entity would ''assume risk for the costs of services'' and could incur losses if the costs exceed payment. In other words, when funds are put at risk, the contract is a risk contract that would be subject to MCO requirements if it were comprehensive. We agree with the commenter, however, that a partial risk contract that is less than comprehensive and does not involve prepaid capitation, arguably would not technically fall within the existing definition of PHP. This could create an unintended loophole. We therefore are revising the definition of PHP to include these payment arrangements by adding the phrase ''or on other payment arrangements that do not employ State plan payment rates.'' This language would continue to exempt entities paid on a fee-for-service basis based on State plan payment rates from the PHP (and thus MCO) requirements, even if they were paid a ''case management fee'' as a primary care case manager. In this latter situation, there is no financial incentive to deny services.

We also agree with the commenter that the parenthetical in proposed § 438.50(a) (which has been moved to § 438.50(b) as part of a reorganization of that section) excludes partial risk payment arrangements that do not involve capitation. We therefore are adding a ''for example'' at the beginning of the parenthetical to indicate that these are just examples of what might be specified.

Comment: One commenter suggested that we add the sentence, ''An entity must be found to meet the definition of an MCO to enter into Medicaid's comprehensive risk contract'' under the definition of MCO. Other commenters were concerned that the requirement that an MCO is ''organized primarily for the purposes of providing health care services'' could be read to preclude from participation a legal entity that is not necessarily organized primarily to provide health care, such as a county government.

Another commenter noted that although it appears clear from the discussion of the purpose of the definitions in this section and the provisions of § 438.8 that the definition of an MCO is not intended to include PHPs, it would be clearer if this was explicitly stated. The commenter suggested that we include in our definition of an MCO, a statement that specifies PHPs are not considered MCOs. The commenter also suggested that we add language to the definition of PHP to address the potential for risk arrangements with PHPs other than capitation by adding the phrase ''or other risk arrangements'' after the words ''prepaid capitation fees'' because some waivers do not make capitation payments. Another commenter requested that we clarify if MCE includes PCCM programs.

One commenter thought that we interchangeably used the terms MCO and MCE, and used MCE when PCCM was intended, and therefore suggested that we further define the term MCE. The commenter recommended changing MCE to PCCM when appropriate and also revising text to indicate the conditions under which regulations apply to both MCOs and MCEs.

Response: We believe that it would be inaccurate to add the sentence ''an entity must be found to meet the definition of an MCO to enter into Medicaid's comprehensive risk contract'' because certain statutory exemptions allow for other entities to enter into these contracts. We also believe that § 438.6(a) makes clear the entities with which a State agency may enter into a comprehensive risk contract, and makes clear that this includes an MCO. We agree that a county is not organized ''primarily'' for the purpose of providing health care services and that counties should be permitted to contract as MCOs if all of the requirements in sections 1903(m) and 1932 of the Act are otherwise satisfied. In our proposed definition of MCO, we retained the requirement that the entity be organized ''primarily for the purpose'' of providing health care services from our pre-BBA definition of HMO. Since this requirement is not included in the statutory definition of MCO in section 1903(m)(1)(A) of the Act

and could potentially provide an impediment to the availability of county-sponsored managed care arrangements, we are deleting this requirement in response to this comment.

While we do not agree with the commenter's suggestion that it be specified in the definition of MCO that PHPs are excluded, we agree that it would not be clear from the current definition of MCO that an entity that otherwise meets the definition would be excluded if it does not have a comprehensive risk contract. While the definition of MCE refers to an MCO that has a comprehensive risk contract under section 1903(m) of the Act, the MCO definition itself does not include this restriction. Since the regulations use ''MCO requirements'' as a shorthand for requirements that apply to comprehensive risk contractors, we agree that it would be a good idea to include this concept in the definition of MCO. Because an entity is required to meet the definition of MCO as a condition for qualifying for a comprehensive risk contract, we are revising the definition of MCO to provide that it is an entity ''that has, or is seeking to qualify for, a comprehensive risk contract under this part.'' With this qualification, it should be clear that a PHP would not be included since a PHP is by definition an entity that ''does not have a comprehensive risk contract.'' With respect to the commenter's suggestion that ''or other risk arrangements'' be added to the definition of PHP after ''prepaid capitation basis,'' we believe that the commenter's concern has been addressed by the revision we have made in response to the previous comment. The alternative arrangements to capitation suggested by the commenter would be included in the phrase ''other payment arrangements that do not employ State plan payment rates.'' The reason we did not adopt the commenter's specific suggestion of ''other risk arrangements'' is that this would imply that the reference to ''prepaid capitation basis'' was exclusively a risk arrangement, when in fact there have been nonrisk PHPs. (In these cases, capitation payments have been subject to a cost-reconciliation process.) Our alternative approach continues to accommodate nonrisk contracts as PHPs.

With respect to comments on the use of the terms MCO, MCE and PCCM, we do not believe that the terms are used interchangeably in the September 29, 1998 proposed rule, but we understand that the application of these terms to various provisions of the regulation has caused confusion. There is a significant difference between an MCO and MCE. An MCE is either an MCO with a risk comprehensive contract or a primary care case manager. The terms MCO and MCE are used in the statute and in the rule to identify when different requirements apply.

However, in the interest of clarity, we are changing the regulations text to indicate when regulations apply to MCOs, PCCMs, or both. We are also deleting the definition of MCE since the term will no longer be necessary as a result of this change.

3. Contract Requirements (Proposed § 438.6)

Proposed § 438.6 set forth rules governing contracts with MCOs, PHPs, or PCCMs. Paragraph (a) of proposed § 438.6 set forth the entities with which a State may enter into a comprehensive risk contract. Paragraph (b) provided that the actuarial basis for capitation payments must be specified in the contract and that the capitation payments could not exceed the upper payment limit in § 447.361. Paragraph (c) contained requirements regarding enrollment, that enrollments be accepted in the order of application up to capacity limits, that enrollment be voluntary unless specified exceptions apply, and that beneficiaries not be discriminated against based on health status. Paragraph (d) provided that MCEs can cover services for enrollees not covered for nonenrolled individuals. Paragraph (e) required that contracts must meet the requirements in § 438.6. Paragraph (f) required that risk contracts provide the State and HHS access to financial records of MCEs. Paragraph (g) required compliance with physician incentive plan requirements in §§ 422.208 and 422.210. Paragraph (h) required compliance with advance directive requirements. Paragraph (i) provided that with certain exceptions, HIOs are subject to MCO requirements. Paragraph (j) set forth the new rules in section 1905(t) (3) of the Act that apply to contracts with primary care case managers.

Computation of Capitation Payments (Proposed §§ 438.6(b), 438.64)

The September 29, 1998 proposed rule proposed that two provisions addressing capitation rates be moved from part 434 to the new part 438 but proposed to retain the existing requirements governing capitation payments, which are incorporated in a new proposed §§ 438.6(b) and 438.64. Proposed § 438.6(b) required that contracts specify the actuarial basis for capitation and that ''the capitation payments and any other payments provided for in the contract do not exceed the payment limits set forth in § 447.361.'' Proposed § 438.64 reflected the requirement in section 1903(m)(2)(A)(iii) of the Act that rates be computed on an ''actuarially sound basis.''

Comment: A large number of comments from States, provider associations, and advocates objected to the requirement in proposed § 438.6(b)(2) that capitation payments and other payments to the provider cannot exceed the upper payment limit (UPL) set forth at § 447.361. The commenters stated that many States no longer have a fee-for-service base to use in computing the UPL and that it was no longer a valid measure of costs, since it did not recognize or include: (1) additional costs resulting from new regulatory requirements in the September 29, 1998 proposed rule; (2) the costs of required expanded or mandated benefits; (3) overall administrative costs of MCOs; (4) MCO start-up costs; or the decline in MCO profits (in commercial, Medicare, and Medicaid plans). Several commenters indicated that this requirement potentially contradicted the requirement in § 438.64 that rates be computed on an actuarially sound basis since rates that are truly actuarially sound could in some cases exceed the UPL. Commenters recommended that HCFA revise or eliminate the UPL requirement and replace it with new rules on rate setting.

Two commenters stated that there were no good arguments for changing the current UPL provisions.

Response: We agree with the commenters that problems are presented by our decision in the September 29, 1998 proposed rule to retain the current UPL requirement in proposed § 438.6(b)(2). We acknowledge that many States no longer have fee-for-service base year data recent enough to use as a reasonable comparison to the costs of a current capitated managed care system. We therefore are accepting the recommendations of the commenters and are in this final rule deleting § 447.361 and revising § 438.6 by creating a new § 438.6(c), Payments under risk contracts, which (1) does not include a UPL; (2) requires actuarial certification of capitation rates; (3) specifies data elements that must be included in the methodology used to set capitation rates; (4) requires States to consider the costs for individuals with chronic illness, disability, ongoing health care needs or catastrophic claims in developing rates; (5) requires States to provide explanations of risk sharing

or incentive methodologies; and (6) imposes special rules, including a limitation on the amount that can be paid under FFP in some of these arrangements. While these changes are being included in this final rule in response to comments on the September 29, 1998 proposed rule, because they involve a new approach to regulating capitation payments, we are providing for a 60-day comment period limited to our decision to replace the existing UPL with new § 438.6(c).

In making these changes, we are moving from a review that compares capitation rates in risk contracts to the historical fee-for-service cost of the services under contract for an actuarially equivalent nonenrolled population to a review of the utilization and cost assumptions and methodology used by the State to set the actual capitation rates. We believe that this change will result in a more appropriate review of capitation rates by examining how the rates have been established rather than how they compare to an increasingly difficult to establish fee-for-service equivalent.

This change does not affect the rules governing UPLs for other types of providers or services including the currently applicable provisions in § 447.272, § 447.304, § 447.321 or those in a proposed rule on payments to hospitals, nursing facilities, intermediate care facilities for the mentally retarded, and clinics published on October 10, 2000 (65 FR 60151). Nor will this change affect the UPL for nonrisk contracts in § 447.362, which remains in effect.

While comments are solicited on all aspects of this change, we are specifically requesting comments and suggestions on the provisions in § 438.6(c) and § 438.814 that impose special rules on contracts with incentive arrangements or risk-sharing mechanisms. As set forth above, FFP is only available for risk contracts to the extent that payments are determined on an actuarially sound basis. ''Under these provisions, we have determined that where total payments exceed 105 percent of the capitation payments paid under the contract, these payments are no longer actuarially sound. Thus, no FFP would be available for payments resulting from risk corridors or incentive arrangements for amounts that exceed 105 percent of the capitation payments made under the contract. If the risk corridor or incentive arrangement does not apply to all enrollees or services under the contract, the 105 percent limit is based only on that portion of total capitation payments for the enrollees or services covered by the arrangement.'' States could make payments under these arrangements with their own funds but would be precluded from claiming FFP for these payments.

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

Without any upper limit on the amount that can be paid in incentive arrangements or risk-sharing mechanisms, the potential exists for inefficiency or inappropriate actions by the contractor to maximize funding, resulting in rates that bear no relationship to those certified by actuaries and which thus are no longer ''actuarially sound.'' We have provided for the limitations in §§ 438.6(c)(5)(ii) and 438.814 as a workable alternative to the current UPL, which meets the following criteria: (1) it provides a clear, consistent rule that can be applied to all risk contracts, regardless of the authority under which the contract operates (waiver or otherwise); (2) it should not discourage the use of any of these arrangements; (3) it explicitly conditions Federal matching funds on the imposition of these limits under any of these arrangements to prevent any potential abuses; and (4) it can be easily administered.

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

Comment: Several commenters stated that the current UPL limit does not recognize the cost of providing care to particularly vulnerable populations and that States should be required to use risk-adjusted capitation rates for homeless and other populations with special health care needs. Some of these commenters added that HCFA should encourage States to reimburse MCOs their actual costs for these populations until sufficient data is developed to apply the risk adjustors.

Response: HCFA encourages States to develop capitation rates that are as accurate as possible in predicting the costs of any population enrolled in managed care. To this end, most States already use rates that are risk-adjusted for demographic factors such as age, gender, locality, and adjusted for category of eligibility, all of which will now be required under § 438.6(c)(3)(iii). Only a few States use diagnosis-based risk adjustors, which under § 438.6(c)(3)(iii)(E) of this final rule would be optional. We are not mandating the use of risk adjustment as suggested by the commenter because risk adjustors (both health status and demographic risk adjustors) can only be used when the population falling into any one category is both readily identifiable and large enough to be a statistically valid-sized group. When States have the capability to identify and separate the costs of any individuals with chronic illness, disability, or extensive ongoing health care needs, we would encourage the State to take this into account in its rate-setting methodology. Because the ability to apply these methodologies will vary from State to State, we are not willing to impose this requirement.

However, we are requiring States to utilize risk adjustment, risk sharing, or other mechanisms or assumptions to account for the cost of services for individuals with chronic illness, disability, ongoing health care needs, or catastrophic claims when setting the capitation rate. Other identifiable factors, which may have impact on the expected health care costs of an individual, may also be used in setting more accurate capitation rates.

Further, we believe that moving from the UPL requirement to an enhanced documentation of the assumptions and methodology used to develop capitation rates will result in rates that are determined on a more reasonable and predictable basis specific to the population enrolled than the UPL requirement's comparison to fee-for-service costs.

Current regulations provide authority for States to contract with MCOs on a

nonrisk basis. This type of contract reduces the contractor's risk for changes in enrollee utilization of services under the contract. This provision permits payment to the contractor based on the contractor's costs, subject to the nonrisk upper payment limit in § 447.362 (which is based on FFS costs of the services actually provided, plus an adjustment for administrative costs). However, currently there are very few States with nonrisk contacts. Given our new model of rate review, and the requirement in § 438.6(c)(3)(iv) that ''individuals with chronic illness, disability, ongoing health care needs or catastrophic claims'' be taken into account, we do not believe it is necessary or appropriate to encourage the greater use of nonrisk contracts as suggested by the commenters.

Comment: Several commenters contended that States' rate-setting processes can be inconsistent, arbitrary, and secretive, and recommended that HCFA require a public process in which States would have to disclose the actuarial information and assumptions in the rate setting process. One commenter wanted HCFA assurance that it would continue to review capitation rates in contracts.

Response: We do not believe that requiring a public process in State rate setting would be conducive to more effective rate setting by States. There are currently 19 States that use some form of competitive bidding and 35 States that use a negotiation process to set rates (including some that use a combination of these methods). Imposing a public participation process outside of the requirements for competitive procurement, or in the midst of negotiations between the State and potential contractors, would not be helpful to these processes. We believe that these methods for establishing payment rates differ significantly from FFS under which States establish fee schedules for Medicaid provider payments, such as with institutional payments when a public process is required. Further, we believe that the new rate-setting process set forth at § 438.6(c) will help to make all parties aware of the elements required and assumptions that must be taken into account in establishing capitation rates.

Comment: Several commenters stated that HCFA should define ''actuarially sound.''

Response: In discussions with actuaries, we have found that there is no universally accepted definition of the term actuarially sound. In the past, we have intended this provision to mean a reflection of past costs and prediction of the future costs of specific services for a specific population based upon concepts of predictability and reasonableness. In § 438.6(c)(1)(i), we have defined the term actuarially sound capitation rates. We have used this term in order to reflect that the emphasis in our review of rates is on the State's assumptions and process used in determining capitation rates, rather than payment amounts. These are defined as rates that are certified by an actuary, developed in accordance with generally accepted actuarial principles and practices, and appropriate for the population and services covered under the contract. The American Academy of Actuaries defines generally accepted actuarial principles and practices as:

> * * * those derived from the professional actuarial literature from their common use by actuaries. Actuarial principles and practices are generally accepted when they are consistent with practices described in the actuarial standards of practice adopted by the actuarial Standards Board and to the degrees that they are established by precedent or common usage. (From Section 2, Second Exposure Draft, Proposed Actuarial Standard of Practice, Utilization of Generally Accepted Actuarial Principle and Practices, American Academy of Actuaries.)

The required certification by the State's actuary should include the actuary's determination of the range of soundness for the proposed rates (or specific rate cells). This would be helpful in resolving any disputes that could arise over the soundness of the rates and would supplement the required documentation of the elements and process used to set the capitation rates.

We believe that our definition of actuarially sound capitation rates and new rate setting review requirements provide HCFA's interpretation of actuarial soundness as set forth in section 1903(m)(2)(A)(iii) of the Act.

Comment: One commenter wanted HCFA to apply the actuarial soundness requirement to MCO payments to providers.

Response: We do not have the authority to impose these requirements on rates paid by MCOs to their subcontractors. The only instances in which the statute provides authority to regulate payments by MCOs to subcontractors are the physician incentive plan requirements imposed under section 1903(m)(2)(A)(x) of the Act, and the requirement in section 1903(m)(2)(A)(ix) of the Act that payments by MCOs to FQHCs and RHCs be no less than rates paid to similar subcontractors providing a similar range of services.

Comment: Several commenters stated that HCFA should develop an administrative process for the resolution of rate issues between MCOs and States when potential contractors do not believe that their payment rates are sufficient .

Response: We do not believe it would be appropriate for us to mandate a specific administrative review process for MCO disputes with States over payment rates. It is a State's decision whether to utilize a managed care delivery system in its Medicaid program, and part of that decision may be based upon the rates it believes it can afford to offer prospective MCOs or PHPs. If the rates are not high enough to obtain a sufficient number of contractors, the State must make a decision whether to raise its rates or discontinue its managed care program. HCFA has no authority to require a state to continue or begin a managed care program. We note, however, that under the new procedures in § 438.6(c), HCFA will be reviewing rates for actuarial soundness, so this review provides certain protections to MCOs as to the adequacy of payment rates and should at least in part address the commenters' concerns.

Comment: HCFA should offer technical assistance to States in setting capitation rates.

Response: Section 1903(k) of the Act specifically authorizes us to provide this assistance at no cost to the State, and we have done so in the past. Currently, however, most States have elected to contract with actuarial firms for this assistance.

Comment: One commenter was concerned that language in the September 29, 1998 proposed rule implied that HCFA would no longer review capitation rates and wanted HCFA assurance that it would continue to review capitation rates in contracts.

Response: HCFA will continue to review rates established between states and MCOs or PHPs. In fact, new § 438.6(c) applies these rate-setting requirements to all risk contracts, and we have created a new § 438.6(a) that provides that the HCFA Regional Office must review and approve all MCO and PHP contracts.

Prohibition of Enrollment Discrimination (Proposed § 438.6(c))

Proposed § 438.6(c) (recodified as § 438.6(d) in this final rule) established rules for enrollment and set forth prohibitions against discrimination in the enrollment process. Specifically, proposed § 438.6(c) required that enrollees be accepted in the order in which they applied up to specified capacity limits, provided that with specified exceptions enrollment must be

voluntary, and prohibited discrimination based on health status.

Comment: Several commenters noted that the September 29, 1998 proposed rule appropriately prohibits health plans from ''cherry picking,'' which is the concept of discriminating against persons who may have high health care needs. However, they noted that the requirement only applies during open enrollment. The commenters believe that the requirement should not apply only to ''official'' open enrollment periods, since enrollment can occur at any time during the year as individuals become Medicaid-eligible. The commenters suggested that we revise the September 29, 1998 proposed rule to include the following: ''MCE contracts must provide that MCEs will not discriminate on the basis of race, color, or national origin. In addition, the MCE must not use any policy or practice that has the effect of discriminating on the basis of race, color, or national origin.'' This is required under Title VI of the Civil Rights Act and implementing regulations.

Response: We agree with the commenter that there is no reason for limiting the requirement that the MCE accept individuals for enrollment in the order in which they apply only to open enrollment periods. Therefore, we are revising § 438.6(d)(1) to specify that ''The MCO, PHP, or PCCM accepts individuals eligible for enrollment in the order in which they apply without restriction (unless authorized by the Regional Administrator) up to the limits set under contract.''

We also agree that MCOs, PHPs, or PCCMs should not discriminate based on health status, race, color, or national origin and that MCO contracts should contain assurances of compliance with Title VI of the Civil Rights Act and other applicable civil rights and other Federal and State statutes. Thus, we are revising § 438.6(d)(4) to include this provision.

Comment: A commenter noted that the September 29, 1998 proposed rule provides that the contract must prohibit MCEs from discriminating in its enrollment process based on health status or need for health care. The commenter further noted that its State controls the enrollment process and requires the MCO to accept individuals who choose or are assigned the MCO. Thus, the MCO is incapable of discrimination. The commenter suggested that we require that States comply with this requirement without necessarily requiring language in MCO contracts.

Response: Section 438.6(d) implements sections 1903(m)(2)(A)(v) and 1905(t)(3)(D) of the Act, which prohibit discrimination on the basis of health status by an MCO or PCCM, not the State. We believe that this is because the Congress presumed that the State would engage in no such discrimination, since it would have no incentive to do so. Indeed, in the case of an MCO, PHP, or PCCM paid on a risk basis, it would be in the State's financial interests for beneficiaries with higher health care costs to be enrolled. To the extent a State does not permit an MCO to make enrollment decisions, this would ensure compliance with section 1903(m)(2)(A)(v) of the Act and § 438.6(d). We believe that requiring this provision in the contracts is the best approach to ensure that all MCOs, PHPs, and PCCMs consistently comply with this requirement.

Comment: One commenter contended that requiring MCOs, PHPs, and PCCMs to accept individuals eligible for enrollment in the order in which they apply without restriction contradicts the requirement in § 438.50(f)(2) that MCOs, PHPs, and PCCMs seek to preserve the established relationship that an individual has with his or her primary care provider.

Response: We do not believe that the enrollment requirement under § 438.6(d)(1) contradicts the continuity of patient and physician relationships, since it affects only the effective date of enrollments and not the extent to which provider relationships can be maintained once enrollment is effective. We also note that the requirement in § 438.6(d)(1) refers to individuals who ''apply'' for enrollment, while § 438.50(f)(2) applies in the context of ''default'' enrollments under a State plan mandatory enrollment program.

Additional Services Under MCO Contracts (Proposed § 438.6(d))

Proposed § 438.6(d) (recodified in this final rule at § 438.6(e)) provided that an MCE is permitted to cover services for enrollees that are not covered under the State plan for beneficiaries not enrolled.

Comment: One commenter noted that the discussion of the purpose of proposed § 438.6(d) in the preamble identifies the provision as applicable to MCO contracts, but the text of the September 29, 1998 proposed rule references MCE and not MCO. The commenter suggested that we change the reference from MCE to MCO. The commenter believes that this change would also have the effect of applying this provision to PHPs, which the commenter thought was appropriate.

Response: The commenter was correct that the text of the preamble to the September 29, 1998 proposed rule identifies this provision as applicable to MCOs and that the text of the section references MCEs. Typically, only an MCO (which by definition is paid on a risk basis) or a primary care case manager paid on a risk basis (which would make it a PHP) would offer additional services not covered under the State plan for nonenrollees. This is because these entities would typically use ''savings'' (a portion of the risk payment not needed to cover State plan services) to cover the additional services in question. This is why the preamble to the September 29, 1998 proposed rule spoke only of MCOs (which, as the commenter pointed out, would extend to PHPs as well). However, this provision of the regulations is based on the fact that under a voluntary enrollment situation, section 1915(a) of the Act permits contracts with an organization ''which has agreed to provide care and services in addition to those offered under the State plan'' only to individuals ''who elect to obtain such care and services from such organization.'' Under section 1915(a) of the Act, States are deemed to be in compliance with statewideness and comparability requirements in this situation. There is nothing in section 1915(a) of the Act that limits this result to an MCO (or to MCOs and PHPs) or even requires the organization offering additional services to those who choose to enroll to be paid on a risk basis. In the case of mandatory enrollment under section 1932(a) of the Act, an exemption from Statewideness and comparability requirements permitting additional services for enrollees is similarly provided without regard to whether the entity is an MCO or a primary care case manager. Finally, there is nothing in section 1915(b) or section 1115(a) of the Act that would limit the applicability of the waivers of Statewideness and comparability provided for thereunder to MCOs and PHPs. For these reasons, even though it is unlikely that a nonrisk PHP or PCCM would offer additional services, we are clarifying the reference in what is now § 438.6(e) to apply to MCOs, PHPs, and PCCMs.

Comment: While several commenters recognized that the language in proposed § 438.6(d) exists in the current regulation, they believe that the current regulation has been subject to varied interpretation over the years. The commenters suggested that we clarify whether or not these additional services are included in the base used to determine the upper payment limit (UPL). In other words, if the MCO provides additional services, the commenters believe we should clarify whether or not the State is free to

increase the capitation rates to reflect the costs of those services, even if the costs did not occur in FFS.

Response: Under the former UPL requirement, the costs of additional services would not have been included in the FFS base in computing the UPL. However, as indicated above, we are eliminating the UPL requirement and substituting a requirement that rates be actuarially sound, certified by an actuary to this effect, and developed in accordance with generally accepted actuarial principles upon the projected cost of services contained in the State plan. Section 438.6(c)(4) requires States to base their capitation rates *only* upon the costs of services covered under the State plan. Thus, even in the absence of the UPL requirement, capitation rates may not reflect the cost of these additional services.

Comment: One commenter wanted us to clarify what additional services could be offered under proposed § 438.6(d) and whether these services would be eligible for FFP.

Response: The additional services that can be offered may be optional services described in section 1905 of the Act or any other medically related services, that are not covered under the State plan. However, as noted in the previous response, the provision of the additional services authorized here is not to be recognized in the capitation rate paid to an MCO or in the FFP available to the State.

Comment: One commenter disagreed with the position that these additional services should not be subject to the statewideness and comparability requirements. This commenter believes that waiving these requirements could potentially lead to discrimination on the basis of health status or disability.

Response: Additional services have been provided by HMOs and PHPs under § 434.20(d) for many years prior to the enactment of the BBA, and we do not believe that this has led to enrollment discrimination. Further, the prohibition on enrollment discrimination in § 438.6(d) requires that MCOs, PHPs, or PCCMs accept individuals in the order in which they apply without restrictions, which will protect enrollees from discrimination on the basis of health status or disability.

Compliance With Contracting Rules (Proposed § 438.6(e))

Proposed § 438.6(e) (recodified in this final rule at § 438.6(f)) required contracts with MCOs and primary care case managers to comply with the requirements in § 438.6.

While we received no comments on this provision, the comment discussed above suggesting that the discrimination provision include language requiring compliance with civil rights laws has prompted us to include a general provision that contracts comply with all applicable State and Federal laws in what is now § 438.6(f). This provision merely recognizes obligations that already exist as a matter of law, and does not impose any new obligations or alter any existing ones. It essentially is a statement that HCFA expects contractors to comply with the law. The revised text now reads as follows:

(f) *Compliance with applicable statutes and contracting rules.* All contracts under this subpart must—

(1) Comply with all applicable State and Federal laws; and

(2) Meet all the requirements of this section.

Inspection and Audit of Records (Proposed § 438.6(f))

Proposed § 438.6(f) (codified in this final rule at § 438.6(g)) required risk contracts to include provisions allowing State and Federal inspection and audit of MCE and MCE subcontractors' financial records. We received no comments on this provision.

Physician Incentive Plan (Proposed § 438.6(g))

Proposed § 438.6(g) (codified in this final rule at § 438.6(h)) required that contracts provide for compliance with the rules governing physician incentive plans that apply to Medicare+Choice organization contracts. These rules require that stop loss protection be provided when a physician incentive plan puts a physician at ''substantial financial risk'' (defined in the June 29, 2000 Medicare+Choice regulations) for the costs of services he or she does not provide.

Comment: One commenter supported requiring Medicaid MCOs and nonexempt HIOs to comply with Physician Incentive Plan requirements.

Response: The requirement is maintained as set forth in the September 29, 1998 proposed rule.

Advance Directives (Proposed § 438.6(h))

Proposed § 438.6(h) (recodified in this final rule at § 438.6(i)) required that MCOs comply with the advance directive requirements in subpart I of part 489, provide oral and written information on advance directives, and reflect changes in State law within 90 days.

Comment: One commenter supported requiring MCOs and nonexempt HIOs to comply with advance directive requirements. Several commenters noted that the current advance directive requirement in § 434.28 does not include a requirement to provide adult enrollees with oral information on advance directives. They added that this requirement was not included in the BBA and that written information should suffice. They suggested that we revise proposed § 438.6(h)(2) to eliminate the requirement for oral information, which would permit MCOs to respond orally only to answer questions that arise. Another commenter recommended deleting the entire requirement as excessive and unwarranted, except upon request by enrollees. Another commenter noted that MCE Member Handbooks address advance directives but not in the detail now required and will require possible revisions and reissuance by MCEs.

Response: The commenter is correct that §§ 434.28 and 489.100 do not require MCOs to provide adult enrollees with oral information on advance directives policies. Section 434.28 notes that the requirement in § 489.100 includes provisions to *inform* and distribute written information to adult individuals concerning policies on advance directives. However, § 489.102 does not specify that individuals must be *informed* orally but describes the requirement to provide written information. Therefore, we agree with the commenters that oral information is not required, and we have revised the advanced directive requirement now codified at § 438.6(i)(2) to eliminate the requirement to provide oral information. Because section 1903(m)(1)(A) of the Act requires MCOs to provide information on advance directives to enrollees, we do not have the authority to delete the entire requirement. Since the advance directive policies did not change before the September 29, 1998 proposed regulation, we do not believe Member Handbooks would need revisions, unless they did not comply with § 434.28 before the September 29, 1998 proposed regulation.

Comment: Although proposed § 438.6(h)(2) provided that an MCO must include a description of applicable State law and proposed § 438.6(h)(3) specified that the information must reflect changes in the State law as soon as possible but no later than 90 days after the effective date of the change, several commenters believe that it was too administratively burdensome for MCOs to comply with these requirements and recommended that we remove them from the regulation.

Response: This provision is required by section 1903(m)(1)(A) of the Act, which extends the advance directives requirements of section 1902(w) of the

Act to MCOs. As a statutory requirement, we do not have the authority to remove this requirement from the regulations.

Nonexempt Health Insuring Organizations (Proposed § 438.6(i))

Proposed § 438.6(i) (recodified in this final rule at § 438.6(j)) clarifies that HIOs that began operating on or after January 1, 1986, and are not exempted by statute, are subject to MCO requirements and may not enter into a comprehensive risk contract if they do not meet the definition of MCO. We received no comments on this provision.

Primary Care Case Management Contracts (Proposed § 438.6(j))

Proposed § 438.6(j) (recodified in this final rule at § 438.6(k)) implemented the requirements in section 1905(t)(3) of the Act that apply to ''primary care case management contracts.'' Specifically, proposed § 438.6(j) required that these contracts (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 reenrollment based on the recipient's health status and need for health care services; and (5) provide that enrollees have the right to terminate enrollment.

Comment: One commenter contended that the primary care case manager contract standards in proposed § 438.6(j) were minimal at best. The commenter asked that patients have rights of access, coverage, information, and disclosure that are as strong as those that apply to MCOs and PHPs.

Another commenter noted the importance of the primary care case manager contract provision to rural beneficiaries because they are more likely to live greater distances from primary care case manager delivery sites. This commenter asked that we define ''sufficiently'' and ''reasonable'' as used in proposed § 436.8(j)(2) (''sufficiently near . . . to reach . . . within a reasonable time'') and ''sufficient'' in proposed § 436.8(j)(3) (''sufficient number of physicians or other practitioners''). This commenter asked us to adopt a ''lesser of 30 minutes rules'' for rural areas with a defined exception for frontier areas approved by HCFA.

Another commenter believes that in the case of direct contracts with primary care providers, our regulations should take into account that these providers may have small group practices and not impose requirements on these providers that are more appropriate for large organizations. The commenter suggested that there should be a way to distinguish the small group provider from the larger group provider and that we should place fewer requirements on primary care case managers. Specifically, this commenter cited requirements such as specific driving or travel distance or 24-hour availability to services as not practicable for small providers and not always important to beneficiaries willing to travel long distances to be with a doctor they trust. The commenter also contended that recipients who have ongoing satisfactory relationships with personal doctors should be allowed to maintain those relationships and that most of the requirements for MCOs are not appropriate for medical group or individual doctors. The commenter believes that there have not been serious problems of quality and access with PCCM programs; and that the management component has proven cost efficient. The commenter is concerned that managed care has already driven out many small health care providers and that HCFA should ensure that further regulation does not drive out more small providers (who are essential to people with disabilities).

Response: As noted above, the contract requirements for primary care case managers in proposed § 438.6(j) largely mirror the language set forth in section 1905(t)(3) of the Act, which was added by section 4702 of the BBA. The BBA is clear in setting forth which contracting requirements should be placed on PCCMs, which should be placed on MCOs, and which apply to all MCOs and PCCMs. As we discussed in the preamble to the September 29, 1998 proposed rule at 63 FR 52026, PCCM contracts must include those requirements set forth in section 1905(t)(3) of the Act as well as any requirements in section 1932 of the Act that apply to MCEs. For example, a PCCM must meet the information requirements set forth in § 438.10 that apply to it. We also have applied access, coverage, and information requirements to primary care case managers when applicable. When the BBA specifies that requirements apply to MCOs, these requirements are not applicable to primary care contracts as long as the services are reimbursed on a fee-for-service basis based on State plan payment rates. (To the extent that a primary care case manager meets the definition of a PHP, however, it would also be subject, by regulation, to specified MCO requirements.)

The requirement in proposed § 438.6(j)(1) that primary care case manager contracts ensure 24-hour availability of information, referral, and treatment for emergency medical conditions simply reflects the requirement in section 1905(t)(3)(A) of the Act, and therefore cannot be revised. We note, however, that providers have flexibility as to how they meet this requirement. For example, providers can have an employee or an answering service or machine that immediately pages an on-call medical professional. This requirement is essential to allowing referrals to be made for nonemergency services, or information to be given about accessing services, or medical problems to be handled during nonoffice hours.

The requirement in proposed § 438.6(j)(2) that beneficiaries be able to access care within a reasonable time using affordable modes of transportation similarly reflects statutory language in section 1905(t)(3)(B) of the Act that cannot be changed. Again, however, States have the flexibility to determine their own standards to allow for differences based on the needs of the beneficiaries, provider availability, and the geographic uniqueness of the State. HCFA anticipates that State agencies will take responsibility for ensuring that these standards are met. One example, as noted in the preamble of the September 29, 1998 proposed rule, is the 30-minute travel time standard. Many States have adopted this standard and apply it to urban areas. Other State agencies have established 10-mile to 30-mile travel distance depending on the area. HCFA encourages States to develop their PCCM programs so that an enrollee residing in the services areas should not have to travel an unreasonable distance beyond what is customary under FFS arrangements. Due to enrollee-specific needs, types of providers needed to meet enrollee needs, availability of public transportation, etc. HCFA is not proposing a set of standards for each PCCM program.

We encourage States to, and States often do, make exceptions for beneficiaries who request to travel further than the time and distance standards set by the State. We also encourage States, to the extent practical,

to allow beneficiaries who have ongoing successful relationships with providers to maintain those relationships. However, section 1905(t)(3) of the Act does not require this in the case of PCCM contracts.

Section 1905(t)(3) of the Act does not distinguish between small group providers and large group providers and applies its requirements to all primary care case manager contracts. We, therefore, do not have the authority to exempt smaller providers from requirements in section 1905(t)(3) of the Act that are reflected in what is now § 438.6(k), which therefore will remain as written in the September 29, 1998 proposed rule.

4. Provisions That Apply to PHPs (Proposed 438.8)

Proposed § 438.8 provided that specified requirements that apply to MCOs and MCO contracts apply to PHPs and PHP contracts. Specifically, under proposed paragraph (a), the requirements in proposed § 438.6 would apply with the exception of those that pertain to physician incentive plans, advance directives, and HIOs. Proposed paragraphs (b), (c), and (d) incorporated, respectively, the information requirements in proposed § 438.10, the provider discrimination requirement in proposed § 438.12, and the enrollee protections in proposed subpart C of part 438. Proposed paragraph (e) incorporated the quality assurance requirements in proposed subpart E of part 438 to the extent they are applicable to services furnished by the PHP. Proposed paragraph (f) incorporated the requirements in proposed subpart F of part 438 except for proposed § 438.424(b). And proposed paragraph (g) incorporated the enrollment and disenrollment requirements in paragraphs (e) through (h) of proposed § 438.56 and the conflict of interest safeguards in proposed § 438.58.

Physician Incentive/Advance Directives

Comment: Several commenters are concerned that HCFA has not included provisions relating to physician incentive plans and advance directives in its regulations of PHPs. These commenters believe that these two provisions are of vital importance to people with disabilities and chronic illnesses. They believe that to the extent that PHPs perform the same responsibilities as MCOs, they should be subject to the standards comparable to those applied to MCOs.

Some commenters focused on physician incentive plan requirements, agreeing with the above commenters that they should apply when PHPs transfer substantial financial risk to physicians or physician groups. If a State elects to carve out behavioral health, these commenters believe that the same financial arrangement between a PHP and that medical group should be subject to the physician incentive requirements.

The commenters believe that physician incentive plan requirements provide some measure of protection for beneficiaries who might otherwise be under-treated or not treated at all because they have expensive or on-going care needs. They noted that people with chronic and disabling medical or psychiatric disabilities are at high risk for receiving inadequate care because of the high costs often associated with meeting their needs. Moreover, some of the most noted media coverage of treatment cut backs and cut offs has occurred in behavioral health managed care settings when financial incentives are almost always an issue.

These commenters also suggested that enrollees of PHPs should have the same opportunities to execute advance directives prior to the need for this hospitalization, as should enrollees of behavioral health PHPs that cover and provide stabilization and other types of short-term, acute psychiatric interventions in nonhospital settings when psychiatric advance directives might be warranted. Our September 29, 1998 proposed regulations seem to undermine this movement and would likely make acceptance of advance directives by PHPs more difficult. They strongly urged HCFA to make the consumer protections regarding physician incentive plans and advance directives applicable to PHPs.

Another commenter noted that HCFA should give State agencies the discretion to apply advance directives requirements to PHPs. Depending on the nature of the services provided by the PHP, State agencies may believe that it is appropriate for the PHPs to meet the advance directive requirement.

Response: We agree with the commenter that PHPs should provide their enrollees with an opportunity to execute an advance directive to the extent that the PHP performs similar responsibilities as an MCO. So, for example, it may be appropriate for those PHPs that furnish institutional services to provide the opportunity for advance directive. However, there are many PHPs that do not furnish institutional services. Further there are some PHPs that furnish nonclinical services only, such as transportation services. We believe these types of PHPs should not be subject to the advance directive provisions. As a result, we are changing § 438.8(a) to read ''(b) The requirement of § 438.6(h) except for—(1) PHPs that contract for nonclinical services, such as transportation services; and (2) when a State believed it is not appropriate for PHPs to meet the advance directive requirement, such as PHPs that only provide dental coverage.''

With respect to physician incentive plan requirements, we also agree that these provisions represent significant beneficiary protections that should be extended to enrollees in PHPs that transfer substantial financial risk to physicians or physician groups. We have modified § 438.8(a) to reflect this change.

Comment: One commenter recommended that this section be carefully reviewed to ensure that it is clear about the requirements applicable to PHPs. The commenter apparently believes that requirements only apply to PHPs when the term MCO is used in the sections referenced in paragraphs (a) through (g). In a number of these sections, the commenter concluded from this belief that this would exempt PHPs from provisions that the commenter believes should apply. The commenter also believes that § 438.8 does not include references to sections that the commenter believes should be applicable. For example, § 438.802 is not included, although the commenter believes that paragraphs (a) and (c) should apply. The commenter suggested HCFA re-evaluate the use of this mechanism to identify PHP requirements and consider adding specific references to PHPs in each applicable section.

Response: Section 438.802, which discusses the conditions under which FFP is available to MCOs, is based on section 1903(m) of the Act, which does not apply to PHPs. This provision thus does not provide authority to disallow FFP in payments to PHPs. In order to avoid any confusion as to which provisions apply to PHPs, we have added specific references to PHPs in each applicable section. We are also keeping § 438.8, which identifies most of those provisions that apply to PHPs.

Inapplicability of Sanctions Provisions to PHPs

Comment: One commenter noted that the list of MCO provisions that apply to PHPs omitted the sanctions under subpart I. It is unclear whether this sanction authority applies to PHPs through other regulatory provisions. If not, the commenter recommended that HCFA amend the September 29, 1998

proposed rules to apply the subpart I sanction authority to PHPs.

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

PHPs Regulated as MCOs

Comment: Several commenters were pleased that we, relying on our authority under section 1902(a)(4) of the Act, decided to require by regulation that PHPs comply with regulations implementing many consumer protections which the Congress applied to MCOs in the BBA. One commenter believes that it would be a terrible irony for those with these specialized and significant health care needs to be relegated to having fewer rights than other Medicaid recipients. These commenters believe that PHP enrollees should be entitled to the same protections as MCO enrollees since PHPs perform the same responsibilities as MCOs and have similar financial incentives through risk contracts with States.

Several other commenters, however, believe that the BBA did not give the statutory authority in effect to extend statutory MCO requirements by regulation to PHPs. They were concerned that this would be a strong deterrent for some plans and providers who may want to participate but would see meeting the requirements of BBA as too burdensome. The commenters noted that it may be difficult for behavioral health PHPs and dental health PHPs to meet some of the BBA regulatory requirements. These commenters believed that this would create an undue administrative burden on both the State agency and capitated behavioral health providers. The commenters requested that HCFA carefully consider the administrative costs associated with the application of the MCO requirements to risk-bearing providers that provide limited Medicaid services. Particular areas of concern for PHPs included meeting some of the licensing and certification requirements, information requirements, and State plan and contract requirements. Other commenters noted that the enrollment and disenrollment requirements are simply not suitable for capitated behavioral health providers. They believe that this requirement would result in higher cost and less choice because of the negative impact it will have on subcontractors' participation. One commenter suggested that PHPs should not be covered by provisions of the September 29, 1998 proposed rule.

Response: 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 change the fact that managed care entities regulated as PHPs are only subject to regulatory requirements that we may publish. We agree with the commenter that the BBA does not itself provide us with authority to regulate PHPs, and we are not relying on the BBA as authority for these regulations. Rather, as noted above, we are relying on our authority under section 1902(a)(4) of the Act to establish requirements found by the Secretary to be ''necessary'' for ''proper and efficient administration.'' This has been the basis of PHP regulations from the beginning. The existing PHP regulations in part 434 similarly extended to PHPs by regulation requirements in section 1903(m) of the Act that otherwise only applied to comprehensive risk contractors. For example, under § 434.26(a), both PHPs and HMOs were required to limit their Medicare and Medicaid enrollment to 75 percent of total enrollment. It is true that under § 434.26(b)(4), this requirement could be waived for ''good cause'' in the case of PHPs. Nonetheless, there is longstanding precedent for applying selected requirements in section 1903(m) of the Act by regulation to PHPs. Other longstanding PHP requirements imposed by regulation under the authority in section 1902(a)(4) of the Act include requirements in § 434.27 related to termination of enrollment (for example, a prohibition on termination because of an adverse change in an enrollee's health status), the choice of health professional requirement in § 434.29, requirements in § 434.30 related to emergency medical services, the requirement under § 434.32 that the contract provide for a State-approved grievance procedure, the requirement in § 434.34 that the contract provide for an internal quality assurance system meeting specified standards, and the marketing requirements in § 434.36. We are extending similar requirements in the State responsibilities contained in subpart B of this regulation to PHPs.

All of these requirements were imposed through the same notice and comment rulemaking process being used in this final rule. The only difference between existing requirements and the requirements imposed under this final rule is a matter of degree, not the nature of the requirements in question. We have determined that the BBA contains important beneficiary protections that should be extended by regulation to most PHPs.

It should be noted that not all MCO requirements are being imposed on PHPs and that some PHPs are not required to meet certain specified requirements. For example, as just noted above, we have declined to require that the provisions for sanctions in subpart I be applied to PHPs. Also, some PHPs do not provide the complete set of inpatient hospital services as this term is used in section 1903(m)(2)(A) of the Act, and the exception to the State solvency standards requirement in § 438.116(c)(1) would apply.

Solvency Standards (Proposed § 438.8(d))

Among the beneficiary protections in proposed subpart C that are applied to PHPs under proposed § 438.8(d) are solvency standards in proposed § 438.116. We received several comments on this requirement.

Comment: Several commenters noted that some PHPs would have problems meeting these solvency requirements because not all PHPs, particularly those providing behavioral health services, would fall under one of the exemptions in proposed § 438.116(c). One of the commenters believes it was unclear what a State would have to do to certify a PHP for solvency. The commenter noted that States often use different methodologies than those used for MCOs to determine the solvency standards for PHPs and suggested that States be given more flexibility in this area to set their own PHP solvency standards. Another commenter noted that the solvency requirement is totally inappropriate to PHPs, especially when they serve as subcontractors to an MCO.

Response: Section 438.116(b) requires an MCO, and by operation of § 438.8(d), a PHP, to meet the solvency standards established by the State for private HMOs or to be licensed or certified by the State as a risk-bearing entity. However, § 438.116(c) provides for several possible exceptions to the State solvency standards requirement. If the PHP does not provide the complete set of inpatient hospital services under

section 1903(m)(2)(A) of the Act, the exception to the State solvency standards requirement in § 438.116(c)(1) would apply. Therefore, the exception in § 438.116(c) would normally apply to behavioral health type PHPs. Even though a PHP may be exempt from the solvency standards in § 438.116(b), it still must meet the basic requirements in § 438.116(a), which requires each PHP to provide assurances satisfactory to the State showing that it has adequate provisions against the risk of insolvency to ensure that its Medicaid enrollees will not be liable for the MCO's debts if it becomes insolvent.

5. Information Requirements (Proposed §§ 438.10 and 438.318)

Proposed § 438.10 set forth requirements that apply to States, MCEs or enrollment brokers concerning the provision of information to enrollees and potential enrollees. Paragraph (a) set forth the basic rule that these entities must comply with applicable requirements. Paragraph (b) set forth requirements relating to language and oral interpretation services. Paragraph (c) set forth requirements regarding the format of materials. Paragraph (d) specified to whom information must be provided and when it must be provided. Paragraph (e) specified the information that must be provided, including information on the amount duration and scope of benefits, procedures for obtaining services, names and locations of providers (and which are accepting new patients), any restrictions on freedom of choice, the extent to which out of network providers can be used and after-hours and emergency coverage are provided, policies on referrals for specialty care, cost sharing, the rights and responsibilities of enrollees, and information on complaints, grievances and fair hearings. Paragraph (f) specifies additional information that must be made available upon request. Paragraph (g) required that services not provided under the contract be identified. Paragraph (h) specified information that primary care case managers are required to provide. And paragraph (i) set forth additional information requirements that apply in the case of a mandatory enrollment program under the authority in section 1932(a)(1)(A) of the Act. Proposed § 438.318 (recodified at § 438.218 in this final rule) required that, as a part of the State's ''quality strategy,'' the requirements in proposed § 438.10 must be satisfied, and that contracts must specify that certain information specified in § 438.318(b)(2) be provided.

Comment: Many commenters remarked that proposed § 438.318, ''Enrollee information,'' is redundant with § 438.10 because both require elements of information that a State, MCE, MCO, or PCCM must provide to enrollees and potential enrollees. Commenters recommended combining these sections with a clear distinction between who must provide information. In addition, several commenters also believed that there should be no distinction between mandatory managed care and nonmandatory managed care with respect to information requirements and that requirements should be applicable to both. Further, commenters believe that the regulation exacerbated a problem that exists to some extent in the statute since some requirements apply to MCOs, some to MCEs, and some to States.

Response: Proposed §§ 438.10 and 438.318 have been combined in response to the commenters' concerns; however, the requirements remain essentially the same, since these requirements reflect statutory requirements set forth in section 1932(a)(5) of the Act. Specifically, as the distinction is made in statute, the requirements distinguish between the information that must be provided by MCOs, PHPs, and primary care case managers. There is a further distinction in the statute for mandatory managed care systems under section 1932 of the Act. In specifying in the proposed regulations who had to provide information, States were afforded the maximum flexibility possible since some States have prohibitions regarding distribution of information by MCOs, while some States require MCOs or enrollment brokers to distribute information. Although the specific requirements are now part of § 438.10, in the quality requirements now codified in subpart D, § 438.218 requires that § 438.10 constitute part of the State's quality strategy.

Comment: A commenter indicated that the term ''potential enrollee'' needed to be defined because it was unclear if it meant eligible for Medicaid or eligible for enrollment in a managed care plan.

Response: The term ''potential enrollee'' in this section refers to an individual that has been found eligible for Medicaid and is either required to, or permitted to, join an MCO, PHP, or PCCM. We believe this is clarified with the revised format; therefore, we will not be adding a definition to the regulations text.

Comment: Commenters indicated that the language and format requirements should also apply to member newsletters, health risk appraisal surveys, and health education and preventive care information.

Response: Section 438.10(a)(4) (codified at § 438.10(a)(2) in the September 29, 1998 proposed rule) expressly provides that the provisions of paragraphs (b) (language) and (c) (format) apply to all information furnished to enrollees and potential enrollees, such as enrollment notices, informational, and instructional materials *and* the information specified within the section. HCFA believes that this addresses the commenter's concerns, since the language and format provisions apply to all information furnished to enrollees and potential enrollees, and not just those specified in the § 438.10 itself.

Comment: Many commenters wanted HCFA to require in the regulation that all information and instructional materials (including charts and upon request information) be designated public records and be available to the public.

Response: Assuming that the material the commenters referenced is general information and not specific to an enrollee or potential enrollee, we believe that the information specified in § 438.10 is generally publicly available and therefore may be obtained from the State by following State procedures if the State is in possession of the information. If we are in possession of the information, the information can also be obtained from us under the Freedom of Information Act. We note that States may have procedures to follow for obtaining information.

Comment: A commenter recommended that HCFA encourage States to develop other mediums of notification about managed care options such as public service announcements on radio or TV, posting information on the Internet, and billboards.

Response: While we are not mandating how a State makes individuals aware of their health benefit options, § 438.10 requires that States undertake the activities necessary to fully educate and inform enrollees and potential enrollees about their health care options and how to access benefits.

Comment: Commenters believe that all information provided to enrollees by the State, MCE, or enrollment broker should be developed in consultation with consumers and stakeholder groups.

Response: Although we encourage States to work with consumer and stakeholder groups in the development of material, we do not believe it is necessary to mandate this as part of §§ 438.10 or 438.218. However, many of the elements listed within § 438.10 would be considered marketing material

and would therefore have to be reviewed in accordance with the marketing standards at § 438.104, which require consultation with the Medical Care Advisory Committee (MCAC) established under § 431.12 or a similar entity. The MCAC's or similar entity's membership is required by regulation to include consumer membership. Further, under § 438.218, information standards are part of the overall quality strategy at § 438.304, which includes requirements regarding consumer involvement.

Language Requirements (Proposed § 438.10(b)

Comment: Several commenters found the requirement to make information available in the languages that predominate throughout the State to be problematic; however, commenters offered differing opinions on what they wanted to see in the regulation. Many supported our decision not to include a specific percentage threshold for a language to be considered prevalent in a geographic area but remained concerned that the preamble language referenced a 5 percent figure and that HCFA's Medicaid Managed Care Marketing Guidelines include a 10 percent figure. One commenter suggested that it was too costly for MCOs to meet the costs of printing and distributing materials in other languages at the 5 percent threshold. Another commenter believes that the requirements for language and format were overly prescriptive in light of the absence of any evidence that information is not being given to enrollees in an understandable format. Commenters pointed out that these additional administrative costs are funded out of the same dollar that supports the delivery of care.

In contrast, we also heard from many commenters who understood the need for balance between State flexibility and beneficiary protections but believe that HCFA favored State flexibility too much. Commenters stated that only offering guidance in this area was insufficient. They contended that States should be afforded flexibility in developing methods to provide linguistically and culturally competent services but not in determining whether there is a need for these services in a particular State or service area. Commenters requested that the regulation itself include specifics like those discussed in the preamble. Numerous commenters recommended using a prevalent language threshold as a numerical value rather than a percentage. Several commenters recommended that HCFA adopt the standard employed in California, which calls for translation of written material when there are 3,000 Medicaid beneficiaries in an MCO's service area who have limited English proficiency, or 1,000 such Medicaid beneficiaries residing in one zip code, or 1,500 such beneficiaries in two adjacent zip codes. Some commenters noted that even if an individual was not a member of a prevalent language group, he or she had to have access to information.

Response: We believe that the language and format requirements are essential elements for ensuring that enrollees and potential enrollees receive the information necessary to make an informed choice and access benefits. While we believe they are essential elements, we also continues to believe that the best methodology for determining the prevalent language spoken by a population in a geographic area may differ from State to State and therefore we will not be modifying the regulation to mandate a specific methodology. Further, as we are leaving this methodology for States to determine, the 5 percent rate provided in the preamble should be viewed only as an example and not as a standard. The 10 percent figure in the ''Medicaid Managed Care Marketing Guidelines,'' which also contain suggested guidelines and not mandates, may also be acceptable if it meets the needs of the State. We note, however, that a number of commenters believe that a numeric threshold rather than a percentage was more appropriate because of variations in population density. The commenters believe that percentage thresholds would result in empirically low threshold numbers in low density population areas and unacceptably high threshold numbers in high density populations. We find merit in this argument, which we believe further supports our decision to permit the State to determine the best methodology for its situation. We do note the commenters' suggestions as another example for making this determination. We also note that the HHS Office of Civil Rights (OCR) has issued policy guidance on meeting the language needs of recipients of public funds. (See ''Policy Guidance on the Prohibition Against National Origin Discrimination as it Affects Persons with Limited English Proficiency,'' 65 FR 52762, August 30, 2000.) This guidance gives further examples and guidance on meeting individuals' language needs. Lastly, we agree with the commenter that oral interpretation services must be available free of charge to each potential enrollee and enrollee even if he or she is not a member of a prevalent language group.

Comment: A commenter noted that the oral interpretation requirements in proposed § 438.10(b) apply to MCEs and interpreted this to mean that it would not apply to PHPs. The commenter apparently interpreted § 438.8 to incorporate only requirements for which MCOs are mentioned by name. Under this interpretation of § 438.8, requirements that apply to MCEs (such as the language requirements in § 438.10(b)) would not be incorporated for PHPs. The commenter believes that the language requirements in § 438.10(b) should apply to PHPs.

Response: As noted above, § 438.8 subjects PHPs and PHP contracts to the requirements in paragraphs (a) through (g) that apply to MCOs and MCO contracts. Therefore, since the requirements in § 438.10 are specified in § 438.8(b), these requirements apply to PHPs.

Comment: In addition to requiring that States develop a methodology for determining the prevalence of beneficiaries needing language assistance, some commenters wanted HCFA to recommend a methodology for States to use in determining the prevalence of disabilities in the enrollee population.

Response: While we understand that it may be useful to know the percentage of individuals that may have a disability, we note that the State and MCOs and PHPs must meet the needs of *all* potential enrollees and enrollees and are specifically required under the Americans with Disabilities Act to accommodate the special needs of disabled individuals. We also note that there is a requirement in § 438.206(d) (codified in § 438.306(d) in the September 29, 1998 proposed rule) that States ensure that MCOs maintain a network that is sufficient to provide adequate access, taking into consideration the anticipated enrollment, with ''attention to pregnant women, children, persons with complex and serious medical conditions and persons with special health care needs,'' as well as ''the expected utilization of services, considering enrollee characteristics and health care needs.'' We therefore do not believe that an additional requirement is warranted; however, the State is free to implement such a requirement.

Comment: A commenter recommended that in addition to making oral interpretation services available, HCFA should mandate States to require professional training of interpreters, appropriate accreditation, and appropriate confidential

interpretation services. In addition, the commenter recommended the elimination of family members as translators because of confidentiality issues and sufficient reimbursement for translation services, as well as interpretation services. A commenter further indicated that the State should adjust the capitation rate to reflect reimbursement of interpretation services if the MCO is expected to provide the services.

Response: We believe that it is appropriate and necessary to require that interpretation and translation services be available for all potential enrollees and enrollees and have added this requirement to the regulations text. We also believe that the States should be afforded the flexibility to determine how these translation services are provided and paid for (except that beneficiaries cannot be charged for these services). The Office of Civil Rights has issued policy guidance on the training and use of translators, which may be helpful to States in determining how to meet this requirement.

Format Requirements (Proposed § 438.10(c)(2))

Comment: A commenter noted that proposed § 438.10(c)(2) required that informational material take into consideration people with special needs such as the visually impaired or those with limited reading proficiency. The commenter suggested adding language that specifically states that material in alternative formats will be provided to an enrollee *only upon request*.

Response: While we do not expect a State and MCO, PHP, or PCCM to provide information in alternative formats to all potential enrollees and enrollees, regardless of whether or not they have a special need, we do expect the State and MCO, PHP, or PCCM to provide the information when requested and to fully inform potential enrollees and enrollees about the availability of the information. We have modified § 438.10(c) to provide in § 438.10(c)(1)(ii) that information only need be ''available'' in alternative formats that take into account enrollees with special needs and to make clear in revised § 438.10(c)(2) that enrollees will be informed ''on how to obtain information in the appropriate format.''

Comment: Several commenters were pleased with language in the preamble to the September 29, 1998 proposed rule discussing what constitutes accessible information for people with disabilities and/or limited reading proficiency but believe that this language should be placed in the regulations text. For example, these commenters favored including references in the regulations to 14-point type, a fourth or fifth grade reading level, and the use of focus groups to test cognitive understanding. One commenter suggested that a failure to do so would be a violation of the Americans With Disabilities Act.

Response: Because there is not one commonly accepted standard for providing formats for beneficiaries with special needs, and in light of variances in enrolled population across States, we believe that a State is in the best position to determine the best formats for information. Allowing States to determine the format for information is consistent with the Americans With Disabilities Act, because States have a requirement under § 438.10(c)(1)(i) to present the information in easily understood language and format, and under § 438.6(c)(1)(ii) to take into consideration the special needs of enrollees. Therefore, States are required to meet the information needs of all enrollees; however, we are allowing the States flexibility in determining how they will meet these needs. Additionally, States are required to comply with the Americans with Disabilities Act without regard to the provisions of this regulation

Comment: A commenter objected that the prescriptive nature of the preamble language requiring information to be written at a fourth or fifth grade level could be problematic when providing information on the amount, duration, and scope of benefits.

Response: We do not agree that the preamble language is too prescriptive. While we have recommended that information be provided at a fourth or fifth grade level, the regulation currently affords the flexibility for States to set their own reading level standards, based on the needs of their population.

Comment: Commenters recommended that the requirement in proposed § 438.10(c)(2) that special needs of the visually impaired be taken into account also be applied to persons with hearing impairments and persons with cognitive impairments.

Response: Section 438.10(c)(1)(ii) of this final rule requires that materials take ''into consideration the special needs of those who, *for example,* are visually impaired or who have limited reading proficiency.'' (Emphasis added.) Thus, this list is not intended to be exhaustive, and the special needs listed are just two examples. Individuals with hearing impairments and cognitive impairments would also be considered individuals with special needs that must be considered in material development. We do not believe that it would be possible to have an exhaustive list of special needs as the enrolled populations and needs of enrollees vary by State. In addition, the individuals with special needs vary depending on the circumstance for providing information. For example, an individual with a hearing impairment would not need custom material for mailings but would for educational presentations. We do expect a State and an MCO, PHP, or PCCM to take into consideration the needs of all potential enrollees and enrollees in their State and MCO, respectively.

Comment: A commenter indicated that communications to homeless persons regarding Medicaid Managed Care benefits must take into account a high level of transience, illiteracy, and cognitive impairment in this group.

Response: As stated above, the requirement to take into consideration special needs of individuals applies to all individuals with special needs including people who are homeless.

Comment: Commenters indicated that the regulation should recognize that effective communication may not only require accessible formats but also requires the need for staff training in the managed care plan, health care provider's office, and the Medicaid agency to effectively interact with persons with disabilities, including hearing impairments and cognitive learning problems. Commenters further indicated that to be effective, face-to-face interactions may be required.

Response: We agree with the commenter that effective communication may require more than printed material and have revised the language at § 438.10(c)(1)(ii) to also require that material is provided in an ''appropriate manner' that takes into consideration the special needs of individuals. We have also added a requirement in § 438.10(c)(5) that the State and MCO have mechanisms in place to assist potential enrollees and enrollees with understanding the managed care program and their benefits.

Comment: A commenter believes that the regulations lack the detail needed to assure that States and MCE's understand their obligation to ensure culturally and linguistically appropriate benefits for Medicaid beneficiaries at all levels of the health care delivery system.

Response: We do not agree with the commenter because there are various sections of the regulation that address cultural issues and impose obligations on States to take these issues into account, including the requirements in § 438.10 discussed in this section and requirements in § 438.206 (codified at § 438.306 in the September 29, 1998

proposed rule) discussed below. While we have not provided detailed ''specifications'' in all cases as to *how* States fulfill these obligations, since we believe States should be provided some flexibility in this area, States will be responsible for accomplishing the commenter's desired results, regardless of what methods they use to achieve them.

We have required that oral interpretation services and translation be provided free of charge to beneficiaries and that information on primary care providers include languages spoken.

Comment: Some commenters advocated that all information should be reviewed and approved by the State if not distributed by the State.

Response: Many of the elements listed in § 438.10 are considered marketing material and must therefore be reviewed in accordance with the marketing standards at § 438.104. Paragraph (b)(2) of § 438.104 specifies that each MCO, PHP, or PCCM contract must provide that the entity does not distribute any marketing materials without first obtaining State approval. Further, those that might not be considered marketing materials, such as appointment notices, etc. still must meet the information standards in § 438.10, including understandability.

When Information Must Be Provided (Proposed § 410(d) and (f)).

Comment: Several commenters sought clarification of when complete benefit information was required to be provided to beneficiaries. One commenter recommended that the ''once a year'' requirement of § 438.10(d)(2) be changed to ''at least once a year'' to make it clear that this information need not be provided at a specific anniversary time but rather may be included with other information in the normal course of business during the year.

Response: We agree with the commenter that greater flexibility is needed, and we therefore have provided in a recodified § 438.10(e)(1)(ii) that after the initial provision of information to new enrollees, any significant change in this information must be provided 30 days prior to the effective date of the change. We have also added a requirement in a new § 438.10(f)(4) that all of the information that is ''provided'' pursuant to new paragraphs (d) and (e) (proposed § 438.10(e)) also be available ''upon request'' at any time.

Comment: One commenter expressed concern that the proposed requirement for primary care case managers to provide additional information ''before'' or ''during'' enrollment is confusing as ''before'' or ''during'' can refer to two separate time frames. The commenter recommended that the primary care case manager, or State on behalf of the primary care case manager, be required to provide information ''on'' enrollment.

Response: We agree with the commenter that further clarification is necessary. The regulation has been modified to reflect the same time frames as those required of MCOs, or the State on behalf of the MCO.

Comment: A commenter believes that in addition to annual notification, there should be notification ''as soon as changes occur'' in any of the provisions listed in proposed § 438.10(e) (now in §§ 438.10(d)(2) and (e)(2)).

Response: We agree with the commenter that enrollees should be notified if there is a significant change within the program and have modified the regulations in response to this comment. In the new § 438.10(e)(1)(ii), we are requiring that when there is a significant change (as defined by the State) in the information provided under § 438.10(e)(2), a revised version of the information in paragraph (e)(2) must be provided at least 30 days prior to the effective date of the change. We believe the State is best suited to define what is considered to be a significant change.

Comment: Commenters wanted us to further define when the MCO (or the State) must provide information to enrollees. One commenter suggested that the provision be modified to state that the information should be given within ''a reasonable time after the MCO receives the notice of the recipient's enrollment *or* the effective date of the enrollment, whichever is later.'' Another commenter suggested 7 days after enrollment.

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

Comment: Commenters indicated that the dissemination of information is very costly. Additionally, commenters believe that the States were in the best position to provide comparative information. The preference of these commenters was that the State agency assume the administrative responsibility for providing information.

Response: We believe we have provided States with significant flexibility, given the detailed statutory requirements in section 1932(a)(5) of the Act. We agree with the commenter that States should assume responsibility, within the constraints of the requirements in section 1932(a)(5) of the Act, and specifically that States should have the flexibility to decide whether they or MCOs provide comparative information.

Comment: A commenter suggested that the regulations should require States to have a mechanism for notifying their enrollees of their right to request and obtain basic information.

Response: Section 438.10(e)(1)(i) requires that States ensure that enrollees are provided the information at least once a year, rather than just be notified as in the proposed rule.

Comment: A commenter recommended that MCOs provide information directly to enrolled adolescents.

Response: While it is probable that adolescents would receive information directly when enrollment is not linked by family unit, in the case of a family unit we believe that sending one copy of information to each household is sufficient and would constitute providing the information to all ''enrollees'' in that household, provided alternative formats are not necessary for special need reasons. The cost of requiring MCOs to mail directly to multiple family members could be prohibitive. However, this regulation does not prohibit States from imposing this requirement.

Comment: A commenter urged that HCFA ensure that individuals not have to go great lengths to obtain information and that a general request for information should trigger the provision of full information.

Response: We agree with the commenter. Section 438.10(f) includes a requirement that all elements of information be available ''upon request.'' We expect that States and MCOs will not make the process of obtaining information difficult and will provide comprehensive information if any information is requested, since it is in the best interest of all parties that the individuals be as knowledgeable as possible about their health care options, rights, and responsibilities.

Required Information (Proposed § 438.10(e))

Comment: Some commenters argued that proposed §§ 438.10 and 438.318 would impose information requirements upon States or their contracted representatives that go far beyond what is required in statute. Specifically, these commenters pointed out that the statute requires that information on the identity and location of health care providers need only be provided ''upon the request'' of enrollees or potential enrollees, rather than that it be

''provided'' as specified in proposed § 438.10(e)(3). However, there were also a number of commenters who applauded HCFA for requiring that information be ''provided'' and suggested that the provision of additional information on the nature of managed care arrangements would also be appropriate.

Response: Section 1932(a)(5) of the Act spells out information that must be available to all enrollees and potential enrollees. The statute, however, only requires that this information be available ''upon request.'' We believe that the information listed is so basic and fundamental to an enrollee's ability to access services and exercise rights that it is ''necessary for * * * proper and efficient operation'' for this information to be in the hands of all enrollees. For example, an enrollee needs to know about the network of providers in order to access care and about appeal rights to exercise these rights. Therefore, pursuant to our authority under section 1902(a)(4) of the Act to specify what is ''necessary for * * * proper and efficient operation,'' we have required that information such as the names, locations, and telephone numbers of the MCO's network of providers be provided to beneficiaries. We have developed these requirements in keeping with what we believe to be the Congress' general intent that potential enrollees and actual enrollees have this important information. Also, in response to the latter comments that specifically called for information to be given to enrollees on a variety of characteristic features of managed care (for example, prior authorization of services and provider networks), we have added a new type of required information to include ''Description of basic features of managed care'' and ''MCO responsibilities for coordination of enrollee care.'' We have also required the States and MCOs to have in-place mechanisms to assist potential enrollees and enrollees in understanding the managed care system and their benefits. In the BBA-mandated report to the Congress on safeguards for individuals with special health care needs who are enrolled in Medicaid managed care, we noted the extensive evidence that exists on Medicaid, Medicare, and commercial MCO enrollees that demonstrates their lack of knowledge of the characteristic features of managed care and the implications of their enrollment in an MCO. Similarly, evidence exists that there is widespread confusion about MCO responsibilities for care coordination. The nature of comments received support these additional requirements.

Comment: Commenters believe that the elements of information that the MCO (or State) must provide are often elements that are currently included in the member handbook that is supplied by the MCO or by an enrollment broker. A commenter expressed concern that too much information could be overwhelming, causing people to ignore all of it.

Response: We agree with the commenter that the information that must be provided under the September 29, 1998 proposed regulation generally is already provided to enrollees as a common practice. To the extent this is the case, these existing practices could satisfy the requirements in § 438.10(e) with respect to enrollees. It is not our intent that this information be duplicative of what is currently provided. Section 438.10 allows States to continue their current practice of including information as part of an enrollee handbook or requiring that the MCO or (in the case of potential enrollees) that an enrollment broker provide the information. Therefore, HCFA does not believe that the regulation is duplicative or burdensome. We have modified the regulation to specify in § 438.10(d)(1) that the ''State, or its contracted representative'' may provide the information in § 438.10(d)(2) to potential enrollees. Because this information is generally currently provided, we also do not believe that the requirements in § 438.10 would result in ''information overload.''

Comment: Commenters suggested that information on service authorization requirements and provision of transportation to services should be included as elements of the basic information about procedures for obtaining benefits.

Response: Section 438.10(e)(2)(iii) expressly requires that information containing the procedures for obtaining benefits be provided, including any authorization requirements. This should include information on transportation to the extent this is necessary to obtain benefits.

Provider Directories/Provider Information (Proposed § 438.10(e)(3).

Comment: Some commenters believe that information on specialists should only be provided upon request due to the volume of information. These commenters supported this recommendation. They believe that if enrollees are provided with information on specialists, the enrollees may believe that they do not need a referral for speciality care. These commenters believe that this information should only be provided upon request and that it is best provided with the assistance by someone over the phone that has access to timely data. In contrast, we received a number of comments from individuals applauding us for requiring that information on specialists be included in the information, citing that a significant number of Medicaid beneficiaries have special needs and are more reliant on the specialists than the primary care physicians.

Response: Although we acknowledge that including information on specialists adds to the volume of information and further complicates the process of keeping information current, we do believe that a significant number of enrollees rely on this information and therefore continue to believe that, at a minimum, information on provider networks should include information on primary care physicians, specialists, and hospitals, as stated in the preamble to the September 29, 1998 proposed rule. To clarify this point, we have included this preamble reference to specialists in the regulations text at § 438.10(e)(3)(iv).

Comment: A commenter recommended that homeless enrollees receive information about which providers in the network in which they are enrolled have demonstrated competency in meeting their complex health and social needs. Similarly, commenters indicated that information should be available about (1) the ability of providers to treat adolescents and individuals with HIV; (2) the providers' language proficiency; and (3) the accessibility of providers for individuals with disabilities. One commenter suggested that this be required as part of the additional information on education and board certification status of health professionals.

Response: We believe that this type of information should be maintained by the State, MCO, PHP, or PCCM, or enrollment broker (as appropriate) and be available upon request in order to assist individuals when they have a question about a particular service, provider, or location. We have added a requirement in new § 438.10(f)(3) to specify that enrollees, and potential enrollees, are able to obtain any other information on requirements for accessing services or other factors necessary (such as physical accessibility) that may be needed to effectively access benefits.

Comment: Many commenters expressed the view that the requirement to include identification of those network providers who are not accepting new patients is difficult to keep timely and may be out of date by

the time it is printed. In contrast, we also received comments from individuals indicating that this information is critical if a beneficiary is expected to make an informed choice.

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

Comment: Several commenters strongly recommended that HCFA require, and not simply suggest, that information on ancillary care provider options be provided. Additionally, commenters wanted information provided on Federal or State community health centers, dialysis centers, and mental health and substance abuse treatment centers (in addition to primary care physicians, specialists, and hospitals).

Response: As the enrolled population, and therefore the health needs of the enrollees, varies from State to State, we believe that the State is in the best position to determine what information needs to be included on ancillary care providers (including those listed by the commenters) in order to meet the needs of their respective beneficiaries. We do expect that this information will be available in all cases and that enrollees and potential enrollees will be notified about availability of additional information upon request.

Comment: A commenter recommended that the requirement for ''name and location'' of network providers be expanded to require the State to provide the name of the clinic or facility, as well as that of the provider, because many patients relate to the clinic and not the provider's name.

Response: While we acknowledge the commenter's point that an individual may be more familiar with a clinic name than a provider name, this is not always the case. We believe that the State or the MCO, PHP, or PCCM is in the best position to know the level of detail regarding site identification that should be included in the information a potential enrollee and enrollee receives.

Comment: A commenter stated that information regarding the education and board certification (and recertification) status of the health care professionals staffing the emergency departments in the enrollee's geographic region should also be provided. They further believe that this additional information should be provided, and not simply made available upon request, because of the need for quick decisions in emergency situations.

Response: Since emergency room physicians are considered health care professionals, *in a situation in which there is a direct contractual relationship* with emergency room physicians, they would be included in the provision at § 438.10(f)(2) that requires information be provided that includes the education and board certification and recertification of health professionals. While it is our belief that some beneficiaries may be interested in receiving these elements, and should be able to obtain them, they are not elements of information that every beneficiary typically uses in selecting a provider. In most cases, in an emergency situation in which time is of the essence, an enrollee would not be ''shopping'' for the best emergency room doctor but would go to the nearest emergency room. Therefore, while the information must be available ''upon request,'' we have not changed the regulation to require that this information be ''provided.'' Further, we note that if there are not direct contractual relationships with the emergency room physicians, as often is the case, there would be no way for an MCO or State to know this information, and therefore the enrollee or potential enrollee could not obtain the information from the MCO or State.

Comment: A commenter was concerned that HCFA was silent on how frequently the provider directory needs to be updated. The commenter recommended that we convey that the intent is not to mandate that the printed directory be updated more often than periodically, although the commenter expressed that we should expect that current information be available through the MCO and through other sources.

Response: We agree with the commenter's clarification regarding the frequency of printing provider directories, but do not believe that a regulation change is necessary. Specifically, we expect the provider directories to be updated periodically, as defined by the State, but also expect that current information always be available to the enrollee or potential enrollee through the State, MCO, PHP, or PCCM, or State contracted representative.

Comment: Several commenters strongly urged HCFA not to permit the use of ''subnetworks'' by MCOs. They believe it would be unfair to consumers to join an MCO and then discover that they could not access all providers because they had been assigned to a subnetwork. In addition, commenters recommended that HCFA require that plans clearly indicate if a network listing does not include all clinics and providers located at the facility.

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

Information on Benefits

Comment: A commenter recommended that information also should be provided on which populations are excluded from eligibility to enroll, are subject to mandatory enrollment, or may enroll voluntarily. Commenters specifically cited the Native American population.

Response: We revised the regulations to include a requirement in § 438.10(d)(2)(i)(B)(vi) that requires State to provide information on which enrollees are excluded from eligibility to enroll, are subject to mandatory enrollment, or may enroll voluntarily.

Comment: Several commenters recommended that information be made available on drug formularies.

Response: As a requirement of § 438.10(e)(2)(i), information must be provided to enrollees on the benefits offered, and the amount, duration, and scope of benefits available under the contract, with ''sufficient detail to ensure that enrollees understand the benefits to which they are entitled, including *pharmaceuticals*, and mental health and substance abuse benefits.'' (Emphasis added.) In addition, there is now a requirement in § 438.10(f)(3) specifying that enrollees and potential enrollees can request other information on requirements for accessing services to which they are entitled under the contract. Therefore, although we support the commenter's goals, we believe that this is sufficiently addressed in the regulation.

Comment: A commenter recommended that this section should clearly define all Federally mandated ''benefits'' and ''services'' to which Medicaid enrolles are entitled, including nurse-midwifery services, consistent with section 1905(a)(17) of the Act. The commenter and others recommended the use of both ''benefits'' and ''services'' to convey the full range available under the State Plan.

Response: The terms ''benefits'' and ''services'' are synonymous. Section 1932(a)(5) of the Act uses the terms ''benefits'' in the information section, and therefore ''benefits'' is the word we have used throughout this section of the regulations. The terminology may be different in other sections if the statute used the word ''services'' with a different meaning in mind; however, the words are interchangeable.

Comment: A commenter recommended that information be provided on those benefits that are carved out of the program entirely, as well as those that overlap (for example, mental health benefits and prescription coverage).

Response: Information must be provided on all covered and noncovered benefits for each MCO and PHP. While States may determine that this additional information is necessary, it is our belief that it is the duty of the State, MCOs, PHPs, and providers to coordinate programs and not that of the enrollees.

Comment: Several commenters urged that proposed § 438.10(e) be amended to specifically require that the MCO's basic information list include the availability and scope of EPSDT benefits and family planning benefits. Another commenter stated that the information to enrollees should clearly state that the amount, duration, and scope of benefits provided to children under EPSDT are not limited.

Response: Section 438.10(e)(2)(i) requires that information be provided on the benefits offered and the amount, duration, and scope of benefits available under the contract. Section 438.10(e)(xii) requires that information be provided on the benefits that are not available through the contract but are covered as part of the State plan. Finally, § 438.10(e)(2)(vi) requires that information be provided on the extent to which an enrollee may obtain benefits from out-of-network providers. The preamble specifically cites family planning benefits (when appropriate) as an example. HCFA believes that EPSDT benefits are also benefits that fall within the purview of this requirement. Therefore, sufficient information on EPSDT and family planning benefits will be provided.

Comment: Many commenters believe that while providing information on benefits, as well as those carved out, seemed reasonable, the requirement to include information on the amount, duration, and scope was problematic and too voluminous to provide.

Response: We expect that States and MCOs, PHPs, or PCCMs would use general terms and groupings for benefits that have no limitations; however, additional information would be expected if there was a limitation in a particular service. We believe that individuals need sufficient detail to ensure that they receive the benefits that they are entitled to receive and therefore have not modified the regulation as suggested by the commenters.

Grievance Information (Proposed § 438.10(e)(11)

Comment: Proposed 438.10(e)(10) (recodified at § 438.10(e)(2)(xi)) required that enrollees and potential enrollees be provided information about any appeal rights made available to providers. Commenters suggested that we remove that requirement because it is not directly relevant to enrollees.

Response: This regulation reflects the requirement under section 1932(a)(5)(B)(iii) of the Act, ''Grievance and appeal procedures,'' which refers to information on procedures available to an enrollee *and* a health care provider seeking to challenge or appeal a failure to cover a service.

Primary Care Case Manager Requirements (Proposed § 438.10(h))

Comment: Some commenters contended that primary care case managers generally are provided a minimum case management fee that would not cover the cost of providing the information required under proposed § 438.10(h) (recodified as § 438.10(g)). A commenter suggested that the enrollment broker would be in a better position to provide this information. Another commenter believes that the State should be able to decide who provides the information required under proposed § 438.10(h).

Response: Under § 438.10(g), the State is afforded the flexibility of determining whether the State, contracted representative, or primary care case manager is to provide the information. However, if an enrollee requests information about the grievance procedure from the primary care case manager, he or she should be able to obtain it without having to contact the State. As this information must be available only ''upon request,'' we do not believe that it will be overly burdensome for the primary care case manager to provide the information.

Comment: Some commenters were concerned that a primary care case manager's duty to inform consumers about their grievance rights ''upon request'' may be perceived as supplanting the obligation of MCOs and States to provide written notice of an adverse decision, regardless of whether it is requested. They supported the requirement that case managers be aware of the procedures for filing a grievance and be required to provide information upon request but wanted a statement included that this did not replace the requirement to provide notification for adverse decisions.

Response: The requirements in § 438.10(g) are information requirements, analogous to the information requirements for MCOs under § 438.10(e)(x), and have no effect on the notice and appeal requirements in subpart F of part 438. We therefore do not believe any revisions to the regulations are warranted in response to this comment.

Comment: Certain commenters were displeased that there was no requirement that MCOs provide information about their quality assurance program to enrollees and potential enrollees in the Medicaid program. They believe the regulation should include, as information provided ''upon request,'' information of the type provided under § 422.111(c)(2), (4) and (5) of the June 29, 2000 Medicare+Choice regulations. Specifically, commenters believe that Medicaid beneficiaries should also have access to the following information that is provided to Medicare+Choice enrollees under those regulations: information on utilization control procures; information on the financial condition of the MCO; and a summary of physician compensation arrangements. They also recommended that States require MCOs to provide treatment protocol information to beneficiaries upon request and provide information on HEDIS indicators; results of plan quality studies; external reviews; compliance audits; and summarized complaint and grievance data.

Response: We agree with the commenters that the cited information would be useful to beneficiaries and have revised § 438.10(f) to require that MCOs provide the same information, upon request, that Medicare+Choice organizations are required to provide under § 422.111(c)(2), (4), and (5). With respect to the additional information requested regarding HEDIS indicators and the results of quality studies and external reviews, the results of external reviews under section 1932(c)(2) of the Act will be made available to enrollees and potential enrollees, as required under section 1932(c)(2)(A)(iv) of the Act. Given the lack of experience in analyzing HEDIS indicators or quality results, we are not requiring the disclosure of this information to enrollees at this time but would consider doing so at a future date after

we have more experience concerning the reliability and usefulness of these data.

Comment: Some commenters supported the requirement in proposed § 438.10(i)(2)(iv) (recodified in this final rule at § 438.10(h)(3)(iv)) that information on disenrollments be provided in the case of mandatory enrollment programs under section 1932(a) of the Act; however, many believe these reports would not be meaningful unless they specified the various types of disenrollment, such as voluntary disenrollments, emergency disenrollments, and involuntary disenrollments that occur, for example, due to the loss of Medicaid eligibility as these latter categories of disenrollments are outside of the MCO's control. In the absence of this level of specificity, commenters stated that the data were not useful and could be misleading.

Response: We recognize that disenrollment rates can mean different things, depending on what is included in the rate. For this reason, § 438.10(h)(3)(iv) refers to disenrollment rates ''as defined by the State.'' At a minimum, by requiring the State to define ''disenrollment rates,'' there will be uniform comparison of disenrollments among MCOs, PHPs, or PCCMs. We encourage States to consider the concerns noted by commenters when defining disenrollment rates.

Comment: Commenters observed that providing comparative information in chart form as required under proposed § 438.10(i)(1)(ii) (recodified at § 438.10(h)(1)(ii)) is relatively new and if done inappropriately could be misleading. These commenters stressed that to be effective, the presentation of comparative information needs to take into account the characteristics of each MCE as compared to others, as well as the relative size of the MCE, which may make sampling too small for validity.

Response: The actual design and format of the comparison chart required under § 438.10(h)(1)(ii) in the case of mandatory enrollment programs under section 1932(a) of the Act is left to the State to design. We suggest that States note the concerns listed.

Comment: A commenter sought clarification on how a comparative chart-like form is to be used for the proposed information if the MCE is a primary care case manager under a PCCM program.

Response: The comparative chart-like format specified in § 438.10(h)(1)(ii) is expressly required under section 1932(a)(5)(C) of the Act in the case of a mandatory enrollment program under section 1932(a)(1) of the Act. Section 1932(a)(5)(C) of the Act expressly refers to comparing ''managed care entities [MCEs] that are (or will be) available and information (presented in a comparative, chart-like form) relating to'' specified areas. The statute thus requires the use of these comparative charts in the case of MCOs, PHPs, or PCCMs, whether they be MCOs or primary care case managers. We believe that this is possible, though we would not expect information on primary care case managers to necessarily look similar to that used for comparing MCOs. For example, the chart could list only those primary care case managers that were different in regard to benefits covered and cost sharing imposed. Additionally, § 438.10(h)(3)(ii) requires that quality indicators be provided to the extent available.

6. Provider Discrimination (Proposed § 438.12)

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

Comment: We received several comments requesting that we clarify our September 29, 1998 preamble language in which we indicate that we did not interpret section 1932(b)(7) of the Act to be an ''any willing provider'' provision. Several commenters specifically recommended that we reference this statement in our final rule, while others recommended that we reiterate this statement in the preamble to the final rule. One commenter suggested that we reconsider this provision so as to require all willing providers to be included in an MCO's network.

Response: As we stated in the preamble to the September 29, 1998 proposed rule, we believe it is clear that section 1932(b)(7) of the Act does not require that MCOs contract with all licensed providers willing to undertake the provision of services to the MCO's enrollees. To the contrary, section 1932(b)(7) of the Act expressly provides that it ''shall not be construed'' to prohibit an organization from ''including providers only to the extent necessary to meet the needs of . . . enrollees.'' It also makes clear that restrictions based on maintaining quality or controlling costs are permissible. We believe that the requirements contained in this section of the regulation were intended only to ensure that providers are selected in a fair and reasonable manner and not discriminated against solely because of their license or certification. Thus, we indicated in the September 29, 1998 proposed rule, and we reiterate here, that this section does not require MCOs to contract with ''any willing provider.'' We do not believe it is necessary or appropriate to amend the regulations to expressly reflect this fact, since by its own terms, § 438.12 does not require contracting with all willing providers.

Comment: One commenter requested that we clarify how a State will determine compliance with this provider discrimination provision.

Response: We expect each State agency to develop its own mechanism to ensure that MCOs contract with providers in a fair and reasonable manner. Our regulation provides States sufficient flexibility to determine which mechanism works best for them. We plan to work with States to provide additional guidance on this issue in the future.

Comment: One commenter recommended that the final rule include written notice and appeals procedures for providers participating in an MCO. The commenter suggested that the process for a written notice and appeals procedure should be based, in part, on the interim final Medicare+Choice regulation.

Response: While the Medicare+Choice regulations do require, in the last sentence in § 422.205(a), that Medicare+Choice organizations provide written notice to providers or groups of providers stating the reasons why they were not accepted as part of the organization's provider network, there is no provision for a right to ''appeal'' such a decision. Under §§ 422.202(a) and 422.204(c), providers have appeal rights only once they have been accepted as a member of the Medicare+Choice organization's provider network. We similarly are not providing for any right to an appeal in this final rule, though States are free to do so. We agree with the commenter, however, that it would be helpful in enforcing the anti-discrimination requirement in section 1932(b)(7) of the Act if MCOs were required to provide written notice to providers seeking to contract with them of the reasons why

the providers were not included in the MCO's network. We therefore have revised § 448.12(a) to include the same written notice requirement that applies to Medicare+Choice organizations under § 422.205(a).

Comment: Several commenters suggested that additional protections be added to the regulation to further ensure nondiscrimination of providers. The commenters recommended that the regulation expressly prohibit nondiscrimination of providers who serve limited English-proficient populations, high-risk populations, and persons with HIV and AIDS. One commenter stressed the importance of culturally competent providers and recommended that we add a provision to require physicians to be added to an MCO's network because of the ''value'' they would add in terms of cultural competence.

Response: The statutory provision implemented in § 438.12(a)(1) and (b), section 1932(b)(7) of the Act, addresses only discrimination that is based solely on licensure and not the other types of discrimination addressed by the commenters. However, § 438.12(a)(2) incorporates requirements elsewhere in part 438 that we believe, along with other provisions in part 438, address the commenters' concerns. Specifically, § 438.12(a)(2) requires that providers be selected in accordance with the requirements in § 438.214 of subpart D. Section 438.214(c) in turn requires States to ensure that MCOs use provider selection and retention criteria that ''do not discriminate against particular providers, including those who serve high risk populations or specialize in conditions that require costly treatment.'' We believe that this prohibits the types of discrimination referenced by the commenters. In addition, we refer the commenters to § 438.206(e)(4), which requires MCOs to provide services in a culturally competent manner, including at least complying with the language requirements of § 438.10(b).

Comment: One commenter believes that there was a contradiction between proposed § 438.12 and proposed § 438.306 (recodified at § 438.206 in this final rule) and that clarification was needed in order to comply with the requirements of section 1932(b)(7) of the Act, as the commenter interpreted them. Specifically, the commenter referred to the preamble discussion of proposed § 438.306 in which we stated that 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 access standards define which providers are to be used and ensure that those standards are consistent with State laws.

Response: Section 438.12 speaks to discrimination by MCOs against providers of services solely on the basis of licensure. In contrast, § 438.206 requires States to establish standards to ensure the availability of services by MCOs. Although the preamble to proposed § 438.306 referred to ''types''of providers to be used, it specifies that the MCO's standards for inclusion of providers must be consistent with State law. We do not believe that § 438.206 could reasonably be read as inconsistent with § 438.12 (that is, to permit an MCO to discriminate against providers solely based on licensure or certification). Section 1932(b)(7) of the Act makes clear that MCOs may limit the number of providers with which they contract based on need or to control costs. If more than one type of provider can provide a State plan service, and an MCO already contracts with one such type of provider, we believe that it could under section 1932(b)(7) of the Act and § 438.12 decline to contract with the other type of provider based on cost-effectiveness considerations, unless there is a State plan service that only that type of provider can furnish. For example, if the State plan includes ''nurse-midwife'' services under section 1905(a)(17) of the Act or certified pediatric nurse practitioner/certified family nurse practitioner services under section 1905(a)(21) of the Act, these services can, by definition, only be provided by the type of provider in question.

Comment: One commenter expressed concern regarding a Medicare Operational Policy Letter, indicating that it could be used as a basis for denying chiropractic services to a Medicaid beneficiary.

Response: First, we note that Medicare Operational Policy Letters do not establish Medicaid policy and are not a valid basis for denying services to Medicaid beneficiaries that would otherwise be covered in accordance with a Medicaid State Plan. The Medicare Operational Policy Letter in question also would not have any applicability even by analogy, because of differences between the way chiropractic services are treated under Medicare and Medicaid. Under Medicare, ''chiropractor services'' are not listed as a specific covered service or benefit. Rather, under section 1832(a)(2)(B) of the Act, beneficiaries with Medicare Part B are entitled to coverage of ''medical and other health services,'' which in turn is defined in section 1861(s) of the Act as including ''physicians services.'' While there thus is a right to coverage of ''physician's services,'' there is no specific coverage category for the services of a chiropractor. Instead, under the definition of physician in section 1861(r) of the Act, a chiropractor can be considered a physician for purposes of being eligible to provide Medicare covered physician services but only to the extent the chiropractor is performing a manual manipulation of the spine to correct a subluxation. This manual manipulation thus can be reimbursed by Medicare as a physicians' service whether it is performed by a chiropractor or any other physician, such as an orthopedist, who performs this manual manipulation.

In Medicaid, in contrast, section 1905(a)(6) of the Act permits States the option of covering medical or remedial care ''furnished by licensed practitioners within the scope of their practice as defined by State law.'' To the extent a State has decided under section 1905(a)(6) of the Act to cover chiropractor services under its State plan, this covered service by definition could only be provided by a chiropractor.

Comment: We received several comments questioning the statutory basis for § 438.12(b)(2), which permits the MCO to pay different amounts for different specialties. Several commenters suggested that a provider performing the same service should be paid the same amount, regardless of the provider's specialty. They recommended that we remove paragraph (b)(2) or revise it to prohibit MCOs from paying lesser amounts for the same service when provided by different types of practitioners. Other commenters stated that paragraph (b)(2) had the practical effect of requiring MCOs to pay all specialists within the same specialty the same amount. These commenters suggested that HCFA clarify this provision, with one commenter recommending that we amend paragraph (b)(2) to not permit the MCO to use different reimbursement amounts for different specialties or for the same specialty.

Response: We disagree that the statute does not allow an MCO from establishing different reimbursement amounts for different specialties. Section 1932(b)(7) of the Act states that an MCO ''may establish measures designed to maintain quality and control costs consistent with the responsibilities of the organization.'' We believe that paying different amounts to individuals with different specialties can clearly be dictated as a ''measure[ ] * * * to control costs.'' This is because we believe that, in order to attract

highly qualified providers of all types, and to attract an adequate number of certain categories of specialists, MCOs may need to pay a higher amount than they would need to pay to attract other types of providers. It would not be cost-effective if the MCO was then required to pay this higher amount to other providers who would be willing based on market rates to join the network for a lower amount. Also, as a quality measure, MCOs should be free to pay providers with more training and experience a higher rate of reimbursement for the services they perform. Moreover, we do not want to preclude MCOs from using incentive payments to reward providers for demonstrating quality improvement or from attracting experienced providers to its network.

For the reasons stated above, we agree with commenters that paragraph § 438.12(b)(2) should be clarified to also permit different reimbursement amounts for the same specialty. Accordingly, we have amended the final regulation at § 438.12(b)(2) to state clearly that an MCO may use different reimbursement amounts for different specialties or for the same specialty.

B. State Responsibilities (Subpart B)

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

1. State Plan Requirements: General Rule (Proposed §§ 438.50 and 438.56(b), (c), and (d))

Proposed §§ 438.50 and 438.56, implemented section 1932(a)(1) and (2) of the Act, which permits mandatory enrollment of Medicaid beneficiaries in MCOs or PCCMs on the basis of a State plan amendment, without a waiver under section 1915(b) or 1115 of the Act. Under these regulations, a State agency can require most Medicaid beneficiaries to enroll in MCOs or PCCMs without being out of compliance with provisions in section 1902 of the Act on statewideness, comparability, or freedom of choice. Paragraph (b) and (c) set forth the requirements for these programs and the assurances that States must provide. Proposed § 438.56(b) identified limitations on populations that could be mandatorily enrolled. Paragraphs (c) and (d) set forth requirements for enrollment priority and default assignment under these programs.

Comment: One commenter requested that we clarify that § 438.50 does not apply to 1915(b) and 1115 waiver programs since States can mandate enrollment in MCOs and PCCMs under theses waiver authorities without amending their State plan.

Response: We agree with the commenter and we have amended the final rule with comment period to expressly provide that programs operating under section 1915(b) or 1115 the waivers are exempt from the requirements of this section.

Comment: A few commenters expressed the concern that the Federal requirements permit certain SPAs to be effective as early as the first day of the quarter in which the SPA was submitted to us and recommended that we eliminate the retroactive approval of these SPAs. Two commenters erroneously believed that the State risk loss of federal money if the SPA is disapproved, apparently confusing this State plan process with the process of approving contracts under section 1903(m) of the Act. These commenters also expressed a concern that beneficiaries may be permanently adversely affected in the event they are harmed during the retroactive period. One commenter remarked that the State could begin enrolling beneficiaries into a mandatory managed care system that does not guarantee access to reproductive health services prior to the submission of the SPA. Another commenter emphasized that the short timeframes in implementing managed care have caused problems for the consumers and providers in the past, and guidelines from us are needed in areas of payment, enrollment, network adequacy and continuity of care, etc.

Response: We do not believe that the rules governing effective dates for SPAs which mandate enrollment in managed care should differ from the rules that apply to any other amendments to a State's plan. By allowing States to implement a SPA effective the first day of the quarter in which they submit the SPA to us for approval, § 438.50 is consistent with the other SPA effective date provisions in §§ 430.20 and 447.26. The retroactive effective date is only applicable in the case of an approvable SPA. During the retroactive period, the increased beneficiary protections such as grievance procedures, quality assurance, and disenrollment are applicable. Also, before the State may actually enroll beneficiaries into MCOs under this authority, all contracts between the State and the MCO must be approvable and in place and all statutory and regulatory requirements must be satisfied.

Comment: Two commenters indicated that the pre-print form is not sufficiently descriptive. They recommended that the form require the States to provide more detail on family planning, prenatal care, labor and delivery and other reproductive health services. In addition, they would like the States to specify the type of entities with which the State will contract in order to assure access to reproductive health services, supplies and procedures.

Response: We are in the early stages of developing this section of the State plan preprint for amendments under § 438.50, and will take these comments into consideration when designing that form. However, some States have already implemented approved programs under § 438.50 utilizing existing guidance issued in a December 17, 1997 letter to all State Medicaid Directors. We believe that the commenter's specific concerns are addressed in § 438.50(b), which requires States to specify the types of entities with which they will contract under a mandatory managed care program, in combination with § 438.206(c), which requires that contracts with the MCO specify the services that the entity is required to provide, and that States make arrangements to cover all Medicaid services available under the State plan, including any that may not be in the MCO contract.

Comment: One commenter stated that while States can assure that contracts between MCOs and themselves meet all requirements of the Act, a commitment that all MCOs and PCCMs will be in compliance at all times is unrealistic. This commenter recommended that the preferable language would be that the State/local district will take appropriate action against an MCO or PCCM whenever it is determined that one of these entities is not in compliance with the contract.

Response: We agree that a State cannot assure in advance that an MCO or PCCM will always be in compliance with all requirements, and that all we can ask is that the State take appropriate action if it is determined that one of these entities is out of compliance. Subpart I below discusses intermediate sanctions and civil money penalties that can be imposed when MCOs or PCCMs are out of compliance, and subpart J discusses the fact that FFP can be denied in contracts with MCOs that are substantially out of compliance. Proposed § 438.50(b)(4), however, refers to the State being in compliance with requirements in this part relating to MCOs and PCCMs.

Comment: We received one comment stating that the current regulations allow

our Regional Offices (ROs) to approve SPAs based on policy statements and precedents previously approved by the Administrator. Only disapproval of an amendment must come from the Administrator's office. Currently there are no policy statements or precedents from the Administrator's office to provide guidance to ensure uniform decision making by the ROs. This commenter recommended that approval of the managed care plan amendments should be the responsibility of our Administrator with assistance from the Regional Office until comprehensive guidelines have been developed and disseminated to the Regional Office.

Response: Section 430.15(b) gives our delegated authority to approve the State plan and plan amendments. The consults with our Central Office during the review process to ensure that the SPA meets the requirements of all relevant Federal statutes and regulations as stated in § 430.14. All reviewers in our Central and Regional Offices reference the same tools when reviewing a State plan amendment, including State Medicaid Director letters implementing the managed care provisions in the BBA of 1997 provisions. The delegations of authority are clear on the review of State plan amendments, and the collaboration between the our RO and central office is a long established process. Consequently, we are not making any changes in the approval authority for these SPAs.

State Plan Assurances (Proposed § 438.50(b) and (c))

Comment: A number of commenters felt that the regulation should require the States to publicize any plan amendment for mandatory managed care, and to solicit public involvement in all levels of development before the amendment is approved and implemented. Suggested methods for informing and involving the public included:

- Public hearings and comment periods;
- Involving the State Medical Care Advisory Committee in reviewing amendments and contracts.
- Using our website to notify the public of the submission and approval of State plan amendments.
- Publishing a **Federal Register** notice when States first submit an amendment.
- Requiring that the MCO and PCCM contracts, as well as bids, be designated public record and be available to the public.

Response: We agree with the commenters, and we have amended the final rule with comment period at § 438.50(b)(4) to require state plans to specify: ''The process the State uses to involve the public in both design and initial implementation of the program, and the methods it uses to ensure ongoing public involvement once the State plan has been implemented.'' This language is consistent with the public notice requirements of the State Children's Health Insurance Program.

Comment: One commenter recommended that we establish specific procedures to closely monitor, track and evaluate these State plans.

Response: We acknowledge this concern, and assure the commenter that we will continue to monitor, track, and evaluate State plans via review of provider contracts, site visits, and reporting requirements such as for external quality reviews. Amending the state plan to implement a program of mandatory managed care may eliminate the need for a State to apply for waiver renewals every two years, but does not eliminate the State's obligation to guarantee access to services and provide quality care to its beneficiaries, nor does it eliminate necessary monitoring and evaluation of these programs by us.

Comment: One commenter recommended that State plans and contracts with MCOs provide that the choice of primary care providers for children must include pediatricians, and ensure access to pediatric services. The commenter also recommended a pediatric definition of medical necessity. Other recommendations included that the contracts should ensure that information and training is provided to recipients, physicians and other providers, local agencies and human health services agencies regarding various aspects of the managed care programs. This commenter requested that we require States to describe their plans for conducting performance evaluations.

Response: For reasons discussed in more detail in section II. D. below, in a response to comments on proposed § 438.306 (now codified at § 438.206), with some exceptions (such as a women's health specialist), we generally do not believe it is necessary or appropriate to require that MCOs contract with specific categories of providers. However, also as discussed in that section, we are requiring in § 438.206(d) that in establishing an MCO's provider network, it must consider the anticipated enrollment, with ''particular attention to * * * children,'' and ''[t]he numbers and types (in terms of training and experience) of providers required to furnish the contracted services.'' We believe that these requirements address the commenter's concern about participation of pediatricians. With respect to the recommendation for a ''pediatric definition of medical necessity,'' also as discussed below in section II. D, we are requiring in § 438.210(a)(4)(ii)(B) that an MCO's definition of ''medical necessity'' address the extent to which it is responsible for covering services related to the ability to achieve age-appropriate growth and development, which is obviously ''pediatric-related.'' We have not required a separate definition. We believe that the commenter's suggestion concerning information requirements has been addressed in § 438.10(d) and (e). Finally, with respect to the issue of ''performance evaluations,'' as discussed in section II. D. below, § 438.240(c)(i) requires that MCOs and PHPs measure performance, while § 438.240(c) requires performance improvement projects.

Limitations on enrollment (Proposed § 438.56(b))

Comment: One commenter correctly noted that if a State wished to use the State plan option, yet wished to mandate managed care enrollment for elements of the Medicaid population exempted under that option, the State must still request a waiver to include the exempt populations, thereby negating the benefits of the State plan option. Another commenter complained of the continued administrative time, expense and confusion in the current waiver renewal process. This commenter also expressed the view that if the BBA is designed to allow greater flexibility for State administration, then greater allowance should be given to the State plan option rather than the waiver.

Response: The proposed rule implements section 1932(a), of the Act as enacted by the Congress. While it provides States with an alternative to the 1915(b) of the Act waiver process with respect to individuals not exempted, we acknowledge that the State plan amendment is not applicable to all situations, and that the State will need to submit a 1915(b) of the Act waiver to enroll exempted population into mandatory managed care programs. We have no discretion to change, this however, because the Congress was clear in exempting these populations.

Comment: One commenter noted that nothing in the BBA prohibits States from exempting populations other than those specified in the Act for mandatory enrollment in managed care, and recommended that language be added to the regulations to indicate that the State may exempt other populations. Another

commented that the regulation only lists categories of persons who may not be enrolled in managed care under the State plan managed care option. The commenter suggested that this rule should also allow States using the waiver option to exempt categories from mandatory managed care.

Response: We do not agree that it is necessary to add language to the regulation indicating that States may exempt other populations. Section 1932(a)(2), of the Act identifies those populations which *must be* exempted from mandatory enrollment under this provision. States have had and continue to have the discretion to exempt other populations from mandatory enrollment in managed care.

Comment: Several commenters expressed concern that beneficiaries might not be identified or notified of their exemption from mandatory enrollment, and run the risk of being defaulted into MCOs or PCCMs. They recommended that the State provide a mechanism to ensure that exempt populations are not enrolled into MCOs or PCCMs, and that State be required to permit exempt individuals to self-identify.

Response: Section 438.10(d)(2)(B) of the final rule with comment period has been modified to require that potential enrollees be informed of populations which are exempt from mandatory enrollment in any such program. We agree that self-identification would be an effective tool for individuals who fall into an exempt category, but are not identified as such by the State. Once identified, the State would be obligated to exempt such individual from mandatory enrollment, and to disenroll he or she immediately, if they had been enrolled by default.

Comment: We received comments concerning the applicability of the limitations in section 1932(a)(4) of the Act on the right to disenroll without cause to exempted populations. One commenter urged that the ''12 months lock-in'' provided for under section 1932(a)(4) of the Act should be restricted to individuals whose enrollment in managed care was mandated. Two commenters suggested that the 12 months lock-in should not be allowed for exempted groups unless a State can demonstrate in a waiver that the population's access to services will not be diminished due to enrollment in an MCO or PCCM.

Response: If an exempted individual voluntarily enrolls in an MCO or PCCM, the same lock-in and disenrollment provisions in section 1932(a)(4) of the Act apply, including the ability to disenroll without cause during the first 90 days of enrollment. This is because section 1903(m)(2)(A)(vi) of the Act incorporates section 1932(a)(4) of the Act in the case of MCOs, while section 1905(3)(E) of the Act incorporates section 1932(a)(4) of the Act in the case of PCCMs. With respect to the last recommendation concerning demonstration of access to services, MCOs must meet the requirements for access and availability of services as specified in §§ 438.206 and 438.207 of the final rule with comment period, while a PCCM contract must meet the requirements for access and services under § 438.6(k).

Comment: Some commenters agreed with the exempted groups as outlined in the proposed rule and recommended that we maintain this provision. Specifically, two commenters agreed that foster care children should be exempted as foster care children move frequently and they may need to change providers for geographic reasons. These commenters also noted that if the child has a disability and moves often because of foster care, it may be important to maintain a single provider to prevent frequent disruption of complex care. Another comment indicated that children under 19 years of age who are eligible for SSI and eligible for dental coverage under EPSDT should not be subject to mandatory enrollment in managed care.

Others felt certain populations should not be excluded from managed care programs, with one commenter recommending legislative action to revise the rules to delete all impediments to enabling managed care programs for the broadest possible populations. The commenters cited positive experiences with exempted populations in mandatory managed care programs and felt that the special needs can best be addressed and coordinated through a network of providers. The commenters' experience has shown that Medicaid clients believe the service is better and the more complicated the care, the more there is a need for managed care. Two commenters expressed the concern that by limiting managed care for certain populations, the message conveyed is that managed care does not work for these populations. They continued to say that many States have been very successful in operating managed care for these exempted populations and it has been shown to be a strong factor in assuring access to primary and preventive care and other needed medical services. One commenter stated that they have taken steps to ensure that MCOs identify and serve children with special health care needs appropriately, including the implementation of broad, functional definitions of Disability and Special Health Care Needs. This commenter partnered closely with the advocate community to develop appropriate standards for this population. They felt that we were incorrect to assume that managed care will not work for these populations.

Response: Section 1932(a)(2) of the Act identifies those groups exempted from mandatory enrollment under this provision. We do not have the authority to add groups or delete groups from this list. The statute does not prevent voluntary enrollment if a voluntary contract exists and an individual believes that his or her needs will be best met with an MCO or PCCM. If a State desires to enroll any of these exempted populations into a managed care program, it may do so by offering voluntary enrollment as an alternative to unrestricted fee-for-service, or it may mandate enrollment through section 1915(b) of the Act or 1115 of the Act waiver authority.

Comment: We received many comments requesting that additional populations be exempt from mandatory managed care because of the complexity of the beneficiaries' medical needs. Commenters recommended that the additional exempted groups should include—

Children with HIV, but who have not developed AIDS;
Patients awaiting transplants and organ transplant recipients;
Patients suffering from cancer;
Patients suffering from arthritis, osteoporosis, chronic and debilitating musculoskeletal conditions;
Children and adults with mental retardation;
Patients with severe and persistent mental illness (SPMI), brain disorders;
Adults with disabilities;
Homeless persons; and
People for whom English is not their primary language or people residing in areas where provider awareness of cultural diversity is limited.

Several commenters suggested that the language in § 438.56(b)(3)(v) (redesignated as § 438.50(d)(3)(v)) narrowly defines children with special needs in Title V programs who are exempted from enrollment. These commenters recommended that this section should be amended to cover all children eligible for Title V special needs as defined by the State's Title V agency. Commenters proposed definitions for foster care or ''otherwise in an out-of-home placement.'' A few commenters recommended the adoption of the Maternal and Child Health

Bureau's definition of children with special health care needs.

A couple of commenters recommended voluntary enrollment for dual eligibles and for adults with disabilities. One commenter recommended that individuals who have significant, chronic disabilities should have the option to voluntarily enroll and not be subject to any State being eligible to obtain such a waiver from HCFA.

Response: As indicated above, in section 1932(a)(2), of the Act the Congress specified the groups that are exempt from mandatory managed care enrollment through the State plan provision. We do not have the statutory authority to exclude any other populations. Because of variations in States regarding the identification of individuals receiving services through a family-oriented, community based, coordinated care system receiving grant funds under Section 501(a)(1)(D) of Title V, of the Act the December 17, 1997 SMD letter offered guidance to States about developing more detailed operational definitions of this group. The State also has the option to define this group in terms of their special health care needs and to develop a process whereby individuals who are not identified through the initial exemption process could request exemption based on special needs as defined in the State plan.

Although we considered using the Maternal and Child Health Bureau's definition of children with special health care needs, we believe that the identification of this specific group by either program participation or accepted State definition more closely reflects the statutory language while being more administratively feasible.

Enrollment by Default (Proposed § 438.56(d)

Proposed section 438.56(d) set forth the requirements relating to default enrollment of beneficiaries in SPA programs who do not make a choice from among the available MCOs or PCCMs. (**Note:** As indicated above, this section is being moved to § 438.50 in the final rule with comment period because it applies only to SPA programs.) This provision required that the default enrollment process preserve existing relationships between beneficiaries and health care providers, and relationships with providers that have traditionally served Medicaid beneficiaries. If this is not possible, States are required to distribute the beneficiaries equitably among the available MCOs or PCCMs qualified to serve them.

Comment: A number of commenters pointed out that the proposed rule did not address what constituted an acceptable level of default enrollments. The commenters urge us to encourage States to keep the rate of default enrollments as low as possible, and to use the comment/response section of the final rule with comment period to discuss the successful practices of States like New Jersey and Rhode Island to keep default enrollments low. The commenters urged us to require States to collect and report uniform data on default enrollments (some commenters suggested that the data be broken down by geographic area). Most commenters identified 25 percent as the threshold at which further action should be taken, although one commenter suggested that default enrollments be halted in cases where the default rate goes above 10 percent. The commenters had various suggestions as to what should happen in cases where the rate of default enrollments exceeded the threshold—some said default enrollments should be halted, some said we should review the State's processes, and some said the State should develop and implement corrective actions in their outreach and enrollment processes.

Response: Although the BBA did not specify an acceptable level of default enrollments, we agree that this can be an important measure of the extent to which beneficiaries make informed decisions about enrollment. We agree that States should endeavor to keep default rates low, and the enrollment and information provisions of the regulation are designed to help States achieve a high rate of enrollee choice. Default enrollment rates vary widely because States have greatly different levels of experience with managed care, and because of measurement variation. Although we have decided not to mandate a single acceptable level of default enrollments in the final rule with comment period we will continue to monitor default enrollments in Medicaid managed care programs.

Comment: A number of commenters pointed out that the proposed rule did not specify the time allowed for beneficiaries to choose an MCO or PCCM before default enrollment takes place. The commenters suggested a number of minimum timeframes—20, 30, or 60 days. One commenter also suggested that States be required to offer a longer time period for persons with serious and persistent mental illness.

Response: Section 1932(a)(4)(D)(i) of the Act, as established by the BBA, refers to ''the enrollment period specified by the State.'' Therefore, we believe the Congress intended for each State to be able to set its own enrollment period, depending upon its population and its own experience with managed care. To date, States have demonstrated that a wide variety of time periods can be effective, depending upon their own populations and outreach and educational programs. For example, one State with a low default enrollment rate only allows enrollees 10 days to choose a plan. We have decided not to specify a minimum time period in the final rule with comment period.

Comment: We received one comment urging that default enrollments be prohibited. A number of other commenters indicated that some limitations should be placed upon a State's ability to make default enrollments. A number of limitations were suggested. One commenter said default enrollments should be prohibited in cases of persons with disabilities. Another indicated that the enrollment period should be suspended if the beneficiaries had requested information and not received it, or had requested a face-to-face meeting that could not be scheduled during the enrollment period. Also, this commenter said if the recipient or his guardian could not be reached through no fault of their own, there should be no default enrollment. One commenter said States should be required to assign beneficiaries to a PCCM instead of default enrolling them into an MCO.

Response: The Congress spoke clearly on which groups should be exempt from mandatory enrollment in SPA programs, and these groups are similarly not subject to default enrollments pursuant to section 1932(a)(4)(D) of the Act. For those individuals who are not exempt, the statute requires a default enrollment process for MCOs and PCCMs generally, not just primary care case managers. Specifically, section 1932(a)(4)(D) of the Act provides that under a mandatory program under section 1932(a)(1) of the Act, ''the State *shall establish* a default enrollment process * * * under which any * * * individual who does not enroll *with a managed care entity* during the enrollment period. * * *'' In granting States the discretion to specify the time period for making an enrollment, we believe that the statute gives States the flexibility to provide for extensions of this time period, or other accommodations when warranted by the needs of the population, so long as they are applied in a uniform manner. We recommend that States grant extensions and other accommodations when they consider it to be appropriate.

Comment: One commenter pointed out that many persons with disabilities, who may be subject to mandatory

enrollment, have a representative payee. The commenter recommended that we require States to notify representative payees when default enrollments are made.

Response: We agree with the commenter that there may be situations when it would be appropriate for the State to notify someone other than (or, at State option, in addition to) the enrollee. However, we believe the final rule with comment period should provide for notification of a broader scope of enrollee representatives than representative payees. In response, we have added language to the final rule with comment period adding references to an enrollee or his or her ''authorized representative.'' This would cover situations including, but not limited to, a representative payee situation. (We have added this language to § 438.56.)

Comment: One commenter said the final rule with comment period should address how enrollees are assigned to PCPs once they have been default enrolled in an MCO, and recommended that we require that MCOs consider geographic, cultural, and linguistic accessibility when assigning enrollees to a PCP.

Response: In requiring States to preserve existing provider-recipient relationships in the default enrollment process, the Congress clearly intended there to be as little disruption as possible in the provision of medical care. We encourage States to monitor this process and to require that MCOs, to the extent possible, make PCP assignments that promote recipient access to care. Additionally, we believe that the access requirements for MCOs contained in § 438.206 will assist in this regard. We do not believe, however, that it is necessary to insert an additional regulatory requirement.

Comment: We received a large number of comments on the default enrollment methodology. One commenter expressed general support for the enrollment by default provisions. A handful of commenters indicated that they thought we had placed too many requirements in the default enrollment section. The bulk of the commenters, however, encouraged us to place additional requirements on States in developing their default enrollment procedures. The commenters who disagreed with our proposed regulations believed either that States should not have to take relationships with existing providers into account, or that the default enrollment procedures should not favor traditional providers. Two commenters felt that favoring traditional providers may discourage participation in managed care programs by commercial MCOs. The commenters who want us to place additional requirements on States disagree with the concept of equitable distribution if it means States are not permitted or required to take additional factors into consideration. Commenters suggested that the rule should require States to take the following factors into account when default enrolling beneficiaries: Geographic accessibility, especially for rural residents; cultural and linguistic competency; experience with special needs populations; physical accessibility; and capacity to provide special care and services appropriate to the needs of the individual. Commenters said persons who are homeless, persons with HIV, and individuals with special health care needs or developmental disabilities should only be assigned to MCOs or PCCMs with demonstrated competency serving them. In addition, commenters said that we should not allow States to favor MCOs or PHPs in their default enrollment methodologies just because they are the lowest cost Entity, and that no default enrollments should be made to plans that do not offer the full scope of basic health care services, including family planning services. Commenters said States should be allowed to consider such factors as success rates in completing EPSDT screens, price, quality, and customer satisfaction in their default enrollment methodology.

Response: The statute clearly indicates that States must take existing relationships into account, ''or relationships with providers that have traditionally served beneficiaries under this title.'' Section 1932(a)(4)(D)(ii)(II) of the Act goes on to specify that if maintaining such relationships is not possible, States must arrange for ''the equitable distribution of such individuals among *qualified* managed care entities available to enroll such individuals, consistent with the *enrollment capacities* of the entities. (Emphasis added)'' We believe that in using the term ''qualified,'' the Congress intended to permit States to consider such factors as experience with special needs populations. Additionally, for rural residents or beneficiaries with needs for special cultural or linguistic competencies, States may consider MCOs or PCCMs that are equipped to serve them as more qualified. Also, the statute does not define the term ''enrollment capacity.'' We believe States have flexibility to determine that cultural and linguistic competency and other similar factors are related to MCOs'or PCCMs' capacity to serve certain individuals, depending upon their needs. We believe the language as proposed gives States sufficient flexibility to consider these factors, therefore, we have not added new requirements to the final rule with comment period.

Comment: Commenters were divided on the subject of whether members of the same family should be default enrolled to the same plan. Four commenters indicated that family members should be default enrolled in the same MCO or PCCM. One commenter in this group said family members ''in general'' should be enrolled in the same MCO or PCCM; presumably this indicates there may be circumstances in which family members could be enrolled in different MCOs or PCCMs. Four commenters said there may be circumstances in which family members could be better served by different MCOs or PCCMs. Other commenters raised the same question with regard to whether family members could choose to enroll in different MCOs or PCCMs, as opposed to being defaulted into them.

Response: The statute is silent on whether the default enrollment rules should require family members to be enrolled together. Because State enrollment and eligibility systems may not permit family members to be divided up, we do not recommend placing any requirements on this subject in the final rule with comment period. If States have the capacity to allow family members to choose different MCOs, they should be permitted to do so. Likewise, we assume States will want to default enroll families to the same MCO, and we believe they should be permitted to do so as well. This same policy applies to the question of whether States wish to permit individual family members to choose to enroll in different MCOs or PCCMs.

Comment: A number of commenters discussed our definition of existing relationships between enrollees and providers in the context of making default enrollments. Opinion was divided on the extent to which States should be required to consider existing relationships between beneficiaries and providers. The proposed rule defined an existing relationship as ''one in which the provider was the main source of Medicaid services for the recipient during the previous year'' and goes on to say that States may establish this through fee-for-service or managed care records, or by contacting the recipient. Several commenters specified that this provision would be difficult to operationalize or even ''unworkable.'' One indicated that if the recipient's previous experience with Medicaid was

in a fee-for-service system where it was difficult to find participating providers, the existing relationship may not have been an ideal one. However, a number of commenters said the language in the proposed rule did not go far enough. The majority of these commenters indicated that we should require States to examine previous records, and that the look-back period should be 3 years instead of 1 year. One commenter also said States should be required to examine payment records pertaining to services from ancillary providers such as DME suppliers and home health agencies as well. Some commenters also said MCOs should be subject to similar requirements in making enrollee assignments to PCPs.

Response: Because section 1932(a)(4)(D)(ii)(I) of the Act refers to considering existing relationships, we do not have statutory authority to exempt States from this requirement. We do, however, have the authority to define how States meet the requirement. We believe that the regulation gives States the flexibility to determine existing relationships in whatever way makes sense in the context of their program. Therefore, we have decided not to include additional requirements in the final rule with comment period.

Comment: We received a large number of comments urging us to present a more comprehensive definition of traditional providers than the one included in the preamble and proposed rule. The text defined a traditional provider as a provider who has ''experience in serving the general Medicaid population.'' Many commenters pointed to what they felt was confusing language in the preamble: ''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.'' Commenters felt this definition either unnecessarily confused existing relationships with traditional providers, or indicated that any provider who had been the main source of care for any recipient could be considered a traditional provider. Two commenters said States should be permitted to develop their own definitions of traditional providers. However, most commenters favored a HCFA definition that would be much more specific than the definition included in the proposed rule. Examples of what commenters said that we should include in the definition are: A certain percentage of Medicaid and uninsured utilization (either a set percentage or a percentage at least equal to the statewide mean); a significant number of years spent serving Medicaid patients; DSH hospitals; public hospitals; FQHCs; CHCs; and Health Care for the Homeless projects.

Response: Although default enrollments may be made to MCOs and not necessarily to individual providers, the statutory language refers specifically to providers. Section 1932(a)(4)(D)(ii)(I) of the Act requires that the default enrollment process take into consideration maintaining ''relationships with providers that have traditionally served beneficiaries under this Title.'' Clarification can be found in the BBA Conference Report, which states that the default enrollment process ''must provide for enrollment with an MCO that maintains existing provider-individual relationships or *has contracted with providers that have traditionally served Medicaid [beneficiaries]''* (emphasis added). Therefore, we believe the Congress intended for States to favor MCOs and PCCMs that contract with traditional providers in their default enrollment process. However, because the statute does not define traditional provider, we have the flexibility to either write a definition or allow States to develop their own. Because of the volume and variety of comments, we decided to allow States to develop their own definitions that could include, but not be limited to, DSH hospitals, public hospitals, FQHCs, CHCs, and Healthcare for the Homeless projects.

2. Choice of MCOs, PHPs, or PCCMs (Proposed § 438.52)

Proposed § 438.52 implemented the requirement in section 1932(a)(3) that States must permit an individual to choose from at least two MCOs or PCCMs, including the exceptions to this requirement in a case in which a State elects the option under section 1932(a)(3)(B) to offer a single MCO in a ''rural area,'' and the exception in section 1932(a)(3)(C) permitting a State to offer a single HIO in certain counties.

General Rule

Section 438.52(b) of the proposed rule required that States allow beneficiaries to choose from at least two MCOs or PCCMs.

Comment: We received comments expressing general support for the requirement for choice. One commenter, however, said that merely offering choice may not provide sufficient beneficiary protection, and we should consider alternative ways to provide consumers with accountability and responsiveness.

Response: The requirement for choice of MCO or PCCM appears in the statute, and is consistent with our longstanding policy of generally requiring at least two options in a mandatory managed care program. However, choice is only one piece of an overall strategy to ensure that beneficiaries receive quality services. This regulation implements new requirements for quality, access and availability, and beneficiary protection. We believe these requirements address the concern voiced by the commenter.

Comment: We received a number of comments disagreeing with our decision to apply the requirement for choice to PHPs. The commenters indicated that in the case of behavioral health carve-outs and certain long term care programs, it is not appropriate to require choice. Commenters indicated that the requirement for choice in carve-outs increases administrative costs because the State would be required to solicit business from two MCOs which would utilize the same limited set of providers. One commenter believed that in the case of PHPs, States should be allowed to request waiver authority to limit choice to one PHP, so long as that PHP offers beneficiaries a choice of providers. The commenter stated that we should clarify this in the final rule. The commenter also believed that PHPs should be chosen through a competitive process except when the State has decided to utilize a local governmental organization as a sole source provider. One commenter recommended that § 438.8 be amended to state that the provisions of subpart B apply to PHPs.

Response: Under this final rule with comment period, outside the context of a demonstration project or waiver program, we believe it is appropriate to give enrollees a choice of PHPs, along with the right to disenroll that is provided under section 1932(a)(4) to MCO and PCCM enrollees. As in the case of other PHP requirements, we have based this rule on the authority in section 1902(a)(4) of the Act to provide for methods of administration determined to be necessary for proper and efficient operation of the Medicaid program. Regulations based on provisions in section 1902, however, may be waived by the Secretary under section 1915(b) of the Act or as part of a demonstration project under section 1115 of the Act. Nothing in this regulation changes this waiver authority. Thus, we agree with the commenter that States should be allowed to request a waiver to permit a State to limit enrollees to a single PHP if the enrollees have a choice of providers within the PHP. With respect

to the comment on competitive procurement, § 434.6(a)(1) requires that in the case of all Medicaid contracts, States comply with competitive procurement requirements in 45 CFR, part 74. Under these requirements, States are required to engage in competitive procurement ''to the maximum extent practical.'' Thus, we agree with the commenter that PHPs should be chosen through a competitive process. We do not agree, however, that the State necessarily should be exempted from this requirement when it contracts with a government entity. While part 74 at one time exempted such cases from competitive procurement requirements, there is no longer such an across the board exemption. HCFA has, however, exercised discretion it has under part 74 on a case-by-case basis to permit government entities to contract as PHPs without a competitive procurement.

Finally, in response to the last comment, in the final rule with comment period, we have amended § 438.8 to specify that all subpart B provisions except § 438.50 apply to PHPs, because we agree with the commenter that the reference should be made more explicit.

Comment: One commenter said we should clarify our preamble language pertaining to PCCMs. This commenter said it appeared that States could satisfy the requirement for choice with a single PCCM. This commenter said that was contrary to the intent of the BBA, and pointed out that the only exception to the requirement to choice is for rural areas and certain HIOs.

Response: The commenter has confused a PCCM, which we clarify in this final rule with comment period refers to a ''primary care case manager'' as defined in section 1905(t)(2), with a primary care case management ''system,'' under which beneficiaries have the option of enrolling with one of two or more PCCMs. We recognize that our use of two terms in proposed § 438.2 that would fit with the acronym ''PCCM'' may have caused this confusion. The term ''primary care case management'' refers to ''a system under which a primary care case manager contracts with the State,'' while the term ''Primary care case manager'' is defined as the contracting individual or entity. As discussed in section II. A. above, we have clarified in §§ 400.203 and 438.2 of this final rule with comment period that PCCM refers to a primary care case manager. We agree with the commenter that unless the rural area exception in section 1932(a)(3)(B) applies, a State cannot satisfy the choice requirement through the use of a single PCCM. It can, however, do so through a primary care case management *system,* under which a beneficiary has a choice of two or more PCCMs. We have clarified § 438.52(b) to emphasize this distinction.

Comment: We received a comment recommending that the final rule specify that all beneficiaries must have a choice between two MCOs or PCCM providers that are qualified and experienced in HIV/AIDS care.

Response: We agree that for persons with special needs, including those with HIV/AIDS, being able to choose from MCOs or PCCM providers qualified to meet their needs is essential. Section 438.206 of this final rule with comment period requires States to develop standards for access to care, including attention to special needs populations. The section requires all MCOs to assure that they have the adequate capacity and appropriate services to meet the needs of the expected enrollment. This includes being able to serve any special needs populations that could potentially be enrolled in the MCO. We also require MCOs to consider the experience needed by network providers to serve the expected needs of their enrollees. Lastly, we expect States to aggressively monitor such indicators as grievances, appeals, fair hearing requests, and disenrollment requests as indicators that persons with special needs are not being adequately served.

Comment: One commenter recommended that where there is choice between two MCOs, at least one MCO must offer the full scope of services, including family planning services.

Response: Unlike the case of the Medicare program, the Congress chose not to require that MCOs agree to contract to provide particular services. The text for a comprehensive contract in section 1903(m)(2)(A) makes clear that the MCO and the State have the discretion to decide which Medicaid services will be covered under the MCO's contract. Also, in the case of family planning services, under section 1902(a)(23), an MCO is not permitted to restrict an enrollee to using the MCO's network providers for family planning services. This creates an incentive for MCOs to exclude family planning services from their contracts, since they have no control over when and where such services are obtained. Whether for this reason, or for reasons of conscience, some MCOs are likely to not agree to cover family planning services under their contracts.

However, § 438.10(d) and (e) of this final rule with comment period, enrollees and potential enrollees must be informed of ''benefits that are available under the State plan but are not covered under the contract, including how and where the enrollee may obtain those benefits, any cost sharing, and how transportation is provided,'' and in the case of enrollees ''the extent to which, and how, enrollees may obtain benefits, including family planning services, from out-of-network providers.'' We believe that these provisions ensure that enrollees have information on the availability of, and access to, required family planning services, regardless of whether these services are included in their MCO's contract.

Comment: We received a few comments recommending that each MCO offer each beneficiary a choice between at least two providers who are geographically, culturally, and linguistically accessible.

Response: This final rule with comment period contains requirements addressing geographic, cultural, and linguistic accessibility. Section 438.206, contains a requirement that MCOs maintain a network of providers sufficient in number, mix, and geographic distribution to meet the needs of the anticipated number of enrollees. Section 438.206(d)(1)(v) specifically requires that MCOs consider the geographic location of beneficiaries in developing their provider networks. Section 438.206(e)(2) requires that MCOs deliver services in a culturally competent manner, and § 438.10 requires that States and MCOs, PHPs and PCCMs make information available in languages in use in the enrollment area. MCOs, PHPs, and PCCMs are also required to provide translation services under § 438.10.

Definition of Rural Area

For the purpose of applying the exception for ''rural areas'' in 1932(a)(3)(B) to the choice requirement in section 1932(3)(A), the notice of proposed rulemaking proposed three definitions of a ''rural area.'' The choices included (1) any area outside an ''urban area'' as defined in § 412.62(f)(1)(ii), the definition found at § 491.5(c), or an alternative State or HCFA definition. After considering all comments, in this final rule with comment period we define a rural area as any area other than an ''urban area'' as the latter is defined in § 412.62(f)(1)(ii) of the HCFA rules.

Comment: There was no clear consensus among commenters. A few commenters said our proposed provision was overly broad, and recommended that HCFA make clear in the final rule with comment period that the rural exception would be very

narrowly construed. Others said there should be no State or HCFA definition apart from the two Medicare definitions. One commenter said we should keep the choice of three definitions, but if we are required to choose only one, we should use the definition found at Part 412 of this chapter. Other commenters said they agree with our prohibition against designating an entire State as a rural area, but one commenter said in some cases it may be appropriate to designate an entire State as a rural area. One commenter said we should choose a single definition of rural, but indicated no preference as to which definition we chose.

We also received a number of recommendations of alternative definitions or criteria. One commenter said any area with at least two qualified bidders should not be considered rural. One commenter said we should allow any medically under served area to be considered rural, and one commenter recommended that we use the Office of Management and Budget definition of non-metropolitan counties as a proxy for rural areas. One commenter recommended that we clarify that any area that is part of a Metropolitan Statistical Area could not be considered rural under a State or HCFA definition.

Response: We have considered all of the comments and decided to accept the commenter's suggestion that a single definition be adopted, as well as the suggestion by the commenter that if a single definition is adopted, we adopt the first definition incorporating the definition of ''urban area'' in part 412.

Exception for Rural Area Residents

Proposed § 438.52(c), outlined the rural exception to the requirement for choice. Under the proposed rule, in a ''rural area'' as defined in § 438.52(a), a State may limit beneficiaries to one MCO provided the beneficiary—

- Can choose from at least two physicians or two case managers; and
- Can obtain services from any other provider under any of the following circumstances:

(1) The service or type of provider the enrollee needs is not available within the MCO network.

(2) The provider is not part of the network, but has an existing relationship with the enrollee.

(3) The only plan or provider available to the enrollee does not, because of moral or religious objections, provide the services sought by the enrollee.

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

In the final rule with comment period, in response to comments discussed below, § 438.52(b)(2)(ii)(D) also provides that enrollees may also go outside the network for services if he or she needs related services (for example, a cesarean section and a tubal ligation) to be performed at the same time; not all of the related services are available within the network; and the enrollee's primary care provider or another provider determines that receiving the services separately would subject the enrollee to unnecessary risk. Also in response to comments, we have revised the provision permitting a beneficiary to go out of plan to a provider with ''an existing relationship with an enrollee'' to be limited to cases in which the provider is the ''main source of a service.''

Comment: We received a few comments on the overall issue of whether a rural exception should exist. One commenter agreed with the rural exception, while other commenters disagreed. One of these commenters said that in cases where there is only one MCO, States should be required to offer higher capitation rates in order to entice more MCOs to join the market. Other commenters said that in rural areas, States should be required to offer a PCCM option if they cannot get two MCOs to bid. One of these commenters also said States should ensure that primary care providers in rural areas should receive high enough capitation rates to cover their costs.

Response: The rural exception is provided by statute as a State option, and we thus have no authority to deny States this option by either requiring a second managed care entity (a PCCM) or mandating that payment be increased enough to attract a second MCO.

Comment: A few commenters said they do not believe HCFA should allow plans that do not offer family planning services to serve as the single MCO in a rural area. One commenter pointed out that if the only plan available does not offer family planning services, and a pregnant enrollee desires a cesarean section and a tubal ligation, the enrollee would be required to have her cesarean section through the MCO and would then have to go out of network for the tubal ligation, thus having a separate surgical procedure that would subject her to undue risk. Other commenters said the final rule with comment period should specify that when rural enrollees go out of plan for a service that is not offered by the MCO, they should also be able to get ''related services'' out of network. The commenters said this would assist pregnant women who desire a tubal ligation simultaneously with a cesarean section delivery.

Response: As discussed above, the statute allows MCOs to decide which services they choose to agree to cover under their contracts. However, in the case of a single MCO in a rural area, these decisions could affect the health of a Medicaid beneficiary in the manner suggested by the commenter. Thus, as noted above, in response to these comments, we have provided in § 438.52(b)(2)(ii)(D) that enrollees may also go outside the network for services if he or she needs related services (for example, a cesarean section and a tubal ligation) to be performed at the same time; not all of the related services are available within the network; and the enrollee's primary care provider or another provider determines that receiving the services separately would subject the enrollee to unnecessary risk.

Comment: A number of commenters recommended that we add language to § 438.52(b) requiring that rural enrollees have a choice between two physicians or case managers. One commenter said we should require that the two physicians or case managers are ''qualified to provide the beneficiary with appropriate and necessary health care services consistent with the beneficiary's initial assessment and treatment plan.'' One commenter said that in the case of enrollees with HIV, they should have a choice between two PCPs who are qualified and experienced in providing HIV/AIDS care. One commenter said the PCPs should be within 30 minutes or 30 miles from the beneficiary, except in frontier areas. Another commenter said there should also be a requirement for choice between two specialists or the ability to continue existing provider relationships out of network, and the final commenter said if the choice is between two PCCM case managers, they should be affiliated with separate practices if possible. Another commenter said rural beneficiaries in general do not have enough protection. This commenter suggested that we add a new subsection to the final rule with comment period cross-referencing all other exemptions and requirements, such as geographic accessibility, language and cultural competency, etc.

Response: The comments listed above all pertain in some way to accessibility to qualified and experienced providers. As stated above, this regulation contains extensive requirements designed to ensure beneficiary access to services, and these requirements pertain to rural as well as non-rural managed care providers. The relevant requirements can be found in § 438.6 (Contracting

requirements), § 438.10 (Information requirements), § 438.110 (Assurance of adequate capacity and services), and § 438.206 (Availability of services). Also, under § 438.52(b)(2) (rural beneficiaries have the ability to continue existing provider relationships under this regulation. In light of the above protections, discussed in detail elsewhere in this preamble, we do not agree that it is necessary to add additional language to § 438.52 in response to these comments.

Comment: One commenter suggested that we delete § 438.52(b)(2), which lists the reasons rural beneficiaries may go out of network. This commenter believes these provisions go beyond our statutory authority and are in some cases redundant because if a certain service is not available within the network, the MCO would be contractually obligated to pay for it anyway.

Response: We disagree with the commenter. Section 1932(a)(3)(B)(ii) of the Act, provides that rural beneficiaries can be limited to one MCO, if the MCO ''permits the individual to obtain such assistance from any other provider in appropriate circumstances (as established by the State under regulations from the Secretary).'' The Congress clearly intended for rural beneficiaries to access out-of-network services in appropriate circumstances, and clearly granted HCFA the discretion to define those circumstances in regulations. Section 438.52(b)(2) of the final rule with comment period extends these rights in a manner that recognizes both State flexibility and the importance of protecting enrollees.

Comment: We received one comment suggesting that the final rule include an additional reason beneficiaries can access out of network services. This commenter said the State should be required to let beneficiaries go out of network if treatment or services have been reduced or eliminated within a geographic area covered by the MCO.

Response: As discussed in section II. D. below, § 438.206(d)(5) allows beneficiaries to seek out-of-network treatment if the type of service or provider needed is not available within the network. We believe this language responds to the situation outlined by the commenter.

Comment: Another commenter suggested that we add a new subsection to the final rule outlining an additional reason beneficiaries can go out of network. This commenter suggested allowing beneficiaries to go out of network because ''The only plan or provider available to the enrollee is not able, because of prior court-ordered (involuntary) receipt of services from that provider, to develop a therapeutic relationship with the enrollee for the provision of mental health services.''

Response: We agree that in cases where the only available provider had previously treated the enrollee against his or her will, it would be difficult to establish a therapeutic relationship. We have decided not to add the suggested language to the final rule with comment period, however, because we believe the scenario outlined by the commenter would be covered by the existing language, particularly the section indicating that rural enrollees can go out of network in ''other circumstances.''

Comment: One commenter stated we should add clarifying language to this section indicating that when rural enrollees go out of network for services under the circumstances outlined in the regulation, they do not incur any additional cost.

Response: Section 438.106, Liability for payment, already covers these circumstances. Section 438.106(c) specifies that MCOs cannot hold Medicaid enrollees liable for ''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.'' We believe enrollees in rural exception areas going out of network in the circumstances outlined in this chapter are protected by this provision. Therefore, we do not believe it is necessary to include the suggested language in § 438.52(b)(2). However, if a beneficiary chooses to go out of network for reasons other than those outlined in the rural provisions, the beneficiary would be liable for payment for the service.

Comment: We received a few comments recommending that the provisions allowing beneficiaries to go out of network be rewritten to specifically address the needs of rural enrollees with disabilities who have multiple medical needs. The commenters are concerned that enrollees be able to preserve existing relationships with DME suppliers. In addition, one commenter said enrollees should be able to go out of network if the only provider available does not have experience with the individual's disability, a provider cannot meet the needs of an enrollee (for example, an enrollee needs a home health aide in the morning but the only agency in the network only has aides available mid-day), or the enrollee has had ''previous problems'' with the provider. In addition, this commenter said the rural exception should make clear that in border areas, the out of network provider can be in a different State if that provider is geographically closer.

Response: Regarding the comment about border areas, the Medicaid program already accommodates crossing State lines in circumstances in which this is consistent with traditional patterns of care. We do not expect that this regulation will disrupt or change this situation. Regarding the other situations mentioned by commenters, as we have stated previously, the ability to go out of network is meant to be interpreted broadly. We expect that in cases in which enrollees with disabilities can make a case that their needs are not well-served by the MCO, they would be allowed to go out of network by the State pursuant to § 438.52(b)(2)(A) or (E). However, we also expect that because of the breadth of these provisions, MCOs serving rural beneficiaries will make strong efforts to have a comprehensive network that meets the needs of all of their enrollees. Rural MCOs, like all other MCOs, are responsible for making sure they have a network adequate to meet the needs of their anticipated enrollment, and this includes individuals with disabilities.

Comment: We received a few comments recommending that the provisions allowing enrollees to go out of network be expanded. Some commenters said all enrollees in all mandatory and voluntary managed care systems should have the same rights to go out of network. One commenter said urban beneficiaries should be able to use FQHC services if they are enrolled in MCOs that do not offer FQHC services.

Response: We believe that where there is a choice between MCOs, it is not necessary to give beneficiaries the same rights to go out of network that exist in rural areas with a single MCO. Regarding the FQHC comment, FQHC services are already a mandatory service under the Medicaid program. FQHC services must be available through a State's managed care program, or be provided as an out-of-network option. We expect beneficiaries who have a choice of MCOs and who wish to use FQHCs to choose their MCO accordingly. In addition, beneficiaries who either choose or are enrolled by default into an MCO that does not include an FQHC have 90 days to disenroll without cause.

Comment: We received a number of comments stating that the provision allowing beneficiaries to go out of network if the service or type of provider desired is not available within the MCO network is too broad. One commenter simply said the provision is

inappropriate. Other commenters said that this should be permitted only if the MCO does not have other in-network alternatives.

Response: In providing for a rural exception to choice, the Congress clearly intended to protect enrollees by giving them the right to go out of network in appropriate circumstances. We expect States to monitor their managed care programs, particularly in rural areas, to ensure that enrollees have access to appropriate services. We are not revising § 438.52(b)(2) in response to these comments.

Comment: We received a number of comments recommending that we clarify what is meant by not available within the network. The commenters recommended that we define ''available'' to encompass such factors as geographic accessibility, cultural and linguistic competency, appointment waiting times, and appropriateness of provider (for example, pediatric verses adult specialist). One of the commenters also recommended that we make it clear that when we refer to providers in this provision, we are including safety-net providers and clinics.

Response: We do not agree that it is necessary to amend the regulation. Under this final rule with comment period, rural MCOs must meet many new requirements addressing geographic, cultural, and linguistic accessibility. Section 438.207(b)(2) requires that MCOs maintain network of providers sufficient in number, mix, and geographic distribution to meet the needs of the anticipated number of enrollees. Section 438.206(d)(1)(v) requires that MCOs consider the geographic location of enrollees in developing their provider networks. Section 438.206(e)(2) requires that MCOs deliver services in a culturally competent manner, and § 438.10 requires that States and MCOs, PHPs, and PCCMs make information available in languages in use in the enrollment area. In the instance of a service for which there is no available provider who meets the above provisions, that service would not be considered available, and under § 438.206(d)(5), the enrollee would be able to obtain the service out-of-network. Regarding the comment about appropriateness of provider, we do expect States and MCOs to consider this when evaluating requests to obtain needed services out-of-network. In evaluating such requests, States may consider such factors as age, medical condition, general medical practice in the area, and overall availability of specific providers. Regarding the clinic and safety-net services, we have decided not to amend the regulation in response to this comment. This provision is meant to address beneficiary choice, and is not meant to single out certain types of providers for guaranteed participation.

Comment: A large number of commenters disagreed with giving rural beneficiaries the right to go out-of-network when they have an existing relationship with a provider who is not in the MCO network. Some commenters recommended that HCFA place a time limit on how long the relationship can be continued, and a few said the final rule should define what is meant by an existing relationship. Other commenters recommended that various limitations be placed on this provision, such as only allowing it when the beneficiary also meets one of the other criteria for going out-of-network; only permitting it when the individual has a chronic or terminal illness; only permitting it when the provider is in the MCO's service area; and permitting it only when a change in the provider relationship will result in an adverse health outcome. In addition, one commenter said it should be left to the MCO's discretion whether the relationship should be continued, and one commenter said the provider should be required to pass the MCO's credentialing process. One commenter said we should clarify that an existing relationship includes the example of a pregnant woman who initiated prenatal care with a provider before enrolling in the MCO.

Response: The requirement for choice in managed care programs is an important right granted to enrollees by the Congress. Where there is no choice, such as in rural areas with one MCO, The Congress intended for beneficiaries to have the protection of going out-of-network in appropriate circumstances, and directed the Secretary to publish regulations to specify the circumstances. However, we agree with the commenters who urged us to clarify what is meant by an existing relationship, and how long the relationship should be continued. Therefore, we amended the regulation to specify that this provision applies when the provider is the main source of a service to an enrollee and that the enrollee may continue to see the provider as long as the provider continues to be the main source of the service. We believe that these provisions cover a pregnant enrollee who, before enrolling in the MCO, had initiated prenatal care with a provider outside the MCO's network, and wished to continue seeing that provider.

Comment: We received a few comments recommending that we add to the scope of the provision allowing rural beneficiaries to go out of plan to a provider with whom they have an existing relationship. Some commenters recommended that the final rule clarify that this exception applies to specialists as well as primary care providers. One commenter said the final rule should specify the scope of services the out-of-network provider may provide. For example, this commenter said an obstetrician caring for a high-risk pregnant woman should be able to order tests without any limitation.

Response: In providing for this exception, and in further clarifying it, we clearly intend for specialists as well as PCPs to be included. We do not believe any further clarification is necessary. Furthermore, we intend for the scope of services provided by the out-of-network provider to be directly related to the beneficiary's overall condition and medical history, and we expect out-of-network providers and the MCO to share information regarding the patient's care for all treatment, because the MCO is ultimately responsible for payment. Again, we do not believe it is necessary to add language allowing providers the right to provide unlimited diagnostic and treatment services.

Comment: We received two comments recommending that the provision allowing rural beneficiaries to go out of network also apply to urban beneficiaries who want to go out of network to use Indian Health Service/Tribal providers/Urban Indian (I/T/U) providers.

Response: We disagree that it is necessary to add the suggested language to the regulation because Indian enrollees, whether in urban or rural areas, already have the right to access I/T/U providers outside of their networks in programs established under section 1915(b) or section 1115 authority, and in voluntary programs. Neither the BBA nor this regulation removes that authority. Additionally, Indians are exempt from mandatory enrollment into an MCO or PCCM under the new section 1932(a) authority, except where the MCO or PCCM is an I/T/U provider.

In responding to this comment, we have noted that Urban Indian health programs were inadvertently omitted from the list of entities into which an Indian eligible could be mandatorily enrolled under section 1932(a). In this Final rule with comment period, we have modified § 438.50(d)(2) to correct this omission.

Comment: One commenter recommended that we increase the State requirements for quality monitoring in areas falling under the rural exception.

Response: This regulation implements strong new quality requirements for

Medicaid managed care arrangements. We expect States to aggressively monitor quality in all managed care programs, including those covered by the rural exception. We do not agree with the commenter that the quality requirements for rural programs should be different from the general quality requirements.

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

Applicability

Section 1932(a)(4) sets forth a number of requirements relating to enrollment and disenrollment in Medicaid managed care programs. Proposed § 438.56(a)(2) specified that most of the enrollment/disenrollment provisions apply to all MCO, PHP, and PCCM contracts, regardless of whether enrollment is mandated under a waiver or section 1932, or is voluntary. The only provisions in this section that apply only to programs under which enrollment is mandated under section 1932(a)(1)(A) are the limitations on enrollment and default enrollment provisions. (In the final rule with comment period, these Section 1932 provisions have been moved to § 438.50.)

Comment: We received a number of comments objecting to the proposed rule's provisions concerning the applicability of enrollment requirements. One commenter contended that the 90-day right to disenroll without cause, the disenrollment for cause provisions, and the appeals provisions should apply only to mandatory managed care programs under section 1932(a)(1)(A) of the Act. A number of other commenters did not believe a 12-month lock-in should be applied in cases of voluntary enrollment. Two comments appear to be based upon misunderstanding because the proposed rule as written already reflected their suggestions. (One comment urged us to apply subsections (e) through (h) of the proposed rule to PHPs, and one comment says subsections (b) through (d) should apply only to section 1932 programs.) The commenters who indicated we applied various provisions too broadly would like HCFA to restrict the applicability of the provisions to mandatory enrollment under section 1932 programs.

Response: The BBA amended section 1903(m)(2)(A) of the Act to require, in a new paragraph (xi), that MCOs and MCO contracts ''comply with the applicable requirements of section 1932.'' The BBA also amended section 1903(m)(2)(A)(vi) to require that contracts with MCOs permit ''individuals to terminate * * * enrollment *in accordance with section 1932(a)(4)*,'' and must provide for ''notification in accordance with [that] section.'' (Emphasis added.) These requirements apply to all MCO contracts, regardless of whether enrollment in the contracts is voluntary, mandated under a waiver, or mandated under section 1932(a) of the Act. The enrollment requirements the proposed rule applies to MCOs all either apply by their own terms to MCOs, or are incorporated as set forth above under section 1903(m)(2)(A)(vi) of the Act.

In the case of primary care case managers, section 1905(t)(3)(F) similarly requires that primary care case manager contracts comply with ''applicable provisions of section 1932,'' while section 1905(t)(3)(F) requires that enrollees be provided the ''right to terminate enrollment in accordance with section 1932(a)(4).'' Again, this provision is not limited to cases in which the primary care case manager is participating in a mandatory program under section 1932(a).

The only provisions of section 1932 of the Act that not are applicable to all MCO, PHP, and PCCM contracts are those which include the language ''In carrying out paragraph (1)(A),'' which refers to the statutory authority to establish mandatory managed care programs through the State Plan Amendment process. These are the provisions we have designated as applicable to section 1932(a)(1)(A) programs only. In order to prevent any future confusion regarding which provisions apply only to section 1932(a)(1)(A) programs, we are in this final rule with comment period moving all such provisions to § 438.50.

With respect to the commenters who believed that the 12-month lock in should not apply when enrollment is voluntary, again, this result is dictated by the statute. Under section 1903(m)(2)(A)(vi) of the Act, an enrollee in an MCO has the right to disenroll only to the extent this is provided for in section 1932(a)(4) of the Act, which permits disenrollment without cause only in the first 90 days and annually thereafter. Under section 1915(a) of the Act, where enrollment is voluntary such an arrangement will not be considered to violate the general freedom of choice provision in section 1902(a)(23).

Disenrollment by the Recipient: Timing

Section 438.56(e) of the proposed rule (recodified at § 438.56(c) in the final rule with comment period) set forth the general rules regarding disenrollment rights. These provisions apply to all situations in which States choose to restrict disenrollment. Beneficiaries are permitted to disenroll for cause at any time, without cause during their first 90 days of enrollment, and annually thereafter. In certain circumstances (rural areas with only one MCO, or areas in which the statute permits contracting with only a single county-sponsored HIO), these rules apply to changes between individual physicians or primary care case managers.

Comment: We received one comment suggesting that the proposed rule did not go far enough in setting up a consistent process for disenrollment. The commenter recommended that HCFA include a requirement in the final rule that the disenrollment (and enrollment) process should be consistent across all MCOs, and PCCMs in a State.

Response: We are sensitive to the concern that to the greatest extent possible, a State's program should be consistent in order to avoid confusion and misunderstanding on the part of enrollees. We encourage States to establish uniform procedures in the area of enrollment and disenrollment, and we note that this section sets forth rules regarding the process that must be followed in all Medicaid managed care programs that restrict disenrollment in any way. We believe the proposed regulation provided a great degree of consistency in this process. We also believe the information requirements in § 438.10 and the notice requirements in § 438.56 will alleviate any potential confusion among enrollees. Therefore, we have decided not to change the final rule with comment period in response to this comment.

Comment: Several commenters noted that the proposed rule did not include a provision providing for MCO or PCCM disenrollments of beneficiaries for cause. Commenters recommended that HCFA adopt the language in the Medicare+Choice regulation allowing MCOs and PCCMs to request disenrollment of beneficiaries for uncooperative or disruptive behavior, or for fraudulent behavior.

Response: The previous regulation (at § 434.27) required PHP and HMO contracts to specify the process by which they could request that the State disenroll beneficiaries. It appears that the omission of this provision in § 438.56 was simply an oversight. In response to this comment, we are including a provision in this rule allowing MCOs, PHPs, and PCCMs to request disenrollment of enrollees. Section 438.56(b) of the final rule with comment period requires that MCO, PHP, and PCCM contracts specify the

reasons for which an MCO, PHP, or PCCM may request disenrollment of an enrollee. This section also prohibits MCOs, PHPs, and PCCMs from requesting disenrollment on the basis of the enrollee's adverse changes in health status, diminished mental capacity, utilization of medical services, or uncooperative or disruptive behavior resulting from an enrollee's special needs. The only exception to this rule is where the beneficiary's continued enrollment in the MCO, PHP, or PCCM seriously impairs the entity's ability to furnish services to either this enrollee or other enrollees in the entity.

Contracts must also specify how the MCO, PHP, or PCCM will assure the State agency that it will not request disenrollment for reasons other than those permitted under the contract. As suggested by the commenter, these changes reflect the provisions contained in the Medicare+Choice regulations.

Comment: We received comments regarding the special circumstances of persons who are homeless, particularly related to their transience and special needs in obtaining information critical in choosing an MCO or PCCM.

Response: We agree that persons who are homeless present a unique situation. Due to the lack of a mailing address and general transience, it is likely that they may not receive information about choice of MCOs or PCCMs or the fact they have been enrolled in an MCO or PCCM until they attempt to receive care. As a protection for this population, we are revising the regulation to include, as a cause for disenrollment, (under paragraph (d)(2) of the section) the fact that a person was homeless (as defined by the State) or a migrant worker at the time of an enrollment by default. This is in addition to all other disenrollment rights offered to all enrollees.

Comment: We received many comments asserting that cause is not adequately defined. Commenters urged HCFA to publish a broad definition of cause. Comments suggesting what would constitute cause included—inadequacy of an MCO's medical personnel in treating HIV; inability to access primary and preventive care; inability to access family planning services; the MCO's failure to offer family planning services; geographic, cultural, and linguistic barriers; an enrollee's PCP has left the MCO; lack of access to pediatric and pediatric sub-specialty services; the need for the enrollee to access local Indian health care services that are not available in the MCO; inability to obtain information in an accessible format; and inability to receive services appropriate to the medical condition. In addition, one commenter suggested that States be required to ''look behind'' HIV-related disenrollment requests to determine whether there are systemic problems in serving individuals with HIV.

Response: We agree that cause should be more specifically defined, and have revised § 438.56(d)(2) to provide examples that will be deemed to constitute cause. These reasons for disenrollment are similar to the grounds for going out of plan where the rural area exception applies. Specifically, under § 438.56(d)(2), an enrollee may disenroll for cause if (1) the enrollee was homeless (as defined by the State) or a migrant worker at the time of enrollment and was enrolled in the MCO, PHP or PCCM by default, (2) the MCO or PCCM does not, because of moral or religious objections, cover services the enrollee seeks, (3) the enrollee needs related services (for example a cesarean section and a tubal ligation) to be performed at the same time; not all related services are available within the network; and the enrollee's primary care provider or another provider determines that receiving the services separately would subject the enrollee to unnecessary risk, and (4) other reasons, including but not limited to, poor quality of care, lack of access to services covered under the contract, or lack of access to providers experienced in dealing with the enrollee's health care needs.

Further regarding the related services provision, we recognize that enrollees in this situation who are otherwise satisfied in their MCO or PHP may not want to disenroll in order to receive the related services together. We note that § 438.206 specifies that if the network cannot provide the necessary services covered under the contract (including related services) needed by the enrollee, these services must be adequately and timely covered out-of-network for as long as the MCO or PHP is unable to provide them. Under this provision, the enrollee would be able to avoid the need to disenroll from his or her current MCO or PHP but could still receive the related services concurrently.

Comment: One commenter pointed out that while a later section of the proposed rule speaks to the effective date of for-cause disenrollments, it does not address the effective date for without-cause disenrollments. The commenter recommended that there be a required effective date, and that it be no later than the timeframe provided for in the for-cause section, that is the beginning of the second calendar month following the month in which the request for disenrollment was made.

Response: We realize that the heading of § 438.56(f) in the proposed rule, ''Procedures for Disenrollment for Cause,'' suggests that we intended to limit these requirements to disenrollment for cause. However, HCFA did not intend that States be required or encouraged to set up a different process based upon whether or not the disenrollment request is for cause. Therefore, we have retitled the two paragraphs which now contain the same provisions (§ 438.56(d) and (e)) as ''Procedures for Disenrollment'' and ''Time-frame for disenrollment determination''

Comment: We received a number of comments disagreeing with giving enrollees the right to disenroll without cause for 90 days after enrolling in (or being default enrolled into) an MCO, PHP or PCCM. Several commenters believed that the 90-day period was too lengthy, but one commenter stated that ''[t]he removal of the right to disenroll at any time troubles us.'' The commenters opposing the 90-day period did not offer suggestions of a shorter time period. One commenter recommended that there should only be one 90-day period, and not a new opportunity to disenroll without cause every time a recipient enters a new MCO, PHP, or PCCM.

Response: The requirement to allow beneficiaries to disenroll without cause for 90 days appears in section 1932(a)(4), so we do not have authority to remove or alter this right, or the length of the 90 day time period. As for the question of whether there is a new 90-day period with each new MCO, PHP, or PCCM enrollment, the statute refers to enrollment with the MCO or PCCM and not initial enrollment in the managed care program. Therefore, there is no room for interpretation of that provision as just allowing for a single 90-day disenrollment period without regard to whether the beneficiary enrolls in a new MCO or PCCM.

Comment: A number of commenters disagreed with our interpretation that the right to disenroll for 90 days without cause only applies the first time a recipient is enrolled in a particular MCO, PHP, or PCCM. The commenters recommended that the final rule provide for a right to disenroll for 90 days each time a recipient enters an MCO, PHP, or PCCM, even if he or she has been enrolled in that MCO. PHP, or PCCM previously. Commenters indicated that this is justified on the basis that there could have been substantial changes in an MCO, PHP, or PCCM since the recipient's previous enrollment.

Response: The statute does not make clear whether the 90 day period

following notice of enrollment with an MCO or PCCM applies only once, when the individual is initially enrolled with the MCO or PCCM, or each time the individual enrolls with an MCO or PCCM, even if he or she has been enrolled in the MCO or PCCM before. We believe that the purpose of the extended 90 day disenrollment period is to allow the beneficiary to become familiar with an MCO or PCCM before deciding whether to remain enrolled. Once a beneficiary has been an enrollee of an MCO or PCCM this rationale no longer applies. While it is true that an MCO, PHP, or PCCM might change in the interim, this is equally true of an MCO, PHP, or PCCM that the enrollee might remain enrolled with. A beneficiary would still have an annual opportunity to disenroll in both cases. We believe that the interpretation the commenter has suggested would create a potential for abuse by providing an incentive for frequent changes in enrollment that could result in multiple 90 day periods for the same MCO, PHP, or PCCM.

Comment: The proposed rule specifies that the 90-day clock for enrollees to disenroll without cause begins upon the actual date of enrollment, and further provides that if notice of enrollment is delayed, the State may extend the 90-day period. All comments we received on this issue urged HCFA to adopt what they consider to be stronger language. The commenters suggested that HCFA provide that the 90-day disenrollment period begins when notice of enrollment is actually received. Furthermore, they contended that States should be required, rather than permitted, to extend the 90-day period in the event that notice to the enrollee is delayed. A couple of commenters also believed that States and MCOs, PHPs, and PCCMs should be required to guarantee that the notice is actually received; and in the case of homeless individuals, that the notice is received prior to the initial assessment by the MCO, PHP, or PCCM.

Response: By providing for the 90-day period to begin when the enrollment takes effect, HCFA was attempting an interpretation of the statute that would offer maximum protection to enrollees. That is because in many States, notice of enrollment may be sent to the recipient up to 60 days before the effective date of the enrollment. However, because there is such a high level of concern that beneficiaries will be harmed in cases when notice of enrollment is mailed after the effective date, we are adding regulation text providing that the 90 day period begins upon the enrollment, or the date the notice is sent, whichever is later. Regarding the request that States and MCOs, PHPs, and PCCMs be required to guarantee that notices are actually received, we do not believe it is appropriate to require such a guarantee when there are certain factors beyond the control of the State or MCO, PHP, or PCCM. However, it is in a State's best interest to make the maximum effort possible to ensure that notices are received, and we encourage States to take measures to ensure this to the best of their ability.

Comment: We received one question about whether States should be able to differentiate between different types of MCOs, PHPs, and PCCMs in the 12-month lock-in provision. The commenter recommended that States be allowed to have different lock-in periods depending upon whether the enrollee was locked into a PCCM or an MCO.

Response: Section 1932(a)(4), which applies to both MCOs and PCCMs, requires that enrollees be allowed to disenroll for cause at any time, and without cause during the initial 90 days, and ''at least every 12 months thereafter.'' As long as no enrollee is locked-in for a period of more than 12 months, there is no prohibition against States implementing different lock-ins for MCOs, PHPs, and PCCMs.

Comment: A number of commenters said they believe the provision for an annual disenrollment opportunity may create confusion. The commenters suggested that States be required to hold an annual open enrollment period.

Response: The statute requires States to permit enrollees to disenroll from an MCO or PCCM for a 90-day period at the beginning of enrollment, and ''at least every 12 months thereafter.'' As long as the State meets the requirement to inform beneficiaries of their right to terminate or change enrollment at least 60 days in advance, the State may structure the annual opportunity in whatever way it sees fit. This may involve holding an annual open enrollment period as the commenters suggested, or individually offering each recipient an opportunity to change enrollment upon his or her enrollment anniversary.

Comment: Section 438.56(e)(2) of the proposed rule (moved to § 438.52(c) in the final rule) provided that in rural areas with only one MCO, States may meet the disenrollment requirements by allowing enrollees to change physicians or case managers within the MCO. A commenter contended that PCCM enrollees in rural areas should be allowed to disenroll and transfer to fee-for-service Medicaid if only a single PCCM is available, since section 1905(t)(3)(E) of the Act requires that a beneficiary have a choice.

Response: Section 1905(t)(3)(E) of the Act requires that primary care case manager contracts permit disenrollment in accordance with section 1932(a)(4) of the Act. As defined in § 438.2, a primary care case manager may be an individual physician or a group of physicians. Therefore, a State arguably would be complying with the requirement in section 1932(a)(4) of the Act if it allows enrollees to change primary care case managers since (to the extent these individual managers are each considered managed care entities.) More importantly, however, we believe that section 1932(a)(3)(B) provides an exception not only to the rule set forth in section 1932(a)(3)(A) of the Act that an enrollee have a choice of more than one MCO, but as an implicit exception to the requirement in section 1932(a)(4)(A) of the Act that a beneficiary be able to disenroll from an MCO. Thus, even if the State has only a single MCO contract in a rural area pursuant to section 1932(a)(3)(B) of the Act, we believe that the requirements in section 1932(a)(4) of the Act would be satisfied by permitting disenrollment from an individual primary care physician. The authority in section 1932(a)(3)(B) of Act to permit the choice of entity requirement in section 1932(a)(3)(A) of the Act to be fulfilled by providing a choice of individual physicians would be meaningless if section 1932(a)(4) of the Act were nonetheless construed to permit an individual to disenroll from an MCO, as opposed to changing individual physicians. Thus, where the conditions in section 1932(a)(3)(B) have been satisfied, the requirement in section 1932(a)(4), as made applicable by section 1905(t)(3)(E), is satisfied by permitting beneficiaries to disenroll from their primary care physician.

Procedures for Disenrollment

Section 438.56(f) of the notice of proposed rulemaking set forth the required procedures for processing disenrollment requests. (We note here that the proposed rule referred to ''Procedures for disenrollment for cause,'' but as noted above, in response to comments, we have renamed the two paragraphs containing material from proposed § 438.56(f) ''Procedures for disenrollment'' and ''Timeframe for Disenrollment Decisions.'') In § 438.56(f), we proposed that enrollees be required to submit written requests for disenrollment to the State agency or to the MCO, PHP, or PCCM. MCOs, PHPs, and PCCMs are required to

submit copies of disenrollment requests to the State agency. Proposed § 438.56(f) provided that while MCOs, PHPs, and PCCMs may approve disenrollment requests, only the State agency may deny such requests.

In cases where the State agency receives the request, under proposed § 438.56(f) it could either approve the request or deny it. Requests for disenrollment had to be processed in time for the disenrollment to take effect no later than the first day of the second month following the month in which the enrollee made the request. Proposed § 438.56(f) further provided that if the State or MCO, PHP, or PCCM does not act within the specified timeframe, the request was considered approved.

Response: This comment is quoting language from proposed § 438.56(e)(1), which is retained in the final rule with comment period in § 438.56(c). This language states that if the State chooses to limit or restrict enrollment, it must permit enrollment without cause in the first 90 days an individual is enrolled in an MCO, PHP, or PCCM, and annually thereafter. This rule would be irrelevant if a State chose not to limit disenrollment at all. To clarify our position in response to the commenter, if a State wishes to permit disenrollment at any time, or more frequently than the minimum disenrollment rights required under § 438.56(c), the same rules on notice and effective date apply as apply when a State ''chooses to restrict disenrollment.''

Comment: Several comments felt that the final rule should specify that disenrollment requests may be submitted by either the enrollee or his or her representative. In addition, others felt that we should delete the reference to 20 CFR part 404, subpart R in the definition of authorized representative. The commenters believed that these rules, which generally govern representative payees for Social Security programs, have little, if any, relevance to the Medicaid program and that these requirements would limit assistance to beneficiaries in the Medicaid managed care enrollment process. They indicated that current rules recognize that beneficiaries may require assistance in a variety of circumstances and provide that applicants and recipients may obtain that assistance from a variety of sources. For example, commenters pointed out that in formal proceedings such as fair hearings, Medicaid beneficiaries enjoy the right to ''represent themselves, use legal counsel, a relative, friend or other spokesman.'' (42 CFR 431.206). If the applicant is incompetent or incapacitated, anyone acting responsibly for the applicant can make application on the applicant's behalf (42 CFR 435.907). People with disabilities who are incompetent or incapacitated can currently be represented by anyone acting responsibly on their behalf. Commenters indicated that State law is available, and is used to step in when a person cannot make medical decisions on his or her behalf.

Response: We concur with the commenters and have modified § 438.56(d) to add ''his or her representative'' to enrollee. In addition, we have deleted the reference to 20 CFR Part 404. We have also deleted the reference to ''authorized'', using only the term representative to allow for a broad range of representatives, consistent with existing policies and practices. The definition, which has been moved to § 430.5, now reads ''Representative has the meaning given the term by each State consistent with its laws, regulations, and policies.''

We agree with the commenters that the appropriateness of a representative depends on the significance of the activity for which they are acting as representative, so that States should have the flexibility to determine who may represent the beneficiary in various activities. The State may establish various criteria depending upon the situation (for example, disenrollment requests, choice of health plans, receiving notices, filing grievance and appeals (including requests for expedited review, being included as a party to the appeal and the State fair hearing, receiving marketing materials, being provided opportunity to review records, etc.) In determining who may represent beneficiaries, we anticipate that States will provide special consideration for individuals with cognitive impairments, who are unable to appoint their own representatives, but who may be especially vulnerable and require assistance in accessing the protections offered in these regulations.

Comment: A number of commenters disagreed with the requirement that disenrollment requests be submitted in writing, contending that this may present a barrier to some enrollees, and that the process should be as barrier-free as possible.

Response: We agree and are interested in reducing or eliminating barriers wherever possible. Therefore, § 438.56(d) has been amended to specify that disenrollment requests may be written or oral. Further, we note that States cannot impose a requirement that beneficiaries appear in person to request disenrollment.

Comment: We received a number of comments relating to the time allowed for processing disenrollment requests. The only references to a timeframe appeared in the proposed rule at § 438.56(f)(2)(ii) and § 438.56(f)(4)(i). (These sections are redesignated as § 438.56(d)(3)(ii) and § 438.56(e)(1) in the final rule.) Disenrollment requests, if approved, must take effect no later than ''the first day of the second month after the enrollee makes the request.'' (This is re-wording of previous statutory language, formerly found at section 1903(m)(2)(A)(vi) of the Act, which required disenrollment requests to be effective at the ''beginning of the first calendar month following a full calendar month after the request is made for such termination.'' This specific language was removed by BBA and was not replaced with any alternative timeframe.) Commenters urged HCFA to spell out a more specific list of requirements relating to processing of requests. Although not all comments suggested a specific timeframe, most urged an ''expedited'' process for urgent or emergency situations. Commenters who did specify a timeframe for urgent or emergency situations indicated that requests should be required to be processed within 3 or 5 days. One commenter said disenrollment requests on behalf of children with special health care needs should be processed within 72 hours. It is important to note that the comments addressed ''processing'' of disenrollment requests, and not the effective dates. It is safe to assume, however, that the commenters would support an expedited effective date as well as expedited processing.

Response: Because of the removal of the effective date requirement in section 1903(m)(2)(A)(vi) of the Act, the statute is silent on how long the disenrollment process should take.

In response to the above comments, we believe that other beneficiary protections within this final rule with comment period, for example § 438.206(d)(5), provide adequate protection and access to necessary medical services covered under the contract out-of-network for as long as the MCO pro PHP is unable to provide them.

Comment: One commenter recommended that HCFA require States to establish an Ombudsman program to intervene in the disenrollment process.

Response: We are sensitive to the need for enrollees to have adequate protection in the enrollment and disenrollment process. This is particularly a concern for those who may have limited experience with managed care systems. We believe we have built numerous protections into

§ 438.56, including a provision for an appeals process when disenrollment requests are denied. In addition, it is important to note that many States use enrollment brokers, who act as independent third parties and assist enrollees in making their choice of managed care organizations. We believe that it is not necessary to require States to establish Ombudsman programs, although we would encourage them to do so.

Comment: One commenter believed the provision describing how MCOs, PHPs, and PCCMs should process disenrollment requests was too prescriptive. The commenter felt we should allow States to individually develop the process for MCO, PHP, and PCCM handling of disenrollment requests. However, other commenters felt this provision was too flexible, and recommended that MCOs, PHPs, and PCCMs not be permitted to process disenrollment requests. These commenters recommended that only the State or an independent third party, such as an enrollment broker, be permitted to handle disenrollment requests.

Response: Disenrollment is an important right granted to beneficiaries by the Congress, especially in an environment in which States can now require a lock-in period of up to 12 months. The consistent process required under this regulation is intended to guarantee that beneficiaries will be able to exercise this right as intended by the Congress. However, the statute is silent on certain aspect of disenrollment, including who should process such requests. Allowing MCOs, PHPs, and PCCMs to process requests is longstanding policy, and is based upon the principle of State flexibility, because States are closest to the situation and should be aware of whether such a policy would be beneficial to enrollees.

Further, we understand the concern that MCOs, PHPs, and PCCMs may have an incentive to discourage beneficiaries from disenrolling, or to disenroll more costly beneficiaries, but we believe adequate safeguards have been built into the process to protect enrollees. For example, MCOs, PHPs, and PCCMs may approve disenrollment requests, but they may not disapprove them. If an MCO, PHP, or PCCM does not take action to approve a request, it must refer the request to the State agency for a decision. States are also required to give enrollees who disagree with disenrollment decisions access to the State fair hearing system. It is important to note, also, that involving the MCO, PHP, or PCCM in the process may benefit enrollees. In many instances, the MCO, PHP, or PCCM may be able to resolve the problem that led the enrollee to request disenrollment, thus meeting the beneficiary's needs while preventing the necessity to disenroll. In addition, we expect that MCOs would track reasons for these requests as part of their quality improvement programs.

In this rule we believe we have taken the interests of beneficiaries and States into account and balanced the need for beneficiary protection with the need for flexibility in program administration. We therefore disagree with the commenters, and have decided not to change this provision in the final rule with comment period.

Comment: A number of commenters asked for clarification of the requirement that MCOs, PHP, and PCCMs to notify the State if they do not take action on a request for disenrollment. Commenters recommended that the final rule be revised to provide that MCOs, PHPs, and PCCMs are required to notify the State when they disapprove requests, as well as when they do not take action. In addition, one commenter proposed that HCFA require the State to aggressively monitor MCO, PHP, and PCCM denials of disenrollment requests. These commenters apparently did not understand that MCOs, PHPs and PCCMs would not be permitted to disapprove disenrollment requests.

Response: We disagreed with the commenters who argued the provision (re-designated as § 438.56(d)(5) in the final rule with comment period) should be deleted. We have decided to retain the provision for two reasons. First, the internal grievance process can eliminate the need to disenroll by resolving the issue that led to the disenrollment request. We consider this to be beneficial from a continuity of care standpoint, as well as a quality standpoint. Secondly, we believe that States should have flexibility to decide whether the internal grievance process is helpful in the context of disenrollment requests. States are in the best position to make this determination based upon their programs and beneficiaries. We do agree, however, that there are cases where requiring the use of the internal grievance process may not be appropriate, therefore, we have specified that in cases expedited disenrollment, this provision does not apply.

Comment: Proposed § 438.56(f)(3) provided that States may require beneficiaries to use the internal MCO grievance process before making a determination on a request for disenrollment if a delay would not pose jeopardy to the enrollee's health. Some commenters disagreed with this provision, while another recommended that enrollees be required to use the internal grievance process. Other commenters said enrollees should be allowed to go straight to the State's fair hearing process for disenrollment requests. Still other commenters commented proposed that HCFA clarify that the exception for jeopardy to health should apply in cases in which the harm to an enrollee's health may not become apparent until later. Also, the commenter recommended that we include language indicating that in the case of pregnant women, jeopardy to the health of the fetus also be considered. Another commenter recommended that in the case of children, the delays that would jeopardize development be addressed.

Response: We disagreed with the commenters who argued the provision (redesignated as § 438.56(d)(5) in the final rule) should be deleted. We have decided to retain the provision for two reasons. First, the internal grievance process can eliminate the need to disenroll by resolving the issue that led to the disenrollment request. We consider this to be beneficial from a continuity of care standpoint, as well as a quality standpoint. Secondly, we believe that States should have the flexibility to decide whether the internal grievance process is helpful in the context of disenrollment requests. States are in the best position to make this determination based upon their knowledge of their programs and beneficiaries.

Comment: The proposed rule requires disenrollment requests, if approved, to take effect no later than the first day of the second month following the month in which the enrollee makes the request. A number of commenters were dissatisfied with this provision and said it should be made more specific. One commenter recommended that the timeframes specified in the Subpart F (Grievance System) be applied to the disenrollment process. A number of commenters recommended that the timeframe be made more specific, with a number of recommendations that requests be processed within five days.

Response: As stated elsewhere, the required timeframe for processing disenrollments is meant to be a maximum, not a minimum. However, the regulation is also designed to be workable in all States, and States have very different systems capabilities to accommodate changes in managed care enrollment. As noted above, the timeframes we have adopted were in place for many years under section 1903(m) before the BBA. Because

capitation payments are made on a monthly basis, most States may want to make disenrollments effective on the first day of a month. However, there is no prohibition against a State adopting a process that calls for timeframes that mirror those contained in Subpart F, as the commenter recommended.

Comment: Proposed § 438.56(f)(4)(ii) provided that if the State agency fails to make a determination on a disenrollment request within the specified timeframe, the request is deemed approved. Commenters recommended that HCFA make clear that the ''deemed approved'' language applies whether the State or the MCO, PHP, or PCCM is processing the disenrollment request.

Response: We agree that in cases where MCOs, PHPs, and PCCMs are permitted by the State to process disenrollment requests, the same timeframes should apply. Section 438.56(e)(3) of the final rule with comment period makes this clear.

Notice and Appeals

Section 438.56(g) of the proposed rule (§ 438.56(f) in the final rule with comment period) specified that States restricting disenrollment in Medicaid managed care programs must require MCOs and PCCMs to notify beneficiaries of their disenrollment rights at least 60 days before the start of each enrollment period and at least once a year. The paragraph further required that the State establish an appeal process for any enrollee dissatisfied with a State agency determination that there is not good cause for disenrollment.

Comment: Some commenters disagreed with our approach of providing for MCOs and PCCMs to provide disenrollment rights notices, while others agreed with this general approach, but said we should impose additional requirements on States. In addition, some commenters believed that the provision is too prescriptive.

The commenters who disagreed with permitting MCOs and PCCMs to provide disenrollment rights notices said the final rule should provide that only the State or an enrollment broker should notify enrollees of their disenrollment rights. In addition, these commenters proposed that States be required to develop a model from which would be translated into all languages in use in the State, and field tested before being used in the Medicaid program.

Commenters who supported additional requirements said the regulation should require such notice to be provided upon initial enrollment, and that we should add language requiring that the notice be understandable to beneficiaries, consistent with the provisions of regulations that apply to the Medicare + Choice program.

The commenters who said the provision was too prescriptive recommended that we mirror the statutory language requiring one annual notice 60 days before the beginning of the enrollment period, and that the final rule should reflect that the enrollee handbook constitutes sufficient notice regarding disenrollment rights. One commenter suggested that we require ''adequate notice'' at a time specified by the State.

Response: Section 1932(a)(4) requires an annual notice at least 60 days before the beginning of an individual's annual opportunity to disenroll, but does not specify whether the MCO, PHP, PCCM or the State should send the notice. In response to the concerns raised by the commenters, and in recognition of the fact that some States may want to send the notices themselves (or employ an enrollment broker to perform this function), the final rule with comment period (at § 438.56(f)) requires the State to provide that enrollees are given written notice and ensure access to State fair hearing for those dissatisfied with a denial based on lack of good cause. Regarding the model form comment, this seems to be a reasonable approach and it is one we believe many States will employ, but we do not believe it is necessary or prudent to make this a regulatory requirement. Regarding the comment about mirroring the Medicare+Choice regulation, we believe that the statutory requirements provide sufficient protections to beneficiaries in this case. We also believe the information requirements found at § 438.10 provide a great degree to specificity in terms of how States will inform enrollees of their rights and responsibilities.

Comment: One commenter said we should require that the notice of disenrollment rights be sent to a representative payee, if one exists.

Response: The concerns of this commenter have been addressed by our decision to revise the final rule with comment period to provide that notice be provided to an enrollee or his or her representative. We note that a representative payee would not necessarily be authorized by the enrollee, or under State law, to represent the enrollee for purposes other than handling the benefits check. The final rule with comment period provides for notice to the representative.

Comment: Two commenters said that in addition to laying out notification requirements, the final rule should speak to the form used to request disenrollment. One commenter suggested that HCFA develop a model form, while the other suggested that HCFA require States to develop a single form for use throughout their program.

Response: We agree that in many cases, use of a standard form for disenrollments (both annual and for-cause) can aid in program administration. Many States will probably choose this approach, which they are free to do under this final rule with comment period as long as they also permit oral disenrollment requests as required under § 438.56(d). Because we believe that States may have legitimate reasons for choosing other approaches, however, and in light of our decision in response to comments to permit oral disenrollment requests, we have decided not to make this a regulatory requirement.

Comment: We received a number of comments on the requirement for States to establish an appeals process for enrollees who disagree with denials of disenrollment requests. The commenters said that when enrollees disagree with a State denial of a disenrollment request, they should be able to proceed directly to the fair hearings process without going through a separate appeals process.

Response: The cited provision was not intended to require States to establish a process separate from the fair hearing system. As noted above, § 438.56(f)(2) of the final rule with comment period requires that State fair hearings be made available.

Automatic Re-enrollment

Proposed § 438.56(h) reflected the provision in section 1903(m)(2)(H) of the Act specifying that if the State plan so provides, MCO and PCCM contracts must provide for automatic re-enrollment of individuals who are disenrolled only because they lose Medicaid eligibility for a period of two months or less.

Comment: One commenter pointed out that the proposed language did not specify how the enrollment/disenrollment provisions (such as timeframes for changing MCOs and PCCMs) in this rule apply in cases of automatic re-enrollment.

Response: Section 438.56(h) reflects a statutory provision that was enacted in 1990, and is simply being incorporated into regulation. The commenter is correct that the proposed rule did not address how to apply the enrollment/disenrollment provisions to enrollees who have a temporary loss of Medicaid eligibility. We have decided to add

clarifying language to the final rule with comment period in § 438.56(c)(2)(iii) indicating that if a temporary loss of eligibility causes a recipient to miss the annual right to disenroll without cause, that right will be given upon re-enrollment. The enrollee would not, however, be entitled to a new 90 day period.

Comment: Two commenters pointed out that the preamble and regulations text of the proposed rule were in conflict regarding the re-enrollment timeframe. (The preamble indicated a window of up to four months.) The commenters indicated their preference for the four-month window. One commenter said they favor State flexibility and indicated they currently use a window of 90 days in their program. Two other commenters suggested a three-month window.

Response: Section 1903(m)(2)(H) provides a re-enrollment window of two months, therefore, the reference to four months in the preamble to the proposed rule was an error. States may use a shorter timeframe, but not a longer one.

4. Conflict of Interest Safeguards (§ 438.58)

Proposed § 438.58 required as a condition for contracting with MCOs that States establish conflict of interest safeguards at least as effective as those specified in section 27 of the Office of Federal Procurement Policy Act.

Comment: One commenter supported the provision as written requiring that there be conflict of interest safeguards on the part of State and local officers and employees and agents of the State who have responsibilities relating to MCO contracts or default enrollments.

Response: The final rule with comment period makes no change in the proposed language, other than to reflect the applicability of this provision, like other provisions in subpart B, to PHPs (see section 2. above).

Comment: Two commenters suggested that the safeguards be applied to all MCOs, PHPs and PCCMs, not just MCOs.

Response: Section 438.58 implements section 1932(d)(3), which specifies only contracts under section 1903(m) (i.e, contracts with MCOs). For this reason, we referenced only MCOs in proposed § 438.58. However, while the conflict of interest standards in § 438.58 are triggered by MCOs, in the sense that the State cannot enter into MCO contracts unless they are in place, they apply to anyone with responsibilities ''relating to'' MCOs or to the ''default enrollment process specified in § 438.56,'' which would also include responsibilities for PCCMs. In addition, as discussed in section 2. above, we have made all provisions in subpart B except for § 438.50, applicable to PHPs.

Comment: One commenter agreed that these safeguards regarding conflicts of interest for State and local officials were necessary and welcome; however, it envisioned additional protections for any entity engaged in ''determining or providing managed health care to Medicaid-eligible beneficiaries [should] have policy-making bodies that consist of at least 60 percent'' of beneficiaries who will be served by the program.

Response: We do not believe that the regulation should be amended. Ensuring 60% Medicaid beneficiary representation on any board involved in determining how managed care will be provided to Medicaid eligibles is not feasible, given resource constraints at the State level. Furthermore, we have no statutory basis for requiring such representation.

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

Proposed section 438.60 prohibited payment for services which were covered under a contract between an MCO and the State, except for emergency and post-stabilization services in accordance with section 438.114(c) and (d).

Comment: All commenters maintained that the language in § 438.60 is too restrictive: the only exempted service are emergency services and post-stabilization services. Additional ''exceptions'' proposed were—family planning, school-based services, immunizations by local health agencies, certified nurse midwife services, tribal health provider services, and EPSDT services.

Response: We believe that the commenters have misunderstood this provision and that the exemption for emergency and post stabilization services in the proposed rule may have helped create this confusion. The intent of section 438.60 is to prohibit duplicate payments (once through capitation, once through FFS) for services for which the State had contracted with an MCO to provide. We believe that the exemption for emergency and post stabilization services was incorrect, since the MCO is obligated to cover and pay for these services for its enrollees. Thus, any payment by the State would be a duplicate payment. We are deleting this exemption from the final rule with comment period.

A State has in effect already paid for services that are included in an MCO's contract, and does not have an obligation to pay for them a second time, if a beneficiary obtains the services outside of the MCO's network.

In instances where out-of-network services may be authorized, e.g., the rural exception to the choice requirement, family planning, school-based services, immunizations, CMN or tribal services either the MCO or the state has the financial obligation to pay for the services. The State may pay for the services that were under the contract only if there is an adjustment or reconciliation made to the amounts paid the MCO in its capitation payments. In this situation, the services were not considered ultimately to be covered under the MCO contract. In situations where any of these services are carved out of the contracts (and the capitation rates paid the MCO) this is not an issue. State option to allow beneficiaries to go out-of-network for these services is not hindered by this section.

In addition, this provision precludes States from making additional payments directly to providers for services provided under a contract with an MCO or PHP, except when these payments are required by statute or regulation, such as with DSH or FQHC payments. We have clarified this provision accordingly in the final rule.

Comment: One commenter wanted HCFA to clarify what ''service availability'' actually means.

Response: For purposes of this provision, ''available'' would refer to services covered under the contract. A State is held accountable (§ 438.306) for ensuring that all covered services are available and accessible to enrollees—both services under the contract and those State plan services not included in the contract with the MCO.

6. Continued Service to Recipients (§ 438.62)

Proposed § 438.62 required States to arrange for continued services to beneficiaries who were enrolled in an MCO whose contract was terminated or beneficiaries who were disenrolled for any reason other than a loss of Medicaid eligibility.

Comment: We received a series of general comments that, overall, § 438.62 did not address the continuation of an enrollee's ongoing treatment when transitioning to managed care. Specifically, the commenters expressed concern that the proposed regulation did not highlight the need for identification and continuation of an enrollee's treatment when transitioning from FFS into managed care or from one managed care organization to another. Several commenters stated that the interruption of treatment for only a short period of time could have serious

and possibly irreversible consequences on an individual's health. Other commenters suggested that ongoing treatment without interruption was especially critical for persons suffering from mental illness, substance abuse, and chronic conditions such as HIV/AIDS.

Response: Section 438.308 addresses continuity and coordination of care requirements on MCOs, and comments on this provision generally are discussed in more detail in section II. D. below, discussing comments on proposed subpart E. We believe, however, that some comments on perceived inadequacies in § 438.308, specifically those expressing concerns about continued access to services as beneficiaries are transitioned from FFS into managed care, could be addressed in part by amending proposed § 438.62. Proposed § 438.62 represented a recodification of a longstanding requirement in part 434, at § 434.59, which required that provision be made for continued services when enrollment in an MCO or a PHP is terminated. This requirement was imposed under our authority in section 1902(a)(4) to specify methods necessary for proper and efficient administration. In response to the above comments, we believe it is appropriate to extend the requirement in § 438.62 (previously in § 434.59) to situations other than the transition out of an MCO or PHP.

We believe that most States already have mechanisms in place to transition enrollees into managed care from fee-for-service and from one MCO to another. However, we acknowledge the commenters' concerns that our proposed regulation does not address an enrollee's potential disruption of services, even for a short period of time, from the period of initial enrollment until the time of assessment by the new primary care physician or specialist in the receiving MCO or PHP.

In response to the large number of comments received on this issue, we are in this final rule with comment period, again under our authority in section 1902(a)(4), expanding the scope of § 438.62. The commenters referred to ''managed care'' generally, in asking that our regulations address ''transitioning from FFS into managed care.'' We therefore are extending § 438.62 to enrollees in PCCMs, as well as MCOs and PHPs. The language of the proposed version of § 438.62 becomes paragraph (a) in the final rule with comment period, except with reference to MCOs, PHPs, and PCCMs rather than only MCOs, to afford enrollees of PHPs and PCCMs the same protections. The added paragraph (b) requires States to have mechanisms to ensure continued access to services when an enrollee with ongoing health care needs is transitioned from fee-for-service to an MCO, PHP, or PCCM, from one MCO, PHP, or PCCM to another, or from an MCO, PHP, or PCCM to fee-for-service.

We wish to emphasize that we are not mandating any specific mechanism that States must implement, nor are we mandating a specific list of services or equipment that must be covered during the transition period. However, we are requiring that the mechanism apply to at least the following categories of enrollees: (1) Children and adults receiving SSI; (2) children in Title IV–E foster care; (3) recipients aged 65 or older; (4) pregnant women; (5) any other recipient whose care is paid for under State-established, risk-adjusted, high-cost payment categories; and (5) any other category of recipients identified by HCFA. We also specify that the State must notify the enrollee that a transition mechanism exists, and provide instructions on how to access the mechanism. Further, the State must ensure that the enrollee's ongoing health care needs are met during the transition period by establishing procedures to ensure that, at a minimum, the enrollee has access to services consistent with the State plan, and is referred to appropriate health care providers; new providers are able to obtain copies of appropriate records consistent with applicable Federal and State law; and any other necessary procedures are in effect.

Comment: One commenter believes that it is unclear what level of effort by the State is sufficient to comply with the requirement. In an FFS environment, referral services are less comprehensive and ''delays'' might be defined differently.

Response: We believe that both terms, ''without delay'' and ''delay'' represent straightforward guidance and that no further changes are needed.

7. Monitoring Procedures (§ 438.66)

Proposed section 438.66 states that a State must have in place procedures for monitoring MCO practices and procedures with regard to enrollment/termination, implementation of grievance procedures, violations subject to intermediate sanctions (such as failing to provide services for which it has contracted), and violations for the conditions for FFP (such as conditions of FFP for enrollment broker services). As noted above, we have made this and most other provisions applicable to PHPs in response to comments. We therefore in this final rule with comment period have added ''to the extent applicable, for PHPs,'' since not all of these provisions apply to PHPs.

Comment: One commenter noted that with regard to enrollment and termination practices, HCFA did not specify ''beneficiaries'' or ''providers,'' but assumes we meant beneficiaries only.

Response: This section of the regulation does not implement a BBA requirement, and was incorporated from existing regulations without substantive changes. We did not intend to modify or expand its meaning. That said, we agree that paragraph (a) needs clarification, and in response to this comment, the final rule with comment period specifies that it applies to ''recipient enrollment and disenrollment,'' and adds a paragraph (e) ''All other provisions of the contract, as appropriate.''

Comment: Another commenter states that the regulation should specify timeframes, and suggests annual monitoring for grievance procedures, and quarterly monitoring for enrollment/termination. This commenter furthermore notes that we have required the latter in some 1915(b) waivers and 1115 demonstrations.

Response: Given our desire to maximize States' flexibility in administering their State plans, we do not specify for each item how often the monitoring must be done, merely that it is a requirement to do so. Our experience with States' monitoring of MCOs in section 1115 demonstrations and in 1915(b) program waivers suggests to us that States implementing these procedures will do so on an annual or quarterly basis—if not more often than that.

Comment: One commenter suggested that HCFA require States to have procedures to monitor specialty referral services.

Response: With respect to the suggestion of monitoring procedures for specialty referral services, we note that 438.10 already requires MCOs to make available information to beneficiaries on how to access services, including those (such as referrals) that may require authorization. If these procedures are not being followed, we believe that the complaints and grievances data (which the State is required under this subsection to monitor) will demonstrate whether the MCO is following its own (State-approved, see § 438.700) procedures. Furthermore, we have clarified with new paragraph (e) what has always been our expectation; namely, that States monitor compliance with all aspects of the contract. Such a requirement implicitly includes the monitoring of special referral services.

Comment: One commenter believed that HCFA should require States to have procedures in place to monitor the degree of enrollment of pediatricians/other providers, the provision and access to services not covered under the contract, and EPSDT services.

Response: We believe that it would be unnecessarily onerous to add requirements regarding monitoring the participation of pediatricians and other providers and EPSDT services. The MCOs have already agreed to provide all medically necessary services in their contract (including EPSDT, if included in a particular contract) and therefore have strong incentives to have adequate provider and specialist network capacity, especially because if it they do not, the State can impose intermediate sanctions or terminate the contract before it would otherwise expire (see § 438.718). Furthermore, it is a contract requirement that MCOs provide for arrangements with, or referrals to, ''sufficient numbers of physicians and other practitioners to ensure that services under the contract'' are furnished (see § 438.6). Furthermore, again, we have clarified in paragraph (e) that States monitor contract compliance. Such a requirement implicitly includes the monitoring of number of pediatricians and other providers. Moreover, States are required at § 441.56 to meet certain EPSDT targets, whether or not they are contracted services. With regard to ''wraparound services,'' we note that § 438.206(c) makes clear that it is the responsibility of the State to ensure that services not covered by the contract are provided to Medicaid beneficiaries. If such services are not being provided, a State's monitoring of trends in its Fair Hearings process should reveal any problem with respect to access to ''wraparound'' services.

Comment: One commenter believed that HCFA should require the State to have procedures for monitoring training (of both beneficiaries and providers).

Response: We believe the fact that under § 438.218, the information requirements in § 438.10 are part of the State's quality assurance program provides assurance that the State will have to monitor the training and education of beneficiaries with respect to their enrollment and participation in MCOs or PCCMs. Furthermore we have clarified with (e) what has always been our expectation; namely that States monitor contract compliance. Such a requirement implicitly includes the monitoring of beneficiary education. We believe that with respect to provider training, it is the responsibility of the State to ensure that MCOs, PHPs, or their subcontractors have the requisite training and information for program participation.

Comment: One commenter requests that States be required to monitor samples of all notices sent to the enrollee by the MCO, PHP, or PCCM, and by all subcontractors.

Response: HCFA believes that the requirement at 438.700, which makes a plan's or subcontractor's distribution of materials that are not State-approved subject to sanctions addresses the concern raised by this commenter. Such a requirement implicitly includes the State's monitoring of materials sent to beneficiaries by the MCOs, PHPs or PCCMs. This also would be the subject of monitoring under § 438.66(e).

Comment: We received a number of general comments on the need for greater understanding of persons with special health care needs by MCOs and their providers. Specifically, in the area of coverage and authorization, a commenter contended that the managed care industry has very little knowledge of the needs of persons with disabilities. commenters further argued that the importance of certain services is often overlooked by the managed care industry. Another commenter argued that we should require MCOs to make every effort to provide training and education for their practitioners on the diagnosis of certain conditions such as HIV and AIDS. We also received comments on the need for MCO providers to have appropriate knowledge and skills to treat adults and children with special health care needs, including recipients with mental illness, substance abuse problems, developmental disabilities, functional disabilities, and complex problems involving multiple medical and social needs. One commenter specifically recognized the need for MCO recognition of the unique needs of the homeless population.

Response: Based on comments described here and other general comments requesting additional consumer protections for persons with specific conditions or disabilities, we are persuaded that additional requirements are necessary to ensure appropriate education of all managed care entities and providers on the unique care needs of special needs populations. Accordingly, the final rule with comment period contains a new § 438.68 Education of MCOs, PHPs, and PCCMs. This section requires that the State agency have in effect procedures for educating the MCO, PHP, and PCCM and any subcontracting providers about the clinical and non-clinical service needs of enrollees with special health care needs.

C. Subpart C (Enrollee Protections)

Proposed subpart C set forth a variety of enrollee protections including the following: (1) requiring information on benefits be specified (proposed § 438.100); (2) rights concerning provider communications with enrollees (proposed § 438.102); (3) limits on marketing activities (proposed § 438.104); (4) limits on enrollee liability for payment (proposed § 438.106) and cost-sharing (proposed § 438.108); (4) an obligation for MCOs and PHPs to provide assurances of adequate capacity (proposed § 438.110); (5) rights in connection with emergency and post-stabilization services (proposed § 438.114); and (6) MCO solvency standards (proposed § 438.116).

1. Benefits (§ 438.100)

As proposed, § 438.100 required that Medicaid contracts between States and MCOs specify the benefits the MCO is responsible for providing or making available to Medicaid enrollees. The proposed section also required States to make arrangements for furnishing those State plan services that MCOs were not responsible to provide under the contract, and to give written information to enrollees on how and where they may obtain these additional services. Many commenters were confused by this section because it duplicated provisions in other sections. To eliminate duplication, the requirements in proposed § 438.100 have been incorporated into other sections, notably § 438.10, Information requirements; § 438.206 Availability of services; and § 438.210 Coverage and authorization of services. The requirement in proposed § 438.100(a) that contracts specify the services the entity is required to provide to Medicaid enrollees is now set forth in § 438.210(a)(1). The requirement in proposed § 438.100(b) concerning the State's obligations to services not covered under the contract is now set forth in § 438.206(c), while the requirement to provide information to enrollees and potential enrollees is in § 438.10(d)(2)(ii)(E), § 438.10(e)(2)(vii), and § 438.10(g).

We have moved the requirements relating to enrollee rights from proposed § 438.320 to § 438.100. Throughout the preamble, we have responded to comments according to their numerical sequence in the proposed rule. This section only addresses responses to comments regarding proposed § 438.100 (Benefits). Comments and responses relating to the enrollee rights are now in § 438.100 but were in the proposed § 438.320 are discussed in section II. D.

below in the discussion of comments on the subpart in which these enrollee rights appeared in the proposed rule. In this final rule with comment period the content of proposed subpart E has been redesignated as subpart D with sections redesignated from the 300 series to the 200 series.

Comment: One commenter believed that we went beyond the authority in the statute by requiring the contract to specify the services the MCO, PHP, or PCCM is required to provide.

Response: We believe that the commenter apparently read the proposed rule to preclude States from incorporating the description of the benefits covered under the contract by referencing a separate document describing the benefits (for example, a provider agreement). However, the proposed rule was not intended to prohibit accepted methods of incorporating substantive contract provisions by cross-referencing separate documents. The reference documents must be sufficiently detailed to make clear to all parties the types and scope of the services for which the MCO is responsible.

Comment: Several commenters urged that we require States to include specific contract language holding MCOs responsible for the early prevention, screening, diagnosis and treatment (EPSDT) of eligible enrollees through the full scope of EPSDT benefits required under States' Medicaid plans. Commenters also expressed the view that States must make arrangements for providing at no cost to enrollees EPSDT services and benefits that are not covered or are not provided by the entities in accordance with the contract.

Response: These issues are addressed in section II. D. below in responses to similar questions raised with respect to § 438.210 Coverage and authorization of services and § 438.206(c) Availability of services.

Comment: Commenters strongly recommended that we clarify that contract language must address MCO, PHP, or PCCM and State agencies' roles for case management when covered services overlap with services that are not the responsibility of the MCO, PHP or PCCM to provide or to make available. Some of the commenters noted that mental health services for chronic conditions are frequently not included under MCO, PHP, or PCCM contracts. Without clear delineation of responsibility between the mental health services provided by the entity and those covered outside the MCO, PHP, or PCCM, enrollees may not receive the services they are entitled to receive under the State plan.

Response: We agree that coordination of care is an important component of managed care and that coordination may be challenging because an MCO may not cover all of the services included in the State plan. To ensure that care is appropriately coordinated, § 438.208(h)(7) of this final rule with comment period requires that each MCO and PHP implement a program to coordinate the services it furnishes to the enrollee with the services the enrollee receives from any other MCOs or PHPs. In section 438.10(d)(2)(i)(C), we also require that the information furnished to potential enrollees include general information about MCO responsibilities for coordination of care.

Comment: One commenter recommended that a mechanism be established to assist enrollees with obtaining the services they are entitled to under the State plan, but that are not covered by the MCO, PHP, or PCCM. Proposed § 438.100 required States to give enrollees written instructions on how to obtain those services, but it did not specify how enrollees would know to contact the State for instructions.

Response: Proposed § 438.100(b) set forth the State's obligation to make services under the States plan available and give enrollees instructions on how to obtain them, but did not specifically address the general provision of information to beneficiaries on this obligation as required under section 1932(a)(5)(D) of the Act, Information on Benefits not Covered. As noted above, in § 438.10(d)(2)(ii)(E), § 438.10(e)(2)(vii), and § 438.10(g) of this final rule with comment period, we address the information requirements relating to availability of services, and specify that this information include information about benefits that are available under the State plan but not covered under the contract, including how and where the enrollee may obtain these benefits, any cost sharing, and how transportation is provided.

Comment: Several commenters urged that MCO, PHP, or PCCM contracts specify the services that the entity is to provide to Medicaid enrollees. For those Medicaid services that are not included in the MCO, PHP, or PCCM contract, the commenters believed that the State should make arrangements for providing those services and give enrollees written instruction on how to obtain them. Another commenter found the meaning of the term ''arrangement'' in proposed § 438.100(b) unclear.

Response: Proposed § 438.100(a) required that MCO contracts (and § 438.8(d) PHP contracts) specify the services that have to be provided to Medicaid enrollees. In this final rule with comment period, this requirement is in § 438.210(a). In proposed § 438.100(a), we did not require that PCCM contracts specify this information, this was an error, since section 1932(b)(1) of the Act requires that PCCM contracts ''specify the benefits the provision (or arrangement) for which the PCCM is responsible.'' Section 1932(a)(5)(D) of the Act sets forth the obligation to inform enrollees in an entity of services ''not made available to the enrollee through the entity,'' and of ''where and how enrollees may access'' benefits, applies to ''managed care entities,'' or ''MCEs'' (a term that includes both MCOs and PCCMs). We therefore are including PCCMs in § 438.210(a)(1) (which contains the requirement that contracts specify covered services that was in proposed § 438.100(a)) and § 438.206(c) (which contains the State obligation formerly in proposed § 438.100(b)).

With respect to the requirement that information be provided on what State plan services are not covered by the contract, and how and where enrollees may obtain services, proposed § 438.10(g) already extended this requirement to PCCMs. This is retained in § 438.10(g) of this final rule with comment period.

Proposed § 438.100(b) provided that States must make ''arrangements'' for furnishing services not covered under the contract with the MCO. We agree with the last commenter that the term is unclear. Therefore, in § 438.206(c), we provide that if an MCO contract does not cover all of the services under the State plan, the State must make available those services from other sources and provide to enrollees information on where and how to obtain them, including how transportation is provided. We interpret the phrase ''make available from other sources'' to mean that the State must directly pay for the service through a fee-for-service contract or contract with another organization to provide the service.

Comment: One commenter recommended that the representative payee or other responsible person be included in dissemination of information advising enrollees on how and where to access these additional benefits.

Response: We did not adopt the exact language recommended. The information requirements in § 438.10 provide for informing authorized representatives.

2. Enrollee-Provider Communications (§ 438.102)

Medicaid beneficiaries are entitled to receive from their health care providers

the full range of medical advice and counseling that is appropriate for their condition. Section 1932(b)(3) of the Act added by the BBA clarifies and expands on this basic right by precluding an MCO from establishing restrictions that interfere with enrollee-provider communications. In § 438.102 of the proposed rule, we provided a definition of the term ''practitioner'' and outlined the general rule prohibiting interference with provider-enrollee communications. We also specified that this general rule would 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 provides information to the State, prospective enrollees, and to current enrollees within 90 days after adopting the policy with respect to any particular service.

Comment: Several commenters found the definition of ''practitioner'' at § 438.102(a) too restrictive and felt that it needed to be expanded to include professionals as: dental hygienists; marriage, substance abuse, and family counselors; interns; licensed psychiatric technicians; and pharmacists. One commenter pointed out that the proposed definition referred to a limited number of providers and excluded several of those referenced in the statute. Commenters recommended either adding those professions referenced in the statute or specifying that those listed in the regulations served as examples only. Another commenter suggested adding ''including, but not limited to'' language.

Response: Section 1932(b)(3)(C) of the Act provides an exact list of professions that are covered under this provision. In the proposed rule, we erroneously omitted several classes of professionals that were included in the statute. Therefore, we have revised § 438.102(a) to mirror the list contained in the statute. We have also replaced the term ''practitioner'' with ''health care professional'' in order to be consistent with the statute.

Comment: One commenter expressed concern that proposed § 438.102(b) did not require that State contracts with MCO or MCO contracts with providers be made available for public viewing.

Response: In this final rule with comment period, we do not require that contracts be made available to the public because doing so may deter MCOs from bidding on Medicaid contracts and may result in States not getting the best price. However, in § 438.10(f)(5), we have required that States and MCOs make available, upon request, information relating to the type of compensation arrangements that physicians have with MCOs and States.

Comment: Several commenters preferred the language included in the Medicare+Choice regulation implementing statutory authority for protecting provider-enrollee communications that is similar to that in the BBA for Medicaid. The commenters believed that the Medicare+Choice provisions in § 422.206 are more encompassing than those in proposed § 438.102 because they also bar Medicare+Choice organizations from—(1) restricting providers from advocating on the patient's behalf; (2) prohibiting providers from sharing information regarding alternative treatment; and (3) prohibiting providers from discussing the risks, benefits, and consequences of treatment or lack of treatment, and the opportunity for the enrollee to refuse treatment or express preferences for future treatment. The commenters also state that violations are subject to Federal sanctions. Two commenters stressed that providers must be free of all restrictions on communicating with enrollees and be able to provide complete information on all treatment options.

Response: We agree with the commenters who favor the approach taken in the Medicare+Choice regulations and have revised § 438.102(b) to parallel the requirements in § 422.206. We note that since the intermediate sanctions in subpart I apply only to MCOs, the new paragraph referring to sanctions applies only to MCOs.

Comment: Some commenters suggested that we reinforce the fact that a health care professional cannot be prevented from furnishing needed information to patients during the course of routine primary and preventive care visits or other treatment. These commenters expressed concern about language in the preamble to the proposed rule which states that, '' an MCO may not limit a provider's ability to counsel or advise an enrollee on treatment options that may be appropriate for the enrollee's condition or disease, unless the terms of § 438.102(c) apply and are satisfied.'' Specifically, the commenters requested that we remove reference to § 438.102(c).

Response: We agree with the commenters that the preamble language was misleading in implying that § 438.102(c) would permit an MCO to actually prevent a provider from providing counseling. We have revised § 438.102 in this final rule with comment period so that it is clear that § 438.102(c) only relieves an MCO from being required to provide, arrange, or pay for counseling or referrals as the result of the prohibition in § 438.102(b)(1), but does not give the MCO the right to prevent a physician from giving counseling if the physician is willing to forego any payment that may be associated.

Comment: One commenter recommended allowing an enrollee to terminate or change enrollment at any time after they receive notification that an MCO will exercise its right under § 438.102(c) not to provide, reimburse, or provide coverage of a counseling or referral service that is provided as the result of the requirement in § 438.102(b).

Response: We agree with the commenter. Section 438.56(d)(2)(ii) of this final rule with comment period provides that if an MCO does not provide a service because of moral or religious objections (whether pursuant to § 438.102(c), or otherwise) the enrollee may disenroll for cause. It is important to note that regardless of whether the MCO covers a certain service that is included in the State plan, the enrollee will have access to that service. If an MCO contract does not cover all of the services under the State plan (regardless of the reason) the State must make available those services from other sources. In addition, the Medicaid statute guarantees freedom of choice for family planning services so an enrollee may always seek services out-of-network. Therefore, we permit enrollees to disenroll if services are not covered because of moral or religious objections. We emphasize that disenrollment is not necessary in order to access the services.

Comment: Most commenters supported the conscience clause provision at proposed § 438.102(b)(2) which provides that, subject to certain information requirements, an MCO is not required to provide, reimburse for, or provide coverage of a counseling or referral services furnished as the result of the rule in § 438.102(b)(1) if the MCO objects on moral or religious grounds. However, several commenters objected to the policy that MCOs may elect not to provide coverage for some services that are included in the State plan. They stated that if the MCO objects to a Medicaid-covered service on moral or religious grounds, it is their responsibility to arrange for coverage through subcontracts or by providing access to the service out-of-network. Others stated that to allow MCOs to pick and choose what services they will be responsible for runs counter to how

managed care contracts are designed and bid out. This provision would in these commenters' view complicate bid pricing and evaluation, increase administrative costs to the State (to make separate arrangements for these services and provide notice to beneficiaries), and could be confusing to beneficiaries.

One commenter believed that the proposed rule creates an undue burden for enrollees who are seeking family planning services and disrupts their continuity of care, and that these disruptions could result in lower quality of family planning care for women. Commenters recommend either removing the conscience protection provisions or changing the regulation to allow States to require MCOs that have moral objections to providing certain services to obtain them through subcontracts or out-of-network arrangements.

Response: We do not have the authority to delete the conscience protection provision because it is required by section 1932(b)(3)(B) of the Act. However, this conscience provision alone would not by itself permit an MCO to avoid providing a State plan service that it has contracted to provide. As noted in the preamble to this final rule with comment period, the conscience protection in section 1932(b)(3)(B) of the Act only protects an MCO from being required to pay for something as the result of the rule in section 1932(b)(3)(A) of the Act. Section 1932(b)(3)(B) of the Act begins with the words ''*Subparagraph (A) shall not be construed as requiring* a Medicaid managed care organization to provide, reimburse for, or provide coverage of, a counseling or referral service'', if the MCO objects and gives the required notice. This is an exception to the obligations under paragraph (A), not a ''blanket'' authority to decline to cover services the MCO would otherwise be obligated to provide. As noted in section II. B above, however, unlike a Medicare+Choice organization, that must contract to provide Medicare services, a Medicaid contracting MCO is free to negotiate with the State over which services it will provide. Clearly, section 1932(a)(5)(D) of the Act (requiring that certain arrangements be made with respect to State plan services not furnished through an MCO or PCCM) contemplates an MCO's right to decide which State plan services to agree to include in its contract. An MCO that objects to covering a State plan service would not agree in the contract to provide that service. In such a case, the State is clearly obligated to ensure the availability of the service out of plan. If the MCO did agree to provide a State plan service under its contract, it could not attempt to ''change its mind'' by relying on the ''conscience protection'' in section 1932(a)(3)(B) of the Act, since its obligation to provide the State plan service would be pursuant to its contract, not section 1932(a)(3)(A) of the Act. It is important to note that under existing regulations, MCOs may not restrict an enrollee's freedom of choice with respect to family planning services. In other words, enrollees may always seek family planning services out-of-network.

Comment: Commenters expressed concern about how enrollees will receive notice of an MCO change in policy. One commenter recommended linking this requirement with the information requirements in § 438.10(c), which requires plans to use easily understood language and format and take into consideration the special needs of those, for example, are visually impaired or have limited reading proficiency. Others recommended that we explain how an MCO should provide notice to ensure enrollees are adequately informed.

Response: We agree with the commenters that the information furnished to enrollees and potential enrollees under this section should be governed by the same rules as the information furnished under § 438.10. Therefore, we have revised § 438.102(c) to require that the information furnished under this section be ''consistent with the provisions of § 438.10.''

We believe that it is critical that enrollees and potential enrollees have sufficient information to understand how and where to obtain a service that is not covered by the MCO. This responsibility is shared by the MCO and the State. As discussed in section II. A. above under § 438.10(e)(1)(ii), an MCO or PHP must inform potential enrollees of any ''significant'' change in the information in § 438.10(e)(2) at least 30 days prior to the change. Section 438.10(e)(2) includes a description of what services the MCO or PHP covers. This advance notice requirement would ordinarily apply to a change in what the MCO or PHP would cover. While section 1932(a)(3)(B) of the Act requires only that notice be provided within 90 days after a decision was made not to cover something under its provisions, and meeting this condition would permit an MCO to qualify for the exception in section 1932(a)(3)(B) of the Act. We believe that the general rule in § 438.10(e)(1)(ii) should continue to apply, and are revising § 438.102(b)(1)(B) to clarify this fact.

Comment: Commenters were concerned that public entities may want to exercise the conscience protection exception at § 438.102(c), which the commenters believe could violate the Constitution (presumably because the first amendment ''establishment clause'' would prevent a public entity from citing a ''religious'' objection to covering a service). These commenters recommended that we state that public entities that sponsor or operate MCOs cannot assert moral or religious objections, and thus decline to provide, reimburse for, or provide coverage of any counseling or referral service.

Response: We have not incorporated the commenters suggestion because section 1932(b), (3)(B) of the Act and § 438.102(c) are not limited to an objection on ''religious'' grounds, but also on ''moral'' grounds, and there is nothing to preclude a governmental entity from expressing a moral objection. However, there is no basis in the BBA for making a distinction between public and private MCOs in this area.

Comment: One commenter was concerned that subcontractors may not be required to adhere to the provisions of § 438.102 regarding enrollee-provider communications. The commenter suggested that subcontractors should expressly be covered as they were in proposed § 438.310(b)(1), which explicitly sets forth requirements for ''the MCO and its subcontractors.''

Response: In § 438.6(l) of this final rule with comment period, we state that all subcontracts must fulfill the requirements of this part that are appropriate to the service or activity delegated under the subcontract. In addition, § 438.230 provides that for all 1903(m) contracts, ''the State must ensure that each MCO oversees and is accountable for any functions and responsibilities that it delegates to any subcontractor * * *''. We believe that the combination of these two provisions satisfies the commenter's concerns and that additional subcontractor language is not needed in § 438.102.

Comment: One commenter indicated that § 438.102 does not address enforcement mechanisms nor remedies for providers that believe they were penalized or terminated by the plan for providing information to an enrollee. The commenter suggest that we provide these enforcement mechanisms.

Response: If providers believe that an MCO has violated the requirements of section 1932(b)(3)(A) of the Act and § 438.102(b), they should bring this to the attention of the State Medicaid agency, which could then investigate the situation and determine whether to

impose sanctions under § 438.102(e) and § 438.700(d). We believe that this sanction authority provides a sufficient enforcement mechanism.

3. Marketing (§ 438.104)

In accordance with section 1932(d)(2) of the Act, proposed § 438.104 set forth requirements for, and restrictions on, marketing activities by MCO, PHP and PCCMs. (The regulations text referred to ''MCEs,'' includes MCOs and PCCMs and proposed § 438.8(d) made the requirements applicable to PHPs.). Proposed § 438.104 included definitions of ''choice counseling'', ''cold-call marketing'', ''enrollment activities'', ''enrollment broker'', ''marketing materials'', and ''recipient and potential recipient.'' The definitions related to enrollment broker functions (''choice counseling,'' ''enrollment activities,'' and ''enrollment broker'') were included in error and have in this final rule with comment period been moved to § 438.810, Expenditures for Enrollment Broker Services. We also proposed requirements and prohibitions for MCO, PHP, or PCCM contracts. Specifically, § 438.104(b)(1) proposed that the contract must specify the methods by which the entity assures the State agency that the marketing plans and materials are accurate and do not mislead, confuse, or defraud the recipients or State agency. Section 438.104(b)(2) proposed restrictions on MCO, PHP, or PCCM contracts, which are discussed in detail below. Section § 438.104(c) proposed to require the State to consult with a MCAC or an advisory committee with similar membership in reviewing marketing materials. Comments we received on these issues and our responses follow.

a. General Comments

Comment: Proposed § 438.8(d) provided that the error of subpart C, including § 438.104 applies to PHPs to the same extent that the sections apply to MCOs. Section 438.104 only includes references to managed care entities (MCEs) which appears to mean the section is not applicable to PHPs.

Response: The marketing rules set forth in § 438.104 apply to MCOs, PCCMs and, as specified in § 438.8(d), to PHPs as well. Given the confusion reflected in this comment, throughout this final rule with comment period, we have revised the regulation text to indicate in each requirement whether it applies to PHPs, while also retaining § 438.8.

Comment: One commenter believed that we should establish specific and significant monetary fines for coercive or unethical marketing practices.

Response: Many States have already determined what marketing violations are punishable and have set significant fines or sanctions. In addition, § 438.700 requires States that contract with MCOs to establish intermediate sanctions and includes as reasons for imposing these sanctions: (1) discrimination among enrollees based on health status or need for services; (2) misrepresenting or falsifying information furnished to either the State, enrollees, potential enrollees, health care providers or us; and (3) distributing marketing materials that have not been approved by the State, or that contain false or materially misleading information. States have the flexibility to impose sanctions or restrictions as they find appropriate. In addition, § 438.730 allows us to impose a sanction either based upon a State agency's recommendation, or directly.

Comment: Several commenters urged HCFA to prohibit other types of marketing, and require more strict oversight of MCOs'', PHPs'', and PCCMs' activities.

Response: Some degree of flexibility is needed if MCOs, PHPs, and PCCMs are to continue offering Medicaid products in a competitive environment. Section 438.104(b)(2)1)(i) requires States to review and approve all marketing materials prior to distribution, and § 438.104(b)(2) requires assurances that marketing materials do not confuse, mislead or defraud. Section 438.104(b)(1)(v) prohibits specific marketing practices, such as door to door, telephone, or other ''cold call'' marketing. It is not clear what ''other types of marketing'' would warrant a prohibition. Therefore, we do not believe that additional regulatory requirements are necessary.

Comment: Commenters suggested that we revise the preamble to indicate that the marketing limitations apply to homeless shelters as well as other institutional settings. The commenters believe that it is not appropriate to approach homeless people, and that strong Federal protection is needed.

Response: The general prohibition on ''cold call'' marketing would prohibit ''approaching'' homeless people in a shelter (or elsewhere) or other institutionalized individuals. We agree with the commenters, and are stating here that all limitations on marketing apply equally in these settings.

Comment: One commenter indicated that it makes little sense to mandate choice of an MCO when under the proposed regulation, MCOs may not use marketing to effectively differentiate their Medicaid products and compete for greater enrollment.

Response: We do not believe that these marketing rules unfairly restrict an MCO, PHP, or PCCM's ability to compete in the marketplace. We do not prohibit all types of marketing activity. States may permit MCO, PHP, and PCCMs to—(1) participate in health fairs and community presentations; (2) use various forms of ''broadcast'' advertising; (3) send mailings to potential enrollees; (4) respond to individual requests for information; and (5) engage in other activities as long as they are approved and subject to sufficient oversight. Even where MCOs, PHPs, and PCCMs have similar structures and networks, it is possible for them to offer additional benefits, for example, child care to differentiate one MCO, PHP, or PCCM from another. In addition, MCOs, PHPs and PCCMs can provide results of enrollee satisfaction surveys, report cards, or other types of information on quality of care to potential enrollees.

b. Cold-Call Marketing

Proposed § 438.104(a) defined cold-call marketing as any unsolicited personal contact by the MCO, PHP, or PCCM with a potential enrollee for the purpose of influencing the individual to enroll in that particular MCO, PHP, or PCCM. Cold-call marketing includes door-to-door, telephone or other related marketing activities performed by MCOs, PHPs, or PCCMs and their employees (that is, direct marketing) or by agents, affiliated providers, or contractors (that is, indirect marketing). In the preamble to the proposed rule, we noted that cold-call marketing includes activities as a physician or other members of the medical staff, or a salesperson, or other MCO, PHP, or PCCM employee or independent contractor approaching a beneficiary in order to influence a beneficiaries decision to enroll with a particular MCO, PHP, or PCCM. In proposed § 438.104(b)(2)(v), we expressly prohibited MCO, PHP, or PCCMs from directly or indirectly engaging in door-to-door, telephone, or other cold-call marketing activities.

Comment: One commenter felt that the definition of ''cold-call marketing'' could inadvertently prohibit appropriate marketing activities, for example, direct contact at health fairs and community-based organization offices.

Response: The prohibition on cold-call marketing only applies to ''unsolicited'' contact by the MCO, PHP, or PCCM. For example, if a beneficiary attends a health fair or similar event, the beneficiary would be seeking information about health care and, therefore, the contact between the MCO,

PHP, or PCCM and the beneficiary would not be considered ''unsolicited.'' We note, however, that MCO, PHP, or PCCM participation in health fairs and other community activities is considered marketing and, therefore, must have the State's approval.

Comment: Commenters suggested that we return to the statutory language defining cold-call marketing. The commenters' rationale was that because the regulations apply to voluntary as well as mandatory programs, the prohibited activities would preclude viable enrollment numbers.

Another commenter contended that the proposed definition of ''direct marketing'' went beyond the statutory prohibition of ''cold-call'' marketing. Another commenter believed that the restriction against providers attempting to influence patients' choice could severely limit opportunities for MCOs, PHPs, and PCCMs to attract members and might unintentionally create an unlevel playing field because this sort of marketing is currently conducted by PSOs, hospital systems, and providers with a particular interest in one health plan.

Response: Section 1932(d)(2)(E) of the Act prohibits direct or indirect door-to-door, telephonic, or other ''cold-call'' marketing of enrollment. These provisions were added to the Act by section 4707 of the BBA, Protections Against Fraud and Abuse. Our interpretation of the Congress' intent is that the statutory language was meant to minimize the potential for abusive marketing practices in both voluntary and mandatory programs. Specifically, we interpreted the term ''direct marketing'' to mean marketing by an MCO, PHP or PCCM or its employees; the term ''indirect marketing'' to mean marketing by an MCO, PHP, or PCCM, or its agents, affiliated providers, or contractors. The terms ''door-to-door'' and ''telephonic'' marketing are self-explanatory. We interpreted the term ''other cold-call marketing'' as other unsolicited contacts. If the Congress intended to prohibit only unsolicited door-to-door or telephone contacts, the ''other'' forms would not have been included in the prohibition. There are several other types of marketing that are permitted under this regulation. For example, States may permit the use of billboards, newspaper, television, and other media to advertise MCOs, PHPs, MCOs, or PHPs. Mailings are also permitted as long as they are distributed to the MCO's, PHP's, or PCCM's entire service area covered by the contact. States may also provide marketing materials on behalf of MCOs, PHPs, and PCCMs.

Comment: Several commenters, while indicating support for the ban on door-to-door, telephonic and other cold call marketing, expressed concern over the inclusion of physician activities including approaching a beneficiary to influence a decision to enroll with a certain plan. The commenters considered it inappropriate to place any limits on information provided to a beneficiary within the context of a doctor-patient relationship. Another commenter stated that the prohibition on contact by affiliated physicians and medical staff seems to conflict with the need to preserve continuity of care between patients and providers. The commenters observed that, although these providers may have incentives to recruit patients, these incentives must be balanced against the desire of many Medicaid patients to continue seeing providers with whom they have established a relationship.

Response: There is no prohibition against a physician responding to a patient's request for advice in the context of the doctor-patient relationship, or identifying all MCOs, PHPs, or PCCMs with which the physician has a contract. The intent of § 438.104(b)(1)(v) is to prohibit unsolicited marketing activities. Medical advice given as part of a doctor-patient relationship is not considered marketing. Our definition of cold-call marketing as ''unsolicited'' leaves patients free to seek out the advice of their providers. However, the cold call prohibition would prevent providers or their staff from approaching a patient about choosing an MCO, PHP, or PCCM. Providers are often members of several MCOs, PHPs, and PCCMs and permitting them to approach a member about any particular MCO, PHP, or PCCM could give the appearance of influence by factors not necessarily in the best interests of the patient.

Comment: One commenter called the cold-call provision ''overly restrictive'' and felt that it presented serious problems for MCOs, PHPs, and PCCMs that use clinic-based community providers. The commenter also felt that the regulation contradicted the proposed default assignment process because States are expected to assign individuals to existing providers and these providers would be restricted from giving information to assist in the process. The commenter recommended that participating physicians be permitted to provide approved informational materials about plans in which they participate to patients in their offices in an unbiased, non-threatening manner, and that the State monitor to ensure compliance.

Response: The default assignment process is considered a State's last resort for matching a non-responding individual with a provider. The fact that an individual is in a physician's office inquiring about what MCOs, PHPs, or PCCMs the provider participates in, indicates that default assignment is not likely to be necessary. However, if the individual does not make a selection, the office visit may facilitate the default assignment process because, under § 438.50(f), the State's default enrollment process must seek to preserve existing provider-beneficiary relationships. In addition, a State may choose to permit providers to display approved materials about all plans in which they participate. The regulation only prohibits unsolicited personal contact by any person or entity representing a particular MCO, PHP, or PCCM.

Comment: A commenter pointed out that safety net providers often perform outreach to uninsured individuals who may be eligible for Medicaid. The commenter believes that the marketing prohibition could discourage providers from promoting Medicaid enrollment. It was suggested that a discussion on the subject of maintaining an existing provider relationship could be interpreted as cold-call marketing. A safety-net provider indicated that they allow their physicians and medical staff to discuss options and provide literature supplied by MCOs, PHP, or PCCMs. They felt that a patient's physician often provides the best assistance and information for making an informed decision.

Response: We encourage outreach to those individuals who may be eligible for Medicaid. However, outreach which relates to establishing Medicaid eligibility should be distinct from marketing, which is considered to have a bias in favor of one MCO, PHP, or PCCM or provider option over another. Medical staff will be assumed to be acting in the best interest of the beneficiary's health when discussing or encouraging a Medicaid application. This activity would not be considered marketing unless it also includes a distinct attempt to encourage selection of a particular MCO, PHP, or PCCM. If, in the course of a discussion, a beneficiary inquires about how to continue seeing a particular provider, there is no prohibition on providing information on the MCOs, PHPs, or PCCMs in which that provider participates. On the other hand, contact with an enrollee or potential enrollee by any other person or entity on behalf of a particular MCO, PHP or PCCM (prior to establishing Medicaid eligibility or

selecting an MCO, PHP, or PCCM option) will be considered marketing and will be subject to State and Federal scrutiny.

Comment: A commenter called the restriction on physicians advising their patients ''an unnecessary gag rule'' and indicated that it would prevent a physician from steering a severe asthmatic to an MCO, PHP, or PCCM that excels in managing asthma care. The commenter also pointed out that the rule would not prevent physicians from ''trashing'' other MCOs, PHPs, or PCCMs.

Response: A distinction should be made between patient counseling based on a patient's request done by medical staff on the basis of medical factors, and steering, which may be based on inappropriate factors such as administrative or fiscal issues. Providers are free to advise their patients, as specified in § 438.102, and they may respond to questions about the availability of specific services from MCOs, PHPs, or PCCMs with which they are affiliated. States should keep in mind, however, that medical staff providing patient counseling may not necessarily be aware of other factors, such as health conditions of other family members required to join an MCO, PHP, or PHP or of areas in which other MCOS, PHPS, or PCCMs may excel.

We agree with the commenter that negative marketing activities (''trashing'') should also be addressed in this regulation, and we have done so through a new definition of ''marketing'' in § 438.104(a). Under this definition, any communication by an MCO, PHP, or PCCM (or any of its agents or independent contractors) with an enrollee or potential enrollee that can reasonably be interpreted as intended to influence that individual to decide to enroll or re-enroll in that particular Medicaid product, or either not to enroll in or to disenroll from another MCO's, PHP's, or PCCM's Medicaid product would be considered marketing and, therefore, would be covered by this regulation. We also have revised the definitions of ''marketing materials'' and ''cold call marketing to incorporate the new marketing definition.

Comment: One commenter contended that the language of the regulation was inconsistent with the language in the preamble because the regulation merely prohibits unsolicited personal contact by the MCO, PHP, or PCCM with a potential enrollee for the purpose of influencing the individual to enroll. The commenter noted that the preamble describes cold-call marketing as unsolicited contact by an employee, affiliated provider or contractor of the entity. The commenter stated that the language of the regulation was clear and concise and did not require the explanation in the preamble.

Response: In § 438.104(a), we state that any reference to MCO, PHP, or PCCM and entity includes ''any of the entity's employees, affiliated providers, agents, or contractors.'' Therefore, the regulatory language is consistent with the preamble.

Comment: Commenters agreed with the prohibition against providers attempting to influence patients to join a particular MCO, PHP, or PCCM. However, the commenters pointed out that it is difficult for States to detect this type of activity.

Response: As systems have become more sophisticated, new and more effective methods of oversight continue to evolve. The difficulty in detecting certain inappropriate activities does not relieve MCOs, PHPS, and PCCMs or States from the obligation to protect the interests of the beneficiary. Many standard methods of monitoring marketing, such as reviewing grievances and appeals from beneficiaries and providers, tracking enrollment and disenrollment trends, and conducting beneficiary surveys will help detect patterns of aggressive or unfair marketing practices.

Comment: A commenter expressed concern that this provision unduly restricts the ability of MCOs to educate enrollees or potential enrollees about managed care and does not focus on group settings for example, schools, day care centers, and churches, where MCOs could target larger groups of Medicaid enrollees. The commenter asked HCFA to broaden the provision by giving additional examples of State approved activities.

Response: This regulation does not prohibit educational activities on the part of MCOs. However, any contacts other than patient counseling by any MCO, PHP, or PCCM staff or representative would be considered marketing, subject to State oversight. The regulation does not prohibit States from permitting MCOs, PHPs, or PCCMs to market to groups, for example, schools, churches, and day care centers. States are responsible for approving and monitoring these types of presentations and ensuring that beneficiaries attend voluntarily with knowledge that they are attending a marketing presentation.

Comment: Another commenter indicated that the definition of ''cold-call marketing'' might be too broadly defined and should not apply to public places where MCOs are engaging in marketing practices approved by the State.

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

Comment: One commenter expressed concern that the regulation narrows marketing options by restricting the role of MCOs in community-based efforts.

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

Definition of Marketing Materials

In the NPRM, we proposed to define marketing materials as materials that—(1) are produced in any medium, by or on behalf of an MCO, PHP, or PCCM; (2) are used by the MCO, PHP, or PCCM to communicate with individuals who are not its enrollees; and (3) can reasonably be interpreted as intended to influence the individuals to enroll or re-enroll in that particular MCO, PHP, or PCCM.

Comment: Some commenters said that the definition of marketing materials should not include communication intended to serve the needs of existing enrollees and suggested that the regulation be revised to clarify that marketing materials are those materials intended to influence non-enrollees to join a particular MCO, PHP, or PCCM. One commenter thought the definition of marketing materials was incomplete and should be changed to read ''can reasonably be interpreted as intended to influence the individual to enroll or re-enroll in that particular MCO, PHP, or

PCCM.'' Another commenter indicated that the combination of requirements at proposed § 438.104(a) (definition of marketing materials) and proposed § 438.104(b)(2)(1) (prohibition on the distribution of marketing material without State approval) required States to approve all marketing materials prior to distribution, whether or not they are targeted to Medicaid beneficiaries. It was pointed out that this would be administratively impossible and could raise constitutional issues.

Response: We disagree with the first commenters who favored limiting marketing materials to those directed at individuals who are not enrollees (which was the position taken in the NPRM), and agree with the second commenter who endorsed the language in the definition referring to influencing individuals to ''re-enroll.'' In such a case, the individual already is enrolled and the portion of the definition referring to ''individuals not enrolled'' conflicts with the language favored by the commenter. We therefore have removed the portion of the definition limiting its applicability so that it is clear that marketing materials include those intended to influence both enrollees and potential enrollees. States retain the authority to interpret the term and are responsible for evaluating whether certain materials satisfy the definition. States may interpret this term broadly and determine that all materials are subject to review, but we assume that many States will determine that routine correspondence (such as appointment reminders) do not fall within the definition of ''marketing materials'' and therefore are not subject to review.

We have incorporated the new definition of marketing into the definition of ''marketing materials.''

Comment: Commenters supported our broad definition of marketing materials and our efforts to ensure the accuracy and truthfulness of the materials. However, some commenters felt that an absence of a clear definition of marketing could mean that many activities, for example, hiring community residents to talk about the benefits of belonging to a particular plan or persuading neighbors to join a plan, might not be covered. The commenters indicated that a common usage understanding of the term ''materials'' would not appear to include a spokesperson or representative. They also stated that it was unclear whether paying neighbors to say nice things about a plan would constitute cold call marketing. They suggested that we include a broad definition of marketing and include examples of marketing, and of false and misleading marketing. One commenter suggested that the following language, ''inaccurate, false, or misleading statements include, but are not limited to, any assertion or statement (whether written or oral) that—(1) the beneficiary must enroll in the MCO, PHP, or PCCM in order to obtain benefits or in order not to lose benefits; or (2) the MCO, PHP, or PCCM is endorsed by the Federal government, State government or us.'' Another commenter recommended that we expand the regulation by requiring States to review marketing materials to ensure that MCOs do not imply that all persons are required to enroll in managed care in order to continue receiving Medicaid benefits.

Response: The comments recommending a ''definition of marketing'' have been addressed by our inclusion of a separate definition of marketing in this final rule with comment period. As noted above, we have defined ''marketing'' as ''any communication, from an MCO, PHP, or PCCM to an enrollee or potential enrollee that can reasonably be interpreted as intended to influence the recipient to enroll or re-enroll in that particular MCO's, PHP's, or PCCM's Medicaid product, or either not to enroll, or to disenroll from another MCO's, PHP's, or PCCM's Medicaid product.'' We also agree that language suggested by the commenter would be helpful, and provide in § 438.104(b)(2) that inaccurate, false, or misleading statements include, but not limited to any assertion or statement (whether written or oral) that the beneficiary must enroll in the MCO, PHP, or PCCM in order to obtain benefits, not to lose benefits, or that the MCO, PHP, or PCCM, is endorsed by either the Federal government, State government, similar entities or us.

States are required to review and approve all marketing materials under § 438.104(b)(1)(i). We expect this review to include screening for misleading information including any implication that individuals who are not required to enroll will lose their benefits if they do not enroll. In addition, the revised information provision at § 438.10(d)(2)(i)(B) requires that beneficiaries must be informed prior to selection of an MCO about which populations are excluded from enrollment, subject to mandatory enrollment, or free to enroll voluntarily.

Comment: One commenter believed that the definition of marketing materials was too narrow because it did not address materials developed by State agencies (for example, the Office of Mental Hygiene and the Office of Developmental Disabilities) that participate in informing and encouraging potential enrollees about managed care. The commenter recommended that other parties have the authority to refer materials being used for marketing purposes to the MCAC or similar reviewing body to review and determine if the materials are unbiased.

Response: Section 438.104 addresses marketing materials that are produced by or on behalf of an MCO, PHP, or PCCM. To the extent that a State agency such as those mentioned by the commenter is acting as a PHP (for example, as a provider of behavioral health services under a ''carve-out''), any materials it generates would be subject to the requirements in § 438.104. If, however, the agency has no stake in where an individual enrolls, and is essentially acting on behalf of the State Medicaid agency, it is not clear what ''bias'' the agency would have that would be detected by review. We therefore do not believe that review of such materials pursuant to § 438.104 is necessary or appropriate.

We note that § 438.10 requires that all information for enrollees and potential enrollees meet language and format requirements to facilitate understanding and take into consideration special needs. This applies to information furnished by any State or local agencies. States may choose to require the review of materials other than those subject to review as marketing materials under § 438.104.

Comment: A commenter suggested that we require that marketing material be distributed to the entire geographic area at least 90 days prior to enrollment, and only after the material is approved.

Response: The length of time needed for distribution of marketing materials may vary from State to State depending on factors, for example, Medicaid managed care penetration. Therefore, we do not mandate specific time frames for marketing activity. We encourage States to carefully consider the timing of the distribution of any marketing or other materials to maximize informed choice. The information provision at § 438.10(d)(1)(iii) requires that basic information be provided within a time frame that enables potential enrollees to use the information in choosing among available MCOs. With respect to mandatory managed care programs, we require States to establish standards and time requirements for fully informing and providing sufficient time to make an informed choice.

In response to the last part of the commenter's concerns, the regulation does require that all marketing materials

be reviewed and approved by the State prior to distribution. Failure by an MCO, PHP, or PCCM to submit materials for review may result in sanctions by the State in accordance with § 438.700(c).

Comment: Several commenters asked that we clarify requirements related to reproductive health services. The commenters believe that we should require marketing materials to contain clear and prominent information about any reproductive health services not covered by the plan. Commenters recommended that marketing materials specify any Medicaid-covered reproductive health benefits that are not provided by the plan and state that all Medicaid beneficiaries have the right to obtain family planning services and supplies from any Medicaid participating provider. They also recommended that materials clearly indicate which subcontracting entities, for example, hospitals, medical groups, or subnetworks restrict access to reproductive health services.

Response: We agree with the commenters that Medicaid beneficiaries should have clear and complete information on the availability of family planning services. We have not, however, included specific requirements relating to family planning services in this section. In § 438.10, we require that the information furnished to enrollees and potential enrollees specify any benefits that are available under the State plan but are not covered under the contract, including how and where the enrollee may obtain those benefits, any cost-sharing, and how transportation is provided. We have also revised the information requirements to require that the information furnished to enrollees identify the extent to which, and how, enrollees may obtain benefits, including family planning services, from out-of-network providers. We refer the commenters to the comments and responses for proposed § 438.10.

Comment: A commenter asserted that the requirement that the State approve marketing materials prior to distribution would be difficult to implement because of time constraints. The commenter speculated that documents would have to be provided at least 30 days in advance and the State would incur additional administrative burden and costs. The commenter recommended that legislative action be taken to delete this requirement. Another commenter stated that the regulations did not specify that all health plan information and marketing materials must be approved by the State agency. The commenter suggested that we mandate strict requirements for accuracy and disclosure and require State review of all health plan information.

Response: The commenter is correct that legislative action would be required to eliminate the requirement for State review and approval of marketing materials under section 1932(d)(2)(A) of the Act. We note that many States already required prior approval of marketing materials prior to enactment of this requirement in the BBA. One State commented that these provisions posed no problem because its contracts and marketing manual already contained provisions that comply with or exceed these requirements. We believe that State review and approval is extremely important and that any burden should be offset by the additional protections afforded Medicaid beneficiaries. Marketing materials for MCOs contracting with Medicare undergo similar review prior to distribution, so this provision aligns Medicaid more closely with the Medicare rules.

Comment: A commenter suggested that marketing materials be made available in formats other than Braille for the visually impaired. The commenter believes that States and MCOs, PHPs, or PCCMs need flexibility in determining the appropriate formats, such as large print, audiotape or other formats in addition to Braille.

Response: There is no requirement in the regulations that marketing materials be in Braille for the visually impaired. The discussion of § 438.10 in the preamble of the proposed rule stated that all materials take into account specific needs of enrollees and potential enrollees, including furnishing information in alternative formats for the ''visually impaired (through other media for example, large print, Braille, or audio tapes) * * *'' (63 FR 52029). Section 438.10(c)(2) requires that materials be available in alternative formats that take into consideration, for example, the special needs of those who are visually impaired or have limited reading proficiency. States have the flexibility to decide which formats are most appropriate.

c. Requirements and Prohibitions

Proposed § 438.104(b) provided that MCO, PHP, and PCCM contracts must 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 beneficiaries or the State. The proposed rule also stated that MCO, PHP, and PCCM contracts must provide that the entity distribute materials to the entire service area—(1) does not distribute marketing materials without prior approval; (2) complies with the information requirements in § 438.10; (3) does not seek to influence enrollment with the sale of other insurance; and (4) does not engage in cold-call marketing.

Comment: Several commenters believed that the language in proposed § 438.104 was vague, merely repeated the statutory language, and provided little concrete guidance to States or MCOs, PHPs, and PCCMs. Commenters suggested that we establish a detailed review guide with specific criteria developed with input from Medicaid beneficiaries and their advocates and that we review all MCO contracts for their marketing plans.

Response: We currently have marketing guidelines that will be updated to reflect the requirements of this final rule with comment period. In developing these guidelines, we often rely on prior implementation experience, including input from affected parties. We regularly use these types of guidelines, as we review and approve MCO, PHP, and PCCM contracts.

Comment: One commenter argued that it was unnecessary to require that MCO, PHP, and PCCM contracts specify the methods by which they will assure that marketing materials do not mislead or confuse. The commenter stated that the requirement that marketing materials be submitted to the State prior to use would be sufficient to ensure the desired outcome.

Response: We believe that both prior approval and contract review provide important beneficiary protections and both are specifically required by the law. Section 1932(d)(2)(A)(i) of the Act specifically requires prior approval of marketing materials by the State and that the materials do not contain false or misleading information. The requirement that the contract contain such assurances has been in § 434.36 since 1988, based on a provision of the Act which the BBA did not remove. States and MCOs should be used to complying with this provision.

d. Service Area

Proposed § 438.104(b)(2)(ii) required that marketing materials be distributed to the entire service area.

Comment: One commenter applauded this requirement stating that without it health plans might attempt to engage in preferential selection of enrollees by excluding geographic areas where Medicaid beneficiaries have higher costs. The commenter believes that we should expand this requirement to ensure that MCOs, PHPs, and PCCMs do not attempt similar preferential

practices through other means, for example, refusing to provide marketing materials in certain languages, developing marketing materials that are difficult to understand, or by distributing materials in ways or in places that exclude people with disabilities. The commenter recommended that we state explicitly in regulations that discrimination on any of these bases is not permissible. Another commenter suggested that MCOs', PHPs', and PCCMs' marketing activities not be permitted to ''red-line'' certain areas of the community or certain groups of people because vulnerable populations, such as those with mental retardation are often targets for marketing ''scams.''

Response: We believe that the commenters' concerns are addressed in other sections of the regulation. Section 438.10 specifies general requirements that apply to all information furnished to enrollees including requirements relating to language and format. Section 438.6(d)(3) requires that MCO, PHP, and PCCM contracts provide that the MCO, PHP, or PCCM will not, on the basis of health status or need for health services discriminate against individuals eligible to enroll. In addition, MCO, PHP, and PCCM contracts must specify that the MCO, PHP, or PCCM will not discriminate against individuals eligible to enroll on the basis of race, color, or national origin, and will not use any policy or practice that has the effect of discriminating on the basis of race, color, or national origin. In § 438.206(d)(7), we require the State to ensure that an MCO ensure that its providers do not discriminate against Medicaid enrollees. We specifically provided in § 438.100(d) that the State must ensure that each MCO, PHP, and PCCM complies with applicable Federal and State laws, (for example, Title VI of the Civil Rights Act of 1964, The Age Discrimination Act of 1975, The Rehabilitation Act of 1973, and Titles II and III of the Americans with Disabilities Act). We believe that these sections sufficiently protect the beneficiary against the discriminatory practices identified by the commenter, and therefore we have not incorporated any additional changes into § 438.104.

Comment: Several commenters believed that the service area requirement in proposed § 438.104(b)(2)(ii) could impede an MCO's, PHP's, or PCCM's ability to reach targeted populations with unique needs or characteristics within service areas. Commenters provided examples such as mailings to certain zip codes informing members of activities at a hospital in their neighborhood and mailings to specified non-English speaking populations in the service area. One commenter asserted that the proposed policy makes distribution problematic because services must be provided in a culturally competent manner but a marketing plan cannot be varied to target specific populations. In addition, a commenter explained that States often allow new MCOs to begin rolling out a program in certain counties within the service area. The commenter asserted that the proposed rule would prohibit MCOs from mailing to just those portions of the service area in which they are allowed to enroll. Some commenters believed that the proposed requirement was unnecessary, unduly burdensome and costly. One commenter contended that because the proposed definition of marketing materials included billboards and media advertisements, the ''service area'' requirement was unrealistic. One commenter felt that the provision would also inappropriately prohibit activities such as health fairs if material disseminated during these activities has not been distributed to the entire service area. Another commenter suggested that MCOs, PHPs, and PCCMs be encouraged to distribute materials where they have current capacity to serve more members and should be permitted to conduct local advertising, such as that carried out in collaboration with a particular clinic or group practice where appropriate. Another commenter acknowledged the need to ensure that MCOs, PHPs and PCCMs do not engage in risk pool segmentation, but felt that the regulation needed to be more flexible to accommodate circumstances where MCOs, PHPs, and PCCMs may wish to communicate information about locally available services to those residing in subareas of the overall service area.

One commenter recommended that we require MCOs, PHPs and PCCMs to distribute materials to all eligible enrollees in a specified county or region to avoid confusion to those in a particular sector in which the marketing materials do not apply. Some commenters indicated that MCOs, PHPs, and PCCMs, should have the ability to tailor the form and style of marketing to communicate effectively with demographic subgroups of a service area. Others suggested that the service area-wide distribution requirement apply just to MCO, PHP, and PCCM mailings of marketing materials and that those currently enrolled in the MCO, PHP, or PCCM be excluded from the requirement. One commenter thought it reasonable to require that materials be sent only to those who are eligible or potentially eligible for Medicaid in a given service area.

Response: Section 1932(d)(2)(B) of the Act requires that marketing materials be distributed to the entire service area. The intent of this provision is to prohibit marketing practices that favor certain geographic areas over those thought to produce more costly enrollees. However, the regulation might not allow for diversity and cultural sensitivity. In response to the commenters' concerns, we have revised proposed § 438.104(b)(2)(ii) (redesignated as § 438.104(b)(1)(ii) in this final rule with comment period) to require that each MCO, PHP, and PCCM contract must provide that the entity ''distributes the materials to its entire service area as indicated in the contract.'' The phrase ''as indicated in the contract'' is intended to provide States and MCOs, PHPs, and PCCMs with some flexibility in designing and implementing marketing plans and in developing marketing materials. We expect that when States review MCO, PHP, PCCM, or marketing and informing practices, they will not only consider accuracy of information, but also factors such as language, reading level, understandability, cultural sensitivity, and diversity. In addition, the State review should ensure that MCOs, PHPs, and PCCMs do not target or avoid populations based on their perceived health status, cost, or for other discriminatory reasons. For example, a State may permit distribution of materials customized for an Hispanic population group as long as the materials are comparable to those distributed to the English speaking population. While the presentation and formats of the information may be varied based on the culture and distinct needs of the population, the information conveyed should be the same in accordance with § 438.10. In the above example, the materials for the Hispanic population group must be distributed to all those Medicaid eligibles or enrollees who require or request Hispanic-related materials. Materials would not need to be distributed to every individual in a given service area, but they would need to be distributed to all known Medicaid eligibles or enrollees in an area. States that use this flexibility to allow selective marketing may permit distribution by zip code, county or other criteria within a service area if the information to be distributed pertains to a local event such as a health fair, a provider, hospital or clinic. However, States must ensure that health fairs are not held in areas only known to have or perceived

as having a more desirable population. We have chosen not to limit the distribution requirement only to mailings because broadcast advertising and other marketing activities can also be done selectively. All marketing activities should be conducted in a manner that provides for equitable distribution of materials and without bias toward or against any group.

Comment: Some commenters asked whether marketing materials must be distributed to the entire service area all at once. Because materials may generate significant interest and phone calls to the MCO, PHP, or PCCM, and distributing materials to the entire service area at one time could be overwhelming. The commenters asked that staggered mailings be allowed so that responses to potential member inquiries can be timely. They also wanted flexibility to distribute marketing materials by zip code.

Response: States that permit marketing may oversee incremental distribution of marketing materials as long as the service area wide distribution requirements are observed.

Comment: Some commenters believe that States should ensure that when MCOs, PHPs, and PCCMs distribute marketing materials to the entire service area, the materials are in the languages spoken in that area, and proportional to the number of beneficiaries in the area with limited English proficiency. The commenters asserted that it is critical that the enrollment activities and the enrollment staff be capable of communicating effectively with those who have limited English proficiency and that there be adequate supplies of marketing materials in the appropriate languages. Several commenters contended that the regulation was too vague in this area, and should provide more concrete guidance.

Several comments, although not specifically addressing the service area distribution requirement, emphasized that MCOs, PHPs, and PCCMs (and their enrollment staff and written materials) be tailored to the needs of those with limited English proficiency. They also recommended that materials be appropriately translated throughout the service area. The recommendation was that this be required, and that guidelines be established for appropriate marketing to non-English and limited English-speaking individuals. One commenter observed that there are no cultural and linguistic requirements for marketers in the regulation and suggested that we require assurances of cultural and linguistic competency of marketers.

Response: We agree with the commenters that it is important for potential enrollees and enrollees with limited English proficiency have access to information in the appropriate language. Section 483.10(b) provides specific guidance regarding the language requirements applicable to information furnished to potential enrollees and enrollees. These requirements apply to all information, including marketing material, therefore, we do not believe that further guidance is needed in this section of the regulation.

Comment: One commenter urged that providers who contract with an MCO, PHP, or PCCM be able to market their program and services to other managed care entities inside and outside of their geographic area in order to fill vacancies. The commenter believed that the marketing restrictions might allow MCOs, PHPS, and PCCMs to unreasonably restrict the ability of providers to contract with other entities. The commenter recommended that the marketing restrictions not be applicable to marketing materials developed by a provider who contracts with an MCO, PHP, or PCCM to solicit services and fill vacancies.

Response: The marketing restrictions contained in this regulation apply to MCO, PHP, or PCCM marketing directly or indirectly to Medicaid enrollees and potential enrollees. The provision does not apply to certain providers or facilities marketing their services to MCOs, PHPs, or PCCMs.

Sale of Other Insurance

Proposed § 438.104(b)(2)(iv) required MCO, PHP, and PCCM contracts to assure that the entity does not seek to influence enrollment in conjunction with the sale of any other insurance. We stated in the preamble that we interpreted this provision to mean that MCOs, PHPs, and PCCMs may not entice a potential enrollee to join the MCO, PHP, or PCCM by offering the sale of any other type of insurance as a bonus for enrollment. However, we invited comment on this provision because we did not have any legislative history to consider when developing our interpretation.

Comment: Several commenters believed that language in this section was vague and needed clarification. Others expressed support for our interpretation prohibiting the offering for the sale of any other type of insurance as a bonus for enrollment and felt that the choice of an MCO, PHP, or PCCM must be unaffected by extraneous and conflicting incentives.

Some commenters encouraged us to prohibit other types of bonuses or gifts as inducements to enroll. These commenters noted that in the past, gifts have been offered to induce individuals to sign forms that they did not realize would change how they access their health care. Commenters recommended that, if we allow MCOs, PHPs and PCCMs to offer additional health care benefits for which they are not at risk, we should require minimum time periods during which the benefits must be offered, and require advance notice to members and an opportunity to change MCOs, PHPs, or PCCMs for cause if the benefits are discontinued. For example, commenters stated that some MCOs, PHPs, or PCCMs have offered extra benefits (eyeglasses) to induce enrollment and then discontinued these benefits after the initial enrollment period ended. Commenters indicated that Federal regulation was necessary in order to reduce the adverse impact of practices without entirely discouraging the provision of the extra benefits.

One commenter observed that inducements are generally ineffective, except when plans are essentially indistinguishable to beneficiaries. The commenter suggested that MCOs, PHPs, and PCCMs be encouraged to pursue market differentiation by offering better information about their quality and other attributes.

Response: In the past, we have provided guidance to States concerning incentives to enroll and the marketing of these incentives. However, we do not consider the expansion of the list of prohibited incentives to be within the purview of this regulation. States may permit MCOs, PHPs, and PCCMs to offer nominal incentives, similar to those commonly offered to commercial populations, or may choose to prohibit this practice entirely. States may also choose to set standards governing the offering of additional benefits. MCOs, PHPs, and PCCMs should be aware that practices such as offering additional benefits and the discontinuation of these benefits may, under certain circumstances, be considered deceptive, misleading or fraudulent activity and, therefore, could subject them to penalties. In response to commenters requesting clarification, we have revised the language to include situations where additional insurance is offered even if it is not offered for sale. This would include situations where, for example, an MCO offers a free burial insurance policy as an incentive to join that MCO.

State Agency Review

Proposed § 438.104(c) provided that, in reviewing the marketing materials submitted by MCOs, PHPs, and PCCMs, the State must consult with its MCAC or an advisory committee with similar

membership. In § 431.12 of our existing rules, we established the requirements for an MCAC. The MCAC must include Board-certified physicians and other representatives of the health professions who are familiar with the medical needs of low income populations and with the resources available and required for their care. The MCAC must also include the Director of the Public Welfare Department or the Public Health Department, whichever does not head the Medicaid agency, as well as members of consumer groups including Medicaid beneficiaries and consumer organizations such as labor unions, cooperatives, and consumer-sponsored prepaid group practice plans.

Comment: A commenter requested clarification as to whether, when neither the Director of the Public Welfare Department, nor the Director of the Public Health Department was not the head of the Medicaid agency, if both were required to serve on the MCAC. This commenter also asked if the director(s) could designate a staff member to serve on the MCAC.

Response: We recognize that in some States neither the Director of the Public Welfare Department nor the Director of the Public Health Department is the head of the Medicaid agency. In this case, the State has the flexibility to decide if only one of these departments is represented on the MCAC or both are included. We also believe that, as long as the basic requirements at § 431.12 are satisfied, the specific rules governing the administration of the MCAC are properly left to the State's discretion. For example, States may permit the Director of the Public Health Department or the Public Welfare Department to delegate their representation to other qualified individuals representing their Department.

Comment: Commenters suggested that the composition of the MCAC should be revised to include at least one MCO, PHP, or PCCM that provides services to beneficiaries. One commenter suggested that beneficiaries with disabilities be represented on the MCAC. Another commenter suggested that the MCAC membership and role be clearly stated and public.

Response: The State may always add to the current MCAC composition requirements to include representatives of any affected groups or entities, such as MCOs, PHPs, or PCCMs. We encourage States to have an MCAC membership that is diverse and represents groups served by the State's program, for example, minorities and individuals with special needs. With respect to the final comment, we note that § 431.12 requires that the State plan must ''provide for a MCAC meeting the requirements of this section'' and that the State plan is a public document. We would encourage States to ensure that the public is clearly and completely informed about the role and membership of the MCAC or any similar committee.

Comment: One commenter felt that HCFA went beyond the requirements of section 1932(d)(2)(A)(ii) of the Act in requiring consultation with a committee with specific composition since the statute refers only to a ''MCAC.''

Response: We believe that in using the term ''MCAC'' the Congress intended to refer to the requirements in § 431.12 governing MCACs. We recognize, however, that consultation regarding marketing materials is a new and distinct function, and that the State may wish to designate a separate committee to perform this function rather than require the existing MCAC to assume it. We want to afford States the flexibility to develop a second committee, but we require that any committee charged with this responsibility also comply with the existing MCAC requirements in § 431.12.

Comment: Some commenters believed that it was not appropriate to include Medicaid consumers on a MCAC charged with reviewing proposed marketing materials from competing HMOs.

Response: The requirement for consumer participation in the MCAC has been in the regulations for many years. When the Congress specifically identified a ''medical care advisory committee'' as a consultant in the review and approval of marketing materials, we believe that they intended to incorporate by reference the current composition requirements of the required advisory body with this name. We continue to believe that consumers are extremely helpful in this advisory capacity because they are the intended audience of marketing materials and can provide important feedback on the review and approval of materials.

Comment: Many commenters contended that the use of a MCAC to review and approve specific pieces of marketing material was impractical, burdensome, unrealistic, and an example of micro-management. Many States' MCACs meet monthly, bi-monthly, or quarterly. Several commenters believe that it would be difficult, if not impossible, to provide the quick turnaround, in some cases ten days or less, necessary for approval of marketing materials. Some States require that marketing materials be submitted sixty days prior to intended use and some commenters believed that adding another level of review would slow down the process. The regulation was also called, by one commenter ''unnecessary and bureaucratic'' and not in keeping with the guiding principles cited in the preamble.

Many commenters who objected to MCAC review of marketing materials suggested that the MCAC or similar body review generic marketing materials or approve guidelines instead of reviewing each individual MCO's, PHP's, or PCCM's materials. Some commenters stated that the committee could establish review standards and then State or local staff trained in those standards could perform the actual review. They indicated that the committee's role should be consultative and not decision making. Others suggested that marketing materials be reviewed retroactively.

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

States may also consult with the committee in the development of standardized guidelines or protocols that are intended to facilitate State review. States may consult with the committee to develop suggested language and deem approval of an MCO's, PHP's, or PCCM's materials if that language is used. MCOs, PHPs, and PCCMs could also use some of the suggested language and then identify areas where different language has been used, and States could then limit the review or consultation to that particular portion of the materials. In response to the last comment, we believe that the statutory language (''in the process of reviewing and approving'' marketing materials) precludes consulting with the committee retroactively.

Comment: One commenter suggested that the composition requirements of the MCAC could result in a conflict of interest between members and MCOs, PCCMs, and PHPs. Another commenter

suggested that the MCAC be held to confidentiality standards.

Response: The MCAC composition requirements have been in the regulations for over twenty years, and have always involved the potential for conflict between providers and beneficiaries who are served by the providers. We do not believe that this regulation raises any new concerns regarding conflicts of interest. Therefore, we are not revising the composition requirements in this final rule with comment period. We would not anticipate that the MCAC or any similar advisory body would have a need to review or have access to individually identifiable information about Medicaid beneficiaries, but if they did, then they would be governed by the same confidentiality standards that apply to the State Medicaid agency (Subpart F, Part 431).

Comment: Many commenters expressed strong support for requiring that marketing materials be reviewed by a committee to ensure that the materials are not false or misleading and to ensure that the information is understandable. One commenter stated that using established MCACs would not provide a level of consumer and advocate involvement sufficient to identify and resolve problems or develop appropriate policies. This commenter recommended that States be required to actively work with consumers on contract development, client protections, quality assurance, and problem resolutions.

Response: We appreciate the commenters' support. This provision, however, is intended to be limited to requiring consultation with a committee that includes consumer representation on the subject of the review and approval of marketing materials. This provision does not speak to the need for consumer participation in the development of the entire managed care system. We do require consumer involvement in other sections of this final regulation; for example, in § 438.202(c) we require the State to provide for the input of beneficiaries and other stake-holders in the development of the quality strategy, which must include making the strategy available for public comment before adopting the quality strategy. We encourage involvement by stakeholders during all phases of managed care implementation.

Comment: Commenters pointed out that neither the nature of the consultation nor its expected outcome was specified in the proposed rule.

Response: The legislative history do not indicates that the Congress intended for the consultation to be of any specific nature or have any specific outcome. Instead, it prescribe a Federal standard. We believe it is more appropriate to permit States to define the specific role of the committee.

Comment: A commenter pointed out that States that have adopted model legislation developed by the National Association of Insurance Commissioners (NAIC) have regulatory processes in place for the review of marketing materials and that MCAC involvement could lead to conflicts between the MCAC and the regulatory body.

Response: The NAIC's ''Advertisements of Accident and Sickness Insurance Model Regulation'' sets forth minimum criteria to ensure proper and accurate description of products and to protect prospective enrollees. The criteria are similar to the criteria for advertisements of Medicare supplemental insurance. States are free to use all or part of this model to craft their marketing standards and contract language. A State's use of NAIC or similar standards should neither conflict with nor complicate consultation with the MCAC or similar committee because the committee should be following standards adopted by the State.

4. Liability for Payment (§ 438.106)

Proposed § 438.106, consistent with section 1932(b)(6) of the Act, required MCOs to provide that their Medicaid enrollees will not be held liable for—(1) the debts of the MCO in the event of insolvency; (2) services provided to the enrollee for which the State does not pay the MCO or the MCO does not pay the individual or provider that furnishes the services under a contractual, referral, or other arrangement; or (3) 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.

Comment: We received several comments in response to our request for public guidance on § 438.106(c) that refers to beneficiary liability for payments to a provider ''in excess of the amount the enrollee would owe if the MCO provided the services directly''. Most commenters agreed with our position that Medicaid managed care enrollees should not be responsible for more than nominal charges for cost sharing. One commenter sought clarification of when the situation described in § 438.106(c) would apply, and another suggested that the amount owed by the Medicaid beneficiary should be any cost sharing required by the contract. Another commenter suggested that the provision may have been intended to address a recent trend in the managed care industry of establishing coverage options that allow enrollees to go out of network for services in exchange for higher premiums or co-pays (that is, ''point-of-service'' options), as there may have been concern that this type of coverage could be interpreted by MCOs as a non-Medicaid benefit for which they could charge.

Response: As we stated in the preamble to the proposed rule, Medicaid beneficiaries should not ''owe'' an MCO any payment amounts beyond nominal cost sharing. Section 1916 of the Act specifically prohibits States and plans from imposing additional cost sharing. We agree with the comment that § 438.106(c) would prohibit MCOs from offering a point-of-service option. This paragraph states that an enrollee may not be held liable for payment (for services furnished under a contract, referral, or other arrangement) in excess of the amount that the enrollee would owe if the MCO provided the services directly. In other words the enrollee may only be held liable for nominal cost sharing.

Under this regulation, enrollees may obtain out-of-network services under the following circumstances:

- Enrollees may always obtain family planning services out-of-network, as provided in our current regulations at § 431.51;
- Enrollees who reside in rural areas and are mandatorily enrolled in a single MCO, PHP, or PCCM may obtain out-of-network services as provided in § 438.52(b);
- Enrollees may obtain emergency and post-stabilization services from out-of-network providers as specified in § 438.114;
- Enrollees may obtain services out-of-network if the network is unable to meet an enrollee's medical needs as specified in § 438.206(d)(5).

The protection in § 438.106(c) would apply under all of these circumstances, therefore, the enrollee could not be held liable for costs in excess of the amount that the enrollee would owe if the MCO provided the services directly.

Comment: Several commenters were concerned that § 438.106 could be interpreted to require an MCO to pay its network providers for services that are not covered under the Medicaid State plan or are furnished by its network providers not in accordance with the provider's contract terms with the MCO. They suggested that we add language to clarify that the MCO's obligations are limited to those services that are covered under the contract between the

State agency and the MCO, as well as to those services covered under the contract between the MCO and the provider.

Response: In this section, we intend to protect beneficiaries against liability for payment of covered services. We agree with commenters that the proposed language could be interpreted as prohibiting enrollee liability for non-covered services or non-emergency or urgently needed services provided out of network, although this is not the intent. We therefore provide in this final rule with comment period at § 438.106(b) and (c) that enrollees cannot be held liable for ''covered'' services. ''Covered'' services would include any service that the State covers through its managed care program, whether it is a service that is covered under the contract between the State and the MCO (including additional or alternative services to traditional State plan services), or a service that is carved out of the capitation rate and paid fee for service, as long as the service is obtained appropriately. This provision does not preclude enrollee liability for non-covered services, or for covered services that are obtained inappropriately (for example, services obtained without a referral when one was required) unless, on appeal, it is determined that the services are covered.

Comment: One commenter requested that we add language that incorporates the ''hold harmless'' concept developed by the NAIC. Specifically, the commenter suggested that we revise the regulations to provide that beneficiaries should be ''held harmless'' for the cost of covered services except for applicable cost sharing.

Response: We believe that the provisions of § 438.106, as written, sufficiently convey that enrollees may not be held liable for the cost of covered services except for nominal cost sharing. We do not believe it is necessary to add additional language referencing the NAIC's ''hold harmless'' concept.

Comment: Several commenters suggested that we clarify that beneficiaries should not be held liable for family planning services covered under the Medicaid program, nor should they be held liable for reproductive services that are not provided by the health plan or its subcontracting providers or that are not reasonably accessible within the health plan.

Response: As stated above, we have revised § 438.106 to reflect that enrollees may not be held liable for ''covered'' services, which include family planning services. Section 431.51(a)(4), (5), and (6) provide that Medicaid beneficiaries enrolled in an MCO, PHP, or PCCM may not be denied freedom of choice for family planning services. This means that even family planning services that an enrollee obtains out of network are ''covered'' services for which the beneficiary may not be held liable. In addition, § 447.53(b)(5) states that cost sharing cannot be imposed for family planning services and supplies. Therefore, we do not believe it is necessary to specifically address family planning services in § 438.106.

5. Cost Sharing (§ 438.108)

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

Comment: One commenter recommended that we specify in § 438.108 that family planning services and supplies are excluded from cost sharing.

Response: This section specifies that any cost sharing imposed for services provided by an MCO must be in accordance with § 447.50 through § 447.58 of our rules. Because § 447.53(b)(5) states that cost sharing cannot be imposed for family planning services and supplies, we do not believe it is necessary to refer to this exclusion again under § 438.108.

Comment: Several commenters believed that it was important that contracts make clear that any cost sharing imposed under the contract must be nominal. Commenters also expressed concern that cost sharing could become a barrier to care, and that cost sharing requirements could be particularly problematic for enrollees who regularly use the health care system. The commenters believe that even nominal copayments, if consistently collected by MCOs, could deter enrollees from obtaining needed care.

Response: The regulation clearly requires that any cost sharing imposed for services delivered either by an MCO or under fee-for-service be nominal. We agree with the commenters that cost sharing may act as a deterrent to obtaining care. Therefore, in § 447.53, we are adding a new paragraph (e) that states: ''No provider may deny care or services to an individual eligible for the care or services on account of the individual's inability to pay the cost sharing.'' This language closely tracks the statutory language in section 1916(e) of the Act. This provision applies to services furnished either by an MCO or under fee-for-service.

Comment: One commenter suggested that we exclude enrollees receiving home and community-based waiver services from cost sharing.

Response: The BBA did not identify any new groups of enrollees to be excluded from cost sharing. The law only provided that cost sharing for MCO services may be permitted in the same manner as it is permitted under fee-for-service. Enrollees receiving home and community-based waiver services are not excluded under our current fee-for-service program and therefore, we are not excluding them from cost sharing for services furnished by an MCO. We note that States may always elect not to impose cost sharing on all enrollees or on specific groups of enrollees.

Comment: A few commenters stated that cost sharing creates a barrier to American Indian and Alaskan Native (AI/AN) participation in Medicaid programs, because they can access the Indian Health Service (IHS) and tribally-operated programs without paying for services. Further, the commenters noted that IHS and tribal providers are not authorized by the Congress to impose cost sharing for services provided to American Indians. These commenters recommend that we exercise the Federal trust responsibility to provide health care for AI/AN populations by exempting them from any cost sharing in Medicaid programs. Since the Federal government pays 100 percent FMAP for services delivered by tribally operated facilities, the commenters believe there should be a provision explicitly prohibiting States from imposing cost sharing on AI/AN Medicaid beneficiaries.

Response: The Congress has been very specific in section 1916 of the Act in specifying which categories of individuals or services are exempt from cost-sharing, and we believe that it would be inconsistent with Congressional intent to exempt additional groups. We note that under § 447.53(b)(1), all children (including AI/AN children) are exempted from cost sharing.

Comment: One commenter recommended that we eliminate the application of § 447.57 to cost sharing for services furnished by MCOs. The commenter stated that § 447.57 prohibits States from reimbursing providers for unpaid copayments. The

State Medicaid plan must specify that the State agency does not increase the payment it makes to any provider to offset uncollected amounts for deductibles, co-insurance, copayments, or similar charges that the provider has waived or are uncollectible. The commenter expressed concern that this provision inappropriately places the economic burden of unpaid copayments on health care providers, such as community pharmacies. The commenter stated that requiring pharmacies to absorb the cost of unpaid copayments discourages participation by pharmacies in Medicaid MCOs and discourages MCOs from participating in Medicaid.

Response: The BBA allows us to permit copayments under managed care in the same manner as we permit them under fee-for-service. At this time, we are not proposing to revise the rules that apply under fee-for-service to remove the requirement that States not reimburse providers for uncollected payments. Therefore, it will also apply to services furnished by an MCO. We encourage interested parties to work with States in developing their cost sharing policies.

Comment: One commenter felt that MCOs should be required to make cost sharing requirements clear in all cases, and enrollees should be informed of what constitutes ''good cause.'' The commenter recommended that if an MCO advertises that it does not require copayments, then it should be prohibited from charging copayments for two years. The commenter also stated that MCOs should make clear at the time of open enrollment whether they intend to charge copayments during the contract year.

Response: We agree with the commenter that enrollees should have clear information about cost sharing requirements. In § 438.10(d) and (e), we specify that information furnished to potential enrollees and enrollees, respectively, must include information on any cost sharing. MCOs are also required to inform potential enrollees and enrollees of any significant changes in the information that was furnished to them 30 days prior to the effective date of the changes. While the State will determine what qualifies as ''significant'', we assume that States would find that the introduction of new cost sharing requirements would constitute a significant change.

In addition, in § 438.56(d)(2)(iv), we specify that ''good cause'' for disenrollment by the enrollee includes poor quality care, lack of access to necessary specialty services covered under the contract, or other reasons satisfactory to the State agency. Under this provision, the State could determine that a change in the MCO's cost-sharing policy constitutes ''good cause'' for disenrollment.

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

Response: Under § 447.53(b)(4), emergency services are exempted from cost sharing. Specifically, copayments may not be imposed on ''[s]ervices provided in a hospital, clinic, office, or other facility that is equipped to furnish the required care after the sudden onset of a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) that the absence of immediate medical attention could reasonably be expected to result in—(1) placing the patient's health in serious jeopardy; (2) serious impairment to bodily functions; or (3) serious dysfunction of any bodily organ or part.'' We emphasize that as long as the enrollee seeks emergency services that could ''reasonably be expected'' to have the above effects, a copayment may not be imposed, even if the condition was determined not to be an emergency.

The State may decide to impose a copayment for non-emergency services furnished in an emergency room in cases where the enrollee sought services in an emergency room when the standard under § 447.53(b)(4) was not met. Furthermore, the State may request a waiver of the requirement that cost sharing charges be nominal. Section 431.57 provides that for non-emergency services furnished in a hospital emergency room, the Secretary may grant a waiver to permit a State to impose a copayment of up to double the nominal copayment allowed under § 447.54.

Allowing payment of a copayment up front in a hospital emergency room as the commenter suggested would raise the implication of non-compliance with the standard in § 447.53(b)(4). However, enrollees should be aware that if they seek services in an emergency room when the standard in § 447.53(b)(4) is not met, they may be held liable for cost sharing.

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

Under the authority of section 1932(b)(5) of the Act, proposed § 438.110 required that an MCO provide the State and the Secretary with adequate assurances that the MCO has the capacity to service the expected enrollment in its service area.

In proposed § 438.110, we interpreted the term ''assurances'' to require MCOs to submit documentation to both the State and us. While States were given the flexibility to decide the types of documentation to be submitted by MCOs, we specified that the documentation had to address the State's standards for access to care outlined under proposed § 438.306 (redesignated as § 438.206 in this final rule with comment period). In addition, we proposed that MCOs be required to submit documentation to the State and us, along with State certification, at least every two years, and at the time the MCO enters into or renews a contract with the State or when there has been significant change in the MCO's delivery network or enrollee population.

We received many comments on this section from State agencies, professional organizations, and advocates. A number of commenters appeared confused over this section's interface with proposed § 438.306, and argued that we need to be more detailed in both sections of this final rule with comment period. We recognize that the requirements relating to availability of services and assurances of adequate capacity are closely related and therefore, in this final rule with comment period, we have redesignated § 438.110 as § 438.207 so that these requirements may be read and applied together. We will respond to the comments that were received regarding proposed § 438.110 below.

Comment: Several commenters felt that proposed § 438.110, combined with proposed § 438.306, did not recognize the unique needs of homeless persons, women, children, and individuals with disabilities. Commenters believed we should require additional documentation, and establish standards that specifically recognize the needs of these populations.

Many recommendations were offered. With regard to the persons who are homeless, commenters recommended that MCOs and PHPs should create linkages with service providers offering a wide range of culturally appropriate

medical and social services, including case management. They recommended that the services be available at sites such as soup kitchens, drop-in centers, and shelters where homeless people congregate and are willing to receive care.

A few commenters suggested that we should respond to the needs of children by requiring that primary care pediatricians be available to provide care to children under 19 years of age. In addition, commenters suggested that we require pediatricians to serve as primary care providers, and require that such providers be available 24 hours a day, 7 days a week. Further, the commenters believed that we should require MCOs to include specialists with appropriate pediatric training and expertise, and require that they have arrangements with appropriate tertiary care centers. If an MCO fails to have an adequate number of pediatric providers, including primary and specialty care, the commenter urged that we require that these services be available to enrollees out of network at no additional costs.

Other commenters recommended that proposed § 438.110 be amended to require MCOs to document the availability of women's health specialists. Specifically, one commenter recommended that MCOs that do not contract with hospitals and health entities that provide a full range of reproductive services should be required to demonstrate access to alternative sites, which are medically appropriate and geographically, culturally, and linguistically accessible. In addition, if an MCO cannot demonstrate a full range of reproductive health services, the State should demonstrate to HCFA how individuals will be able to access those benefits without any undue burden.

Commenters also recommended that a provision be added to specifically address the needs of disabled individuals. One commenter recommended that we require MCOs to—(1) identify the populations that will be served, if disabled or unique; and (2) identify specialized professionals, DME, and related supply services that will be available to accommodate each population category. Another commenter suggested that MCOs should be required to document an appropriate range of services and networks, given that various communities may speak different languages. Other commenters suggested that we incorporate stronger requirements that address access to ancillary services, linguistic access, and physical access. Finally, one commenter recommended that we require physicians trained in mental illness to act as primary care providers for persons suffering from mental illness.

Response: The proposed rule was developed to address the needs of all Medicaid populations served under managed care. As we indicated in the preamble to the proposed rule, proposed § 438.110 was to address the procedural requirements for submitting assurances of adequate capacity and services, while proposed § 438.306 was to address the substantive requirements ensuring the availability of services. The intent behind both sections was that States be given flexibility to develop access standards and documentation requirements appropriate for the populations enrolled and specific to the unique circumstances in each State.

Although we therefore do not mandate all of the detailed requirements suggested by commenters, we do require in this final rule with comment period that States, MCOs, and PHPs, maintain an adequate delivery network under § 438.206(d)(1), pay particular attention to pregnant women, children, and persons with special health care needs. We added the last category of enrollees to recognize the special needs of individuals who, for example, disabled or homeless, and who require special attention from the MCO in order to access the health care system.

In addition, in this final rule with comment period, we require the State to identify to the MCO or PHP upon enrollment specific groups at risk of having special health care needs. We also require MCOs and PHPs to make a best effort attempt to identify and comprehensively assess pregnant women, and persons with special health care needs.

We believe that the above provisions ensure that the State, when developing its standards for access to care and when monitoring an MCO's or PHP's capacity and adequacy of services, pays particular attention to managed care enrollees who are vulnerable. Although this final rule with comment period does not include all recommendations offered by the commenters, States are free to consider them.

Comment: One commenter noted that neither States nor MCOs have developed a methodology to measure adequate capacity. The commenter states that while many States have required MCOs to submit a great deal of information with the intent to measure adequate capacity, that information for the most part has not been useful. Further, the commenter expressed concern that MCOs will be required to submit unnecessary data and information, thus wasting considerable resources. This commenter suggested that the most expedient and effective way to measure adequacy and access is to ensure that enrollees know how to contact the managed care plan for information and how to file complaints and grievances. The commenter recommended that States be allowed to use their judgment on these issues under their existing certification processes.

Response: Section 1932(b)(5) of the Act requires MCOs to provide the State and the Secretary with adequate assurances that the MCO has the capacity to serve the expected enrollment of Medicaid beneficiaries in its service area. The Congress specified that these assurances must demonstrate that each MCO has an appropriate range of services, and a sufficient number, mix, and geographic distribution of providers. Based on this statutory mandate, we are imposing detailed requirements on MCOs and States, including a requirement that MCOs submit documentation. We believe that States must have documentation in order to assess capacity and adequacy of services. We have clarified in this final rule with comment period that the documentation required under this section must be submitted by MCOs in a format specified by the State and acceptable to us. We recognize that MCOs may not be able to construct a provider network that anticipates all future needs of enrollees. Therefore, in this section we are requiring that the MCO have policies and practices in place to address unanticipated need for, or limitations in availability within their service area of, certain experienced providers when required by enrollees. We agree with the commenter that enrollees must know how to contact the MCO and know how to file grievances, appeals, and State fair hearings. Section 438.10 requires that this information be furnished to enrollees.

Comment: We received one comment questioning whether we should apply proposed § 438.110 to voluntary MCOs. The commenter believed that the provisions are burdensome for MCOs and PHPs in which enrollment is voluntary, especially when they are added to the proposed access requirements. The commenter recommended that this section be applied only to MCOs and PHPs in which enrollment is mandatory.

Response: Section 1932(b)(5) of the Act does not distinguish between voluntary or mandatory managed care organizations; rather, the statute generally references managed care organizations under section 1903(m) of the Act, which applies to both voluntary

and mandatory enrollment MCOs. Section 1903(m)(2)(A)(xi) of the Act requires that all MCOs meet applicable requirements in section 1932 of the Act. We have no discretion to exempt voluntary enrollment MCOs from the requirement in section 1932(b)(5) of the Act. We also do not see any justification for applying a lower standard under section 1932(b)(5) of the Act in the case of MCOs with voluntary enrollment. Under section 1903(m)(2)(A)(vi) of the Act, once an individual enrolls in a ''voluntary enrollment'' MCO, the enrollee may be ''locked in'' after the first 90 days for 12 months at a time. It is just as important to ensure adequate capacity in a case, as it is in the case of a ''mandatory enrollment'' situation.

Comment: We received one comment supporting proposed § 438.110(a), and the grievance and appeals provisions in proposed subpart E. The commenter noted that these provisions are consistent with the broader and more detailed obligations imposed on all health benefit plans in California.

Response: Our intent in the proposed and this final rule with comment period is not to prohibit a State from imposing more stringent standards concerning the adequacy of an MCO's network capacity and services. Our intent is to ensure that States, at a minimum, review MCO network capacity and services, and certify to us that the MCO satisfies the State's requirements for availability of services, as required under § 438.206. We are pleased that our standards are consistent with California's.

Comment: We received many comments suggesting that the documentation described in proposed § 438.110(b) should be sent to the State and not directly to HCFA. Although several commenters favored HCFA becoming more involved in reviewing MCO documentation justifying adequate capacity and services, a large number of commenters recommended that we delete the requirement for direct submission of documentation by MCOs to HCFA.

Specifically, commenters argued that States, and not HCFA, were responsible for entering into and monitoring contracts with MCOs, and ensuring that adequate capacity exists to serve enrollees. Other commenters argued that direct submission of documentation to HCFA would be redundant, unprecedented, and contrary to our stated intent to provide States flexibility wherever possible. A few commenters suggested that the proposed documentation requirements went beyond the statutory provisions in the BBA, which in the commenters' view only require that ''assurances'' be made to the Secretary.

Commenters also asserted that the proposed rule does not recognize the differences among the 50 states, and questioned what HCFA would do with the information once received, and whether we would be diminishing the management authority of the States. Finally, a number of commenters asked that we consider the administrative burden of this requirement, believing it would constitute unnecessary micro-management on the part of the Federal government.

Response: Based on comments received, we have re-evaluated proposed requirement that assurances be routinely and directly provided to us. This requirement was based on the fact that section 1932(a)(5) of the Act requires that MCOs provide adequate assurances to ''the State and the Secretary.'' We believe, however, that the requirement that the Secretary be provided with adequate assurances can be satisfied by requiring the State to provide assurances to us that it is satisfied that standards are met. In this final rule with comment period, we do not require the MCO to submit documentation directly to us. We agree that documentation should be submitted to the States that are the entities that contract with MCOs, and that it might be redundant for us to regularly receive all of the documentation. In this final rule with comment period, we require only that the State submit to us certification of an MCO's adequate capacity and services in accordance with State-established standards for access to care under § 438.206. We also added a provision that allows us to inspect the documentation submitted by MCOs.

We did not intend to interfere with the State's role in determining whether an MCO has demonstrated adequate capacity and services. We believe that the approach in this final rule with comment period satisfies our statutory requirements by providing us with sufficient flexibility to monitor State's actions and it also satisfies the commenters concerns by restoring the role of the States and reducing administrative burden. With respect to the commenters suggesting that our requirements go beyond the statute's requirement for ''assurances,'' we note that the title of section 1932(b)(5) of the Act is ''Demonstration of adequate capacity and services,'' and that the text requires ''adequate'' assurances. We believe it is reasonable, in order for the State to be ''adequately'' assured of an MCO's or PHP's capacity, and in order for the MCO or PHP to ''demonstrate'' such capacity, to expect documentation in support of the assurances it makes.

Comment: One commenter recommended that we request legislative action to eliminate the requirement in section 1932(b)(5) of the Act that assurances be submitted directly to HCFA. The commenter argued that direct submission by an MCO to HCFA would be unprecedented and redundant.

Response: A legislative change is not necessary in light of our decision to interpret our requirement as satisfied by the provision of assurances to us by States.

Comment: We received a number of comments on proposed § 438.110(b) asking that we provide additional clarification on the format of information to be received from MCOs and States assuring adequate capacity. Commenters questioned whether we would specify the electronic format to be used to submit information and whether we would require States to change current formatting requirements. One commenter reminded us that a change in formatting requirements could result in States and MCOs, PHPs, and PCCMs abandoning software already in use. Another commenter noted that for multi-state health plans, different electronic formatting requirements in each State would have enormous cost implications. This commenter suggested that States submit aggregate health plan information to HCFA.

Response: Because we no longer require direct submission of documentation from MCOs, it is not necessary to prescribe formatting requirements. We are requiring in this final rule with comment period that documentation be submitted in a format specified by the State and acceptable to us. We recognize that different States use different systems for collecting information. Accordingly, we permit a State to tailor the format of the documentation to its own unique system and resource capabilities. In meeting this requirement the State should submit to us its proposed format for approval. As we gain more experience in implementing this provision, we will provide formal guidance on acceptable formats. Although we are no longer requiring the direct submission of documentation from MCOs, we are requiring that States certify to us the MCO's assurances of adequate capacity and services. We wish to emphasize that the State certification must address how the MCO demonstrated compliance with the State's access standards developed under § 438.206.

Comment: We received a number of comments on proposed § 438.110(b)(1), which requires an MCO to submit documentation demonstrating that it offers an appropriate range of services for the enrollees in the service area, including access to specialty services. Many commenters supported the reference to specialty services. Several commenters noted that for many individuals with disabilities and mental illness, specialty care often amounts to primary care. In contrast, several commenters objected to this provision and argued that the BBA did not address specialty care as part of this requirement. One commenter indicated that there are no national standards to determine specialty care capacity and services.

Many recommendations were offered. A number of commenters recommended that we maintain this requirement in the final rule with comment period, with a few suggesting that we provide technical assistance to States. One commenter suggested that we only require MCOs to demonstrate that they have the capacity to provide specialty services in a timely and accessible manner, and that we require MCOs to disclose what provisions they have made for infrequently used tertiary care services. Another commenter suggested that the State agency obtain proof, as appropriate, that it furnishes health services required by enrollees as promptly as is appropriate and that the services meet the agency's quality standards. Finally, one commenter suggested that we incorporate into the regulation itself the preamble language discussing proposed § 438.306, which suggests that States consider the volume of services furnished to other enrollees, and reminds States to ensure that providers are accessible to those who rely on public transportation.

Response: Although section 1932(b)(5) of the Act refers expressly only to preventive and primary care services, it requires assurances of ''capacity to serve the expected enrollment,'' presumably including those enrollees who need specialty services. While it specifies expressly that these assurances should ''includ[e]'' assurances with respect to preventive and primary care, this does not mean that assurances about other types of services are not necessary. Indeed, the very clause that references preventive and primary care (section 1932(b)(5)(A)) of the Act also references ''an appropriate range of services,'' which we believe includes specialty services. Section 1932(b)(5)(B) of the Act refers to ''a sufficient * * * mix * * * of providers of services,'' which again in our view refers to having ''sufficient'' capacity for all types of providers, including specialists. We believe that section 1932(a)(5) of the Act, as we interpret it, provides authority for us to require assurances of specialty services. (We also have relied on our general authority under section 1902(a)(4)) of the Act.

We continue to believe that assurances with regard to specialists are important, and agree with the commenters that support this requirement. MCOs and PHPs must demonstrate access to specialty services based on the access standards established by the State under § 438.206. This reflects our recognition of the growing body of evidence showing that individuals secure positive health outcomes when treated by providers experienced in caring for significant numbers of individuals with a particular health care condition (for example HIV/AIDS). Also, in response to the above comments about the importance of specialty care which can serve as primary care for special populations, in § 438.206(d)(1)(iii), of this final rule with comment period, we have added a parenthetical statement to specify that in establishing the network, consideration of the types of providers needed must take into account the providers' ''training and experience''.

We emphasize that to demonstrate adequate access to specialty services, MCOs and PHPs need not contract with specialists in instances where a specialist provides infrequently used services or procedures. An MCO or PHP may satisfy this requirement in these types of cases, for example, by having appropriate arrangements with specialists, and allowing enrollees to go to these out-of-network providers to receive medically necessary specialty care. We note that in circumstances where an MCO's or PHP's provider network is unable to meet an enrollee's needs and the enrollee must seek care from an out-of-network provider, the enrollee may not be held liable for any additional expenses. In other words, for those services, enrollee liability must be the same regardless of whether they were received from in-network or out-of-network providers. Section 438.207(b)(4) of this final rule with comment period recognizes limitations in provider networks that may necessitate other arrangements, and provides for such alternative arrangements.

Although we believe examples in the preamble discussion of proposed § 438.306 referenced by the commenter are appropriate for State consideration, we have not incorporated them in this regulation. Given differences that may exist among States, it would be inappropriate to impose national ratio standards for access to specialty care.

Finally, in terms of providing technical assistance, we are always available to provide specific guidance to States upon request. We regularly provide technical assistance in a variety of different forms, including issuing letters to State Medicaid Directors, publishing Medicaid policy manuals, reviewing waiver applications and contracts, performing on-site monitoring reviews, and engaging in regular dialogue directly with State officials.

Comment: We received one comment requesting that we define the term ''mix'' in proposed § 438.110(b)(2), which stated that the MCO must submit documentation to demonstrate that it ''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.'' The commenter argued that the term ''mix'' is too vague. Further, as used in the context of the proposed regulation, the term could be interpreted to mean ethnic, language, and cultural diversity, or various types of specialties. The commenter recommended that we articulate this term to ensure that rights and protections are not restricted.

Response: The term ''mix'' is taken directly from the statute and we have retained it in this final rule with comment period. We believe that the term ''mix'' refers to provider types, for example, as we have just noted above, the appropriate types of specialists. We note, however, that States will be required to review documentation submitted by MCOs to ensure that each MCO has demonstrated adequate capacity and services in accordance with the State's standards for access to care. One of the requirements of the access provisions is that a State ensure that each MCO provides services in a culturally competent manner (§ 438.206(e)(2)).

Comment: We received a number of comments on proposed § 438.110(c), which required MCOs to submit the documentation described in paragraph (b) at least every two years, specifically at the time the MCO enters into or renews a contract with the State, and at the time the State determines that there has been a significant change in the MCO's delivery network or enrollee population. A number of commenters suggested that the two year time frame for assessing adequate capacity and services was insufficient and would not adequately protect enrollees. The commenters recommended that we

require an annual assessment of adequate capacity.

A number of other commenters suggested that States should have flexibility in determining when to require an MCO to provide assurances of adequate capacity. They argued that the two year time period specified in the proposed rule was too arbitrary and does not tie to existing contracts or waiver periods. Moreover, they noted that many States and MCOs assess adequate capacity within shorter intervals than the 2-year period proposed in the regulation. Their recommendations included a number of the following options: (1) shortening the time frame to one year; (2) revising the rule to allow for certifications to be submitted with waiver renewals, contract processes, or other administrative processes; and (3) requiring that assurances be sent at a time period agreed upon by HCFA and the State.

One commenter specifically noted that changes in reimbursement, limits on services, and the existence of closed panels affect provider composition. This commenter suggested that we require States to re-assess provider adequacy if changes in reimbursement policy or other factors require a change in network composition. Another commenter believed that if there is no substantial change in the delivery system, there is no need to re-submit information at each renewal. Finally, one commenter questioned how long it would take HCFA to review provider networks before approval can be given of a contract or contract amendment, since there were no time frames offered in the regulation for HCFA's review process.

Response: The time frames specified in proposed § 438.110 were never intended to prohibit a State from assessing adequate capacity at intervals shorter than two years. We proposed that, at a minimum, MCOs must submit the documentation at least every 2 years, and envisioned that States regularly would assess adequate capacity at the time it enters into or renews a contract with an MCO and when the State determines that there has been a significant change in an MCO's delivery network or enrollee population.

In response to commenters concerns, we have revised the provision in this final rule with comment period. We now require the MCO to submit documentation annually. The MCO is still required to submit the documentation at the time it enters into a contract and any time there has been a significant change in the MCO's operation that would affect capacity and services. We also in § 438.207(c)(2) provide examples of what constitutes a significant change in the MCO's operations. Although States are free to include other changes, we believe, at a minimum, significant changes include—(1) a significant MCO service or benefit change; (2) an expansion or reduction of the MCO's geographic service area; (3) the enrollment of a new population in the MCO; and (4) a significant MCO rate change. We also specify that after the State reviews the documentation from the MCO, the State must certify to us that the MCO has complied with the State's requirements for availability of services, as set forth in § 438.206.

Finally, we acknowledge that several commenters were confused over the interface of this rule with the section 1915(b) of the Act, waiver review process. Commenters should be aware that, if there has been a significant period of time between the State's assessment of adequate capacity at the time of a waiver renewal, we may ask the State to update its analysis of adequate capacity and services as part of the waiver review process, and may request documentation of an MCO's capacity at that time.

Comment: Several commenters expressed the view that § 438.110 did not have any enforcement mechanism. Citing problems encountered by American Indians in gaining access to specialists in voluntary Medicaid managed care programs, one commenter suggested that as an enforcement tool, we compare the rates paid for Medicaid beneficiaries by an MCO or PHP to those paid under fee-for-service Medicaid to ensure that a sufficient amount is paid to ensure access and availability. Further, the commenter suggested that we also direct detection and enforcement activity at providers that limit the number of appointments they make available to Medicaid enrollees. Another commenter argued that we did not discuss any consequences to the MCO should it fail to demonstrate adequate capacity and services. This commenter suggested that we address corrective action plans and other appropriate consequences in the regulation. Several other commenters recommended that the regulation explicitly describe HCFA's authority to determine whether States and MCOs or PHPs have adequately demonstrated capacity, and describe HCFA's ability to deny FFP if they have not.

Response: In addition to reviewing managed care contracts, we regularly monitor the operation of Medicaid managed care programs throughout the country. We have a variety of different monitoring tools, such as reviewing State reports and MCO or PHP documentation, interviewing representatives of the State, MCO or PHP, interviewing enrollees, reviewing provider agreements and contracts, and surveying participating providers.

We also have many mechanisms to enforce the provisions of this section. They range from issuing letters and corrective action plans to imposing terms and conditions under waiver programs, to conducting regular on-site monitoring reviews, and to withholding FFP under § 438.802(c) of this final rule with comment period (see section II. H. below). Our goal is to work with States to resolve problems and take action, as appropriate for the particular circumstances.

We note, in response to the commenter's concern regarding access to specialists under managed care, that section 1903(m)(1)(A)(i) of the Act requires an MCO to ''make services it provides to individuals eligible for benefits under this title accessible to individuals to the same extent as such services are made accessible to individuals (eligible for Medicaid assistance under the State plan) not enrolled with the organization.'' Accordingly, under managed care, States must ensure that MCOs provide Medicaid enrollees access to contracted services to the same extent such access is available under fee-for-service. Again, FFP could be disallowed in the case of a failure to comply.

Comment: We received a few comments questioning whether there is an adequate process for input and disclosure with regard to proposed § 438.110. One commenter recommended that we require public disclosure, upon request, of criteria used by an MCO or PHP to select and monitor the performance of health care providers, including those providing specialty services to persons with chronic diseases or disabilities. The commenter further recommended that the final rule with comment period require public disclosure of QISMC and accreditation surveys, arguing that we should require the same disclosure of quality assurance in Medicaid managed care as required under the Medicare+Choice program.

Another commenter recommended that we require States and HCFA to provide public access to documents, provide reasonable notice of pending review, permit public comment, and hold review hearings as appropriate. Finally, several commenters recommended that we require States to obtain input from consumers, consumer advocates, and medical providers, for

use in setting access standards. They suggested that States may do this through MCAC, proposed rulemaking, or public hearings on proposed State plan amendments.

Response: In § 438.202(c) of this final rule with comment period, we require the State to provide for the input of recipients and other stakeholders in the development of the quality assessment and performance improvement strategy, including making the strategy available for public comment before adopting it in final. We believe that the quality strategy required in § 438.202(c) is the appropriate venue for public input with respect to State requirements governing MCO assurances of adequate capacity and services.

In § 438.207 of this final rule with comment period, we do not impose specific requirements with respect to public disclosure of documentation. We hope that States, consistent with their own laws, will provide enrollees and other stakeholders access to all relevant documentation submitted by MCOs to demonstrate their capacity to deliver contracted services. We note that States and MCOs, PCCMs, and PHPs must comply with the enrollee information requirements in § 438.10.

Comment: A few commenters questioned whether we would consider granting waivers of the requirement under proposed § 438.110 that adequate capacity be assured. One commenter recommended that MCOs be granted waivers from this requirement if they can demonstrate that a good faith effort has been made to solicit providers to participate in the MCO's network. The commenter asserted that there may not be an appropriate mix or geographic distribution of providers in certain areas, and there may be a limited number of specialty providers. The commenter suggested that, if the MCOs can demonstrate that there are not enough Medicaid providers for a particular zip code, they should be permitted to allow enrollees to go out of the service area.

Response: The provisions of § 438.206, Availability of services, allow States flexibility in designing standards for access to care. States should take into consideration locations where certain provider types may not be available. In these cases, States may permit MCOs to make arrangements with other providers outside of an MCO's service area in order to ensure capacity and services adequate to meet the needs of the enrollee population.

As a general rule, § 438.206 requires the MCO to maintain and monitor a network of appropriate providers. We recognize, however, that geographic mail distribution of providers, limitations in the number of certain providers nationally, as well as other factors, may make it difficult for MCOs to always be able to construct a provider network that will be able to address all the health care needs of its enrollees. For example, we acknowledge that the MCO's providers may not always be experienced in providing care to an individual who has a rare condition. Consequently, in § 438.207(b)(4) we require MCOs to have policies and practices to address unanticipated scarcity of providers to meet the health care needs of the enrolled population. Specifically, these policies and procedures should address the following: (1) the unanticipated need for providers with particular types of experience; and (2) the unanticipated limitation of the availability of such providers. In addition, § 438.206(d)(5) provides that if MCO's network is unable to meet an enrollee's needs, the MCO must permit the enrollee to access out-of-network providers.

Comment: One commenter specified that since deeming is allowed under section 1932(c)(2)(B) and (C) of the Act, we should allow States to deem an MCO or PHP as having met the requirements of § 438.110, if the organization has been accredited by a recognized accrediting body or has been Medicare certified.

Response: Section 1932(c)(2)(B) of the Act provides that States have the option of substituting private accreditation for the external quality review (EQR) required under section 1932(c)(2)(A) of the Act when EQR activities would duplicate an accreditation review. Section 1932(c)(2)(C) of the Act provides States the option to forgo EQR under section 1932(c)(2)(A) of the Act when the Medicaid MCO also has a Medicare+Choice contract in effect, and has complied with Medicaid EQR requirements for at least two years. The deeming provisions cited by the commenter only applies to the EQR requirements in section 1932(c)(2)(A)of the Act, and have no applicability to the requirement for assurances of adequate capacity in section 1932(b)(5) of the Act implemented in proposed § 438.110 and § 438.207 of this final rule with comment period. This final rule with comment period requires that assurances of adequate capacity be made at the time of contract approval and annually thereafter. We believe that it is essential that an adequate provider network be in place when beneficiaries are first enrolled in an MCO. The EQR activities are retrospective, that is, they take place after the fact and review for adherence to standards. While we believe that the EQR review is important, it is not an appropriate substitute for an assurance of adequate capacity.

Comment: We received a few comments questioning our proposal to eliminate part 434, subpart E from the regulations; specifically, the requirements under § 434.50(b) and § 434.52. Under § 434.50(b), a State was required to obtain proof from each contractor, of the contractor's ability to provide services under the contract efficiently, effectively, and economically. Under § 434.52, a State agency was required to obtain proof that each contractor furnished the health care services required by the enrolled recipients as promptly as is appropriate, and that the services met the agency's quality standards.

Commenters argued that these sections contain important consumer protections that should be maintained. Further, commenters asserted that the proposed rule no longer requires the State to obtain assurances that the services meet the State's quality standards, and only addresses the theoretical availability of services as opposed to whether the services are provided in a timely fashion.

Response: We believe that it would be confusing and redundant to retain these requirements. In part 438, we incorporate and expand upon the requirements previously set forth in subpart E of part 434. We disagree that the provisions in the proposed and this final rule with comment period no longer require a State to obtain assurances that an MCO's services meet the State's quality standards, and only address the theoretical availability of services. In this final rule with comment period, States must develop a quality assessment and improvement strategy that requires MCOs to meet State standards for access to care and to submit documentation demonstrating adequate capacity and services. In particular, we note that one of the access requirements is that MCOs adhere to the State's standards for timely access to care (§ 438.206(e)(1)).

7. Emergency and Post-Stabilization Services (§ 438.114)

Section 1932(b)(2) of the Act provides that each contract with an MCO or PCCM must require the MCO or PCCM—(1) to provide coverage of emergency services without regard to prior authorization, or the emergency care provider's contractual relationship with the MCO or PCCM; and (2) to comply with guidelines established under section 1852(d)(2) of the Act (with respect to coordination of post-

stabilization services) in the same manner as those guidelines apply to Medicare+Choice plans.

In proposed § 438.114, we set forth the rules implementing these emergency and post-stabilization requirements. We proposed definitions of emergency medical condition, emergency services, and post-stabilization services. We proposed to require MCOs to provide specific information regarding emergency and post-stabilization services to enrollees at the time of enrollment and annually thereafter. We also outlined proposed rules for coverage and payment of these services.

We interpreted the term ''coverage'' to mean that an MCO that pays for hospital services generally must pay for emergency services obtained by Medicaid enrollees. We interpreted coverage in the primary care case management context to mean that the PCCM must allow direct access to emergency services without prior authorization. We applied different meanings to the term ''coverage'' because while PCCMs are primarily individuals paid on a fee-for-service basis, they receive a State payment to manage an enrollee's care. We determined that while PCCMs, unlike MCOs, are not likely to be involved in a payment dispute involving emergency services, they could be involved in an authorization dispute over whether a self-referral to an emergency room is authorized without prior approval of the PCCM. Accordingly, proposed § 438.114(d)(2) provided that enrollees of PCCM are entitled to the same emergency services coverage without prior authorization as is available to MCO enrollees under section 1932(b)(2) of the Act.

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 services under Medicaid that are needed to evaluate or stabilize an emergency medical condition. Emergency medical condition is 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 bodily 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 were set forth in proposed § 438.114(a). The identical definitions appear in the Medicare+Choice rules at § 422.113(b) and therefore, to avoid duplication, we incorporate those definitions by reference in this final rule with comment period.

Comment: One commenter stated that no protections now exist to require MCOs to cover ambulance services. The commenter cited proposed § 438.100(b), which states that Medicaid contracts with MCOs, PCCMs, or PHPs must either provide for all Medicaid services covered under the State plan or make arrangements to furnish those services. The commenter asserted that ambulance services should be covered in this regulation based on the authority in § 440.170(a), which states that transportation is a Medicaid covered service.

Response: Section 440.170(a) applies to non-emergency transportation, which is an optional Medicaid service that States may choose to provide or not to provide. Ambulance services are not included in the definition of ''emergency services,'' as that definition refers to ''inpatient or outpatient services.'' If a State covers ambulance services under its State plan, and these services are included in an MCO's contract, then the MCO must cover the ambulance services under the same terms they are covered under fee-for-service Medicaid. We recognize that the Medicare program has separate statutory authority to cover ambulance transportation when other transportation may jeopardize an enrollee's health, and that the Medicare+Choice statute thus obligates Medicare+Choice organizations to cover them. We do not, however, have that same statutory authority in the Medicaid program.

Comment: We received a number of comments on the rules governing post-stabilization care. Some commenters objected to requiring pre-approval from MCOs, PHPs, or PCCMs for post-stabilization services. Others opposed requiring an MCO, PHP, or PCCM with a risk contract that covers post-stabilization services to pay for those services without pre-approval if the MCO, PHP, or PCCM does not respond within one hour after receiving the provider's request or cannot be contacted for approval. The commenters believe that the requirement is too burdensome and the time frame is too short for an MCO, PHP, or PCCM to make an informed decision. Others thought the time period was too long for emergency physicians who must keep track of patient condition and be responsible for the stability of the patient. Some commenters believed that our preamble definition of post-stabilization was inconsistent with the definition in the regulation. They noted that the proposed definition in the preamble better described ''maintenance care,'' and that it should not be used in place of the regulation definition.

Response: We acknowledge that the definition of post-stabilization in the preamble differed from that in the proposed regulations text, and that the preamble definition was not consistent with the Medicare+Choice definition that we are required to apply to Medicaid under section 1932(b)(2)(A)(ii) of the Act. We regret any confusion that this may have caused.

Under the Medicare+Choice definition at § 422.113(c)(1), post-stabilization care services means ''covered services, related to an emergency medical condition, that are provided after an enrollee is stabilized in order to maintain the stabilized condition, or * * * to improve or resolve the enrollee's condition.'' The Medicare+Choice rules create a two-step process for post-stabilization care. The first step occurs during the one-hour time frame, while the hospital waits for a response from the MCO. The second step occurs after the first hour. When the MCO receives a call from the treating hospital requesting prior authorization or transfer, the MCO has one hour to make a decision on a course of treatment, and respond to the treating hospital. During that one hour, the MCO is responsible for services related to the emergency medical condition that are necessary to maintain stabilization. Any period of instability that rises to the level of an emergency medical condition that occurs during this time would be covered under provisions at § 422.113(b) related to emergency services.

The rule further establishes that if the MCO fails to respond within the one-hour time frame, or the MCO cannot be reached, the treating physician can proceed with post-stabilization services that are administered not only to ensure stability, but also to improve or resolve the patient's condition. If a nonphysician MCO representative and the treating physician cannot reach an agreement on a course of treatment, the MCO must allow the treating physician to speak with a plan physician and the

treating physician may proceed with care administered to improve or resolve the patient's condition until a plan physician is reached.

The MCO is financially responsible for post-stabilization services until the MCO and the treating physician execute a plan for safe transfer of responsibility. Safe transfer of responsibility should occur with the needs and the condition of the patient as the primary concern, so that the quality of care the patient receives is not compromised.

Comment: Many commenters recommended that we broaden the definition of emergency services to include coverage of ''urgently needed'' services. The commenters believe that expanding the definition would allow enrollees more leeway in seeking care in an emergency department for conditions that may benefit from earlier intervention. Some commenters stated that this policy would create a margin of safety for enrollees who may underestimate the severity of their illnesses and delay care if only the prudent layperson standard applies.

Response: The Congress has defined the obligations of an MCO to cover services received outside of an MCO's network. While MCO's are obligated to cover emergency services and post-stabilization services, there is no counterpart under the Medicaid statute for the obligation under section 1852(d)(C)(i) of the Medicare statute to cover ''urgently needed services.'' This latter obligation generally applies only when an individual is out of the Medicare+Choice organization's service area, since it only permits services to be covered when they were not available through the organization's network. Since Congress in the BBA chose to obligate Medicare+Choice organizations to cover ''urgently needed services, but chose not to do so in the same law in the case of Medicaid-contracting MCOs' we believe it would be inconsistent with Congressional intent to impose an obligation on MCOs to cover urgently needed services received out of area.

Comment: One commenter noted that some MCOs used a retrospective utilization review process to accept or deny an emergency claim based on a professional assessment of the nature of the emergency. The commenter believes that this violates the prudent layperson standard.

Response: Retrospective utilization review does not necessarily conflict with the prudent layperson standard as long as the MCO (or the State) reviews all documentation, takes into account the enrollee's presenting symptoms and applies the prudent layperson standard in making its determination. If the retrospective review reveals that the enrollee acted in a manner consistent with the prudent layperson standard, the enrollee may not be held liable for any additional costs even if it turned out that the case did not present a clinical ''emergency'' (that is, even if it turned out that the reasonable belief of a ''prudent layperson'' was incorrect). Section 438.114(e)(2) of this final rule with comment period expressly states that an enrollee who has an emergency medical condition may not be held liable for payment of subsequent screening and treatment needed to diagnose the specific condition and stabilize the patient.

Comment: Many commenters were concerned that requiring MCOs, PHP, and PCCMs to provide a list of emergency settings and any other locations at which MCO, PHP, or PCCM physicians and hospitals provide emergency services covered under contract would imply that enrollees may not use any hospital or other proper setting for emergency care, but rather are limited to using participating hospitals. They suggested that we require that the list be accompanied by a clear statement of the enrollee's right to use any hospital or other setting for emergency care consistent with this section. One commenter requested that we prohibit MCOs from using lists of examples in their instructional materials of when it is inappropriate to use an emergency room because people with certain disabilities may require emergency treatment for some conditions that would not be emergencies for the general population.

Response: We agree with the first comment and have revised § 438.114(b) of this final rule with comment period to include as item (5) of the information that must be provided to enrollees and potential enrollees, the fact that, subject to the requirements of the section, the enrollee has the right to use any hospital or other setting for emergency care.

We believe that it is appropriate for MCOs, as well as States, to educate enrollees as to when they should or should not access emergency care. However, we have deleted the requirement that information provided to enrollees and potential enrollees include appropriate use of emergency services. States and MCOs can best determine how and when to provide this education to enrollees. Further, to monitor the appropriateness of the information provided, we encourage States to establish information requirements and review enrollee emergency information from MCOs before it is released.

Comment: Some commenters suggested that information regarding access to and availability of emergency and post-stabilization services should be available to potential enrollees upon request at any time, and this information should be posted prominently in emergency rooms and in providers' offices.

Response: We agree that potential enrollees should receive information regarding emergency care access. We have revised the introductory text of § 438.114(b) to require that the information be furnished to potential enrollees upon request. We encourage States, MCOs, PHPs, and PCCMs to disseminate information on access to enrollees as broadly as possible. We do not agree that we should require that this information be posted in emergency rooms as this is more appropriately provided by the State or the MCO, PHP, or PCCM.

Comment: Some commenters suggested that the MCO, PHP, or PCCM or State should be required to provide the enrollee with information regarding the education and board certification and recertification status of the health care professionals staffing the emergency departments in the enrollees' geographical region. They noted that under proposed § 438.10(f)(2)(ii), this information is provided only upon request. The commenters explained that in emergencies, the enrollee will not have time to choose which emergency department to use and that unless the enrollees have the information on the education and board certification and recertification status ahead of time, they will not be able to use these markers of quality in an emergency situation.

Response: Under section § 438.10, enrollees may request information from MCOs, PHPs, and PCCMs regarding education and board certification status of its participating health care professionals and hospitals. If enrollees are particularly concerned about these issues, they may request the information immediately upon enrollment so that they have it available before they need emergency services.

Comment: Some commenters believed that the regulations should prohibit MCOs from developing lists of ''symptoms'' and diagnoses for coverage of emergency services under the ''prudent layperson'' standard. In these commenters' view, the development of such lists is an attempt to establish plan-specific ''prudent layperson'' standards in the commenters' view, and could have the effect of vitiating legislative intent. They believe that lists should be expressly prohibited, and that the prudent layperson standard requires

review on a case-by-case basis that considers not only the patient's complaint, but also age and medical history. The commenters suggest revising the regulation to prevent the use of lists under the prudent layperson definition. If such lists are permitted, these commenters believe that MCOs should be required to conduct broad scale enrollee education regarding the list of symptoms for coverage of emergency services. One commenter suggested that we add the following language to § 438.114: ''What constitutes an emergency medical condition with reference to the definitions in paragraph (a) of this section cannot be limited by lists of diagnoses or symptoms, or by retrospective audits based on such restrictive emergency lists, including refusal by the MCO, PHP, or PCCM, to process any claim which does not contain the primary care provider's authorization number.'' Another commenter also stated that some MCOs require the primary care provider's authorization number to appear on filed claims in order to receive reimbursement, and that this conflicts with the prudent layperson standard

Response: We believe that the use of authorization codes in the payment approval process may be an effective and efficient way for a State, MCO, or PHP to avoid the need to apply the prudent layperson standard on a case-by-case basis, in that it can be assumed that the primary care physician has already done so. However, the absence of such an authorization cannot be used to deny an emergency room claim. Denials must be based on a case-by-case review applying the ''prudent layperson'' standard. We agree with the commenter's suggestion that this final rule with comment period should state what constitutes an emergency may not be limited ''on the basis of diagnoses or symptoms,'' and have included a provision in § 438.114(e)(1)(i) of this final rule with comment period. We also agree that the regulations should expressly state that coverage of emergency room services cannot be denied based on the fact that it does not contain the primary care provider's authorization number. This suggestion is reflected in section 438.114(e)(1)(ii) of this final rule with comment period. With respect to the question of ''retrospective'' audits, we have addressed this above, and believe that this is addressed in the regulations in § 438.114(d)(1)(ii)(A) that makes it clear that coverage cannot be denied because the symptoms turned out not to be a ''real'' emergency in the sense that health was really at risk in the sense a prudent layperson might reasonably believe it would be. This should not be construed as mandating States, MCOs, or PHPs to pay a claim if the hospital or other provider has not submitted the pertinent documentation within either reasonable, or where applicable, legal time frames.

Comment: One commenter believed that the provisions of proposed § 438.114(f) that requires the attending physician to determine when an enrollee is stable, is an important safeguard to ensure that the person most knowledgeable about the enrollee's current condition will make this determination. Others disagreed, stating that allowing the attending physician to be the sole person to determine when an enrollee is stabilized enough for transfer may undercut the MCO's ability to manage inpatient services and has potential for abuse. These commenters recommended allowing the attending physician's decision to come under retrospective review.

Response: Once an emergency medical condition is acknowledged, the emergency physician is in the best position to decide when stabilization is achieved. As noted above, section 1932(b)(1)(2)(A)(ii) of the Act requires that MCOs and PCCMs follow the ''post-stabilization'' guidelines established for the Medicare+Choice program under section 1852(d)(2) of the Act. The Medicare+Choice regulations state that the emergency physician decides when a patient is stable, and that this decision is binding on Medicare+Choice organizations. Because Medicare+Choice post-stabilization rules govern Medicaid, we would have no discretion to adopt a different rule for Medicaid even if we agreed with the commenter.

Comment: Commenters expressed concern that MCOs will argue that in some cases, coverage of screening is not covered under the definition of emergency services in proposed § 438.114, even in cases in which a screening is required under the Emergency Medical Treatment and Labor Act (EMTALA). These commenters contended that MCOs frequently refuse coverage, relying on their own definitions of reimbursable emergency services, when these definitions are more narrow than what the hospital is required to cover under EMTALA requirements. This policy places physicians and hospitals in the position of being legally obligated to render treatment for which they will not be paid. Some commenters recommend adding in the emergency services definition that ''evaluate or stabilize,'' includes those services required under EMTALA. One commenter recommended adding ''within the meaning of 42 U.S.C. 1395dd'' at the end of the emergency services definition at proposed § 438.114(a)(2), and adding preamble language that states that the MCO must ''pay for the cost of emergency services obtained by Medicaid enrollees.'' However, one commenter stated that under such a definition, an emergency condition exists if certain acute symptoms are manifested even though the underlying condition may not be an emergency. The commenter asserted that EMTALA requirements are expansive, and would result in more emergency room services being approved for payment. This commenter believed additional benefits to Medicaid beneficiaries are appropriate, but that unless additional funding is provided, expanding emergency services effectively creates an unfunded mandate for additional services for which an MCO will have to pay.

Response: The definition of emergency services includes the evaluation necessary to stabilize a patient with an emergency medical condition. We believe that all screening (beyond the initial routine procedures for example, checking blood pressure and, temperature) used to determine whether an emergency medical condition actually exists involve medical screens and tests that would have to be covered. We do not agree that MCOs should be required to cover any screening required under EMTALA. The Congress only required MCOs to cover services if the ''prudent layperson'' standard is satisfied. Under EMTALA, a hospital would have certain screening obligations even in a case in which the prudent layperson standard clearly was not met, but an individual nonetheless presented themself for treatment at an emergency room. Because the Congress limited an MCO's obligation to situations in which the ''emergency medical condition'' definition containing the prudent layperson standard is met, we would have no authority to require MCOs to pay for services when this definition is not met, even if EMTALA would require the hospital to incur costs. Under this regulation, MCOs may not refuse coverage by relying on their own definition of reimbursable emergency services if the prudent layperson standard is met, regardless of EMTALA.

We are not addressing the issue of additional funding for emergency services in this regulation. We note, however, that under § 438.6(c) all capitation rates paid under risk contracts must be actuarially sound and

appropriate for the services to be furnished under the contract.

Comment: Some commenters were concerned that States will attempt to obtain a waiver of the emergency services provisions in the BBA under section 1915(b) of the Act or section 1115 of the Act, and require prior authorization for emergency services. They recommend not allowing the emergency services section to be waived through section 1915(b) of the Act or section 1115 of the Act.

Response: We view access to emergency services using the prudent layperson standard as an important enrollee protection and we do not foresee a circumstance under which we would exercise our authority under section 1115 of the Act to permit an MCO to engage in prior authorization. We note that section 1915(b) of the Act only permits waivers of section 1902 provisions, and would not provide authority to permit prior authorization even if we were inclined to do so.

Comment: Some commenters recommended that we establish a central contact point at HCFAs central and regional offices where individuals and entities could direct inquiries regarding State and MCO or PCCM activity with respect to emergency services, establish a process for obtaining a timely remedy for these concerns, and clearly set out penalties that States or HCFA can impose for violations of the regulations and statute.

Response: The appropriate HCFA regional office should be contacted regarding any concerns about application of the emergency services provision of the regulation. In turn, our regional office will contact the central office should they need policy guidance. This is the regular procedure within HCFA and we believe it appropriate to follow it for these issues as well as all others. We note, with respect to penalties, that a failure to comply with the requirements in § 438.114 would constitute a failure to comply with section 1932(b)(2) of the Act, and would be sanctionable under § 438.700(d) of this final rule with comment period.

Comment: One commenter recommended stating in § 438.114 that copayments not permitted under fee-for-service may not be imposed for emergency services under managed care.

Response: Restrictions on copays in managed care are by statute, the same as for fee-for-service. This issue is addressed in the comments on § 438.108, which incorporates the fee-for-service limits on cost-sharing in § 447.50 through § 447.58.

Comment: One commenter believed that the provision of information that describes or explains what constitutes an emergency should be the responsibility of the State and should not be left to the MCO. The commenter recommended allowing States to provide information on what constitutes an emergency service. Others stated that the provision at § 438.114(b) requires States, MCOs, and PHPs to provide information annually, especially on post-stabilization because it is burdensome, unnecessary, and potentially confusing to enrollees. Others suggested removing the annual requirement or making information available upon request of the enrollee.

Response: We have revised § 438.114(b) to require that the information must be furnished by the State or at State option, by the MCO, PHP, or PCCM. We believe that States should be permitted to delegate this dissemination responsibility to MCOs, PHPs, or PCCMs. We do not believe that it is too burdensome to require this information, including post-stabilization requirements to be furnished on an annual basis and therefore, we have retained this requirement. We note that under the Medicare+Choice program, we also require that information regarding emergency services be provided annually.

Comment: One commenter believed that HCFA should include in the regulatory text, rather than just the preamble, a statement that MCOs must pay for the cost of emergency services obtained by Medicaid enrollees. Some commenters felt that the language in proposed § 438.114(e)(1)(i) was confusing, and did not make clear that MCOs must pay for treatment at facilities outside its network. They suggested replacing paragraph (i) with ''(i) An enrollee had an emergency medical condition as defined at § 438.114(a).'' However, some commenters disagreed, stating that the language clearly articulates the requirement to cover and pay for emergency services that meet the prudent layperson standard.''

Response: While we have not changed the policy, we have clarified the requirements in this section by revising paragraph (d) to state that the specified entities must cover and pay for emergency services regardless of whether the entity that furnishes the service has a contract with the MCO, PHP, or PCCM. In addition, we specify that the entities may not deny payment for treatment obtained when either—(1) 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 the definition of emergency medical condition, or (2) a representative of the MCO, PHP, or PCCM instructs the enrollee to seek emergency services. This paragraph also outlines the coverage and payment rules that apply to PCCMs not responsible for payment.

Comment: One commenter believed that paragraph (b)(6) concerning preauthorization was confusing. The commenter noted that ''prior authorization,'' ''pre-authorization,'' and ''pre-approved'' are used synonymously throughout the regulation and that we should choose one word to be consistent. They recommend revising (b)(6) to read, ''* * * but payment is required if the MCO does not provide prior authorization within an hour * * *'' and choose one word for prior authorization throughout.

Response: We agree with the commenter and have adopted the term ''prior authorization'' throughout the regulation. In addition, we have revised § 438.114(b) to add to the list of required information the post stabilization rules set forth at § 422.113(c) of the Medicare regulations. Proposed paragraph (c) (coverage and payment for post-stabilization services) has been replaced by a paragraph (f) that provides for coverage and payment ''in accordance with § 422.113(c) of this chapter.''

Comment: Some commenters urged that the regulation make clear that the attending physician determines the point at which prior authorization must be sought for post-stabilization services. One of the commenters recommended changing ''attending physician'' to ''emergency physician'' to clarify who is actually physically present caring for the patient.

Response: We agree with the commenters' point, and in this final rule with comment period at § 438.114(e)(3), we use the term ''attending emergency physician'' to describe who determines that the patient's condition is stable.

Comment: One commenter suggested replacing ''MCE physicians'' in proposed § 438.114(b)(4) with ''MCO, PHP, or PCCM providers'' to accurately reflect the full range of qualified health professionals.

Response: We agree with the commenter and have revised paragraph (b)(4) as suggested (as noted above, we have also replaced references to ''MCEs'' with references to all entities subject to the rule, in this case, MCOs, PHPs, and PCCMs). In addition, we are changing ''practitioner'' in proposed § 438.114(f) to ''provider'' in § 438.114(e)(3) of this final rule with comment period. However, we want to make clear that an

emergency physician must provide oversight to those providers who are not physicians.

Comment: Some commenters suggested striking the phrase ''with an average knowledge of health and medicine'' from the definition of emergency services at § 438.114(a). The commenters believe the phrase is ambiguous and likely to invite legal challenge because what is average in one community or culture may be different in another.

Response: The language referenced by the commenters is in the statute and therefore we have retained it.

Comment: Some commenters question the meaning of proposed § 438.114(c)(4), specifying the circumstances under which the State must pay for post-stabilization services not covered under an MCE (that is, MCO or PCCM) risk contract. The commenters recommend stating, ''if post-stabilization services are not covered by an MCO, PHP, or PCCM risk contract, the State must pay for all medically necessary services.''

Response: We agree with the commenters that the language in proposed § 438.114(c)(4) was confusing. We have replaced this section with a reference to the post-stabilization requirements in § 422.113(b) of the Medicare+Choice regulations. We note that if the hospital contacts the MCO, PHP, or PCCM for prior approval, and the MCO, PHP, or PCCM determines that it is not at risk for that specific service because it is not obligated to cover the service under its contract, then it should refer the hospital to the appropriate payer. For example, if a hospital contacts an MCO for prior approval for mental health services after the enrollee has been stabilized and the MCO contract does not include mental health services, then the MCO should refer the hospital to either the State or the appropriate PHP.

Comment: Many commenters believed that the prudent layperson standard is not easily adapted to non-medical conditions such as behavioral health which is not generally evaluated based on impairment of bodily function or dysfunction of a bodily organ or part. The commenters felt that individuals with mental health problems should have the same protections as others who may experience a medical emergency. Other commenters stated that the concept of ''danger to others'' inherent in many definitions of emergent behavioral health conditions is absent and arguably is not easily assessed by a person untrained in the assessment of behavioral health risks. They suggested separately defining urgent conditions as mental health crises that require immediate treatment to avoid hospitalization, and suggested establishing authorization criteria similar to post-stabilization criteria in the proposed rule. One commenter believed that both the ''danger to others'' and ''prudent layperson'' standards could be used simultaneously without violating the regulations. Other commenters suggested that the emergency medical condition definition encompasses mental illness as well as physical illness because it states ''* * * could reasonably expect the absence of immediate medical attention to result in placing the health of the individual in serious jeopardy * * *''

Response: We agree that the emergency medical condition definition using the prudent layperson standard pertains to mental health as well as physical health. We note that this is also the case with EMTALA. We believe that the reference to ''placing the health of the individual in serious jeopardy'' is sufficient to cover mental health emergencies.

8. Solvency Standards (§ 438.116)

Section 4706 of the BBA added new solvency standards to section 1903(m)(1) of the Act, requiring that an MCO's provision against the risk of insolvency meet the requirements of a new section 1903(m)(1)(C)(i) of the Act unless exceptions in section 1903(m)(1)(C)(ii) of the Act apply. Under section 1903(m)(1)(C)(i) of the Act, the organization must meet ''solvency standards established by the State for private health maintenance organizations'' or be ''licensed or certified by the State as a risk-bearing entity.'' The exceptions to this new requirement in section 1903(m)(1)(C)(ii) of the Act apply if the MCO—(1) is not responsible for inpatient services; (2) is a public entity; (3) has its solvency guaranteed by the State; or (4) is controlled by FQHCs and meets standards the State applies to FQHCs. Section 4710(b)(4) of the BBA provided that the new solvency standards applied to contracts entered into or renewed on or after October 1, 1998. Proposed § 438.116 essentially reflected these statutory provisions. In addition to the specific comments addressed below, we received many comments indicating general support for the implementation of the new solvency exceptions.

Comment: One commenter expressed concern that proposed § 438.116(c)(5), which would exempt MCOs with contracts entered into on or before October 1998, will lead to the lack of beneficiary protection in the event of insolvency in these plans. The commenter questioned whether this exemption applies to contracts in effect in 1998 as well.

Response: The BBA specified contracts entered into or renewed on or after October 1, 1998, as the effective date of the new solvency requirements. At this time, all contracts are subject to the new requirements. In this final rule with comment period, we have removed paragraphs (c)(5) and (c)(6).

Comment: One commenter asked if all MCOs, PHPs, and PCCMs must be licensed or certified as risk-bearing entities, and if carve-out services provided by PHPs would be considered ''public entities,'' and be exempt from the solvency standards.

Response: This section does not require that all MCOs, PHPs, and PCCMs be licensed or certified as risk bearing entities. First, the solvency requirements in this section are only applicable to MCOs and PHPs, not to PCCMs. While § 438.116(b)(1) provides that subject to certain exceptions, an MCO or PHP must meet the solvency standards established by the State for private HMOs, or be licensed or certified by the State as a risk-bearing entity. The commenter is correct that this requirement does not apply to MCOs that are public entities. With respect to carve-out services provided by a PHP, if the PHP is a public entity, it does not have to meet the private HMO solvency standards or be licensed or certified by the State as a risk bearing entity. However, the PHP would still have to make assurances satisfactory to the State that it has adequate provision against the risk of insolvency.

Comment: One commenter questioned whether in a subcontracting situation, the subcontractor would be subject to the solvency standards. The commenter noted that it is important for all entities serving Medicaid beneficiaries be solvent.

Response: We agree that it is important for all entities serving Medicaid enrollees to be solvent. We believe that the responsibilities of subcontractors and MCOs with respect to their subcontractors are adequately addressed in other sections. We note that § 438.6(l) provides that all subcontracts must fulfill the requirements of this part that are appropriate to the service or activity delegated under the subcontract. In addition, § 438.230 requires that the State ensure that each MCO oversees and is accountable for any functions and responsibilities that it delegates to any subcontractor. It also requires that each MCO monitors the subcontractor's performance on an ongoing basis and subjects the subcontractor to formal review ''according to a periodic

schedule established by the State, consistent with industry standards or State MCO laws and regulations.''

Comment: One commenter noted that under the Medicare+Choice regulations, MCOs are permitted to apply for a Federal waiver (preemption) from State solvency requirements if such requirements are more stringent that the Federal PSO requirements. The commenter suggested that in light of the availability of waivers in Medicare, Medicaid regulations should recognize that some PSOs are not going to meet State solvency requirements, and permit their participation in Medicaid managed care without meeting the State requirements.

Response: We do not have the statutory authority to exempt PSOs from the Medicaid solvency requirements in section 1903(m)(1) of the Act. The waiver authority in the BBA for PSOs that wish to enter into Medicare+Choice contracts BBA applies only to the Medicare program.

Comment: One commenter does not believe that Federally Qualified HMOs should be exempt from solvency requirements.

Response: Federally Qualified HMOs from solvency requirements are subject to detailed solvency requirements under title XIII of the Public Health Service Act and part 417 of this chapter. The commenter is correct, section 1903(m)(1)(A) of the Act provides that ''an organization that is a qualified health maintenance organization as defined in section 1310(d) of the Public Health Service Act is deemed to meet the solvency requirements in section 1903(m)(1)(A)(i) and (ii) of the Act.'' Since this exemption is set forth in the statute, we do not have the authority to change it. This comment has prompted us to recognize that we did not provide for this exemption in proposed, § 438.116, therefore, we have revised this final rule with comment period.

Comment: Several commenters asserted that the basic rule of this section was confusing with respect to the solvency requirements an MCO must meet.

Response: In response to this comment, we have revised § 438.116 to separate the ''basic rule'' from the ''other requirements'' that must be met as required under section 1903(m)(1)(C).

Comment: One commenter believed that proposed § 438.116(c)(2) which provides that the State solvency requirements in paragraph (b) do not apply if the MCO is a public entity, would mean that a county consortium would not need to meet the State's financial solvency requirements. The commenter asked if these Federal regulations preempt the State statute.

Response: Section § 438.116(b)(2) in this final rule with comment period (§ 438.116(c)(2) in the proposed rule) does not exempt public entities from all solvency requirements under Federal regulation. Section § 438.116(b)(1) specifies that unless an exception in paragraph (b)(2) applies, an MCO must meet the solvency standards established by the State for private HMOs or be licensed or certified as a risk bearing entity by the State. While paragraph (b)(2) exempts public entities from this requirement, under § 438.116(a), these entities must still make assurances satisfactory to the State showing that they have adequate provision against the risk of insolvency. States retain the flexibility to determine what assurances must be provided.

Comment: Several commenters supported the provision that exempts public entities from solvency standards imposed on private HMOs.

Response: While we acknowledge the support of this comment, we would like to reiterate that public entities are not exempt from all solvency standards. Public entities must still provide assurances satisfactory to the State showing that they have adequate provision against the risk of insolvency in accordance with § 438.116(a).

Comment: One commenter recommended that Federal requirements for capitalization should apply to all managed care organizations. In addition, the commenter suggested Federal and State governments should pre-approve all contracts with managed care organizations whose enrollees are primarily Medicaid insured, and require both Federal and State governments to guarantee provider payments if organizations become insolvent.

Response: We do not have statutory authority to establish Federal requirements for capitalization to guarantee payments to providers, or to require States to do so. However, under § 438.6 (Contract requirements), our Regional Office will review and approve all MCO and PHP contracts, and under § 438.806(b), prior approval by us is required for all MCO contracts with a value in excess of $1,000,000. While there is no Federal requirement that States guarantee provider payments, if, under § 438.116(b)(2)(iv), an MCO has its solvency guaranteed by the State, the State would be liable for all of the MCO's debts, including provider payments, if the MCO became insolvent.

Comment: One commenter noted that proposed § 438.116(c) provided that public entities are not required to meet the standards a State imposes on its private HMOs. The commenter questioned how this policy would affect a State that imposes the same or similar requirements on both private and public HMOs. In addition, the commenter asked if this provision applies to tribal governments.

Response: Even though public entities are not required to meet the solvency standards established by the State for private HMOs, public entities are still required to make adequate assurances satisfactory to the State that they have adequate provision against the risk of insolvency. States still have the flexibility to determine what assurances they consider adequate. Therefore, a State may require that public entities meet requirements that are the same or similar to those it imposes on private HMOs. With respect to tribal governments, if the MCO operates outside of the reservation, State solvency standards apply. But a State does not have jurisdiction to impose solvency standards on an on-reservation tribal MCO as a general operating condition.

Comment: One commenter expressed concern that we intend to accept State solvency standards rather than imposing Federal solvency standards.

Response: We do not have statutory authority to require a Federal solvency standard because the BBA specifically provides for State flexibility in this area.

D. Quality Assessment and Performance Improvement (Proposed Subpart E Recodified as Subpart D)

Background

Section 4705 of the BBA created section 1932(c) of the Act, paragraph (1) which requires State agencies that contract with Medicaid MCOs under section 1903(m) of the Act to develop and implement quality assessment and improvement strategies. Proposed subpart E (recodified as subpart D in this final rule with comment period) implemented section 1932(c)(1 of the Act), and set forth specifications for the quality assessment and performance improvement strategies that States must implement to ensure the delivery of quality health care through contracts with MCOs and (where applicable) PHPs.

Proposed § 438.302 established standards for State contracts with MCOs and PHPs, and required that each State must have a strategy for continually monitoring and evaluating MCO and PHP compliance with those standards. Proposed § 438.304 set forth minimum elements required in each State's quality improvement strategy. Proposed § 438.306 set forth standards for

availability of services addressing: (1) Beneficiary choice of entities; (2) services not covered by the MCO or PHP; (3) the MCO or PHP delivery network including: assurance of adequate capacity and services; the right to access to a women's health care specialist; credentialing requirements; 24 hour, seven day per week access; and convenient hours of operation; (4) coordination of care including screening and assessment; (5) procedures designed to identify and treat pregnancy and complex and serious medical conditions, and (6) a cultural competency requirement.

Proposed subpart E also contained rules regarding coverage and authorization decisions (proposed § 438.310), provider selection (proposed § 438.314), enrollee information (proposed § 438.318), enrollee rights (proposed § 438.320), confidentiality and accuracy of enrollee records (proposed § 430.324), and enrollment and disenrollment requirements (proposed § 438.326).

Additionally, proposed § 438.328 required an effective grievance system that meets the requirements of subpart F of this part; and proposed § 438.330 provided for oversight and accountability by the MCO or PHP of functions and responsibilities delegated to subcontractors.

Proposed § 438.340 required that MCOs and PHPs have an ongoing quality assessment and performance improvement program for the services it furnishes to enrollees; that the performance improvement programs achieve any minimum performance levels required by the State; and that the MCO or PHP achieves significant 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. The State also would be required under proposed § 438.336 to ensure that each MCO and PHP uses practice guidelines meeting specified criteria and under proposed § 438.342 to maintain a health information system that collects, analyzes, integrates, and reports data on the achievement of the objectives of this subpart.

1. Scope (Proposed § 438.300)

Proposed § 438.300 set forth the scope of subpart E.

Comment: Several commenters found the provisions in subpart E on Quality Assessment and Performance Improvement to be overly prescriptive. One commenter believed that the lack of flexibility would prevent States from accommodating new approaches and standards in a rapidly changing marketplace. One commenter contended that the provisions do not make allowances for resource limitations of States, while another suggested that the provisions of this part are unnecessary because of our review and approves MCO contracts.

Response: We understand the concern that this rule establishes substantial new requirements for States, MCOs, and PHPs. However, we believe that these provisions are important beneficiary protections, and reflect the intent of the Congress in enacting the quality and beneficiary protections of the BBA. As required by a directive from President Clinton, we also sought to incorporate the provisions of the Consumers Bill of Rights wherever permissible under our legal authority. When drafting the proposed rule, we spoke to States as well as representatives of beneficiaries to inform ourselves as to their views. We then tried to strike an appropriate balance that would reflect the Congressional intent, but also maintain flexibility for States, where possible, and avoid unreasonable burden and costs on MCOs and PHPs. Public comment on the proposed rule provided us an additional opportunity to hear the opinions of stakeholders. In this final rule with comment period we make many of the changes suggested by commenters.

Comment: Several commenters believed that these regulations would discourage or prevent State innovation in designing managed care programs, especially as States would fear the loss of Federal financial participation.

Response: We hope that these regulations will not have the effect of discouraging State innovation in managed care, because we recognize the important contributions made by States who have led the way in the past. We will continue to encourage and support State innovation in the future. However, we believe that a formal approach to quality assessment and improvement is an essential component of all successful health care delivery programs, including managed care programs, and that it is appropriate to incorporate such formal quality approaches into Medicaid managed care programs. We note that the approaches to quality assessment and improvement that are contained in this regulation are consistent with quality measurement and improvement activities currently in use throughout the health care industry

Comment: Several commenters contended that the quality provisions of subpart E are so burdensome to MCOs that this will discourage their participation in Medicaid managed care.

Response: We are concerned that some MCOs have decided to leave the Medicaid market and we have seriously considered the burden these regulations carry as we developed this final rule with comment period. While we have made some changes in recognition of this burden, we must balance this concern with beneficiary concerns raised by numerous commenters. This is especially important because the Medicaid population includes many individuals with special health care needs.

Comment: One commenter stated support for the comprehensive quality assessment framework of the proposed rule.

Response: We believe that the statute intends that State quality strategies be sufficiently broad to ensure a high quality of care for Medicaid managed care enrollees. This is the reason why we proposed a comprehensive strategy, and are retaining it in the final rule with comment period.

Comment: Several commenters discussed the provision of the BBA that requires us to conduct a study of the protections (if any) that may be needed when enrolling individuals with special health care needs into managed care. The commenters believed that we should have begun the study promptly following enactment of the BBA so that the results of the study could be reflected in the final rule with comment period.

Response: The research, analysis, and writing of this BBA-mandated study was underway during the public comment period for the proposed rule. As a result, in analyzing and responding to the comments, we were able to consider the comments in light of the findings and evidence resulting from this study. While we believe that the proposed rule addressed the needs of all Medicaid enrollees, including those with special health care needs, we have made revisions to the proposed rule in response to comments that have been informed by the findings in the BBA special needs study.

Comment: Numerous commenters raised questions about the relationship of the requirements of subpart E to our standards and guidelines for Medicaid and Medicare managed care organizations contained in our Quality Improvement System for Managed Care (QISMC) document. Several commenters interpreted the regulation to incorporate QISMC requirements. One commenter contended it was unrealistic to expect a small State to implement QISMC without allowing for incremental implementation over an extended period of time. Another

commenter suggested that the regulation should require the use of QISMC, and that QISMC should be modified and strengthened by incorporating ideas contained in our document titled ''Key Approaches to the Use of Managed Care Systems for Persons with Special Health Care Needs.'' Another commenter asserted that not requiring States to use QISMC for Medicaid, when we are using it for Medicare, discriminates against Medicaid beneficiaries. Another commenter asked how future improvements to QISMC will be incorporated into the regulations. Another commenter asked how we will review State strategies when States choose not to use QISMC. One commenter felt that QISMC was inadequate to improve the health care provided to vulnerable populations.

Response: All these comments reflect some confusion about the relationship of this BBA regulation to QISMC. The quality provisions of the BBA regulation and QISMC are similar, but not identical.

In 1996, before the BBA was enacted, we began an initiative that aimed, in part, to—

- Develop a coordinated Medicare and Medicaid quality oversight system that would reduce duplicate or conflicting quality requirements for Medicaid and Medicare managed care and send a uniform message on quality to managed care organizations and beneficiaries; and
- Make the most effective use of existing quality measurement and improvement tools, while allowing sufficient flexibility to incorporate new developments in the rapidly advancing state of quality measurement.

This initiative was QISMC. The most prominent products of the QISMC initiative were standards and guidelines for Medicaid and Medicare-contracting MCOs. For Medicaid, these standards updated and replaced earlier standards sent by us to States as part of the Quality Assurance Reform Initiative (QARI). The QARI standards were provided to States as technical assistance tools for their discretionary use although most States with MCO contracts used them, in part or in whole. QISMC was intended to replicate the success of QARI, in part by disseminating revised standards that reflected advances in private sector accreditation standards, as well as advances in quality measurement and improvement in both the public and private sectors.

After the BBA was passed in 1997, our development of the regulations to implement the quality assessment and improvement provisions of the law was informed by our prior work in developing QISMC. From the QISMC work, we identified those fundamental activities that formed the essence of quality measurement and improvement. These activities and standards were revised as necessary to reflect a level of detail appropriate for regulations and included in our proposed rule. For this reason, many of the regulations implementing the BBA quality provisions reflect QISMC standards. However, while QISMC was developed as a set of standards that address MCOs and PHPs, the legal requirements set forth in this final rule with comment period address States as well as MCOs and PHPs.

QISMC has been offered to States as a tool to use to the extent the State wishes, as long as the State complies with the requirements in this final rule with comment period. While full compliance with QISMC would help satisfy the quality requirements in subpart D that were based in part on QISMC standards, a State may meet the minimum standards in the regulation without requiring the use of QISMC. If a State requires MCOs and PHPs to follow QISMC, this will promote compliance with the regulatory requirements that overlap the QISMC standards. However, compliance with QISMC is not sufficient to meet all the provisions of the regulation because this regulation includes a much broader range of topics than is covered by QISMC. For the foregoing reasons, we will not use QISMC to monitor States, but rather monitor against the regulatory requirements.

Comment: Several commenters questioned the relationship of Medicaid quality provisions and those used by private accrediting organizations for the commercial managed care market. Two commenters suggested that private sector standards be used for Medicaid, either at State direction or through deeming. Another commenter recommended against use of private sector standards because he believes that they are geared to a generally healthy population while the Medicaid population includes populations with special health care needs.

Response: The Medicare+Choice statute, at section 1852(e)(4) of the Act, provides authority for Medicare+Choice organizations that are reviewed by private accreditation bodies to have a broad range of Medicare+Choice requirements ''deemed'' satisfied based on such private accreditation (if the private accreditation body applies standards at least as stringent as Medicare's). This authority includes the authority to ''deem'' compliance with QISMC standards, which is mandatory for Medicare+Choice organizations. There is no comparable broad deeming authority provided for MCOs or PHPs under the Medicaid statute. The only Medicaid authority for ''deeming'' by private accreditation bodies relates to the deeming of external review requirements under section 1932(c)(2)(A) of the Act. This rulemaking does not address these requirements, or provisions for the deeming of these requirements in section 1932(c)(2)(B) and (C) of the Act. These are being addressed in a separate rulemaking, in which a notice of proposed rulemaking was published on December 1, 1999, 64 FR 67223.

Comment: Several commenters questioned the applicability (or non-applicability) of subpart E to entities other than MCOs. One commenter agreed with applying the provisions of this subpart to PHPs. Another commenter suggested that we extend these requirements to all MCEs, including PCCMs. Another commenter suggested that the provisions of subpart E not be applied to capitated PCCMs. Lastly, another commenter suggested that PHPs be excluded from external quality review, because the commenter believed that this imposes an undue burden on States for contracts that are limited in scope.

Response: In section 1932 of the Act, the Congress included provisions that apply to all MCEs (that is, to MCOs and PCCMs), provisions that apply only to MCOs, and provisions that apply only to PCCMs. Since the Congress thus addressed PCCMs in section 1932 of the Act, we believe that where it applied a requirement only to MCOs, this reflects a clear and expressed intent that the requirement not apply to PCCMs. We therefore are not applying the regulations implementing section 1932(c)(1) of the Act to PCCMs. With respect to PHPs, as we have noted above, the Congress was silent, in section 1932 of the Act and its legislative history, concerning what requirements should be applied to these entities. At the time the Congress acted, we had longstanding regulations in place applying selected section 1903(m) of the Act requirements to PHPs. We believe that given that PHPs are paid on a risk basis, the concerns that caused the Congress to impose the quality requirements in section 1932(c)of the Act on MCOs apply with equal force to PHPs, and that the extension of these requirements to PHPs under our authority in section 1902(a)(4) of the Act is appropriate. With respect to the comment on risk-based PCCMs, they are not subject to these requirements by virtue of their status as PCCMs, since as

we have just noted, we are not imposing these requirements on PCCMs. Rather, as a risk contractor, they also meet the definition of PHP, and are subject to these requirements by virtue of their status as PHPs. Only PCCMs that fall in both categories would be subject to the requirements in subpart D.

Comment: Several commenters questioned the relationship of the quality provisions to waiver approval requirements. One contended that the relationship is unclear and duplicative. Another questioned if waivers of any of the quality provisions will be approved in light of the proposed rule's preamble language which states that waivers will only be granted if the quality requirements in this regulation are met or exceeded.

Response: We believe that the BBA quality requirements that are addressed in this subpart should apply to managed care provided through MCOs and PHPs regardless of the authority used to establish these programs. Quality is equally important whether the managed care program is established through a waiver granted under section 1115 or 1915(b) of the Act or as a State plan amendment under section 1932(a) of the Act. Therefore, generally, States will be required to follow these provisions as a condition for approval of a waiver. However, the Secretary has the discretion to waive these requirements if quality is addressed in the waiver program in a manner that equals or exceeds the quality requirements contained in this subpart. We believe that to do less would deny beneficiaries important protections and be counter to Congressional intent.

Comment: One commenter believed that the most important quality standard for persons with disabilities is that these individuals be served in the least restrictive setting, and that the standard for outcomes should include the achievement of the highest level of functioning for each individual.

Response: We agree that it is important to serve persons with disabilities in the setting that they desire. We further agree that achievement of the highest level of functioning is a desirable outcome for this population. This is consistent with the provisions of the proposed regulation. However, we are not specifying in the regulation particular performance measures for any of the populations served by the Medicaid program. The strength of each particular performance measure is dependant upon the specifications for calculating the measure. Performance measure specifications typically change over time as information systems, coding, survey instruments and other methods of data collection change over time. For this reason, we do not believe it is appropriate to establish specific performance measures in regulation.

Comment: One commenter noted that the proposed rule only addresses requirements that States and MCOs must meet, and suggested that these requirements will be effective in improving the quality of health care only if they are acted upon by external sources.

Response: Subpart D of this final rule with comment period interprets and implements section 1932(c)(1) of the Act and sets forth required quality standards. We agree that these new provisions must be executed well to have the desired impact of improving the health care provided to Medicaid beneficiaries. In this regard, States play a key role. They establish the provisions of MCO and PHP contracts and are primarily responsible for ensuring that the regulatory requirements are effectively implemented by MCOs and PHPs. We are responsible for overseeing the States' adherence to these rules. To this end we have revised, and will be further revising (based on this final rule with comment period), protocols that HCFA Regional Offices use to monitor State compliance with statutory and regulatory requirements.

Comment: Several commenters questioned the consistency between Medicaid and Medicare quality requirements. One suggested that the Medicaid requirements should be the same as those for Medicare. The other commenter suggested that the Medicaid subpart be reworked because it is not appropriate to apply the Medicare standards to Medicaid due to differences in the populations covered by each program.

Response: As stated in the introduction, the proposed Medicaid rule is consistent with the Medicare+Choice regulations wherever we believe it is appropriate. We believe that quality provisions should be consistent for all of our programs unless the statutory requirements differ, or program or population differences necessitate different standards. In creating this consistency, we carefully considered the needs of both Medicaid and Medicare beneficiaries and, where possible, proposed quality provisions that meet the needs of both. We believe that this approach best meets the needs of our beneficiaries (many of whom are eligible for both programs), and reduces burden on MCOs that contract with both programs. In subpart D, the regulatory requirements are consistent with those that apply to Medicare+Choice organizations. As noted above, however, under Medicare, Medicare+Choice organizations are all required to comply with QISMC, while States have the option of using all or part of QISMC in the case of Medicaid-contracting MCOs and PHPs.

Comment: Several commenters suggested that particular quality measures be incorporated into the regulation. One commenter wanted to ensure use of quality standards for patients with end stage renal disease, including a specific standard identified by the commenter. Another commenter suggested that all States measure quality against objectives contained in ''Healthy People 2000 and 2010,'' publications of the Department of Health and Human Services that outline a comprehensive health promotion and disease prevention agenda for the nation. Another commenter suggested that we establish, for children and adults with disabilities, a distinct set of quality standards (that is, performance levels) to ensure that these persons obtain the quality health care and health-related services necessary for them to lead full lives.

Response: We do not believe that particular quality measures should be specified in the regulation. Performance measures and quality standards change over time and it is important that the most current and useful measures can be quickly adopted. However, in response to these comments we have added a provision at § 438.204(c) that requires States to use performance measures and levels prescribed by us, as part of their State quality strategy. We also have provided in § 438.240(c)(2)(ii)(A) of the final rule with comment period that States must require their contracting MCOs and PHPs to meet these specific performance levels. This allows us to establish performance measures and levels for subsets of the Medicaid population, such as persons with end stage renal disease or other disabilities. We plan to use performance measures and levels that are widely accepted, standardized, and have undergone validity and reliability testing. At the present time, we are not aware of large numbers of such measures specific to persons with disabilities such as end stage renal disease that would meet these requirements. However, we expect measures to be developed over time that will meet these criteria. In the meantime, in response to the comment concerning the disabled population, we have added a new § 438.240(b)(4) to require States to have procedures to identify enrollees with special health care needs and to assess the quality and

appropriateness of care provided to these individuals. Also in response to this comment, we have in § 438.204(e)(2) required that the number of MCO and PHP enrollees with special health care needs be reported to us. The identification of these individuals and the assessment of their care and services is an essential step in assuring high-quality health care for them. We note that we also provide, in § 438.240(c)(1), for States to specify performance measures for their MCOs and PHPs to support quality improvement.

Comment: Several commenters suggested that we establish quality performance levels for States and MCOs.

Response: We agree with these commenters, and in response to these comments, and as noted above, we have added a new § 438.204(c) that requires that State quality strategies include our-prescribed performance measures and levels that States must require their MCOs and PHPs to meet. We believe that by requiring States to require their MCOs and PHPs to meet a specified level of performance on specific measures, we are carrying out its responsibility to ensure quality in the Medicaid program. We intend to use widely-recognized measures and establish levels through a public process, or based on statutory requirements. We have retained the States' authority to set minimum performance levels for MCOs and PHPs.

Comment: Several commenters suggested that States and MCOs be required to have vision and mission statements.

Response: We do not agree that it is essential for each State and MCO to have a vision and mission statement to support its quality strategy, nor do we believe it would be appropriate for us to mandate such a statement. While this approach can be an effective management tool, we believe that States should have the discretion to decide whether to adopt this approach, as long as they meet the elements for a comprehensive quality strategy set forth in this final rule with comment period.

Comment: Several commenters suggested that State quality strategies be required to address all statutory and regulatory requirements, not only those addressed in subpart E.

Response: We believe that the scope of this subpart is sufficiently broad to include the wide range of areas related to quality. We note that none of the commenters provided any specific examples of additional areas that they believe would be appropriate for inclusion. Therefore, we are not broadening the scope of the State quality strategy beyond the areas covered in the proposed rule.

2. State Responsibilities (Proposed § 438.302)

Proposed § 438.302 set forth the State's responsibilities in implementing its quality strategy. Specifically, § 438.302 required that each State: (1) have a strategy for assessing and improving the quality of services provided by an MCO and PHP; (2) ensure compliance with standards established by the State agency; and (3) conduct regular, periodic reviews to evaluate the effectiveness of its strategy, as often as the State agency determines appropriate, but at least every 3 years.

Comment: We received a large number of comments suggesting that the regulation require States to involve stakeholders in the development of their quality strategies, as is recommended in the preamble to the proposed rule. One commenter suggested that the Medical Care Advisory Committee perform this function. Another commenter suggested that the proposed State quality strategy should be published and comments from the public should be considered before the plan is made final.

Response: As stated in the preamble of the proposed rule, we expect that State agencies will consider the input of stakeholders when developing performance goals that are clear, fair, and achievable. We also believe that it is reasonable and appropriate for States to consider the ideas of stakeholders and other members of the public in the design of their quality strategies. Therefore, in response to this comment, and earlier comments on § 438.110 discussed in section II. C. above, in § 438.202(c) of the final rule with comment period we require States to provide for input of beneficiaries and other stakeholders regarding their quality strategies, and specifically, to make the strategies available to the public before adopting them. We do not specify what process States must use to obtain public input, because we wish to allow States flexibility to structure this process as they find appropriate. For several years, States with section 1115 demonstration projects have been required to have a process for public input. States with 1115 demonstrations may want to use this process for receiving comments on their quality strategy or choose another process.

Comment: Several commenters suggested that we add more specificity to the requirement for a State quality strategy. Most of the commenters suggested that the regulation should require that the strategy be put in writing. Two commenters suggested that standards be established to measure the success of the strategy. One commenter suggested that we incorporate in the regulation the language contained in the preamble that the strategies should be ''well considered,'' ''well coordinated,'' and ''overarching.'' Another commenter suggested that the regulation require State strategies to address all statutory and regulatory standards, identify each component of the strategy, address how the components are coordinated, ensure adequate monitoring and oversight, and be effective.

Response: We agree that the State quality strategies should be in writing, and in response to this comment, we are including this requirement in the final rule with comment period, in § 438.202(b). We believe that this new requirement, along with the requirement at § 438.202(c) that States consider the input of stakeholders in the design of their strategies, the requirement at § 438.202(e) that States conduct periodic reviews of the effectiveness of their strategy, and the requirement in § 438.204(g) that the State strategy include standards at least as stringent as those set forth in subpart D, provide the best mechanisms to ensure that the strategies will (1) be well considered, well coordinated, and overarching; (2) identify each component of the strategy and how components are coordinated; and (3) be effective. Therefore, we have not added the specific requirements suggested by the commenter to the regulation.

Comment: Several commenters considered the proposed maximum three year period between State reviews of the effectiveness of their quality strategies to be too long. The commenters instead suggested an annual review of MCO or PHP compliance with contract requirements. One commenter believed that the three year time period was inconsistent with QISMC requirements, and certification and licensing procedures. Another commenter expressed support of the three year time frame.

Response: The commenters who objected to the three year maximum period between reviews of the State quality strategy appear to have misunderstood the intent of § 438.202(e). Section 438.202(e) does not apply to State review of MCO and PHP compliance with contracts, but to review of the effectiveness of the *State's* quality strategy. State monitoring and review of MCOs and PHPs is addressed, in the context of the State's quality strategy, in § 438.204(b)(2), which requires States to continuously monitor and evaluate MCO and PHP compliance with the standards specified in the

subpart. The evaluation of the State's quality strategy under § 438.202(e) is intended to be a broad review of the interrelationship of all the elements that the State is required to include in its quality strategy to determine the effectiveness of this strategy as a whole. We believe it is particularly important for States to step back and review the ''big picture'' at least every three years because the field of quality review and measurement is rapidly evolving, making it important for States to reassess their approach at regular intervals. Requiring periodic review on a more frequent basis may not provide the State with sufficient time to effectively implement its strategy. For this reason, we are retaining the provision requiring review at least every three years.

Comment: Several commenters suggested that the final regulation require that beneficiaries be provided information about the State quality assurance program and MCO and PHP quality. In particular, the commenters wanted enrollees and potential enrollees to receive information on quality indicators, quality improvement topics, external review results, compliance audits, summarized complaint and grievance data, and disenrollment counts.

Response: We agree that beneficiaries, upon request, should have access to information concerning the State quality strategy and MCO and PHP performance. In § 438.202(b) and (c) of the final rule with comment period with comment period we require that the States' quality strategies be in writing and that stakeholders have an opportunity to make suggestions and comment on the strategy. We believe that this requirement will also serve the purpose of ensuring that beneficiaries can obtain information on that strategy. Section 438.10 of the regulation specifies what information must be furnished to enrollees and potential enrollees by the State, the MCO or PHP, and the enrollment broker. For MCOs, PHPs, and as appropriate PCCMs that enroll beneficiaries under a State plan program under section 1932(a) of the Act, this includes quality and performance indicators that can be used to compare plans. In addition, the proposed rule implementing the external quality review (EQR) requirements in section 1932(c)(2)of the Act, published in the **Federal Register** on December 1, 1999 (64 FR 67223), identifies EQR results that it proposes must be made available to enrollees. We believe that these requirements will ensure that enrollees and potential enrollees have access to information that will enable them to compare the performance of MCOs and to make an informed choice.

Comment: One commenter suggested that we add a new paragraph to proposed § 438.302 that would require that State strategies address all covered services, including midwifery services.

Response: We do not believe it is appropriate to specify that all covered services be included, since all covered services may not be included under an MCO or PHP contract. We also believe that the existing regulations already cover all services that are covered under the contract, as § 438.202(a) refers to ''managed care services offered'' by MCOs and PHPs. This would include any services they offer. Under § 438.206(c) of the final rule with comment period, the State is responsible for making available to the enrollee any Medicaid service not covered under the MCO or PHP contract, and these thus would not be included in an MCO or PHP quality strategy.

Comment: One commenter believed that furnishing quality oral health services requires planning and treatment decisions that are made by the dentist and the patient together.

Response: We agree with the commenter, and believe that the final rule with comment period addresses this issue. Paragraphs (b)(5) and (b)(6) of § 438.100 (previously designated as § 438.320(b)(4) and (5) in the proposed rule) specify the right of enrollees to receive information on available treatment options, and to participate in decisions regarding their health care.

Comment: One commenter asked what criteria we will use to review and evaluate State quality strategies.

Response: Since the requirement that States develop and follow State strategies is new, we have no experience with reviewing and evaluating these strategies. In response to the commenter's concern, however, we have added a new paragraph (f) to § 438.202 requiring States to submit to us a copy of their initial strategies and all significant revisions thereafter. We also in paragraph (f)(2) specify that States must regularly report to us on the implementation and effectiveness of their strategies.

3. Elements of State Quality Strategy (Proposed § 438.304)

Proposed § 438.304 set forth the minimum elements of a State quality strategy, including contract provisions that incorporate the standards specified in this subpart. Specifically, quality strategies would include procedures for assessing the quality and appropriateness of care and services provided, including but not limited to: (1) contract provisions that incorporate the standards specified in this subpart; (2) procedures for assessing the quality and appropriateness of care and services, including, but not limited to continuous monitoring and evaluation of MCO and PHP compliance with the standards; (3) annual, external independent reviews of quality outcomes, and timeliness of, and access to services covered under each MCO and PHP contract; (4) appropriate use of intermediate sanctions that at a minimum, meet the requirements in subpart I; (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, for access to care, structure and operations, and quality measurement and improvement. In developing a strategy, we communicated our expectations that each State 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.

Comment: As proposed, § 438.304 required States to ''continuously monitor'' MCO and PHP compliance with the quality standards. Many commenters urged that we revise this requirement. Several commenters suggested that the regulation require an annual audit of each MCO for compliance with the standards; that the requirement include monitoring of grievances and logs of calls to beneficiary ''hotlines''; and that a medical records review be required of catastrophic events, random records, and persons with disabilities. Other commenters suggested replacing the continuous monitoring requirement with a more flexible standard related to the MCO's or PHP's contract cycle or to the need for monitoring based on the plan's performance.

Response: We continue to believe that States should be required to continuously monitor and evaluate MCO and PHP compliance with quality standards. States may choose, as part of their quality strategies, to conduct a comprehensive audit of MCOs and/or PHPs on an annual or other basis, but this should not relieve them of the ongoing responsibility to ensure that MCOs and PHPs are meeting the standards at all times. States are in the best position to decide how best to accomplish this activity and may vary their requirements according to their knowledge of particular MCOs and

PHPs. We believe the requirement in § 438.416(d) requiring MCOs and PHPs to submit to the State summaries of their handling of grievances and appeals is sufficient to address the comments regarding monitoring of grievances. However, we have not required MCOs and PHPs to have a ''hotline'', therefore, including a monitoring requirement for hotlines would not be appropriate. With respect to medical records, we do not believe that we should specify what records States should review or the frequency with which they should perform review. Rather, we believe that this should be left to States to determine as part of their overall quality strategies. With respect to persons with disabilities, we have added new requirements for monitoring. New § 438.204(b)(1) requires States, as a part of their quality strategies to have procedures to identify, and assess the quality and appropriateness of care furnished to, enrollees with special health care needs.

Comment: One commenter suggested that, as part of the State quality strategy, States should be required to evaluate the effectiveness of services provided to beneficiaries with limited English proficiency. Another commenter suggested that States should collect and analyze data on cultural competency. This commenter further suggested that States conduct demonstration projects related to cultural competency to better understand this new and critical area of quality assessment.

Response: We agree that in order for States' MCOs and PHPs to effectively address cultural competency, they all must have basic information on the cultural characteristics of their Medicaid enrollees. We therefore have revised § 438.204(b)(1) of the final rule with comment period to require States, as a part of their quality strategies, to include procedures to identify the race, the ethnicity, and primary language spoken of each MCO and PHP enrollee and to provide this information to each MCO and PHP at the time of each Medicaid beneficiary's enrollment in the MCO or PHP. Further, § 438.306(e)(4) of the proposed rule has been modified as § 438.206(e)(2) of the final rule with comment period to require the State to ensure that each MCO and PHP provides services in a culturally competent manner to all enrollees, including those with limited English proficiency and diverse cultural and ethnic backgrounds. This means that, as part of its quality strategy, the State must monitor and evaluate the effectiveness of these provisions. We would welcome State demonstrations or other strategies to develop effective means of evaluating cultural competency in the provision of services.

Comment: Several commenters recommended that we add a State quality strategy element requiring the State to have an information system capable of managing the data that MCOs are required to report under proposed § 438.342. Another commenter stated that the regulation should require compatibility between the MCO's and the State's information systems.

Response: Section 438.204(g) of the final rule with comment period includes, as an element of the State quality strategy, that the State provide for ''structure and operations'' standards (among other standards) at least as stringent as those of this subpart. Because the health information systems requirement is included in the subpart, it is unnecessary to add this as an element of the State quality strategy. Likewise, the information systems requirements in § 438.242 are sufficient. While this section does not specify that MCO and PHP systems must be compatible with those of the State, we believe that it is in the State's best interest to require this. If a State chooses not to impose this requirement on an MCO or PHP, the State remains responsible for obtaining from the MCO or PHP the information specified in § 438.242 and incorporating into its information system. Some States may choose this option for MCOs or PHPs that need time to acquire a compatible system or to modify an existing system to make it compatible.

Comment: Numerous commenters requested information concerning the EQR element of the State quality strategy. Several commenters felt that requiring States to review quality outcomes, timeliness, and access to care under the EQR would be expensive and excessive; and that therefore, review of all three of these areas should not be required annually. One commenter suggested that States should be allowed to conduct an in-house review. Another commenter believed that well performing MCOs and PHPs should not be required to undergo an annual review. One commenter wanted additional information about how EQR fits into the State quality strategy and QISMC. Another commenter suggested that we should establish criteria for EQR organizations. One commenter suggested that we publish interim standards for EQR that would allow States to access the 75 percent matching rate established by the BBA.

Response: As noted above, on December 1, 1999, we published in the **Federal Register** a proposed rule to implement the BBA provision that requires an annual, external independent review of the quality outcomes and timeliness of, and access to, services covered under each MCO contract. 64 FR 67223. This proposed regulation includes information that will address the comments made concerning § 438.304(c) of the proposed rule. The statute requires that we contract with an independent quality review organization to develop protocols to be used in the reviews. That work is now underway. Until that work is completed, we cannot publish standards to permit States to access the 75 percent matching rate provided by the BBA. We note, however, that States may currently receive a 75 percent Federal match under section 1903(a)(3)(c) of the Act for EQR activities conducted by Peer Review Organizations (PROs) and entities that meet the requirements for contracting as a PRO.

Comment: One commenter suggested that we add the word ''items'' before ''services'' in § 438.304(c) of the proposed rule, as it is included in the statute. The commenter also suggested that we include a list of examples of such items, such as durable medical equipment, assistive devices, certain birth control items, and prescriptions.

Response: Ordinarily, we do not use the term ''items'' in our regulations because the term ''services,'' as used in the regulations, includes covered ''items'' as well. While only the Medicare regulations expressly specify that ''services'' includes ''items'' (42 CFR 400.202), section 1905(a) of the Act uses the term ''care and services'' to encompass all services or items for which Medicaid payment may be made. References in the regulations to ''services'' therefore, include covered ''items'' as well. Because of this, we are not adding the word ''items'' before ''services'' in § 438.204(d) (§ 438.304(c) in the proposed rule).

Comment: One commenter expressed the need to clarify that appeals on coverage and claims are handled through the State fair hearing process, and not through complaints to the EQR.

Response: The commenter is correct that appeals on coverage and claims decisions by enrollees are properly addressed through the internal appeals process of the MCO and PHP and the State fair hearings process. The proposed EQR regulation makes clear that handling enrollee appeals is not an EQR function.

4. Availability of Services (Proposed § 438.306)

Section 1932(c)(1)(A)(i) of the Act, as added by section 4704 of the BBA,

requires each State that contracts with MCOs under section 1903(m) of the Act to develop and implement standards for access to care under its quality assessment and improvement strategy. Section 438.306 of the proposed rule established standards for access to care. Paragraph (a) required that States ensure that all covered services are available and accessible to enrollees. Paragraph (b) specified that if a State agency limits freedom of choice, the State agency must comply with the requirements of proposed § 438.52, which specify the choices that the State agency must make available. Paragraph (c) specified that if an MCO or PHP contract did 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. In § 438.306(d) we proposed new requirements for the delivery networks of MCOs and PHPs to ensure that all covered services under a contract are available and accessible to enrollees. These requirements would be imposed on State agencies, which in turn would enforce these requirements on MCOs and PHPs. Specifically, paragraph (d)(1) proposed that the State agency require all MCOs and PHPs 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. 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 or PHP's network. In establishing and maintaining such a network, the proposed rule required that MCOs and PHPs consider (1) anticipated enrollment, with particular attention to pregnant women and children; (2) the expected utilization of services, considering enrollee characteristics and health care needs; (3) the numbers and types of providers required to furnish contract services; (4) the number of network providers who are not accepting new patients; (5) 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.

In § 438.306(d)(2) we proposed that the State be required to ensure that MCOs and PHPs allow women direct access to a woman's health specialist for women's routine and preventive services, and in paragraph (d)(3) we proposed that MCOs and PHPs seeking an expansion of their service area demonstrate that they have sufficient numbers and types of providers to meet the anticipated additional volume and types of services the additional enrollee population may require. Proposed § 438.306(d) also required that: (1) the State agency ensure that each MCO and PHP demonstrate that its providers are credentialed as described in proposed § 438.314, (2) when medically appropriate, each MCO and PHP make services available 24 hours a day, 7 days a week, (3) as part of the State quality strategy, the State must ensure that each MCO and PHP requires its providers to meet the State-established standards for timely access to care and member services, taking into account the urgency of need for services; and (4) that each MCO and PHP establish mechanisms to ensure compliance and monitor continuously for compliance, and take corrective action in cases of non-compliance.

In § 438.306(e) we proposed that each MCO and PHP be required to provide each enrollee with an initial health assessment within 90 days of the effective date of enrollment, and that pregnant women and individuals with complex and serious medical conditions receive this baseline health risk assessment within a shorter period of time. We further proposed that each MCO and PHP have in place State-approved procedures to identify and furnish care to pregnant women and individuals with complex and serious medical conditions; and that appropriate medical procedures be implemented to address and monitor their care, including specifying an adequate number of direct access visits to specialists as required by the treatment plan.

Finally, proposed § 438.306(e)(4) required that the State ensure that each MCO and PHP provide services in a culturally competent manner, including satisfying the language requirements in § 438.10(b).

Comment: We received several comments in support of the proposed rule, but a few commenters suggested that we revise it to include more specific wording. For instance, one commenter recommended that we expand the rule to make clear that access includes receiving services in a timely manner. Another commenter suggested that we change the language to ensure that all covered services are available to each enrollee as medically necessary. Another commenter suggested that the regulation be revised to reflect that both services and ''items'' were available and accessible to enrollees. This commenter was concerned that the proposed language did not address access to medical equipment, drugs, and other supplies covered by a State Medicaid plan.

Response: Paragraph (a) was intended to convey the broad general intent of the subsequent provisions. Subsequent provisions of the final rule provide more detailed specifications for what access standards must include, including timely access to care and medical necessity. As noted in a previous response, we have not added the word ''items'' to explicitly address access to ''items and services'' covered by an MCO or PHP contract because the term ''services,'' as used in the regulations, includes covered ''items'' as well. While only the Medicare regulations expressly specify that ''services'' includes ''items'' (42 CFR 400.202), section 1905(a) of the Act uses the term ''care and services'' to encompass all services or items for which Medicaid payment may be made. References in the regulations to ''services'' therefore, include covered ''items'' as well.

Comment: We received numerous comments in response to proposed § 438.306(c), which requires a State—

- To arrange for State plan services not covered under an MCO or PHP contract to be made available from other sources; and
- To instruct enrollees on where and how to obtain these services, including how transportation is provided.

Most of the commenters supported the inclusion of this provision, indicating that distribution of information on out-of-plan services has been unsatisfactory in the past. However, a few commenters requested clarification of this provision and wondered whether States could delegate this responsibility to MCOs. In contrast, one commenter disagreed that MCOs should have the responsibility to advise enrollees on where and how to obtain services not provided by the MCO.

Response: We recognize that States have discretion to contract with MCOs or PHPs to provide a specific set of services that may not include all services covered under a Medicaid State plan. Our intention in proposing this provision was to ensure that enrollees in managed care have access to services covered under a State plan but not provided by an MCO or PHP. We believe that the duty to inform enrollees on how to obtain those services rests primarily with the State. However, we agree that a State may delegate this responsibility to an MCO or PHP as part of its contract.

Comment: One commenter believed that we have gone beyond our authority

in proposing § 438.306(c). The commenter suggested that our use of the words ''arrange for services to be made available from other sources'' expands the State's responsibility to a greater degree under managed care than under a fee-for-service arrangement. In light of such concerns, the commenter recommended that the clause be deleted, and argued that States should only be responsible for guaranteeing payment for State plan services not covered under an MCO contract.

Response: States continue to have the same responsibility they have always had to ensure that covered benefits are available to eligible beneficiaries in accordance with a Medicaid State plan. In proposing § 438.306(c), it was never our intent to imply that States act as case managers in ''arranging for services to be available from other sources.'' Therefore, we agree that some change to the proposed rule is necessary to clarify the State's responsibility. In the final rule with comment period, § 438.206(c) requires that, if the MCO or PHP does not cover all of the services under the State's plan, the State must make available those services from other sources and provide enrollees with information on where and how to obtain them, including how transportation is provided.

Comment: We received several comments on proposed § 438.306(c) with regard to the provision of transportation. One commenter noted that transportation has been an issue in certain counties within its State. Another commenter noted that transportation is particularly important for adolescents. Several commenters made specific recommendations. For example, one commenter recommended that we clarify how transportation is reasonably provided, and require that it be subject to the availability of public transportation in the region. Other commenters recommended that we make the transportation requirement a separate provision.

Response: Under § 431.53 of our regulations, a State Medicaid agency is required to specify in its State plan that the agency will (1) ensure all necessary transportation for recipients to and from providers, and (2) describe the methods that the agency will use to meet this requirement. Proposed § 438.306(c) was intended to ensure that, under managed care, enrollees still receive necessary transportation services consistent with what is described in the Medicaid State plan. We do not believe any changes are necessary to further require access to transportation services under managed care.

Comment: Several commenters requested that § 438.306(c) specifically refer to services excluded from a contract because of religious beliefs. In addition, commenters requested that we address the knowledge and expertise of providers with respect to the scope of services provided by the MCO.

Response: We believe that the information requirements in §§ 438.10(e)(2)(xii) and 438.102 specifically address the commenters' concerns. Section 438.10(e)(2)(xii) requires that, either the State or the MCE, as appropriate, must furnish enrollees and potential enrollees with information on how to obtain services covered under a State plan. This encompasses information on services not covered under an MCO or PHP contract because of moral or religious objections and information on the education, licensure, and board certification of providers. Section 438.102(c) requires that MCOs or PHPs that elect on moral or religious grounds under § 438.102(b)(3) not to provide, reimburse, or provide coverage of a counseling or referral service that they would otherwise be required to under § 438.102(b)(1), must furnish information about the services it does not cover to the State and to potential enrollees and enrollees at certain times.

Comment: We received several comments suggesting that proposed § 438.306(d)(1), which set forth requirements for establishing, maintaining, and monitoring a network of appropriate providers, imposed an undue administrative burden on States. Commenters objected to the general requirement for the State to ensure that MCOs maintain and monitor 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.'' One commenter believed that documentation referenced in the general requirement was rarely available to the Medicaid agency, much less to MCOs. The commenter viewed the requirement as impractical, and believed that there was potential for large implementation problems. Another commenter suggested that, although it is the duty of the State to monitor MCO contracts, it would be a huge administrative burden to verify that a written agreement exists with each provider.

Response: We do not agree that this requirement is impractical or imposes an undue burden on States. This provision is consistent with § 438.230, which requires written agreements that specify the delegated activities and reporting responsibilities of a subcontractor. We believe that, without written agreements, MCOs and PHPs cannot assure their enrollees sufficient access to network providers. Therefore, States must obtain assurances from and monitor MCOs and PHPs, as appropriate, to verify that such agreements exist.

Comment: Numerous commenters suggested that we revise proposed § 438.306(d)(1) to add a requirement that States and MCOs make available, as part of their network, providers experienced in serving individuals with certain conditions, and providers with specialty training. For example, commenters suggested that we require MCOs to contract with providers experienced in serving individuals with HIV/AIDS, children with special health care needs, individuals with chronic diseases, and individuals with physical and developmental disabilities. One commenter recommended that the final regulation establish minimum standards for a provider's experience in serving persons with chronic diseases and disabilities in managed care plans. Minimum standards suggested by commenters include: (1) current caseload of persons with certain chronic diseases or disabilities, (2) provider training in treating persons with certain diseases or disabilities, (3) extent or duration of experience serving persons with certain chronic diseases or disabilities, and (4) measures of successful outcomes in treating persons with chronic diseases or disabilities.

Response: We agree that States should ensure that MCOs make available, as part of their network or through other arrangements, access to providers experienced in treating conditions such as HIV/AIDS and access to specialty providers for certain chronic conditions. Therefore, in response to this comment, in § 438.206(d)(1)(iii), we have added ''training and experience'' to the list of attributes MCOs and PHPs must consider when establishing their provider networks. We also have added, in § 438.206(d)(1)(i) ''persons with special health care needs'' as a category of enrollees to whom States, MCOs ans PHPs should pay particular attention in meeting this requirement.

We do not believe it is appropriate to further specify in regulation the types of specialists that must be included in an MCO's or PHP's provider network, nor do we believe it appropriate to define what constitutes an experienced provider for certain types of conditions. Because the evidence base regarding how to precisely define all types of ''experienced providers'' is still limited, we believe that States are in a better position to impose specific requirements on MCOs and PHPs,

consistent with their standards for access to care and the population enrolled in managed care. However, also in response to the concerns raised in this comment, we have added a requirement at § 438.206(d)(5) that if the network is unable to provide necessary medical services, covered under the contract, to a particular enrollee, the MCO or PHP must adequately and timely cover these services out of network for the enrollee, for as long as the MCO or PHP is unable to provide them. We intend that the inability to provide medically necessary services would extend to a situation in which the enrollee needs related and covered services (for example, a Cesarean section and a tubal ligation) to be performed at the same time; not all related and covered services are available within the network; and the enrollee's primary care provider or another provider determines that receiving the services separately would subject the enrollee to unnecessary risk. We further specify at § 438.206(d)(8) that the State must ensure that use of out-of-network-providers incurs no greater cost to the enrollee beyond what he or she would have paid had the services been received from a network provider.

We emphasize that § 438.206 is integrally linked to § 438.207, which requires MCOs and PHPs to give the State assurances of adequate capacity and services to serve the MCO's and PHP's expected Medicaid enrollment, including access to specialty services. In meeting the requirements of the final rule with comment period, each MCO and PHP will have to submit assurances of its capacity to States, and States will have to submit certification to us, annually and at any time there has been a significant change in the MCO's and PHP's network that would affect adequate capacity and services. We reserve the right to inspect documentation submitted by MCOs and PHPs to the State. With these requirements, we believe that appropriate checks are in place to ensure that States are monitoring MCOs and PHPs against the State's standards for access to care.

Comment: We received several comments suggesting that proposed § 438.306(d)(1)(i) should specifically consider other populations with special health care needs in addition to pregnant women and children. Commenters recommended that we revise § 438.306(d)(1)(i) to also consider people with disabilities, adults with special health needs, persons with mental illness, persons with substance abuse problems, persons with developmental disabilities, and persons with functional disabilities or complex problems involving multiple medical and social needs such as HIV/AIDS and homelessness.

Response: We agree and have revised this provision. As noted above, § 438.206(d)(1)(i) of the final rule with comment period requires that each MCO and PHP, in establishing its provider network, take into consideration ''persons with special health care needs,'' as well as pregnant women and children. Also, in response to this comment, § 438.208(b) of the final rule with comment period requires that States implement ''mechanisms to identify to the MCO or PHP, upon enrollment'' categories of enrollees at risk of having special health care needs, children under age 2, and other enrollees known to be pregnant or have special health care needs.

''Persons with special health care needs'' is the terminology used by the Congress at section 4705(c)(2) of the BBA that called for the Secretary to conduct a study of the safeguards needed when such individuals are enrolled in Medicaid managed care. In undertaking this study, we conceptualized individuals with special health care needs as persons who either (1) have functional disabilities (e.g., difficulty bathing, dressing, eating, communicating, or problems with mobility) or (2) live with health or social conditions that place them at risk of developing functional disabilities (for example: mental retardation; serious chronic illnesses such as HIV, schizophrenia, or degenerative neurological disorders; disabilities resulting from many years of chronic illness such as arthritis, emphysema, or diabetes; and certain environmental risk factors such as homelessness or family problems that lead to the need for placement in foster care). From this conceptual framework, our study identified six groups of individuals with special health care needs:

(1) children with special health care needs;

(2) children in foster care;

(3) individuals with serious and persistent mental illness/substance abuse;

(4) individuals who are homeless;

(5) older adults (individuals 65 years of age and older) with disabilities; and

(6) adults under 65 who are disabled or who have a chronic condition, whether physical or mental. As noted above, under new § 438.208(b)(1), States are required to identify enrollees in these categories to their MCO or PHP.

Subsequent to the passage of the BBA, we also began to explore the concept of ''persons with complex and serious medical conditions.'' This category of persons was referenced in the proposed rule because they are a group of individuals addressed in the Consumer Bill of Rights and Responsibilities (CBRR). On August 31, 1999, the Institute of Medicine (IOM) submitted a report to us entitled ''Definition of Serious and Complex Medical Conditions.'' This study was requested in order to provide guidance to Medicare M+C organizations (who do not have a BBA mandate with respect to ''persons with special health care needs''). While the IOM recommended that the establishment of an administrative definition for serious and complex medical conditions would be premature at this time, it also described a ''serious and complex condition'' as: * * * one that is persistent and substantially disabling or life threatening that requires treatments and services across a variety of domains of care to ensure the best possible outcomes for each unique patient or member.''

In examining the similarities and differences between the concepts of ''special health care needs'' and ''serious and complex medical conditions'' as articulated in our work for its Report to the Congress and the IOM, respectively, it is clear that individuals with, ''persistent and substantially disabling * * * [conditions] that require treatments and services across a variety of domains of care to ensure the best possible outcomes for each unique patient or member,'' are included in our conceptual framework of ''persons with special health care needs.'' The only component of the IOM description of persons with serious and complex medical conditions that is not readily apparent as included in our conceptual description of persons with special health care needs are those health conditions that are ''life threatening.'' However, we believe that persons with life threatening conditions can reasonably be considered to have a special health care need. Therefore, the provisions of this final rule with comment period require States to ensure that each MCO and PHP establish and maintain a network of providers that considers the MCO's or PHP's anticipated enrollment, with particular attention to pregnant women, children, and persons with special health care needs. We have also, throughout this final rule with comment period, deleted the language, ''individuals with serious and complex health care needs'' where used in the proposed rule, and replaced

it with ''persons with special health care needs.''

Comment: We received numerous comments that generally supported the requirement in proposed § 438.306(d)(1)(iii) that MCOs consider the numbers and types of providers needed to furnish contracted services. Many commenters recommended that, instead of providing examples in the preamble, we establish in regulation specific enrollee-to-provider ratio standards. While several commenters suggested that we incorporate the examples from the preamble into the regulation itself, other commenters suggested that we apply other enrollee-to-primary care provider ratios ranging from 1200:1 to 2500:1. Some providers believed that primary care assignments should be discontinued when a patient load reaches 3,000. Several believed that enrollee-to-provider ratios should encompass all patients treated by a provider, and not just Medicaid patients. Finally, some commenters also believed that specific ratios for specialists should be established in regulation, such as ratios for pediatric specialists and providers serving persons with HIV/AIDS.

Response: We do not believe it is appropriate to set national standards that specify maximum enrollee-to-provider ratios. We believe that the inclusion of such ratios in regulations would be too prescriptive, and would not be appropriate for all Medicaid managed care programs across the country. The variation in the comments we received attests to this. Because of such variation, we believe that States are in a better position to establish specific standards to ensure that an adequate number of providers is maintained within MCO and PHP networks.

Comment: Some commenters requested that we establish specific standards in the final rule with comment period outlining the types of providers that must be included in an MCO's network. One commenter specifically recommended that the term ''provider'' be defined when establishing standards for the various disciplines and specialty areas of practice. Other commenters recommended that an MCO be required to include in its network specified types of providers such as nurse-midwives, obstetricians and gynecologists, pediatric specialists, and providers with demonstrated competence in serving enrollees with mental illness, substance abuse problems, developmental disabilities, functional disabilities, and complex problems involving multiple medical and social needs such as homelessness and HIV/AIDS.

Response: We do not believe it appropriate to impose national standards requiring specific numbers and types of providers. States have implemented varying and often unique programs that cover a variety of benefits. Some of these programs serve a broad spectrum of Medicaid enrollees; while others serve a narrower group. One set of standards may not be appropriate in every circumstance. However, we have required at § 438.206(d) that each State must ensure that each MCO and PHP maintain and monitor a network of providers that is sufficient to provide adequate access to all services covered under the contract, and that in constructing this network, each MCO and PHP must consider (among other requirements): (1) the anticipated enrollment, with particular attention to pregnant women, children and persons with special health care needs, and (2) the numbers and types (in terms of training and experience) of providers required to furnish the contracted services.

Comment: We received a number of comments suggesting that we establish in the final rule with comment period a national geographic access standard. Section 438.306(d)(1)(v) of the proposed rule required MCOs and PHPs, when establishing and maintaining their provider networks, to take into account the geographic location of providers and enrollees, considering distance, travel time, the means of transportation ordinarily used by enrollees, and whether the location provided physical access for enrollees with disabilities. Commenters offered a variety of recommendations to supplement this provision. Some commenters suggested that geographic standards be based on travel time and not distance, and others urged that we liberalize geographic access standards to take into account allowable public transportation time. Several commenters recommended that we require a general time of 30 minutes from an enrollee's residence, and others recommended an exception for frontier areas. Further, other commenters suggested varying standards, such as 30 miles or 30 minutes for rural areas, 20 miles or 30 minutes for urban areas, and 45 minutes for specialty care; whereas other commenters suggested a 30 minute or 30 mile standard, with a 60 minute or 60 mile standard for rural areas.

Response: We do not believe it is appropriate to set national geographic access standards in these regulations. We recognize that there are unique circumstances which exist in each State for which a national standard could be inappropriate. This is reflected in the comments received and in the preamble to the proposed rule in which we noted that a provider network should be structured so that an enrollee residing in the service area does not have to travel an unreasonable distance to obtain a covered service, beyond what is customary under a Medicaid fee-for-service arrangement. The preamble to the proposed rule also acknowledged that many Medicaid enrollees may use public transportation. We stated that ''in areas where Medicaid managed care enrollees rely heavily on public transportation, the State should ensure that providers are accessible through these means within the same time frames as enrollees who have their own means of transportation.'' Because of this, we believe that States are in a better position to establish access standards, including geographic access standards, as part of their States' quality assessment and improvement strategy. Our availability of services requirements under § 438.206 of the final rule with comment period allow States sufficient flexibility to develop access standards that are appropriate for their own circumstances, and ensure that States take into consideration important factors such as distance, travel time, and the means of transportation normally used by enrollees.

Comment: We received several comments requesting that we be more specific with respect to our requirement that MCOs and PHPs take into account a location's physical accessibility for enrollees with disabilities. While the commenters generally supported inclusion of this provision, they also believed that we should be more specific in our final rule with comment period. Several commenters believed that we should require States, at a minimum, to ensure that sites are physically accessible and comply with the Americans with Disabilities Act. One commenter suggested that States and MCOs ensure access not only to locations, but also to all aspects of medical treatment. Other commenters stressed that in addition to physical access, it is just as important for populations with special health care needs, such as persons with mental retardation, to have access to knowledgeable and trained staff, to receive understandable information, to be able to communicate with a provider if he or she is hearing impaired, and to have longer appointment times. They recommended that we reflect these adaptations in the final rule with comment period.

Response: We believe that several of the requirements in this final rule with comment period address many of the commenters' concerns. We specifically refer commenters to the following:

- Sections 438.206(d)(1)(i) and (d)(1)(ii) require each MCO and PHP, when establishing their provider networks, to take into consideration their anticipated enrollment, with particular attention to persons with special health care needs, and their expected utilization of services, considering the enrollees' characteristics and health care needs.
- Section 438.206(d)(1)(iii) requires each MCO and PHP to also consider the numbers and types (in terms of training and experience) of providers needed.
- Section 438.206(d)(1)(v) requires MCOs and PHPs to consider distance, travel time, means of transportation ordinarily used by enrollees, and whether the location provides physical access for enrollees with disabilities.
- Section 438.100 requires the State to ensure that MCOs, PHPs, and PCCMs, comply with applicable Federal and State laws that pertain to enrollee rights. The Americans with Disabilities Act is explicitly mentioned as one of these Federal laws. Section 438.100 also requires States to ensure that enrollees receive information on available treatment options and alternatives, presented in a manner appropriate to the enrollees' conditions and ability to understand.
- Section 438.102(b)(2)(ii) requires that steps be taken to ensure that enrollees with disabilities have effective communication with all health system participants in making decisions with respect to treatment options.

All these requirements were designed to ensure that States address issues such as physical access and composition of provider networks. We have not required in this final rule with comment period that populations with special health care needs always have longer appointment times because it is not yet possible to precisely define all individuals with special health care needs, and because all such individuals may not always require longer appointment times.

Comment: We received several comments on proposed § 438.306(d)(2), which requires that female enrollees have direct access to women's health specialists within the network for women's routine and preventive services, notwithstanding that the MCO maintains a primary care provider for each enrollee.

Overall, many commenters supported inclusion of this provision. However, a few commenters requested clarification of regulatory terms. For example, several commenters expressed concern over what they viewed as the ambiguity of the term ''women's health specialist.'' They requested that we expand the definition of that term in the final regulation to include specific provider types, such as nurse-midwives or obstetricians/gynecologists. Others felt that this provision could be construed to include non-licensed practitioners or laypersons.

Response: We do not define ''women's health specialist'' in this final rule with comment period, because different types of health professionals may, through education and/or clinical experiences, be appropriately thought of by a contracting MCO or PHP or enrollee as a ''women's health specialist.'' However, we intend for the term to refer to licensed health professionals with specific clinical education and training in women's health care, including obstetricians, gynecologists, nurse midwives, and nurse practitioners, consistent with State licensing requirements.

Comment: Several commenters felt that the term ''routine and preventive services'' in proposed § 438.306(d)(2) should be excluded from this provision, while other commenters felt that we should define the term further. One commenter felt that we should define the term based on existing professional guidelines. Others requested that we define the term to include specific services, such as prenatal care, labor and delivery services, breast exams, mammography, and pap smears.

Response: We agree that some clarification is needed. In § 438.206(d)(2) of the final rule with comment period, an MCO or, as appropriate, a PHP is required to provide female enrollees with direct access to a woman's health specialist within the network for covered care necessary to provide women routine and preventive health care services. This would include initial and follow-up visits for services unique to women such as prenatal care, mammograms, pap smears, and for services to treat genito-urinary conditions such as vaginal and urinary tract infections and sexually transmitted diseases.

Comment: Several commenters requested that we expand proposed § 438.306(d)(2) to clarify whether the requirement applies to both adult females and to minor adolescent females. Other commenters suggested that we add language that would allow direct access to a women's health specialist for pregnant enrollees of any age, but otherwise would set a limit for access to a women's health specialist to age 15 or older.

Response: We used the term ''female enrollees'' to include minor females. Thus, we believe that if there is a medical need to see a women's health specialist, there should be no impediment based on the age of the enrolled female.

Comment: One commenter believed that proposed § 438.306(d)(2) would conflict with recent insurance legislation in the State which allows MCOs to require a women's health specialist to have a referral arrangement with, but not actual referrals from, an enrollee's primary care physician. Another commenter stated that it is unclear whether a female enrollee would be able to choose any women's health specialist within the network.

Response: We believe that, within MCO and PHP networks, female enrollees must have direct access to a women's health specialist for covered care necessary to provide women's routine and preventative health care services. We believe that this means that each woman should have access to any women's health specialist within the network, unless some network providers are not accepting new enrollees or there are other network restrictions based on the enrollee's choice of primary care provider. (For example, a woman may choose a primary care provider that is part of a subnetwork of providers within an MCO. As long as the woman was informed of the consequences of choosing a primary care provider that is a part of a subnetwork, at the time of her enrollment, she can be restricted to using only those specialists, including women's health specialists that are part of the subnetwork—although provisions for using out-of-network providers would still apply.) This provision was proposed consistent with statutory authority requiring States to develop standards for access to care ''in a manner that ensures continuity of care and adequate primary care and specialized services capacity'' (section 1932(c)(1)(A)(i) of the Act). Moreover, this provision is consistent with the beneficiary rights in the CBRR.

Comment: We received several comments recommending that proposed § 438.306(d)(2) be applied to all managed care entities, including PCCMs, HIOs, and PHPs. Commenters also suggested that we should apply this provision to individuals in managed care plans with 6-month eligibility.

Response: Section 438.206(d)(2) is based on authority in section 1932(c)(1)(A)(i) of the Act. As noted above, with respect to the quality assurance requirements implementing

section 1932(c)(1) of the Act generally, the Congress chose to apply this provision only to MCOs, while other provisions in the same section were made applicable to both MCOs and PCCMs (*i.e.,* to ''MCEs''). The Congress thus expressed a clear intent that these requirements not apply to PCCMs. With respect to HIOs, if they are required to meet the definition of MCO and comply with section 1903(m) of the Act requirements, these requirements would apply to them. If, however, they have a specific statutory exemption from section 1903(m) of the Act, again, the Congress has spoken directly to the question of whether these requirements should apply, and determined that they should not. We therefore believe it would be inconsistent with clearly expressed Congressional intent to subject PCCMs or section 1903(m) of the Act-exempted HIOs to requirements based on the authority in section 1932(c)(1) of the Act. Also as noted above, however, in the case of PHPs, the Congress was silent as to what standards should apply, and based on our authority under section 1902(a)(4) of the Act, we have applied the requirements in subpart D (including the woman's health requirement in § 438.306(d)(2)) to PHPs, as appropriate. We do not believe that we need to explicitly reference individuals with six-month eligibility because the provision applies to all women regardless of their length of eligibility or enrollment.

Comment: One commenter suggested that § 438.306(d)(2) should not apply to behavioral health organizations, since women's health specialists do not exist in such settings.

Response: We agree with the commenter that this requirement may not apply to PHPs that deliver a limited set of services under a capitated arrangement. PHPs of this type typically include organizations contracted to provide mental health or substance abuse services and organizations that provide dental services. Section 438.8(a) of the final rule with comment period specifies that the quality assessment and performance improvement requirements apply to PHPs ''to the extent that they are applicable to the services furnished by the PHP.'' In the example of a behavioral health organization, access to a women's health specialist for covered care necessary to provide women's routine and preventive health care services would not be applicable.

Comment: Several commenters believed that § 438.306(d)(2), pertaining to women's direct access to a women's health specialist, as proposed, would impede continuity of care. They recommended that this provision be eliminated. Another commenter recommended that we delete the phrase ''notwithstanding that the MCO maintains a primary care provider for each enrollee.''

Response: As we have stated, we believe that female enrollees must have direct access to a women's health specialist within an MCO's and PHP's network as applicable and PHP's network as applicable. This provision was proposed 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 and in order to implement the CORR. To make this purpose and the provision more clear, we have replaced the words ''notwithstanding that the MCO maintains a primary care provider for each enrollee'' with the sentence, ''This [direct access to a women's health specialist] is in addition to the enrollee's designated source of primary care, if that source is not a women's health specialist.'' This change of wording also emphasizes that a female enrollee's right to directly access a women's health specialist cannot be satisfied, under Medicaid, by simply offering the opportunity to choose a women's health care specialist as a primary care case manager. We believe that in the case of the Medicaid population, direct access for these services is critical, and that the opportunity to choose a primary care case manager who provides these services is not sufficient, since a woman may not wish to see a woman's health specialist for general care.

Comment: We received one comment referencing § 438.306(d)(2) which suggested that OB/GYNs be able to serve as primary care physicians. The commenter expressed concern that women may not receive information about when they are entitled to self-refer to OB/GYNs. The commenter recommended that such information be required.

Response: Our intent in the proposed rule was not to require States and MCOs or PHPs to allow (or preclude States and MCOs or PHPs from allowing) OB/GYNs, or other specialists, to serve as primary care providers. The final rule with comment period, as amended, provides flexibility for States to determine the appropriate specifications to impose on MCOs and PHPs regarding the types of primary care providers, depending on the nature of the managed care program in the State and the enrollee population being served. Moreover, the information requirements at § 438.10, as amended, are written to ensure that enrollees receive adequate information on procedures for obtaining all benefits, including information on the right of female enrollees to directly access a women's health specialist within the MCO or PHP network for covered care necessary to provide women's routine and preventive health care services.

Comment: We received a comment on the grievances and appeals provisions urging that enrollees faced with an adverse decision have the right to a second opinion, and that this right be mentioned in the adverse action notice. The commenter felt that enrollees should have the right to out-of-network, unbiased, second opinions, and this right should be specified in the regulations.

Response: We agree that enrollees should have access to an unbiased second opinion. We believe that this right extends beyond an adverse action notice to any instance in which the enrollee requests a second opinion. Therefore, we have added requirements in the regulation, both in Enrollee rights (§ 438.100) and in the Availability of services provisions (§ 438.206(d)(3)), with regard to second opinions. Contrary to the commenter's suggestion, we believe that an enrollee can receive an unbiased opinion from another qualified health professional in the network. Accordingly, we have specified that the MCO or PHP must provide for an enrollee to have access to a second opinion from a qualified provider *within the network* or arrange for the enrollee to obtain a second opinion outside of the network if an additional qualified health care professional is not currently available within the network.

Comment: We received many comments on proposed § 438.306(d)(5), which required the State to ensure that, when medically appropriate, the MCO or PHP makes services available 24 hours a day, 7 days a week. The proposed regulations stated that this provision applies, at a minimum, to emergency services and post-stabilization services, and to non-emergency services that are required immediately because of unforseen illness. A majority of the comments requested further clarification of terms and standards. Specifically, several commenters requested that the term ''unforseen illness'' be clarified or deleted. Many commenters argued that the term is too restrictive, invites legal controversy over its interpretation, and is contrary to managed care's emphasis on prevention, early detection, and treatment. Other commenters urged that we adopt and apply specific standards for urgent care of 24 to 48 hours depending on the day of the week an

unforseen illness occurs. One commenter specifically recommended that we add an additional standard of 24 hour, 7 day ''crisis services'' for beneficiaries with mental illness. Another commenter felt that MCOs should have a mechanism to conduct triage and assessment, but should not have to make available non-emergency, non-urgent care 24 hours a day, 7 days a week. Finally, one commenter stated that the availability of services under this provision should be based on medical necessity and not medical ''appropriateness.''

Response: Our intent in proposing § 438.306(d)(5) was to ensure that individuals who require home health services or other types of non-hospital based services receive care, when medically necessary, during non-business hours. After further review and consideration of comments received, we have revised the policy so that the final rule with comment period requires MCOs and PHPs to ensure that services are available 24 hours a day, 7 days a week, when medically necessary (§ 438.206(e)(1)(iii)). We believe this change ensures access to care without using potentially ambiguous terms such as ''unforseen illness'' and ''medically appropriate.'' We further believe that this requirement is consistent with our overall intent as reflected in other provisions in the final rule with comment period, including § 438.114, Emergency and post-stabilization services, and § 438.210, Coverage and authorization of services.

Comment: Several commenters felt that proposed § 438.306(d)(5) was too prescriptive and costly. One commenter believed that the provision was likely to increase the number of providers who refuse to see Medicaid patients, and suggested that normal physician practice standards should be acceptable for all populations. Other commenters recommended that the provision be deleted.

Response: As we have indicated above, we believe this provision is important to ensure that enrollees have access to medically necessary care during traditional, non-business hours.

Comment: We received numerous comments on proposed § 438.306(d)(6), which required MCOs and PHPs to ensure that its providers' hours of operation are convenient to enrollees, and do not discriminate against Medicaid enrollees. One commenter supported the provision, but suggested that we reference populations with special health care needs. Other commenters believed that the term ''convenient'' in the proposed regulation was too ambiguous and subjective, and that this term required further clarification. One commenter specifically argued that we were imposing a new requirement in Medicaid managed care that we have not imposed in Medicaid fee-for-service. Finally, other commenters suggested that this particular provision, if included in the final rule with comment period, would have widespread implications for the program. They argued that we have exceeded our statutory authority in proposing this provision.

Response: Upon further consideration, and based on comments received, we agree that the term ''convenient'' needs clarification. As a result, we have moved this requirement to § 438.206(e), because we believe that it more appropriately falls under the ''provision of services'' paragraph. Under paragraph (e)(1)(ii), the MCO or PHP must ensure that its providers' hours of operation are convenient for the enrollees, as determined by a State-established methodology, and that they are at least comparable to Medicaid fee-for-service.

We believe that the State should establish standards for what is convenient for enrollees in terms of provider hours of operation. Those standards should be at least comparable to Medicaid fee-for-service. Thus, an enrollee who was able to schedule weekend or evening appointments under the Medicaid fee-for-service program should have access to appointments during those hours under Medicaid managed care.

We continue to believe that the State and MCO or PHP must ensure that providers do not discriminate against Medicaid enrollees. Thus, we retain this requirement in § 438.206(d)(7).

Comment: One commenter suggested that we apply proposed § 438.306(d)(6) to MCEs, and not just MCOs.

Response: We proposed § 438.306(d)(6) under the authority of section 1932(c)(1)(A)(i) of the Act. As discussed above in connection with proposed § 438.306(d)(2), the Congress expressed a clear intent that requirements under section 1932(c)(1) of the Act apply to MCOs, but not PCCMs. When the Congress wanted to apply requirements to PCCMs as well as MCOs, it did so by referencing ''MCEs,'' which includes MCOs and PCCMs. We thus believe it would be inconsistent with clearly stated Congressional intent to apply requirements under section 1932(c)(1) of the Act to PCCMs.

Comment: We received numerous comments on proposed § 438.306(e)(1)(i), which required MCOs and their providers to meet State-established standards for access to care and member services, taking into account the urgency of the need for services. Several commenters recommended that we incorporate into the final regulation the suggested standards outlined in the preamble to the proposed rule. The commenters' rationale for incorporating the suggested standards in the final rule with comment period is that the standards reflect existing managed care contracts and there appears to be no reason for State flexibility regarding maximum wait times for care. The same commenters argued that the BBA gives us the authority to establish minimum standards for quality assessment and improvement strategies. Several other commenters noted the importance of establishing standards for in-office waiting times, especially for mental health services.

Commenters offered a number of recommendations that included standards in addition to, or as alternatives to, those presented in the preamble to the proposed rule. Moreover, the recommendations referenced both in-office waiting times and appointment scheduling times. Specifically, the additional standards included referral appointments to specialists within 30 days for routine care, 72 hours for urgent care, and 24 hours for emergency appointments. Other additional standards included routine, prenatal visits within 2 weeks for the first trimester, 1 week for the second trimester, and 3 days for the third trimester. Recommended alternative standards included in-office waiting times of no longer than 45 minutes or 1 hour, and appointment times for routine appointments ranging from 2 weeks to 30 days.

Response: Section 1932(c)(1)(A)(i) of the Act provides that ''the State shall develop * * * a quality assessment and improvement strategy,'' that shall include ''[s]tandards for access to care.'' Under the authority of section 1932(c)(1)(A)(i) of the Act, we have proposed regulations to ensure that States take into consideration certain requirements when developing their standards for access to care. One of these requirements (contained in § 438.306(e)(1)(i) of the proposed rule) is that MCOs and PHPs and their providers meet State-established standards for access to care.

We disagree with commenters who suggest that national standards should be established in the final regulation. First, as just noted, the statute calls for ''the State'' to ''develop'' such standards, not us. This suggests that the Congress contemplated that standards

be State-specific. Secondly, patterns of care delivery typically vary across the country. Because of this, a single national standard may not be appropriate in all localities. Therefore, we only included suggested standards in the preamble to the proposed rule as examples for States to consider. The various additional and alternative suggestions offered by commenters may also be appropriate for States to consider. However, we will not mandate any of them in this final rule with comment period.

Comment: Several commenters suggested that proposed § 438.306(e)(1)(i) was too burdensome, and not consistent with the common practice of wait times for appointments of six to eight weeks. Further, commenters suggested that if more stringent standards are imposed for Medicaid managed care enrollees than commercial enrollees, providers may avoid serving Medicaid members.

Response: We do not agree with commenters who suggest that we are imposing more stringent standards for Medicaid enrollees than commercial enrollees. In this final rule with comment period, we require MCOs and PHPs to meet State-established standards. Further, we require that provider hours of operation be at least comparable to fee-for-service. We included examples in the preamble of the proposed rule for State consideration only. These examples were not mandatory requirements. In fact, we specifically indicated that States should evaluate a number of factors, including common waiting times for comparable services in the community. We believe that this statement reflects our intent that, in designing standards for timely access to care, States consider existing practice patterns.

Comment: We received one comment that we should revise proposed § 438.306(e)(1)(i) to add the word ''subcontractors'' after providers, to ensure that subcontractors are required to meet State-established standards for timely access to care and member services.

Response: We do not believe that such a change is necessary for the final rule with comment period. Section 438.230 of the final rule with comment period establishes requirements for subcontractual relationships and delegation. It ensures that each MCO and PHP oversees and is held accountable for any functions and responsibilities that it delegates to a subcontractor. In addition, § 438.6(l) requires that all subcontracts meet the contracting requirements that are appropriate to the service or activity delegated under that subcontract. We believe that these provisions are adequate to ensure that subcontractors are held to the same access standards imposed on MCOs and PHPs by the State.

Comment: Several commenters took issue with the examples contained in the preamble for proposed § 438.306(e)(1)(i), which requires States to establish mechanisms to ensure MCO compliance with standards for timely access to care. Several commenters expressed concern that documenting in-office waiting times would be administratively burdensome, would lead to increased costs, and may reduce the willingness of HMOs to participate in Medicaid. One commenter believed that satisfaction surveys would be sufficient to indicate if a problem exists, which can then be explored with audits of individual providers. Another commenter suggested that our preamble discussion on compliance include methods for gaining consumer feedback in addition to mail and telephone surveys.

Response: In the preamble to the proposed rule, we offered a number of mechanisms that States, MCOs and PHPs could use to monitor compliance with timeliness standards, including the use of surveys, analysis of complaints and grievances, provider self-reports, random audits, and test calls. While we cautioned States on the use of general surveys of its enrolled population, we did not discount the use of surveys all together. For example, the Agency for Healthcare Research and Quality's (AHRQ's) Consumer Assessment of Health Plans Study (CAHPS) survey tools are reliable and valid survey instruments that can be used to assess many aspects of health care, including access to quality and timeliness of care. We believe that States should consider all appropriate mechanisms for measuring MCO and PHP performance against State standards, and rely on those mechanisms which are most effective.

5. Proposed § 438.306(e)(2) (Initial Assessment) and (e)(3) (Pregnancy and Complex and Serious Medical Conditions)

Paragraph (e)(2) of proposed § 438.306 required States to ensure that MCOs and PHPs provide initial assessments of each enrollee within 90 days, and within a shorter period of time for pregnant women and enrollees with complex and serious medical conditions. Paragraph (e)(3) of proposed § 438.306 set forth specific requirements for dealing with the two groups and for their treatment plans. We received a great many comments on these proposed provisions which, in the final rule with comment period, are redesignated under § 438.208, and incorporate several additional groups and time frames.

Comment: Many commenters requested clarification on what constitutes an initial assessment as proposed. Several commenters questioned whether a telephone call or questionnaire might suffice. Other commenters suggested that initial assessment should be face-to-face, and should cover both health and social issues. Several commenters suggested that, particularly for enrollees with complex or serious medical conditions, and populations such as the homeless, pregnant women, newborns, and children, assessments should be conducted face-to-face. One commenter specifically recommended that we define initial assessments to include the following services: a comprehensive health and developmental history, a comprehensive unclothed physical exam, laboratory tests including blood level assessments appropriate for age and risk factors, and health education.

Response: We agree that the term ''initial assessment'' is misleading. While our original intent was that this term be analogous to the term ''screening,'' we are persuaded by comments that certain individuals require a more thorough and timely assessment by an MCO or PHP provider after enrollment. Accordingly, in § 438.208(d) and (e) we are now requiring that the MCO or PHP make a best effort to identify, screen, and comprehensively assess pregnant women, children under the age of 2 years old, and enrollees with special health care needs.

In order to assist MCOs and PHPs in conducting the types of assessments suggested by the commenters, in section 438.208(b) we are requiring States to identify to MCOs and PHPs populations ''at risk'' of having special health care needs, children under age 2, and other enrollees known by the State to be pregnant or to have special health care needs. The ''at risk'' populations include: (1) Children and adults receiving SSI benefits; (2) children in title IV–E foster care; (3) enrollees over age 65; (4) enrollees in relevant, State-established, risk-adjusted, higher-cost payment categories; and (5) any other groups of enrollees identified by us (§ 438.208(b)(1)).

Also in order to address the commenters' concerns about ensuring appropriate assessments, in § 438.208(e) of the final rule with comment period,

we require the MCO or PHP to implement mechanisms to ensure the ongoing screening of its enrolled population to identify and comprehensively assess persons who become pregnant or who develop special health needs following enrollment in the MCO or PHP.

We believe that a State and MCO or PHP should have the flexibility to choose the form and substance of the initial screen or screens. Initial screens may take the form of a phone call, mailed questionnaire, home visit or physical examination; however, it must be sufficient to identify individuals with special health care needs. Further, the initial screen should also attempt to collect information on any languages or TTY requirements, and needs for accessible medical facilities and/or transportation services. The comprehensive health assessment, on the other hand, should include a physical examination by an MCO or PHP provider. In fulfilling the screening and assessment requirements, the MCO or PHP must ensure that its providers have the information required for effective and continuous patient care and quality improvement.

Comment: We received many comments with respect to time frames. Commenters varied in their opinions. Several commenters believed that 90 days was too long to wait for an initial assessment (now referred to as ''screening'' in the final rule with comment period), particularly for enrollees with serious and complex medical conditions. Many other commenters expressed concern over whether an MCO or PHP could perform an initial assessment (screening) on each enrollee within 90 days. These commenters noted the difficulty in contacting an enrollee and ensuring the cooperation of an enrollee in seeing a physician in order to have an assessment (screening) completed. They felt that initial assessments (screening) within 90 days was unrealistic and longer time frames were needed. One commenter suggested that the issue of timing can better be addressed in the contract between the State and the MCO or PHP. The commenter believed that the 90 day requirement should not be a Federal mandate.

Many recommendations were offered. One commenter suggested that a health assessment (screen) need only take place once a year, with an initial assessment (screening) occurring within 180 days if (1) the member has not used the emergency room within the last 90 days, (2) the member is in good health, and (3) the member has reported to the MCO or PHP that it has had a health assessment. Other commenters recommended a shorter time frame of 30 days, and recommended special time standards for specific populations, such as requiring an initial assessment (screening) within 15 to 30 days from enrollment for newborns and young children and within 72 hours for enrollees with HIV. Other commenters suggested more general standards of no more than 60 days to complete initial assessments (screening), to 180 days for adults and 90 days for children. One commenter recommended that MCOs or PHPs only be required to make a good faith effort to contact each new member at least two times to schedule an appointment with his or her primary care provider. Other commenters recommended that we revise the final rule with comment period to require MCOs and PHPs to meet a variation of the following language: (1) Make a good faith effort to conduct an assessment (screening), (2) make available within 90 days of enrollment an initial assessment (screening), (3) inform enrollees of the need for an initial assessment (screening), or (4) make a substantial attempt to provide initial assessments (screenings). One commenter suggested that an assessment for a child under the age of 21 should meet the requirements of the EPSDT guidelines set forth in §§ 441.50 through 441.62.

Response: We agree with many of the comments received. Specifically, we agree with the comment that an MCO or PHP should only be required to make an ''effort'' to perform a screening or assessment. We agree that, through no fault of its own, an MCO or PHP may not be able to achieve full compliance with the proposed initial assessment (screening) requirement. We therefore have revised the requirement to provide, in § 438.208(d) of the final rule with comment period that MCOs and PHPs must make a ''best effort'' to perform the screening and assessment required in this section. A ''best effort'' means that the MCO or PHP should follow-up on unsuccessful attempts to contact an enrollee. With this change, we wish to make clear that the MCO or PHP is not relieved of the obligation to screen all enrollees. Rather, we only wish to acknowledge that an MCO or PHP may not be able to achieve 100 percent compliance with the screening and assessment requirements. We also recognize that some enrollees may be unable to cooperate with the MCO's or PHP's efforts to screen and assess them. In these cases, MCOs and PHPs should document the attempt to screen and (as applicable) assess individual enrollees.

We also agree with the commenters who believed that a 90 day time frame was too long, and specifically with the suggestion of a 30 day time frame in connection with enrollees with special needs. Because of this, we have revised the rule to include different time frames for screening the especially vulnerable groups of pregnant women and persons who either have been identified as having special health care needs, or have been identified by the State under § 438.208(b) as being in categories at risk for having special health care needs. Although we have not identified children under 2 years of age as enrollees ''at risk,'' we recognize the importance of timely screening and assessment of young children and have added them to the groups requiring quicker screening. Specifically, under § 438.208(d), we require MCOs (and PHPs as determined by the State in accord with § 438.208(a)(2)) to make a ''best effort'' to screen and comprehensively assess pregnant women, children under 2 years of age, and persons determined to have special health care needs in accordance with the following timeframes:

(1) For enrollees identified by the State as at risk of having special care needs, screening within 30 days of receiving the State's identification, and for those the screening identifies as being pregnant or having special health care needs, comprehensive health assessment as expeditiously as the enrollee's health requires but no later than 30 days from the date of identification through screening.

(2) For enrollees identified by the State as being children under age 2, and for other enrollees who are identified by the State or who identify themselves as being pregnant or having special health care needs, comprehensive health assessment as expeditiously as the enrollee's health requires, but no later than 30 days after the date of identification.

(3) For all other enrollees, screening within 90 days of enrollment and for those the screening identifies as being pregnant or having special health care needs, comprehensive health assessment as expeditiously as the enrollee's health requires, but no later than 30 days after the date of identification.

We believe that these standards are reasonable to ensure that persons requiring special medical attention from MCOs and PHPs receive services as expeditiously as possible. Because we agree with the commenters recommending these shorter time frames that such time frames are necessary to help ensure the health of vulnerable beneficiaries, we are not accepting the comments that suggested

longer time frames, or abandoning this requirement altogether.

Comment: Several commenters suggested that an initial assessment (now referred to as ''screening'' in the final rule with comment period) not be required for enrollees who are continuing patients of the MCO or provider, or when a prior assessment (screening) is available to the MCO.

Response: We recognize that in some situations it would be duplicative and unnecessary to require screening of an enrollee. For instance, we would not expect an MCO to screen enrollees for whom current health care information is available, such as enrollees already under the care of providers with the MCO's network, or who maintain the same primary care provider when enrolling in a different MCO. In such a case, the screening required under this rule could be considered to have been performed. To ensure compliance with the revised requirements for enrollee screening, MCOs and PHPs should document in the enrollee's health record why screening is not necessary.

Comment: We received a few comments that the proposed initial assessment (screening) requirements should not apply to PHPs, such as managed behavioral health organizations. The commenters recommended that this provision apply only to managed care organizations that provide primary and preventive care services.

Response: As previously indicated, § 438.8 makes the subpart D rules applicable to PHPs to the extent that they are applicable to the services furnished by the PHP. Some PHPs provide services to the most vulnerable Medicaid enrollees, many of whom are diagnosed with chronic conditions or who are determined to have long-term care needs. Thus, timely screening and assessment of these individuals by PHPs, in relationship to the scope of services provided by the PHP, is necessary to ensure that those requiring special attention receive necessary medical care.

We acknowledge, however, that a State might design a managed care initiative that involves PHPs for which an initial screening by the PHP might be duplicative. For example, a State may utilize a separate ''carve-out'' program for mental health services in which an enrollee may require referral by the MCO contracted to provide physical health services. In such a case, a State might design its managed care initiative to have the MCO screen for both physical and mental health. The MCO could screen the enrolled population to identify enrollees who likely require mental health services, and could share the results of the screen with the PHP. The PHP, in turn, would conduct a comprehensive health assessment through appropriate health care professionals. States must determine the most effective and efficient strategy for assuring that all Medicaid MCO and PHP enrollees are screened.

While the State is responsible for ensuring that a screening is carried out on all Medicaid managed care enrollees by some combination of the enrollee's MCO and PHP, in response to this comment, we are under § 438.208(a)(2) of this final rule with comment period providing the State with the flexibility to decide how this responsibility will be carried out, and whether PHPs will be required to perform screenings and assessments in cases in which an enrollee is enrolled in both an MCO and a PHP or more than one PHP.

Our decision in response to the comment to permit State flexibility with respect to PHP screening raises issues of coordination between MCOs and PHPs and responsibilities for screening, assessment and treatment planning for Medicaid enrollees who also receive Medicare and are enrolled in a Medicare +Choice plan. The commenter presumably was concerned about possible duplication of efforts in urging that only the single entity furnishing primary care perform screenings. We believe that this concern about duplication can be addressed, while still providing for PHP screening where appropriate, by requiring in a new § 438.208(h)(3), that each MCO or PHP share the results of its screening or assessment of an enrollee (or both, if the MCO or PHP performs both) with other entities serving the enrollee, so that those entities need not duplicate the MCO's or PHP's screening or assessment (or both). To address the issue of Medicaid enrollees also receiving Medicare and enrolled in a Medicare+Choice plan, we have added a new provision at § 438.208(a)(3) requiring the State to determine the extent to which each MCO is to perform initial screening, assessment and treatment planning for such enrollees, consistent with the services the State requires the MCO to provide.

Comment: We received a number of comments on proposed § 438.306(e)(3)(iii) which required the MCO to develop treatment plans that are appropriate for the conditions identified, specify an adequate number of direct access visits to specialists, and are updated periodically by the physician responsible for the overall coordination of the enrollee's health care. Some commenters suggested that MCOs and physicians need to be given the flexibility to evaluate each enrollee's circumstance. Other commenters urged that the regulations require that enrollees participate in treatment planning. Several commenters believed that enrollees with complex and serious medical conditions should be permitted direct access to specialists, even if they are out-of-network providers. Other commenters suggested that this provision be deleted because it can be interpreted to permit unlimited access to specialists. One commenter expressed the view that direct access to specialists is a benefit that has just begun to evolve in commercial plans, and accordingly should not be applied until MCOs and PHPs can further manage a direct access system.

Response: We disagree with commenters who suggest that this provision permits unlimited access to specialists. It was never our intent to guarantee unlimited access. Proposed § 438.306(e)(3)(iii) was drafted to ensure that enrollees with complex and serious medical conditions (now referred to as enrollees with special health care needs) be permitted a sufficient number of direct access visits to specialists as required by the treatment plan. Our overall intent in the final rule with comment period remains the same. We continue to believe that enrollees with special health care needs who are undergoing an approved course of treatment should be able to access specialists within the MCO's or PHP's network without having to obtain numerous authorizations from their primary care providers, and that this is necessary in order to meet the ''access to care'' standard in section 1932(c)(1)(A)(i) that services be available ''in a manner that ensures * * * adequate * * * specialized services capacity.'' In recognition of varying MCO and PHP practices, the final rule with comment period, requires the treatment plan to specify either an adequate number of direct access visits to specialists or a standing referral to specialists. However, we continue to require that the treatment plan be time-specific, and updated periodically to determine whether continued access to a specialist for a course of treatment is necessary. To avoid confusion, in this final rule with comment period, we also have added a specific requirement that we believe was implicit in the proposed rule. Section 438.206(f)(6) now expressly requires that the treatment plan ensure periodic reassessment for each enrollee as his or her health requires. In addition, in response to the comments

on the need for enrollee participation and that treatment planning consider the needs and preferences of the enrollee, at § 438.206(f)(5) we added a requirement that treatment plans be developed with enrollee participation.

Comment: We received a number of comments urging that we revise proposed § 438.306(e)(3) to further address and consider populations with special health care needs. Many commenters wanted us to further clarify and define the term ''complex and serious medical conditions.'' Specifically, one commenter recommended that we revise the wording of proposed § 438.306(e)(3)(ii) to state: ''Timely identifies individuals with complex and serious medical conditions or mental disabilities, assesses those conditions, and identifies appropriate health care services for monitoring, treatment, or rehabilitation.'' Another commenter recommended that the regulation include a list of conditions that mandate the actions spelled out in proposed § 438.306(e)(3)(ii) and (iii). Although the commenter recognized that it would be impractical to include an exhaustive list, he argued that there are some chronic conditions that should be listed, particularly where continuing attention and monitoring are vital. Some of the populations that commenters recommended include persons with mental disabilities, cancer patients, persons with end stage renal disease, persons awaiting organ transplants, persons with HIV/AIDS, children with special health care needs, and persons with cerebral palsy or other conditions related to the presence of a developmental disability. In contrast to identifying an exhaustive list of conditions, one commenter suggested that we develop a definition for complex and serious medical conditions based on patient requirements for higher levels of resources. This commenter argued that such a definition would require MCOs that enroll persons whose needs exceed normal actuarial physical and mental utilization estimates for a working age population to demonstrate higher capacity both in their networks and with respect to their access standards.

Response: We agree that clarification is needed and, as previously discussed, have revised this provision to require that MCOs and—where applicable—PHPs, screen and comprehensively assess ''enrollees with special health care needs,'' which, as noted above, is how we now refer to individuals with complex and serious medical conditions. As we discussed previously, ''persons with special health care needs'' is the terminology used by the Congress at section 4705(c)(2) of the BBA. We have conceptualized this term to include:

(1) children with special health care needs;

(2) children in foster care;

(3) individuals with serious and persistent mental illness/substance abuse;

(4) individuals who are homeless;

(5) older adults (individuals 65 years of age and older) with disabilities; and

(6) adults under 65 who are disabled or who have a chronic condition, whether physical or mental.

We note that this listing of individuals with special health care needs is not an operational definition of persons with special health care needs and that health services research is still in the process of developing conceptual models, screening tools and approaches to identifying individuals with special health care needs.

Comment: We received a number of comments suggesting that under proposed § 438.306(e)(2) and (3), we should require continuing coverage of on-going treatment, even if it is out-of-network, until the time of an initial assessment when a primary care physician, in consultation with a specialist, establishes a new care plan. Commenters believed that unless an MCO is given prior information, it will not know if an enrollee is pregnant or has a complex medical condition to provide an assessment prior to 90 days. Other commenters noted that the disruption of services can be particularly harmful for enrollees with complex and serious medical conditions. To facilitate the initial assessment, one commenter recommended that we require the State Medicaid agency to provide the MCO with information on age, eligibility category, and whether a child is in foster care or is in an out-of-home placement.

Response: We believe that most States already have mechanisms in place to transition enrollees with ongoing health care needs to managed care. However, we acknowledge the commenters' concerns that our proposed regulation did not address the potential disruption of services, even for a short period of time, between enrollment and the time of assessment by the new primary care physician/specialist in the receiving MCO or PHP. To address this concern, as discussed in section II. B. above, we have added a new paragraph (b) to proposed § 438.62 to require a State to have a mechanism to ensure continued access to services when an enrollee with ongoing health care needs is transitioned from fee-for-service to an MCO, PHP or PCCM; from one MCO, PHP or PCCM to another; or from an MCO, PHP or PCCM to fee-for-service. We believe this provision, plus the requirements in § 438.208 for (1) State identification of enrollees with special needs or at risk for special needs, and (2) MCO and PHP screening and assessments, respond to commenters' concerns that MCOs have the means to identify, in an expedient fashion, enrollees who require immediate attention, and provide needed services to such enrollees.

Comment: One commenter objected to the fact that proposed § 438.306(e)(3) required an MCO to implement and update a treatment plan. Specifically, the commenter suggested that requiring an MCO to implement a treatment plan for specific enrollees is not appropriate for such an administrative entity, as such plans should be developed and implemented only by a patient's physician or other health care professional.

Response: We agree with the commenter. Section 438.208(g) of the final rule with comment period, requires MCOs and PHPs to use appropriate health care professionals to perform comprehensive health assessments and to develop and implement treatment plans.

Comment: A commenter suggested that proposed § 438.306(e)(3) be revised to require the MCO to timely provide effective EPSDT screens and mandated EPSDT services.

Response: EPSDT screenings are required in current regulations. We believe it would be duplicative to restate those requirements in this final rule with comment period.

Comment: One commenter believed that proposed § 438.306(e)(3)(iii)(C) is unclear, and recommends that the final rule with comment period be changed to read ''a treatment plan that specifies an adequate number of direct access visits to specialists as appropriate to the enrollee's condition.'' Further, the commenter suggests that we add the phrase ''or, when required by the condition, the names of specialists to whom the enrollee shall have direct access for the duration of the treatment plan.''

Response: We agree that the proposed language was unclear. We have revised the cited provision, which is now redesignated as § 438.208(f), to require MCOs and PHPs to implement a treatment plan that: (1) is appropriate to the enrollee's conditions and needs identified by screening and assessment, and (2) specifies either a standing referral or an adequate number of direct

access visits to specialists. We expect that the treatment plan will specify the specialist(s) to whom the enrollee has direct access, but do not believe it necessary to require in regulations text that the treatment plan must specify the actual names of specialist to whom the enrollee shall have direct access for the duration of the treatment plan.

Comment: Several commenters expressed concern with proposed § 438.306(e)(3)(iii)(D). Commenters suggested that requiring physicians themselves to update a treatment plan is unrealistic and administratively burdensome. One commenter recommended that the final rule with comment period, be revised to permit the updating of a treatment plan by a specialist instead of a primary care provider.

Response: We agree on the need to allow for situations in which a specialist or other health care professional within an MCO or PHP assumes the responsibility for updating an enrollee's treatment plan. While we believe that a treatment plan should be developed in coordination with an enrollee's primary care provider, we recognize that MCOs or PHPs may permit professionals other than the enrollee's primary care provider to update the enrollee's treatment plan. Accordingly, in the final rule with comment period, § 438.208(g) requires MCOs and PHPs to use ''appropriate health care professionals'' to develop, implement, and update any required treatment plan.

Comment: We received a number of comments on proposed § 438.306(e)(4), which required that MCOs and PHPs ensure services are provided in a culturally competent manner, including at least meeting the language requirements of § 438.10. Overall, the majority of commenters supported this provision, but many suggested that we clarify the provision in the final rule with comment period. Several commenters requested that we define cultural competency and strengthen the regulation to require that MCOs include in their networks providers that have an understanding of enrollees' customs and traditions.

Commenters offered many recommendations. One commenter suggested specific language: ''the MCO ensures that services are provided in a culturally competent manner to all enrollees, by providers with appropriate knowledge and skills to treat enrollees who are members of linguistic or ethnic minorities, and adults and children with special health care needs, including recipients with mental illness, substance abuse problems, developmental disabilities, functional disabilities, or complex problems involving multiple medical and social needs (for example, HIV/AIDS and homelessness).'' Several other commenters recommended that we add requirements such as: (1) full attention by the MCO to racial and ethnic minorities, (2) interpreter services, including braille and sign language, (3) an appropriate number of caregivers properly trained in cultural competency, and (4) provider awareness of medical risk related to racial, ethnic, and socioeconomic factors. Finally, other commenters recommended that we: (1) mandate California's standards for cultural competency, (2) limit providers who are culturally aware to 5 percent or 200 in number to combat recruitment or other training burdens, (3) revise the rule to require that MCOs identify enrollees who belong to ethnic minority groups that may have special barriers in accessing care, and make continued efforts to improve accessibility, or (4) mandate that the National Committee for Quality Assurance (NCQA) require MCOs to collect ethnicity data to ensure quality so that appropriate educational, screening, and treatment programs can be developed.

Response: We do not believe it is appropriate to add all of the specificity suggested by the commenters, however we do agree that further strengthening and clarification is needed. As a result, we have added a provision at § 438.204 that requires States, as an element of their State quality strategies, to identify and provide MCOs and PHPs with information, on, the race, ethnicity, and primary language spoken by each Medicaid beneficiary at the time of their enrollment in an MCO or PHP. We will provide technical assistance to States on implementing these requirements. Our final rule with comment period also has been revised at § 438.206(e)(2) to require MCOs and PHPs to ensure that services are provided in a culturally competent manner to all enrollees, including those with limited English proficiency, and diverse cultural and ethnic backgrounds.

While we decline to add a definition of cultural competency in regulation text because the state of the art with respect to standards for cultural competency is still evolving. States should undertake efforts to further define cultural competency in their contracts and in standards for access to care under their quality assessment and performance improvement strategies. We offer the following statement as one that States may consider using in any definition of cultural competency: ''Cultural competency in health care is a set of attitudes, skills, behaviors, and policies that enable organizations and individuals to work effectively in cross-cultural situations. It reflects an understanding of the importance of acquiring and using knowledge of the unique health-related beliefs, attitudes, practices, and communication patterns of beneficiaries and their families to improve services, enhance beneficiary understanding of programs, increase community participation, and eliminate disparities in health status among diverse population groups.''

Comment: Several commenters believed that we needed to further clarify proposed § 438.306(e)(4) to ensure appropriate linguistic access. One commenter recommended that the comment period be strengthened to require, at a minimum, that MCOs and PHPs have a means of communicating during medical and administrative encounters.

Response: We agree that some clarification in the final rule with comment period is needed. As noted above, we have provided in § 438.206(e)(2) that MCOs and PHPs must provide services in a culturally competent manner to all enrollees, including those with limited English proficiency, and diverse cultural and ethnic backgrounds. Further, as noted above in section II.A., we require in § 438.10(b) that States and MCOs, PCCMs and PHPs make interperter services available to meet the needs of all enrollees. We believe that § 438.10(b) is sufficient to ensure that enrollees have means of communication during medical and administrative encounters.

5. Continuity and Coordination of Care (Proposed § 438.308)

Proposed § 438.308 set forth a series of requirements to ensure that a State require MCOs and PHPs to maintain continuity and coordination of care for its enrollees. Proposed § 438.308(a) required that MCOs and PHPs have in place written policies that provide each enrollee with an ongoing source of primary care appropriate to the enrollee's needs, as well as, formally designating a practitioner who is responsible for coordinating the enrollee's overall health care.

In proposed § 438.308(b), MCOs and PHPs were required to ensure coordination of services, both internally and with services available from the community.

Proposed § 438.308(c) required MCOs and PHPs and their providers to have the information necessary for effective and continuous patient care and quality improvement, including procedures to ensure that each provider maintains

health records that meet requirements established by the MCO or PHP, taking into account professional standards, and there is appropriate and confidential exchange of information among providers.

Proposed § 438.308(d) required procedures to ensure that providers inform enrollees of specific health conditions that require follow-up, and if appropriate, provide training in self care, and deal with factors that hinder enrollee compliance with prescribed treatment or regimens.

Comment: We received a number of comments urging that proposed § 438.308 address the continuation of an enrollee's ongoing treatment when transitioning to managed care. (Similar comments, discussed above, were also received on proposed § 438.306(e)). Although many commenters commended us for addressing the issue of continuity and coordination of care once a beneficiary has been enrolled in managed care, many also expressed concern that the proposed regulation did not highlight the need for identification and continuation of an enrollee's treatment when transitioning from fee-for-service into managed care or from one managed care organization to another. Several commenters stated that the interruption of treatment for only a short period of time could have serious and possibly irreversible consequences on a individual's health. Other commenters suggested that ongoing treatment without interruption was especially critical for persons suffering from mental illness, substance abuse, and chronic conditions such as HIV/AIDS.

A number of recommendations were offered. Some commenters recommended that we require continued coverage of ongoing treatment until a new care plan is established as a result of an initial assessment in the receiving MCO. Other commenters suggested that we define continuing treatment to include equipment, medical supplies, and prosthetic and orthotic appliances. Several commenters also recommended specific regulatory language that would permit an enrollee to continue to be covered for a course of treatment for a specified transition period. These commenters suggested that State agencies or the MCO or both be required to notify enrollees of the right to have treatment continued. In addition, the forwarding MCO should be required to share all medical files on a transferring enrollee with the receiving MCO.

Response: As noted above in this section, and as discussed more fully in section II. B., in response to the large number of comments on this issue, we have added to § 438.62 a new paragraph (b) that requires States to have a mechanism to ensure continued access to services when an enrollee with ongoing health care needs is transitioned from fee-for-service into a MCO, PHP or PCCM; from one MCO, PHP or PCCM to another MCO, PHP, or PCCM; or from an MCO, PHP, or PCCM to fee-for-service. We further have specified minimum requirements that the State transition mechanisms must address, and have identified specific population categories that State transition mechanism must cover.

Comment: Several commenters believed that proposed § 438.308 did not adequately address the issue of prior existing relationships. Commenters voiced concerns about the impact on enrollees when existing relationships have to be discontinued as a result of mandatory managed care programs, or as a result of providers leaving the network. These commenters specifically referenced populations with special health care needs and pregnant women as particular populations who would suffer an adverse impact. Some commenters recommended that pregnant women have the option to continue care with their OB/GYN until completion of post-partum care and others recommended that women who have already initiated prenatal care be exempted from the mandatory enrollment requirement. Other commenters focused their recommendations on other populations with special health care needs, with some recommending that we require MCOs to contract with providers currently serving Medicaid beneficiaries, and others requesting that we exempt populations with special health care needs from managed care entirely, particularly children with special health care needs.

Response: In section 1932(a)(2) of the Act, the Congress specifically exempted certain categories of children with special needs and Medicare eligible beneficiaries from mandatory enrollment under section 1932(a)(1) of the Act. Given the level of specificity in the statute, we believe that it would be inconsistent with Congressional intent to exempt additional categories of beneficiaries. With respect to the suggestion that MCOs be required to cover out-of-network services, once again the Congress has specified in detail those circumstances (e.g., post-stabilization services), for which an MCO is required to pay for out-of-network services or those circumstances (e.g., family planning services) for which an MCO cannot limit an enrollee to its network of providers. We do not believe that we would have authority to require MCOs to cover non-emergency services furnished by a provider with whom the MCO has no relationship. However, we understand the commenters' concerns that an existing relationship may be disrupted as a result of a beneficiary enrolling in managed care, and as discussed in the previous comment response, we believe we have addressed this problem in § 438.62(b). We wish to make clear that the requirements in § 438.62(b) are not intended to preempt State laws that require continuation of care outside the network.

Comment: We received numerous comments on proposed §§ 438.308(a)(1) and (a)(2). Several commenters argued that certain individuals with disabilities and other chronic conditions may require a specialist or other qualified and experienced practitioner as their primary care provider. Some commenters recommended that the final regulation explicitly provide for the designation of a specialist as the primary care provider in certain instances, such as for persons with complex and serious medical conditions. One commenter suggested that an MCO be required to refer chronic renal disease patients to a nephrologist for primary care services before a patient develops end stage renal disease. Another commenter suggested that we add language to allow residents, under supervision, to serve in the role of ''continuing physician.'' Finally, one commenter recommended that primary care systems not be allowed as care managers for complex behavioral needs.

Response: We agree that there may be instances where a specialist would be an appropriate choice for a primary care provider, particularly for individuals with special health care needs. However, we decline to impose that degree of specificity in regulation because: (1) the existing evidence base regarding better health outcomes for individuals whose primary care provider is a specialist is limited; and (2) it is not possible at present to specify in this regulation all the decision rules to direct when a given individual must have a specialist as a primary care provider. We believe that States, MCOs, and PHPs have sufficient flexibility under the final rule with comment period to permit specialists or other experienced providers to serve as primary care providers, as appropriate.

We also do not believe that it is appropriate to revise this final rule with comment period, to prohibit primary care systems from acting as care managers for persons with complex

behavioral needs. Again, States have the flexibility to decide the appropriate specifications to impose on MCOs and PHPs regarding the types of primary care providers, depending on the nature of the managed care program in the State and the population being served.

Comment: One commenter recommended that we revise proposed §§ 438.308(a)(1) and (a)(2) to allow an MCO or enrollee to designate a medical group or provider entity, instead of an individual, for primary care and overall coordination.

Response: We agree that the MCO should have the flexibility to include medical groups and other provider entities as sources of primary care and overall coordination. Our intent in drafting the proposed rule was to ensure that enrollees have an ongoing source of primary care and a designated person or entity responsible for coordinating their health care. Section 438.208(h) in the final rule with comment period, now requires the State to ensure that each MCO and each PHP: (1) provide each enrollee with an ongoing source of primary care appropriate to his or her needs; and (2) have a mechanism to identify the person or entity formally designated as primarily responsible for coordinating the enrollee's health care. While we thus have added flexibility to designate a medical group or entity as the primary care source, we urge MCOs and PHPs to make every effort to promote a relationship between an enrollee and a single primary care provider.

Comment: Several commenters requested that we clarify whether we are proposing a ''case-manager'' or ''point-of-entry'' care coordination model in proposed § 438.308(a). One of these commenters stated that under either model, the entity must be intimately familiar with the varied needs of the enrollee, and stressed that appropriate safeguards must be in place to ensure effective coordination among care providers. One commenter specifically recommended that we modify the proposed rule to indicate that, based on the initial assessment under proposed § 438.306(e)(2), the type of care coordination for each enrollee be determined by an analysis of individual need.

Response: Our intent was not to propose a ''case-manager,'' ''point-of-entry,'' or any other particular model of care coordination. Rather, our intent was to ensure that MCOs and PHPs, regardless of the model of care coordination, make every effort to promote a relationship between the enrollee and the primary care provider source. We recognize that some MCOs and PHPs might have systems of care coordination under which a person or entity, other than the enrollee's primary care provider, coordinates services. We believe that our revised language in § 438.208(h) better reflects our intent.

With respect to the specific comment that the type of care coordination for each enrollee be determined by an analysis of individual need, we believe that the comprehensive assessment, treatment plan, and coordination program requirements in § 438.208 sufficiently address this issue.

Comment: A commenter found proposed § 438.308(a)(1) unclear, and thought that it could be interpreted to mean that an MCO must provide each enrollee with a primary care provider, and allow self-referral to a specialist on an as-needed basis. This commenter recommended that we delete this provision because, as the commenter interpreted it, it was unworkable in a managed care environment.

Response: We have clarified our final rule with comment period so that each MCO and each PHP must provide an enrollee with an ongoing source of primary care appropriate to his or her needs, and have a mechanism to identify the person or entity who is formally designated as primarily responsible for coordinating the enrollee's health care. We believe that this language is clear and cannot be interpreted to allow self-referral to a specialist.

Comment: We received several comments supporting the proposed provision in § 438.308(b), which requires an MCO to ensure coordination of services internally and with services available from community organizations and other social programs. Many of these commenters requested that we expand the coordination of services list. In contrast, several other commenters stated that they felt that the proposed regulation was unclear and questioned whether it was practical for an MCO to serve as a gatekeeper for non-medical services. Some commenters questioned our authority in proposing this provision, with a few stating that this provision was a major expansion of State and MCO responsibility. Several of these commenters indicated that this provision would be difficult for States to monitor, and recommended either that we clarify the regulatory language or delete the provision entirely. In addition, one commenter referenced the cost-effectiveness test under 1915(b) of the Act waiver programs, noting that such a test is based on a comparison to historic fee-for-service costs that does not include costs associated with coordinating services with other social programs.

Response: We agree that the extent to which an MCO can coordinate all health and health-related services that are needed by an individual enrollee is variable, and that effective approaches to care coordination has not been well addressed to date by health services research. MCO responsibility for care coordination can range from: (1) coordination of all Medicaid services included in the contract between the MCO and the State; (2) coordination of all Medicaid services regardless of whether they are included in the MCO's contract with the State; and (3) coordination of all health, social, educational, and other services needed to maintain optimal health of an enrollee. Determining the appropriate level of responsibility for the MCO for care coordination is complex. The ability of the MCO to coordinate care is determined, in part, by the authority the MCO has to coordinate care provided by entities not a part of the MCO and by the MCO's available resources. Further, social or community organizations external to the MCO may not desire the MCO to coordinate care out of concern that care will be ''medicalized'' or that the authority of other agencies for care coordination will be weakened.

Since these are complex issues, we encourage all State Medicaid agencies to work with beneficiaries, MCOs and PHPs and other stakeholders in their State to determine the appropriate responsibilities of MCOs and PHPs in the State for care coordination. We accordingly have, in response to the above comments, deleted the requirement in proposed § 438.308(a)(2) that MCOs and PHPs coordinate services available from community organizations and social programs. We note, however, that an MCO or PHP may still have responsibilities for coordination that exist under fee-for-service Medicaid. Under § 431.615, State Medicaid agencies are required to establish, as part of their State plan, ''arrangements'' with State health and vocational rehabilitation agencies and Title V grantees. These arrangements must include coordinating plans for health services provided or arranged for recipients. In addition, similar arrangements are required under § 431.620, between a State Medicaid agency and State mental health authority or mental institutions. Section 431.635 also outlines requirements for the coordination of Medicaid with Special Supplemental Food Programs for Women, Infants, and Children (WIC). While these requirements are imposed on States, we believe that States may

delegate some of these coordination responsibilities to MCOs and PHPs. To the extent that these responsibilities are delegated, MCOs and PHPs must ensure coordination of health-related services with community and other social groups. This is now a State option, however.

In response to comments, § 438.208(h) of the final rule with comment period, thus requires that: ''Each MCO and PHP must implement a coordination program that: (1) Meets the requirements specified by the State; (2) Ensures that each enrollee has an ongoing source of primary care appropriate to his or her needs and a person or entity formally designated as primarily responsible for coordinating the health care services furnished to the enrollee; (3) Coordinates the services it furnishes to enrollees with the services the enrollee receives from any other MCOs and PHPs; (4) Ensures that the results of its screen or assessment of an enrollee (or both, if the MCO or PHP performs both) are shared with other entities serving the enrollee, so that those entities need not duplicate the MCO's or PHP's screening or assessment or both; (5) Ensures that in the process of coordinating care, each enrollee's privacy is protected consistent with the confidentiality requirements in § 438.224; (6) Ensures that each provider maintains health records that meet professional standards and that there is appropriate and confidential sharing of information among providers; (7) Has in effect procedures to address factors (such as a lack of transportation) that may hinder enrollee adherence to prescribed treatments or regimens; and (8) Ensures that its providers have the information necessary for effective and continuous patient care and quality improvement, consistent with the confidentiality and accuracy requirements of § 438.224 and the information requirements of § 438.242. We are further requiring in § 438.10(d)(2)(i)(C) that the scope of MCO and PHP coordination be disclosed to potential enrollees by adding ''MCO and PHP responsibilities for coordination of enrollee care'' as an additional type of information that must be provided to potential enrollees.

Comment: Several commenters suggested that proposed § 438.308(b) would not achieve continuity and coordination of services if an MCO contract does not cover all medically necessary services included in a State plan. These commenters believed that an MCO should take responsibility for coordinating all Medicaid services that are not part of its contract. One commenter requested that we clarify whether a State may determine that a State entity, local organization, or community organization is more appropriate to fulfill the coordination role. As an alternative, the commenter recommends that we revise the final rule with comment period to state, ''With the permission of the enrollee, or when consistent with the State's confidentiality laws, the MCO must provide that its providers release information concerning the enrollee's medical treatment to community organizations and other social programs when so requested by such organizations or programs.''

Response: Consistent with our response to the prior comment, and with our revisions to this section, we do not believe that § 438.208(h) prevents a State Medicaid agency from delegating the responsibility for coordinating health-related services to entities other than the MCO or PHP, such as other State and local organizations. Under the final rule at with comment period, § 438.208(h), States have the discretion to contract with MCOs and PHPs to provide a specific set of services that may not include all services covered under a Medicaid State plan. In a situation where the State has assumed a coordination function or delegated it to an entity other than the MCO or PHP, the MCO or PHP must still coordinate care and services to the extent and manner specified by the State and ensure that in the process of coordinating care, each enrollee's privacy is protected consistent with the confidentiality requirements in § 438.224.

Comment: We received several comments on proposed § 438.308(c)(2), which would require an appropriate and confidential exchange of information among providers. One commenter indicated that he or she was pleased to see the importance of confidentiality stressed. However, several comments suggested that proposed § 438.308(c)(2) lacked specificity about what information should and should not be shared between primary care and behavioral health providers. Several of these commenters recommended that enrollees be provided informed consent before information is shared. One commenter specifically noted that existing confidentiality requirements, especially those related to substance abuse treatment, severely limit the practitioner's ability to exchange treatment information. Another commenter stated that it is difficult to know what proposed § 438.308(c)(2) means without a definition of the term ''confidential.'' This commenter recommended that we reference applicable State law in the final rule with comment period.

Response: Our intent in drafting this provision was to ensure that MCOs and PHPs and their providers have the information necessary for effective and continuous patient care and quality improvement. In proposed § 438.308(c), we referenced the need for providers to maintain health records consistent with the requirements established by MCOs and PHPs, taking into account professional standards. In proposed § 438.308(c)(2), we also referenced the need for confidential exchange of information among providers. Both of these requirements were included in an effort to reinforce the confidentiality requirements in proposed § 438.324. We did not intend that the proposed rule be interpreted to require informed consent or to supersede relevant State law governing the exchange of information between providers.

We decided to revise the requirement to provide further clarification and to avoid confusion over the interface of this provision with § 438.224. Accordingly, § 438.208(h)(7) of the final rule with comment period, specifies that each MCO and PHP must ensure that its providers have the information necessary for effective and continuous patient care and quality improvement ''consistent with the confidentiality and accuracy requirements of § 438.224 and the information requirements of § 438.242''. In addition, at § 438.208(h)(4), we require that MCOs and PHPs have coordination programs that ensure that each enrollee's privacy is protected consistent with the requirements of § 438.224. Based on these revisions, we believe that there is no need to define the term ''confidential.''

Comment: We received several comments in support of proposed § 438.308(d), which would require MCOs and PHPs to have procedures in place to ensure that providers: (1) Inform enrollees of specific 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. One commenter noted that the proposed rule recognizes the value of disease management programs. Another commenter supported the rule but felt that we should further clarify it to ensure that MCOs take responsibility to educate patients as to when they may go to emergency rooms. Another commenter asked that we recognize that there are limits on self-care requirements due to the nature of an enrollee's disability.

Other commenters objected to the proposed rule. One commenter opined that self-care cannot be legislated. This commenter believed that by making this a compliance issue, we were exceeding her authority. Another commenter felt that this provision was not practical and would lead to increased administrative costs.

Response: We continue to believe in the value of providing information and training on conditions that may improve with self-care, and encourage MCOs to provide for this. However, we are persuaded by commenters that some of the conceptual language on ''specific health conditions that require follow-up'' and ''if appropriate, provide training in self-care'' are unclear and subjective. We note that potentially all health conditions that require a visit to a health care practitioner require some degree of ''follow-up.'' Accordingly, in § 438.208(h)(6) of the final rule with comment period, we only require that MCOs and PHPs have in effect procedures to ''address factors (such as lack of transportation) that hinder enrollee adherence to prescribed treatment regimens.''

With regard to the comment that MCOs and PHPs should have the responsibility to educate beneficiaries on the proper use of the emergency room, we encourage MCOs and PHPs to undertake this type of education. However, any training effort must be consistent with the emergency services requirements in § 438.114.

6. Coverage and Authorization of Services (Proposed § 438.310)

Proposed § 438.310 set forth requirements to ensure that each contract with an MCO or PHP 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, the proposed requirements would ensure that utilization management activities are not structured in a manner that is detrimental to enrollees. These standards implement section 1932(b)(1) of the Act, and to the extent appropriate and applicable, are consistent with Medicare+Choice regulations at § 422.112.

In paragraph § 438.310(a) we proposed that the State ensure through its contracts with MCOs and PHPs that each MCO or PHP identifies, defines, and specifies the amount, duration, and scope of all Medicaid benefits that the MCO or PHP must furnish. Furthermore, the contract must specify what constitutes medically necessary services to the extent they are described in the State plan, and provide that the MCO or PHP furnishes the services in accordance with that provision. We believe these requirements are essential, as it is a concern that an MCO's or PHP's authorization procedures, if unduly burdensome, can prevent an enrollee from having access to, or receiving services to which they are entitled under the State plan. In addition to serving as a protection for enrollees, these requirements support the provider's needs and desires to know what is required for authorization determinations.

In § 438.310(b) we proposed to require that, in processing requests for initial or continuing authorization of services, the MCO or PHP and its subcontractors: (1) follow written policies and procedures that reflect current standards of medical practice; (2) specify the information required for authorization decisions; (3) have in effect mechanisms to ensure consistent application of review criteria; (4) consult with the requesting provider when appropriate; and (5) observe time frames specified in paragraph (d) of proposed § 438.310.

In paragraph (c), we proposed that MCO and PHP contracts be required to provide that written notice be provided, within the time frames in paragraph (d), of decisions to ''deny, limit, reduce, delay, or terminate'' services, including specific reasons for the decision, along with information on the enrollees right to file a grievance or request a State Fair Hearing.

In paragraph (d), we proposed that contracts be required to specify that services will be provided as expeditiously as the enrollee's health condition requires, and within State-established time frames not to exceed 14 days in ordinary cases, and 72 hours if a further delay could ''seriously jeopardize the enrollee's life or health or ability to regain maximum function.

In paragraph (e) we required that each MCO and PHP contract must provide that, consistent with § 438.6(g) and § 422.208, compensation to individuals or entities that conduct utilization management activities is not to provide incentives to deny, limit or discontinue medically necessary services.

Comment: Numerous commenters expressed the view that proposed § 438.310(a)(1) would be difficult to implement. These commenters felt that while a general description of categories of core benefits and service limitations seemed reasonable, the requirement to include the amount, duration, and scope of each service in the contract was not reasonable, and would make the contract too extensive to manage; create unintended exclusions; not allow for consideration of patient specific needs; and require frequent contract amendments to keep current. They also urged that States have the flexibility to determine the level of detail to include in contracts, and believed that the requirements in proposed § 438.310 went beyond legislative intent. Commenters recommended that the contract identify, define, and specify each service that must be offered, but that the amount, duration, and scope be defined in a State Plan or other document. In contrast to the commenters who were opposed to the provision, several commenters supported the proposed provision, stating that it was essential that contracts make clear the services that an MCO must offer to ensure that the enrollee receives the services that they are entitled to under the State Plan. Commenters who supported the provision did not distinguish between the requirement to identify the services and the requirement to include the amount, duration, and scope of each service.

Response: The intent behind this provision was to ensure that enrollees receive the services that they are entitled to receive under the State plan, regardless of the MCO or PHP that they elect, with the recognition that some MCOs and PHPs may not directly provide some services, in which case the State must arrange for these services. While we acknowledge the difficulties that were raised concerning implementing this provision as proposed, we also agree with commenters who stated that it was essential that the contract make clear the services an MCO or PHP is to offer. Any limitations in amount, duration and scope are important features of benefit coverage. Failure to address them in a contract creates the potential for confusion between the State and MCO or PHP and thereby the possibility that an enrollee may not have timely access to service to which he or she is entitled. Because of these concerns, the final rule with comment period at § 438.210 still requires that the amount, duration, and scope of services be specified, now on the basis of what is contained in the State Plan. It further requires that the amount, duration, and scope be such as can reasonably be expected to achieve the purposes for which the services are furnished. However, we also note that if an MCO or PHP does not cover a particular service, the State must make arrangements to ensure that enrollees are able to receive all services covered under the State plan.

Comment: One commenter believed that proposed § 438.310(a)(1) gives the impression that States and MCOs may negotiate away existing Federal requirements governing coverage determinations in the Medicaid program. Specifically, the commenter pointed out that existing regulations for fee-for-service at § 440.230 require that services be provided in sufficient amount, duration, and scope ''to reasonably achieve its purpose.'' It further prohibits States from arbitrarily denying or reducing the amount, duration, or scope of such services solely on the basis of diagnosis, type of illness, or condition. Although State agencies may place limits on a service, limitations much be based on appropriate criteria such as ''medical necessity'' or on utilization control procedures. The commenter was concerned that § 438.310(a)(1) could be read to undermine these requirements by implying discretion to define amount, duration, and scope in contracts in a manner negotiated between the State and MCO or PHP.

Response: We agree with the commenter that the provisions at § 440.230 should also apply to a managed care arrangement, and we accordingly have included them in § 438.210 of the final rule with comment period in response to this comment. In addition, we have clarified that services limited for the purpose of utilization control must still be provided in sufficient amount, duration, and scope to reasonably achieve the purpose for which they are furnished.

Comment: One commenter suggested that benefits and services referenced in § 438.310(a)(1) include all Federally mandated benefits and services, including nurse-midwifery services.

Response: Federal law allows States to ''carve-out'' specific Medicaid services from contracts with MCOs and PHPs, and offer them on a fee-for-service basis or through a separate managed care contractor. For this reason, proposed § 438.310(a)(1) was not intended to govern what services are to be included in or covered by an MCO or PHP contract, but to require that, for those services that are included in or covered by the contract, that the contract identify, define and specify those services. Therefore, we are not requiring in the final rule with comment period that each MCO and PHP contract include all Federally mandated benefits and services, including nurse-midwifery services.

Comment: Many commenters suggested the regulation mandate a definition of medical necessity for States to use in their managed care contracts, or more specific guidance regarding the definition. Commenters presented a range of reasons for including a standard definition, including the need for consumers and providers to understand the scope and limits of health care benefits, ensuring enrollees are not denied services to which they are entitled, avoiding disputes between States and MCOs or PHPs and providers, eliminating State variances in the definition, curbing future lawsuits, and improving the incentive for managed care plans to compete based on innovative quality improvements, rather than restrictive authorizations.

Several different definitions were suggested by different commenters. Some of the recommendations suggested that the definition reflect maintenance of functioning, prevention of deterioration, optimum participation in community living, consideration of the differences between children and adults (especially age-appropriate services and the developmental, rather than rehabilitative, nature of some services for children), and should specifically address mental health needs.

Other commenters found the provision regarding medical necessity too prescriptive and believed that medical issues should not be resolved through a regulation or contracting process.

Response: We disagree that the provision is too prescriptive. States have existing medical necessity specifications in Medicaid fee-for-service programs and individuals enrolled in managed care are entitled to the same services as all other Medicaid eligible persons in the State. Clear specifications of medical necessity in the contract are critical in determining what a State is paying MCOs and PHPs to provide and, in some cases, what the State is providing outside the managed care setting for all parties in the program. The application of State specifications in individual situations allows for medical judgement.

However, we also do not agree that a definition of medical necessity should be included in the regulations. There currently exists no widely-accepted national definition, and at present States currently are allowed under § 440.230(d) to ''place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures,'' and have great flexibility in defining that criteria. Therefore, we do not believe it is appropriate to promulgate a national definition at this time. However, we believe that more specific guidance regarding State contract specifications is needed. In particular we believe that medical necessity criteria used by Medicaid MCOs and PHPs should not be more restrictive than the State Medicaid medical necessity criteria used in the State's Medicaid program overall, and that this be evident to all parties, thus decreasing the potential for disputes.

Therefore, we have revised the regulation to require that the specifications of medical necessity in the contract must be no more restrictive than any such specifications in the State Medicaid fee-for-service program, described in State statute, regulations, State plan, or other policy or procedures. This addition of ''State statute, regulations or other policy or procedures'' provides greater specificity than the sole reference to ''State plan.'' found in the proposed rule. We further agree that the contract should be clear about what the State's specifications are with respect to medical necessity criteria. Therefore, we have added provisions requiring that the contract address the extent to which the MCO or PHP is responsible for covering medically necessary services to: (1) prevent, diagnose, and treat health impairments; (2) enable the enrollee to achieve age-appropriate growth and development; and (3) attain, maintain or regain functional capacity. While we are not mandating that services must be covered to meet these goals, the contract must clearly address the extent of each MCO's and PHP's responsibility to provide such services. This provision will promote greater consistency of medical necessity specifications across MCOs and PHPs within a State. We believe that services to meet mental health needs are understood to be under the purview of these specifications without specific mention.

We believe this revised regulatory provision, in conjunction with other provisions in this regulation, will meet commenters' concerns regarding beneficiary understanding as well. Section 438.10 requires that information regarding the kinds of benefits, and amount, duration and scope of benefits available under the contract must be provided to enrollees or potential enrollees upon request. This provision should improve the understanding of beneficiaries so they are not denied services to which they are entitled. This section also requires the provision of information regarding grievance, appeal and fair hearing procedures to assure that beneficiaries understand their ability to dispute decisions made by MCOs and PHPs.

We anticipate that greater specificity in MCO and PHP contracts will reduce the potential for MCOs and PHPs to

develop specifications of medical necessity inconsistent with those developed by the State Medicaid agency. However, it must be noted that medical necessity relates to determinations regarding specific care given to a specific patient with specific medical condition under certain circumstances and is thus more focused on individual situations. Some potential for dispute is inherent in such decisions.

Comment: Many commenters indicated that the regulation should recognize the special status of Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) provisions, and provide specific reference to them under the medical necessity provision.

Response: This regulation does not affect any of the pre-existing EPSDT regulations. Further, some EPSDT services may be provided by the State outside of the managed care contract. We believe it is redundant and unnecessary to repeat all existing requirements in this regulation, which focuses on managed care programs. For this reason, we have not included any specific reference to EPSDT in the provisions on medical necessity.

Comment: Some commenters found that the proposed regulation gave the impression that the States and MCOs may negotiate away the Federal legal requirements governing coverage determinations in the Medicaid program. Comments suggested that the regulations ensure that States include in managed care contracts a definition of medical necessity consistent with Federal law.

Response: The provision addressing medical necessity in no way affects any other Federal requirements governing coverage determination in the Medicaid program. All parties must adhere to all other Federal statutes and regulations. However, we believe it would be redundant to repeat all such requirements in this regulation.

Comment: Commenters urged that we review and approve definitions of medical necessity before approving managed care contracts.

Response: Section 438.6 of this final rule with comment period requires us to review and approve MCO and PHP contracts. As part of that review, we will assure that regulatory requirements at § 438.210 pertaining to MCO and PHP contract provisions on medical necessity are met. While these provisions are not a definition of medical necessity, they will promote greater shared understanding by MCOs, and PHPs and beneficiaries about how medical necessity is determined.

Comment: One commenter asserted that ongoing monitoring by us is essential to ensure that States or MCOs do not define medical necessity so narrowly that they deprive beneficiaries of services to which they are entitled under Medicaid.

Response: We agree that ongoing monitoring of managed care programs is important. We utilize a variety of mechanisms to monitor State contracts and State Medicaid managed care initiatives. These mechanisms include: data reviews, State and MCO on-site reviews, and input from beneficiaries, advocates and providers. Furthermore, other provisions in this regulation, such as § 438.204(d) (which requires external reviews of the timeliness of and access to services covered under each MCO and PHP contract), provide significant additional information to assist us and States in monitoring.

Comment: One commenter believed that each State operating a Medicaid managed health care plan that includes children should be required to consult with the State agency that is responsible for overseeing the delivery of early childhood intervention services (under Paragraph B and C of Individuals with Disabilities Education Act) to ensure that the plan includes adequate provisions for coordination of health and early intervention services to such youngsters.

Response: We strongly support coordination between appropriate State agencies. In § 438.202, we require States to provide for the input of recipients and other stakeholders in the development of the State strategy for quality assessment and performance improvement. We consider other State agencies such as State Mental Health and Substance Abuse agencies, Title V Maternal and Child Health agencies, and IDEA agencies as stakeholders who should have input into the development of the strategy.

Comment: We received comments urging that there be no gaps in Medicaid services. A major problem, in the view of these commenters, is that States often are unaware of their responsibility to fill gaps left in the case of services not provided through an MCO or PHP.

Response: We agree that all needed Medicaid covered services must be furnished. In the final rule with comment period—

Section 438.210 requires that the contract identify, define, and specify services that the MCO or PHP is required to offer; and

Section 438.206 specifies if an MCO or PHP contract does not cover all of the services in the State plan, the State must make those services available from other sources and give enrollees information on how and where to obtain them, including how transportation is provided.

In determining whether services should be provided in individual cases, fair hearing officers are bound by their interpretation of the State's overall Medicaid program coverage criteria, and must apply these criteria rather than specific coverage criteria in the contract if the hearing officer determines that the contract criteria are inconsistent with State criteria. The State retains overall responsibility for covering all services in accordance with the Medicaid State plan and implementing policies and procedures, regardless of whether some or all of these services may have been contracted to an MCO or PHP.

Comment: Commenters expressed divergent views on the basis for medical necessity determinations, including preferences for evidence-based standards, professional standards, generally accepted standards of medicine, or deference to the recommendation by the treating professional. Some voiced concern that the evidence-based standard for determining which services are medically necessary would limit obligations to services deemed effective based on quantitative or scientific studies. Quantitative evidence of efficacy does not always exist with respect to persons with developmental disabilities or other special populations who have not been involved in studies. On the other hand, some commenters felt the professional standard of review was inappropriate because of disputes among professionals.

Response: Because of the variable evidence base for the efficacy of the multitude of therapeutic interventions possible for any population, and the lack of consensus regarding the best approach to medical necessity determinations (as evidenced by the comments received) we do not mandate a single approach for determining medical necessity. States have great flexibility in establishing this standard, which is applicable in both fee-for-service and managed care.

Comment: Commenters indicated that MCO subcontracts should be required to include the same ''medical necessity'' definition, as well as EPSDT requirements and access standards, and the clear description of benefits that are contained in contracts between the State and MCOs.

Response: MCOs and PHPs are responsible for assuring that services are provided in accordance with their contract with the State, regardless of any subcontracts in place. MCOs and PHPs

may delegate activities, but not responsibility, for contract provisions. Section 438.230(a)(1) requires the State to ensure that each MCO or PHP oversees and is accountable for functions delegated to subcontractors. States must monitor this process on an ongoing basis and insure the development of corrective action plans, where necessary.

Comment: A commenter believed that all coverage decisions made by the MCO should be consistent with current standards of medical practice.

Response: Section 438.210(b)(1) of the final rule with comment period, requires that the MCO or PHP and its subcontractors follow written policies and procedures that reflect current standards of medical practice in processing requests for initial and continuing authorization of services.

Comment: A commenter was concerned that proposed § 438.310(b)(1) could be interpreted to require a written authorization for every authorization decision. The commenter felt that while this may be possible for many courses of treatment, it was not universally possible.

Response: Section 438.210(b)(1) of the final rule with comment period requires MCOs and PHPs to follow written policies and procedures that reflect current standards of medical practice. The provision applies to the authorization process in general, not each determination. The intent is to ensure that actual determinations are consistent and made in accordance with policies and procedures that reflect current standards of medical practice.

Comment: Some commenters noted that a stated intent of the service request processing requirements in proposed § 438.310(b) was to ensure that the authorization process was not unduly burdensome for providers. These commenters believed that this objective would be better achieved by a more general requirement that the MCO's process be reasonable, rather than by asking States and MCOs to establish specific requirements in their contracts. They felt the requirements were too detailed for a contract, and that the level of specificity was not called for under the BBA. Commenters were most opposed to the requirement that each contract specify the information required for authorization decisions. In contrast, one commenter believed that there should be more specificity than we proposed, especially in the area of routine authorization decisions.

Response: The reason for proposed § 438.310(b) was that there is concern that the authorization process itself could be one of the reasons enrollees do not receive services to which they are entitled under the State plan. We want to ensure that the authorization procedure itself does not prevent enrollees from receiving services that they are entitled to receive under the State plan, and that the MCO's or PHP's information requirements do not place undue burden on the provider or the enrollee. To make explicit our intent that the authorization process not be unduly burdensome for providers or enrollees, in response to the above comments, we have expressly stated this in § 438.210(b)(2)(i) of this final rule with comment period.

Comment: One commenter believed that the requirement for consistent application of review criteria should be eliminated because in this commenter's view it would require health plans to establish another complicated audit process. The commenter felt that the inconsistencies that this provision addresses would be picked up by existing audit procedures.

Response: We believe that consistent application of review criteria is essential in assuring beneficiaries' access to care. Therefore, at § 438.210(b)(2) we retain the requirement that MCOs and PHPs have mechanisms in effect to ensure consistent application of review criteria for authorization decisions. Whether a mechanism is acceptable, as well as how a mechanism is defined, is not dictated in the regulations, but left up to the discretion of the State and the MCO or PHP.

Comment: One commenter felt that it was important to establish a structure that would assure that MCOs' authorization procedures are evaluated on a periodic basis, with the input of practice managers.

Response: Since the requirements of § 438.210 are part of MCO and PHP contract requirements for access to care, States are responsible for ensuring compliance with service authorization requirements as part of their overall quality strategy, as set forth in § 438.202 (State Responsibilities) and § 438.204 (Elements of State Quality Strategies). MCOs and PHPs are also required by § 438.240 to have an ongoing quality assessment and performance improvement program that has in effect mechanisms to detect both underutilization and overutilization of services. In light of the above requirements, we do not believe it is additionally necessary to require in this rule that authorization procedures separately be evaluated on a periodic basis with the input of practice managers.

Comment: One commenter recommended that the regulation require that initial coverage decisions that alter the request of the provider in any way be made, and certified, by a licensed medical doctor. The commenter also urged that initial coverage decisions mirror the requirement in the grievance process (proposed § 438.406(d)) that the review of a denial based on medical necessity be conducted by a ''provider with appropriate expertise in the field of medicine that encompasses the enrollee's condition or disease.''

Response: We agree, in part, with these comments. While we agree that individuals who make initial coverage decisions should be health professionals who have appropriate clinical expertise, we note that relevant expertise may be possessed by health care professionals who are not always physicians. Dentists, psychologists and certified addiction therapists are examples of health professional who are not physicians, but who may have appropriate clinical expertise. Therefore, in response to the above comments, we have provided in § 438.210(b)(3) of the final rule with comment, that any decision to deny or limit a service must be made by a health care professional who has appropriate clinical expertise in treating the enrollee's condition or disease.

Comment: Commenters contended that the requirement in proposed § 438.310(c) that a written notice be sent to the provider for all authorization decisions not fully approved as requested is not current practice for commercial MCO contracts.

Response: We believe that the provider should be notified of all MCO and PHP service authorization decisions that are not fully approved as requested. In § 438.210(c) of the final rule with comment period, we have removed the requirement that this notice be in writing to ease the burden on MCOs and PHPs.

Comment: Numerous commenters had difficulty distinguishing between the requirements at §§ 438.310(c) and (d) pertaining to a notice of adverse action and the time frames for such action, and those in § 438.404 requiring an MCO to give notice of intended action when an MCO intends to deny, limit, reduce, delay or terminate a service or deny payment for a service. There were other comments on these provisions.

Response: We agree that, in the proposed rule, the distinction between proposed §§ 438.310(c) and (d) and proposed § 438.404 was not clear. In the final rule with comment period, § 438.210(c) requires only that the notice of adverse action meet the requirements of § 438.404, and paragraphs (d) and (e) set forth only the

time frames for standard and for expedited authorization decisions, respectively. For further clarity, we note that the distinction between proposed § 438.310 and § 438.404 is drawn at the point the authorization decision is made. If the decision is authorized outright, there is no link to § 438.404; however, if the decision is made to deny or limit a service, notice must be given in accordance with § 438.404, as these decisions are subject to the grievance and appeal process.

Comment: Some commenters were opposed to proposed § 438.310(d) which specified the time frames for providing services. They did not believe it was reasonable to expect services to be provided within the specified time frames. Several commenters suggested that the time frames be consistent for both the Medicaid and the Medicare programs, since providers participate in both programs.

Response: There was an unintended ambiguity in proposed § 438.310(d). The time frames were intended to apply to authorization of services, not furnishing of services. The final rule with comment period, at § 438.210(d) and (e), makes clear that the time frames are applicable to standard and expedited authorizations. The time frames are necessary to ensure that the appeal time frames can be met when an authorization is not approved. In general, the time frames are consistent with those in Medicare.

Comment: In addition to comments interpreting the time frames in proposed § 438.310(d) to apply to the furnishing, rather than the authorization of services, there were comments that understood § 438.310(d) to apply to authorizations, but found 14 calendar days insufficient for a routine authorization if all of the supporting documentation was not present. The commenters recommended that the 14 days should begin after all of the supporting information is received.

Response: The time frame in proposed § 438.310(d) and § 438.210(d) of this final rule with comment period, allows for an extension of up to an additional 14 days if the enrollee or the provider requests extension, or the MCO or PHP justifies to the State agency that additional information is needed and that the extension is in the enrollee's interest.

Comment: Numerous commenters questioned whether enrollees were adequately protected by the provision in § 438.310(d)(2) requiring authorization to be made no later than 3 working days after receipt of the request for service (with a possible extension of up to 14 additional calendar days) if the ordinary 14 day time frame could seriously jeopardize the enrollees' life or health or ability to regain maximum function. The commenters felt that each case is unique, and that in some cases, immediate authorization is necessary, and in others, 24 hours, etc. A standing minimum of 3 working days, with an extension of 14 days possible, was not acceptable to these commenters. One commenter believed that 14 days was excessive for an ordinary authorization that could be completed in a much shorter time.

Response: We recognize that there may be situations in which 72 hours, or the additional 14 days, would be detrimental to the enrollee's health. Under § 438.210(e) of the final rule with comment period, the time frame for an expedited authorization decision is ''as expeditiously as the enrollee's health condition requires'' and in the case of a decision that denies or limits services, early enough to permit the MCO or PHP to process an appeal within 72 hours after receipt of the request for service. The time frames are provided as minimum requirements, but we expect States, MCOs and PHPs to consider the enrollee's health concern as the foremost deciding factor.

Comment: A commenter suggested that we revise § 438.310(d) to allow the provider, rather than just the enrollee, to request extensions in service authorization time frames. As justification, the commenter said that the time required for the provider to arrange for the enrollee to request an extension may force an MCO to deny services that would otherwise be approved, if the provider had time to submit additional documentation.

Response: We agree with the commenter, and in the final rule with comment period, have provided that the provider, acting on behalf of the enrollee, as well as the enrollee may request extension for a standard authorization decision, but only the enrollee may request extension for an expedited decision.

Comment: A commenter indicated that in § 438.310(d), as well as others in the subsection, the reference to ''physician'' should be deleted and ''attending provider'' should be inserted. The rationale for this recommendation was that the language should more accurately reflect the full range of qualified health professionals.

Response: We agree and have replaced the term ''physician'' with ''provider.''

Comment: Two commenters offered their support for the requirement in proposed § 438.310(e) that compensation to utilization review entities not be structured so as to provide incentives to deny, limit, or discontinue medically necessary services.

Response: We have retained this provision as § 438.210(f) of this final rule with comment period.

Comment: Several commenters encouraged us to avoid duplication in the regulation.

Response: We agree, and have attempted to avoid unnecessary duplication in this final rule with comment period. For example, we have eliminated duplication of information requirements that in the NPRM appeared both in proposed § 438.10 and proposed § 438.318.

7. Establishment of Provider Networks (Proposed § 438.314)

Proposed § 438.314 placed requirements on State Medicaid agencies to ensure that contracted MCOs and PHPs have written policies and procedures for the selection and retention of providers. This proposed section required States to ensure that such policies include requirements for initial provider credentialing and recredentialing in accordance with time frames set by the State, but not less frequently than what the State requires for private HMOs.

Comment: Many commenters believed that proposed § 438.314 was too prescriptive. Some commenters interpreted the proposed rule as extending credentialing requirements to providers who perform services under the supervision of physicians, and argued that these requirements generally should only apply to physicians. These commenters expressed the view that requiring credentialing of a broader range of providers adds no value. There were a number of recommended credentialing approaches ranging from adoption of the NCQA credentialing criteria, the American Medical Association's credentialing process, and Medicare policy.

Response: We reexamined the proposed rule in light of these comments and in response to these comments, have made several clarifications to the final rule with comment period. We believe these changes will address most of the commenters' overriding concerns about ambiguity as to who will be subject to credentialing requirements. The final rule with comment period at § 438.214(b) now includes provisions on credentialing that were intended, but not explicit in the proposed rule. Specifically, in § 438.214(b) we now clarify which providers are subject to credentialling and recredentialling

requirements, distinguishing in § 438.214(b)(1) requirements that must be met by physicians and other licensed, independent providers from requirements in § 438.214(b)(2) that must be met by other providers. Exceptions to these requirements are described in § 438.214(b)(3). These exceptions apply to providers who are permitted to furnish services only under the direct supervision of a physician or other provider, and for hospital-based health care professionals (such as emergency room physicians, anesthesiologists, and certified registered nurse anesthetists) who provide services only incidental to hospital services. The latter exception does not apply if the provider contracts independently with the MCO or PHP or is promoted by the MCO or PHP as part of the provider network.

We did not adopt the NCQA standards as suggested by commenters. While our requirements are not identical to the NCQA standards, they have much in common. For example, the exceptions to credentialing outlined above are the same as the exceptions under the NCQA standards. The AMA credentialling process no longer exists.

Comment: One commenter recommended that board certification be dropped as a credentialing criterion.

Response: No change was required in response to this comment, since board certification was not a requirement in the proposed rule, and is not in this final rule with comment period.

Comment: One commenter believed that credentialing criteria should be appropriate to the nature of the services provided.

Response: We believe the credentialing criteria are sufficiently flexible to recognize the characteristics of each MCO and PHP, and the providers within its network.

Comment: One commenter believed that provider selection should be based on objective quality standards.

Response: We believe that the final rule with comment period, as structured, provides for objective quality standards.

Comment: One commenter recommended that we require ''economic profiling'' to be adjusted to reflect varying practice characteristics.

Response: We cannot respond to this comment because we do not understand what the commenter means by ''economic profiling,'' or what its relationship is to credentialing. The intent of this rule was to ensure that MCOs and PHPs implement a formal selection process and, at a minimum, that the process address provider qualifications, provider discrimination, the exclusion of certain providers and additional requirements States may want to impose.

Comment: One commenter recommended that there be written policies and procedures for selection and retention of physicians.

Response: We agree, and in response to this comment, the final rule with comment period at § 438.214(a) now specifies that States must ensure that MCOs' and PHPs' selection and retention policies and procedures must be in writing.

Comment: One commenter recommended that the final rule with comment period, prohibit MCOs from removing providers from their networks without good cause.

Response: While States would be permitted under § 438.214(e) to adopt such a rule if they believe it would be appropriate based on conditions in the State, we do not believe that such a requirement should be imposed nationally in this final rule with comment period. This is because we believe that it may be reasonable, in some cases, for an MCO or PHP to remove providers from its network without cause. For example, there may be a need for an MCO to reduce the size of its provider network if its enrollment declines, and its payments to providers are based on a certain volume. In addition, evaluating the quality of care of providers may be facilitated by having fewer providers serve greater numbers of enrollees. We wish to note that under § 438.12(a)(1), if an MCO or PHP declines to include a provider in its network, it must give the provider written notice of the reason for this decision.

Comment: A number of commenters believed that there was a need to specifically assure that there be no discrimination against providers who traditionally serve more vulnerable populations, such as those who serve limited English proficient populations, high risk populations, and those requiring high-cost treatments. One commenter suggested that such providers be given priority in network selection and referrals. The same commenter believed that MCO gatekeepers frequently do not have professional credentials, and therefore should not control access to care.

Response: It is not clear why the commenters believe there is a need for assurance that there be no discrimination against providers who traditionally serve vulnerable populations, since proposed § 438.314(b)(3) expressly provided that selection and retention criteria could not ''discriminate against * * * those who serve high risk populations.'' This provision has been retained in the final rule with comment period at § 438.214(c). We believe the commenters' concerns are also addressed in a number of other sections. For example, as discussed above, § 438.10(b) requires that information be available in languages spoken in the service area, and that interpreters be available to meet the needs of all enrollees, and § 438.206(e)(2) requires that MCOs and PHPs provide services in a culturally competent manner. Both of these provisions would encourage the use of providers who ''serve limited English proficient populations.''

Under § 438.206(d), in establishing a provider network, MCOs and PHPs are required to consider persons with special health care needs and include the numbers and types of providers ''in terms of training and experience'' required to serve the population. Again, this favors the use of providers with experience with vulnerable populations. Finally, under § 438.50(f)(2), in the case of a default enrollment process under a mandatory program under section 1932(a)(1) of the Act, an attempt must be made to preserve existing provider-beneficiary relationships, and relationships with providers that have traditionally served the Medicaid populations. Again, this favors giving priority to providers serving the vulnerable populations cited by the commenter.

With respect to the concern that gatekeepers do not have necessary professional credentials, § 438.210(b)(3) requires that any denials of an authorization for services be made by ''a health care professional who has appropriate clinical expertise in treating the enrollee's condition or disease.'' We believe that all of the foregoing provisions adequately address the commenter's concerns.

Comment: Several commenters were unclear on the meaning of ''high-risk populations'' as used in proposed § 438.314(b)(3), and sought clearer standards under this provision. Commenters suggested specific examples of high risk patients, including adults and children with special health care needs, such as those with mental illness, substance abuse problems, developmental disabilities, functional disabilities, or complex problems involving multiple medical and social needs like HIV/AIDS, and the homeless. Other commenters felt that the provision governing providers who serve ''high-risk'' populations should be dropped from the rule as too vague to implement, and questioned the wisdom of employing such standards, which

they believed would lead to unresolvable disputes.

Response: We disagree with the commenters who believe that we should delete the requirement in proposed § 438.314(b)(3), because we believe that many Medicaid beneficiaries are best served by providers who are experienced in caring for individuals with the health or social conditions that make an enrollee ''high risk;'' (for example, poverty, homelessness, disrupted family situations). We agree that the specific examples of high risk populations cited by the commenters are examples of high risk populations. We do not believe, however, that we should include regulations text specifically citing such categories, since this may be seen as limiting the scope of this provision. We instead believe that States should be free to interpret ''high risk populations'' based on their knowledge of the high risk populations in their State.

Comment: One commenter discussed the very valuable role nonprofit social service agencies play in the care delivery system for Medicaid beneficiaries, and expressed the view that these provider agencies would gain more credibility if they were accredited by the Medicaid program. There are now standards for such agencies that are recognized by many States. The commenter recommended that such agencies be accredited, and that they have the option of accreditation from the Council of Accreditation (COA), a body more representative of the social service model, as well as by a medical accrediting body such as the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) or a JCAHO-type accrediting body.

Response: We do not believe it would be appropriate at this time to provide for accreditation of these agencies because (1) accreditation standards and procedures for such entities are in their formative stage, and (2) to the extent these agencies provide specific Medicaid State plan services, they would already be subject to any accreditation requirements applicable to the service in question. We note, however, that there is no Federal prohibition preventing States from adopting such quality standards if they choose.

Comment: One commenter took exception to the requirement at proposed § 438.314(b)(1) that provider selection criterion would be based in part on eligibility for payment under Medicaid. The commenter believed that there would be times when an MCO may wish to provide services through a provider in good standing who is not an eligible provider type under fee-for-service.

Response: We have clarified the final rule with comment period at § 438.214(d) to better reflect our intent to preclude only providers who have been barred from participation in the Medicaid program (for example, providers convicted of fraud). We did not intend to preclude States from allowing MCOs or PHPs to provide services through providers in good standing who do not participate in the traditional part of the Medicaid program (for example, alternative providers or providers who have not otherwise chosen to participate in the Medicaid fee-for-service program).

Comment: A commenter recommended that MCOs not be permitted to have separate panels of providers for Medicaid and for their other lines of business.

Response: Our experience has demonstrated that such a requirement is not practical. We have considered imposing such a requirement in the past, and have determined that it would not be in the best interests of Medicaid beneficiaries to do so. Some of the most successful managed care programs have employed providers with particular experience in treating the Medicaid population. Permitting these providers to exclusively serve Medicaid beneficiaries allows more Medicaid beneficiaries to access these experienced providers. It is also the case that some managed care organizations include physicians in their networks who would not agree to accept Medicaid patients. In such a case, if these MCOs or PHPs were not permitted to limit Medicaid patients to a subset of physicians who agree to treat Medicaid beneficiaries, they would not be available as a Medicaid option. We therefore are not including this requirement.

8. Enrollee Rights (Proposed § 438.320) (Redesignated as § 438.100)

As part of these standards, in proposed § 438.320(a), we required that each contract with an MCO or PHP have written policies with respect to enrollee rights, and the MCO or PHP ensure compliance with Federal and State laws affecting the rights of enrollees, and ensure that its staff and affiliate providers take these rights into account when furnishing services. Under proposed § 438.320(b), States must ensure that 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; participate in decision making regarding his or her health care; receive information on available treatment options or alternative courses of care, and have access to his or her medical records. Proposed § 438.310(c) required that States ensure compliance with various civil rights laws.

Comment: Several commenters felt that the rights in proposed § 438.320 should be extended to individuals enrolled in PCCMs, as well as those in MCOs and PHPs.

Response: As discussed above, to the extent requirements in proposed subpart E are grounded in section 1932(c)(1) of the Act, we determined that it would be inconsistent with the Congressional intent to apply them to PCCMs, since the Congress made a conscious decision not to do so even when other provisions in section 1932 of the Act did so apply. We believe that the rights in § 438.100(a)(2), (b)(1), (b)(4), (b)(5), (b)(6), (b)(8), (c), and (d), however, are supported by our authority under section 1902(a)(4) of the Act to specify methods necessary for proper and efficient administration, and the requirement in 1902(a)(19) of the Act that States provide ''safeguards as may be necessary to assure that * * * care and services will be provided * * * in the best interests of the recipients.'' Therefore, in response to this comment, we are revising § 438.100(a)(2), (b)(1), (b)(4), (b)(5), (b)(6), (b)(8), (c), and (d) to make these paragraphs and subparagraphs applicable to PCCMs.

Comment: Several commenters suggested that without proper enforcement, the ''rights'' that were contained in proposed § 438.320 were just ''paper rights.''

Response: We agree that to be effective, enrollees'' rights must be enforced, and believe that the final regulation with comment period include provision for enforcement. First, under subpart F, discussed in section II. E. below, enrollees have the right to file a grievance with their MCO or PHP if they believe any of their rights have been violated. In addition, (1) § 438.66 mandates that States actively monitor MCOs' and PHPs' operations, (2) § 438.202(d) requires that States ensure compliance by MCOs and PHPs with the quality standards established by the State, and (3) § 438.204(b)(2) requires that State quality strategies include continuous monitoring and evaluation of MCO and PHP compliance with standards. We believe that these provisions do provide for enforcement of enrollee rights.

Comment: Several commenters were concerned that the enrollee rights outlined in proposed § 438.320 contained too much subjective language

that could be construed in any way that an MCO chooses.

Response: We believe that the provisions for Enrollee Rights now set forth in § 438.100 are specific enough to ensure specified rights for enrollees of MCOs, PHPs, and PCCMs, while still affording States the flexibility to determine how to guarantee that these rights are upheld.

Comment: Several commenters found the rights outlined in proposed § 438.320 too sparse, and believed that they did not fully implement the recommendations in the Consumer Bill of Rights and Responsibilities (CBRR).

Response: Proposed § 438.320 was intended to articulate a broad set of fundamental enrollee rights, and was not intended to encompass all aspects of the CBRR, which are reflected in detail in numerous provisions throughout virtually every subpart in part 438. For example, important enrollee rights are reflected in the information requirements in § 438.10 in subpart A, the continuity of care requirements in § 438.62 in subpart B, the rights related to provider enrollee-communication and emergency services in §§ 438.102 and 438.114 in subpart C, the right to access to a woman's health care specialist in § 438.206(d)(2) in subpart D, and the grievance and appeal rights throughout subpart F. See our discussion of these and other provisions for further discussion of how this final rule with comment period implements the CBRR.

Comment: One commenter objected to the provision in § 438.320(c) requiring that MCOs and PHPs must ''comply with any other Federal and State laws that pertain to enrollee rights,'' because the commenter believed it was not appropriate for the Federal government to regulate compliance with State laws.

Response: The language in the proposed rule was intended to acknowledge that there are a number of States with their own requirements pertaining to enrollee rights. We do not believe that it is inappropriate to require that the State ensure that the MCOs, PHPs and PCCMs also comply with these regulations. However, we are not expecting States to take over the enforcement of State and Federal laws that are not within their jurisdiction. In order to more narrowly define the Federal and State laws that are being referenced, we have added the term ''applicable'' to the final regulation.

Comment: One commenter suggested that in addition to providing services in accordance with proposed §§ 438.306 through 438.310, proposed § 438.320(b)(2) should also include the right to ''receive all services provided under the State plan.''

Response: The requirement that a beneficiary receive all services provided under the State plan is set forth in § 438.206(c), which is incorporated in § 438.100(b)(2), so that this right is included in § 438.100.

Comment: One commenter requested that we explicitly state that enrollees have a right to a second opinion.

Response: We agree, and in response to this comment, have added a reference at § 438.100(b)(3) to the right to a second opinion provided for under § 438.206(d)(3).

Comment: Several commenters offered their support for proposed § 438.320(b)(3) which required that enrollees be treated with respect and due consideration for their dignity and privacy. It was the commenter's belief that populations with special needs have not always been treated in this manner. However, one commenter, while supporting the provision, felt that the standard was not appropriate for a Federal regulation, and would be difficult for States to measure or enforce.

Response: We believe that there are ways to monitor compliance with this provision retrospectively through such means as enrollee surveys, site visits, hot lines, and grievance procedures. In addition, including respect, dignity and privacy as explicit enrollee rights attempts to address this issue proactively. As commenters indicated, we believe this is a fundamental and important enrollee right and, as such, should be included in the regulation.

Comment: Several commenters suggested that we revise the language in proposed § 438.320(b)(4) to state that the information must be presented in a language appropriate to the consumer's condition and ability to understand.

Response: Section 438.100 provides that enrollees receive information in accordance with § 438.10, which requires that all information furnished to enrollees and potential enrollees meet specified language and format requirements. We believe these provisions address the commenter's concern. We therefore do not believe that a revision to the language at § 438.100 is necessary.

Comment: While offering support for the provision that requires information to be provided to enrollees, some commenters suggested that we revise the proposed regulation to require ''full and complete'' information on ''all'' available treatment options and ''alternatives,'' including alternatives as to the ''site of care.'' These commenters felt that these revisions are essential in ensuring that enrollees receive information on family planning services that are not covered by the MCO.

Response: We consider the commenters' suggestions already addressed in the regulations. For example, § 438.102(b)(1)(ii) and (iii) give enrollees a right to all ''information the enrollee needs in order to decide among all relevant treatment options.'' and ''the risks, benefits and consequences of treatment or non-treatment.'' With respect to information on family planning services, § 438.10(e)(2)(vi) expressly requires that information be provided on how enrollees may obtain family planning services from out-of-network providers. In the case of services not covered through the MCO or PHP, under § 438.10(e)(2)(xii), information must be provided on how and where the enrollee must obtain the benefits. In the case of benefits not covered on moral or religious grounds, information must be provided on how or where to obtain information about the service.

Comment: Several commenters offered their support for proposed § 438.320(b)(5), requiring that enrollees be permitted to participate in decisions on their health care, but requested that this provision be revised to clarify that enrollees not only have the right to participate in decisions, but that they also had the right to refuse treatment. Additionally, commenters wanted this provision to explicitly state that enrollees had the right to participate in ''all'' treatment decisions and to make ''informed decisions.''

Response: We agree with the commenters that it may not be clear that the right to participate in decisions also includes the right to refuse care, although this was our original intent. Consequently, we have revised § 438.100 (b)(6) to expressly include the right to refuse treatment. However, we believe that the suggested changes to include the qualifiers ''all'' and ''informed'' are not necessary, as these concepts are already contained in the provision as written.

Comment: A number of commenters believed that enrollee ''access'' to records was not sufficient, and that they also needed to be able to receive ''copies'' of their medical records, and all relevant documents, at no cost. They also requested that we revise proposed § 438.320(b)(6) to include the right to correct inaccuracies, and to append the record if there was a disagreement.

Response: We agree with the commenters that enrollees should also have the right to receive copies of medical records, and have addressed the commenters concerns in § 438.224 (Confidentiality and accuracy of

enrollee records), discussed in section II. D. 8. below. In response to this comment, we have provided in § 438.100(b)(7) for the right to receive a copy of records, and request that they be amended or corrected, and have referenced § 438.224. We have not, however, required that enrollees be able to receive a copy of his or her medical record at no cost, because we believe that providers may incur some costs in responding to numerous requests to photocopy medical records and related documents.

Comment: Some commenters suggested that we provide additional detail on the specific relevant sections of the laws cited in proposed § 438.320(c) and citations for the regulations implementing these provisions.

Response: In response to this comment, we have included additional detail, including citations to implementing regulations in some cases, in § 438.100(d) of the final rule with comment period.

Comment: A commenter recommended that the text of proposed § 438.320(c), and not just the preamble, make clear the point that State Medicaid Agencies are not expected to take over the enforcement of State and Federal laws not within their jurisdiction.

Response: We believe that it is clear from the preamble to the proposed rule and to this final rule with comment period, that we are not expecting States to take over the enforcement activities that are not within their jurisdiction. However, as noted above, in order to more narrowly define the Federal and State laws that are being referenced, we have added ''applicable'' to the regulation.

Comment: A number of commenters believed that enrollees should be free to exercise their rights without fear from reprisal from the MCO or PHP in which they are enrolled, including the right to refuse services, without the loss of other desired services or disenrollment.

Response: We agree with commenters, and in response to this comment have added language at § 438.100(c) to ensure that an enrollee's free exercise of his or her rights does not adversely affect the way the MCO, PHP, PCCM, their providers, or the State agency treats the enrollee.

Comment: Commenters requested that we include explicit statements of additional enrollee rights, including the right to: (1) Fully participate in the development of their plan of care and treatment decisions; (2) participate in research or experimentation only with informed, voluntary, written consent; (3) be free from physical, verbal, sexual, or psychological abuse, exploitation, coercion, or neglect; and (4) be treated in a humane environment that affords reasonable protection from harm and ensures privacy.

Response: Section 438.100(b)(6) provides enrollees with the right to participate in decisions regarding their health care, which we believe would include plans of care, treatment decisions, or participation in any research or experimentation. With respect to the right to be free from abuse, exploitation, or neglect, or to be treated in a humane environment that affords protection from harm and ensures privacy, we believe that these rights are inherent in the right under § 438.100(b)(4) to be treated with respect and dignity and the confidentiality rights in § 438.224, discussed in section II.D.9. below. Further, we have revised proposed § 438.306(e)(3)(iii)(now § 438.208(f)(5) to require that treatment plans, developed for individuals who are pregnant or who have special health care needs, are to be developed ''with enrollee participation''.

Comment: Commenters suggested that we add as a right that beneficiaries have the right to be free from seclusion, physical or chemical restraints, used by staff as a means of coercion, discipline, convenience or retaliation.

Response: We agree that this is a fundamental right, and in response to this comment, have added it to the requirements of § 438.100 in the final rule with comment period.

Comment: Commenters proposed the inclusion in proposed § 438.320 of a number of additional rights in the following areas: information standards, complaint and grievance procedures, quality assurance, service authorization, choice, disenrollment, emergency services, access and capacity, and benefits and coverage.

Response: As discussed previously, § 438.100 was intended to put forth a basic and general fundamental set of rights. More detailed and specific enrollee rights are articulated in greater detail in other sections of the regulation. The suggested changes in the areas of information standards, complaint and grievance procedures, quality assurance, service authorization, choice, disenrollment, emergency services, access and capacity, and benefits and coverage are more fully detailed in the corresponding provisions of the regulations which are dedicated to these respective topic areas. Therefore, the specific suggestions offered by the commenters were considered in the context of these other provisions. For example, the comment that the enrollee has the right to receive timely and adequate advance written notice of any decision to deny, delay, reduce, suspend, or terminate medical services is addressed in §§ 438.210(c) and 438.404.

9. Confidentiality (Proposed § 438.324)

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

In proposed § 438.324, consistent with the regulations at part 431 subpart F, we proposed that the State ensure, through its contracts with MCOs and PHPs, that each MCO and PHP (1) maintain records and information (in oral, written, or electronic format) in a timely and accurate manner, (2) safeguard the privacy of any information that identifies a particular enrollee by ensuring that original records are released only in accordance with Federal or State law, or court orders or subpoenas; copies of records and information are released only to authorized individuals; and unauthorized individuals do not gain access to, or alter, patient records, (3) protect the confidentiality and privacy of minors, subject to applicable State and Federal laws, (4) ensure that enrollees have timely access to records and information that pertain to them, and (5) 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. The requirements we proposed in this section are consistent with the right to confidentiality of health information supported by the CBRR.

We received numerous comments in response to this section requesting that we include specific guidelines and address substantive issues in more detail. Prior to addressing these comments, we must first clarify our original intent in proposing this section. We included this section in order to ensure that MCOs and PHPs would be held responsible for safeguarding the confidentiality of enrollee information. We did not intend to impose specific guidelines for the use and disclosure of enrollee information. We recognized that there are many different State and Federal laws that specifically address confidentiality and it was not our intent to interfere with these laws. Several States have enacted strong privacy

protections that will continue to apply to MCOs and PHPs participating in the Medicaid program. In addition, the Secretary is currently developing a final regulation that will address confidentiality of health information at the Federal level in accordance with section 264 of the Health Insurance Portability and Accountability Act (HIPAA) (Public Law 104–191). In order to remain consistent with existing laws and regulations, as well as the forthcoming HIPAA regulation, we only included general requirements in this section.

Comment: We received two comments on proposed § 438.324(b)(1), which provided that original medical records must be released only in accordance with Federal or State law, or court orders or subpoenas. One commenter recommended that we revise the regulation to require that both the original and copies of patient medical records be released to Medicaid fraud control units and other law enforcement agencies. Another commenter suggested that this provision conflicts with requirements in § 431.306(f). That section requires that when a court issues a subpoena for a case record, the Medicaid agency must inform the court of the applicable statutory provisions, policies, and regulations restricting the disclosure of information. The commenter believed that in light of this existing requirement, the release of information should not be required through the use of subpoena power alone.

Response: The requirement proposed in § 438.324(b)(1) was intended to highlight the importance of ensuring the integrity and availability of original medical records. If an MCO or PHP receives a request for an enrollee's information, we would expect that the MCO or PHP would typically only release a copy of that information. However, as the commenters note, the proposed language could create confusion regarding the requirements for this subset of identifiable health information, and how it differs from the protections afforded to other such information. It was our intent that originals should only be released in accordance with applicable laws. Therefore, in order to more accurately reflect this intent, in § 438.224(c) of the final rule with comment period, we have deleted the specific reference to court orders and subpoenas, and eliminated the provision singling out original records from other health information. We rely on the State, the MCO, and the PHP to make appropriate decisions regarding disclosure of copies versus originals, based on the specific circumstances of each disclosure. Procedures to be followed in response to a subpoena are addressed by the requirement (in the parenthetical in the first line of § 438.224) that MCOs and PHPs must follow subpart F of part 431.

Comment: We received several comments in response to proposed § 438.324(b)(2), which requires that copies of records and information from MCOs be released only to authorized individuals. Several commenters believed that we did not define the term ''authorized individual'' or ''authorized representative'' in the proposed rule, and that it was thus unclear who may receive medical records from an MCO or PHP. Other commenters found that this provision did not include necessary language addressing inappropriate disclosures of information within an MCO or PHP. Specific recommendations made by commenters were that the definition of ''authorized individual'' include family members, guardians, and legally authorized representatives.

Response: We recognize that the use of the term ''authorized'' in this section has generated some confusion. It was our expectation that the MCO or PHP would establish and follow procedures to specify who would be ''authorized'' to received confidential enrollee information, and that these procedures would reflect applicable Federal and State law. We recognize that the term could be interpreted in other ways. Therefore, in § 438.224(b) and (c) of the final rule with comment period, we have revised the language to make more explicit our intent as to what would constitute an authorized disclosure, and in doing so, we removed the term ''authorized individual.''

Comment: Several commenters requested that the proposed rule be strengthened with regard to limiting the flow of identifiable data. Some commenters suggested that we require MCOs and PHPs to use non-identifiable data whenever identifiable data is not needed to complete a task. Some commenters stressed that the final rule with comment period should also include additional safeguards to protect a beneficiary's sensitive health information, so that the disclosure of identifiable data can be used only for activities which MCOs or PHPs and providers need for legitimate purposes. One commenter recommended that an MCO or PHP should be required to define when identifiable data is necessary for a particular activity. In addition, several commenters recommended that we include technical standards in the regulations to address electronic and paper records. Finally, other commenters suggested we include incentives in the regulation for MCOs and PHPs to use non-identifiable data, and include a requirement for MCOs and PHPs to justify the use of identifiable data needed for an activity.

Response: These comments describe many standard procedures that should be in place for protection of health information and ones which MCOs and PHPs will likely put in place to comply with the requirements of this section. However, consistent with the above discussion of our purpose in writing this section of the rule, our intent was not to create specific technical mechanisms (including standards regarding the use of identifiable and non-identifiable data) that MCOs and PHPs must have to safeguard data. As discussed previously, we proposed this section because we believe that MCOs and PHPs should have safeguards in place (including, as appropriate, the ones suggested by the commenters) to ensure that patient-identifying information is used for legitimate purposes. To underscore our intent not to create new technical standards, we have deleted sections of the proposed rule (§ 438.224(d) and (e)) that we believe are already covered by the requirements at Subpart F of part 431 and which may have inadvertently lead readers to believe that we were attempting to create new standards.

Therefore, we have not revised this section to include technical standards for securing electronic and paper records, or to impose specific requirements on MCOs and PHPs as to when they must use non-identifiable data. However, in response to the broad concern expressed by commenters about the different ways patient-identifying information might be used or disclosed to others, we have added a new requirement at § 438.224(e) that requires the State to ensure that each MCO and PHP establish and implement procedures to ensure that enrollees receive, upon request, information pertaining to how MCOs and PHPs use and disclose identifiable information.

Comment: We received several comments in support of proposed § 438.324(c), which requires MCOs and PHPs to have procedures to protect the confidentiality and privacy of minors, subject to applicable Federal and State law. Several commenters indicated that a major obstacle to minors obtaining needed health care is due to concerns about the lack of confidentiality. They suggested that we maintain the proposed regulation and preamble, which they believe is clear in that it refers to services and treatment which minors can obtain without parental consent and what information can be

released to a parent upon request. They also suggested that family planning, mental health, and substance abuse services be addressed by the MCO's or PHP's procedures.

In contrast, several commenters contended that all information about a minor should be released to parents barring a court order stating otherwise. One commenter focused on the developmentally disabled population, and believed that copies of medical records, treatment options, and confidential information relevant to the receipt of medical services must be communicated to a family member or guardian prior to proceeding with the proposed treatment. Other commenters suggested that the final regulation stress confidentiality of family planning services for adults as well as minors.

Response: Section 438.324, as a whole, was intended to ensure that MCOs and PHPs have procedures to protect the confidentiality of all enrollees. We proposed a specific provision addressing the confidentiality of minors in recognition of the large number of enrollees under age 18. It was not our intent to interfere with Federal and State laws that address the confidentiality of minors. Therefore, in the final rule with comment period, we have removed the reference to minors because we intend the term ''enrollee'' to encompass all enrollees.

Comment: Several commenters recommended that we revise proposed § 438.324(d) to clarify that, in addition to enrollees, authorized representatives of enrollees must have timely access to records and information. One commenter recommended that we revise this provision to require MCOs to provide enrollees with access to their records within 24 hours (excluding weekends and holidays); and to obtain photocopies. Another commenter pointed out that under their State law, the Medicaid agency is not required to provide timely access to records if the beneficiary is currently under civil or criminal investigation. Another commenter questioned this provision, and suggested that under patient/doctor confidentiality, the patient holds the privilege of confidentiality, not the provider. Further, the commenter contended that patients are the owners of their medical records and always have had the opportunity to review and correct errors. The commenter wondered what role an MCO or PHP should play in enforcing patient rights. Several commenters also suggested that enrollees be able to receive copies of their records. Commenters also recommended that enrollees be able to request amendments or corrections to their records.

Response: We proposed § 438.324(d) to ensure that MCOs and PHPs have orderly procedures to enable an enrollee to access his or her medical records in a timely manner. It was not our intent to interfere with Federal or State laws governing access to medical records or other information. While we have not included specific time lines, exceptions, and rules in this provision, we have, in § 438.224 of the final rule with comment period, clarified the language to more clearly reflect our intent. We have replaced the general term ''access'' with more specific language in § 438.224(f) that requires the State to ensure that each MCO and PHP has procedures to ensure that the enrollee can request and receive a copy of his or her records and information and that the enrollee may request amendments or corrections.

Comment: Several commenters questioned proposed § 438.324(e), which required MCOs and PHPs to 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. One commenter believed that it was redundant for the Federal government to regulate compliance with State law. Another commenter contended that Federal requirements should preempt State and local confidentiality laws. This commenter suggested that requiring multi-state Medicaid MCOs to adopt different State confidentiality procedures in each State was unduly burdensome, and serves no legitimate purpose. This commenter recommended that confidentiality requirements be uniform and pre-empt State and local confidentiality laws.

Response: It was not our intent to preempt or supersede other Federal or State laws governing confidentiality. Rather, we intended to create a baseline of protections for Medicaid managed care enrollees that is consistent with other applicable laws. We continue to believe that it is important to highlight other applicable laws and to require that States ensure that MCOs and PHPs have procedures that comply with these laws; and therefore, we have retained this requirement. With respect to the commenter urging that Federal requirements be established that would pre-empt State law, we believe that this would be inconsistent with the structure of the Medicaid program, which is a State-run program under which States are granted discretion to establish their own approach. While a national MCO or PHP may have to follow different rules in different States under the Medicaid program, this would be equally true for their commercial lines of business in different States.

Comment: We received several comments supporting proposed § 438.324(e). Several commenters appreciated that we made a distinction between medical records, and the sharing of necessary information between physical health providers and mental health and substance abuse providers. While some commenters recommended that the language be maintained, other commenters recommended that we clarify the regulation to require compliance with Federal rules concerning confidentiality of substance abuse treatment and to emphasize the primacy of 42 CFR Part 2, Confidentiality of Alcohol and Drug Abuse Records.

Response: Under this provision, MCOs and PHPs must abide by all Federal and State laws regarding the confidentiality of health information, including laws pertaining to the confidentiality of substance abuse treatments. We have clarified our final rule with comment period to require that the State must ensure that, for medical records and any other health and enrollment information that identifies a particular enrollee, the MCO or PHP establishes and implements procedures to abide by all Federal and State laws regarding confidentiality and disclosure. We believe that this provision, as stated, includes existing laws that govern confidentiality and disclosure of medical records, mental health records, substance abuse records, and any other identifiable information.

Comment: A commenter expressed concern that § 438.324 does not address how confidentiality policies will affect the use of patient information in research. The commenter stressed that studies of disease, epidemiology, therapy, and health services depend on access to patient records, including records for Medicaid managed care enrollees. The commenter recommended that we address the issue of research in the final rule with comment period so that medical records are available through a process that meets confidentiality concerns but is not unduly burdensome.

Response: The use and disclosure of health information for research is an extremely complicated issue. We do not believe that this regulation is the appropriate vehicle to specify when such uses and disclosures are appropriate and what specific safeguards must be in place to protect that information. We do require the State to ensure that MCOs and PHPs safeguard the confidentiality of any

information that identifies a particular enrollee. In addition, we require the State to ensure that MCOs and PHPs have procedures in place that address how the information will be used and disclosed. We would expect that these procedures would specifically address when the MCO or PHP would use enrollee information for research and under what circumstances it would disclose the information to outside researchers. As noted above, the forthcoming HIPAA regulation will address this issue in more detail.

10. Enrollment and Disenrollment (Proposed § 438.326) and Grievance Systems (Proposed § 438.328)

These proposed sections required that a State agency include as part of its quality strategy ensuring compliance with the enrollment requirements in § 438.56, and, consistent with section 1932(c)(1)(A)(ii) of the Act, with the grievance requirements in subpart F. We received no comments on proposed § 438.326, and one comment relating to proposed § 438.328.

Comment: One commenter requested that we mandate that States conduct random reviews of service denial notifications, and other forms of non-coverage to ensure that MCOs and PHPs are notifying members in a timely manner.

Response: We agree with this comment. In § 438.228(b) of the final rule with comment period, we have added a requirement that States must conduct random reviews to ensure that each MCO and PHP and its providers and contractors are notifying enrollees in a timely manner. We have further added at § 438.228(c) a requirement that State must review, upon request of the enrollee, grievances not resolved by an MCO or PHP to the satisfaction of the enrollee.

11. Subcontractual Relationships and Delegation (Proposed § 438.330)

Proposed § 438.330 set forth requirements specifying that the State must ensure that an MCO or PHP entering into a contract with the State oversees and remains entirely accountable for the performance of any activity it delegates to a subcontractor. Under proposed § 438.330, it is the sole responsibility of the MCO or PHP to ensure that the delegated activity or function is performed in accordance with applicable contractual requirements. Specifically, under proposed § 438.330, the MCO or PHP should: (1) Evaluate the ability of the prospective contractor to perform the functions delegated; (2) enter into a written agreement that specifies the delegated activities and reporting requirements of the subcontractor, and provides for revocation of the delegation or imposition of other sanctions if the subcontractor's performance is inadequate; (3) monitor the subcontractor's performance on an ongoing basis, and subject the subcontractor to formal review at least once a year; and (4) if deficiencies or areas for improvement are identified, take corrective action. 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, and in particular, these provisions ensure that States hold MCOs and PHPs accountable for the availability and adequacy of all covered services.

Comment: One commenter recommended requiring certifications to the State that payments under a subcontract are sufficient for the services required. Commenters recommended that all subcontracts should be made available for public inspection, so that they are available to the State, enrollees, and advocates.

Response: While we are not requiring a direct certification to the State, it is the MCO's or PHP's responsibility under § 438.230(b)(1) to evaluate, before delegation occurs, the prospective subcontractor's ability to perform the activities that are to be delegated. This evaluation may include evaluation of the subcontractor's financial stability and financial ability to deliver services. Subsequently, the MCO or PHP is held accountable for any functions it delegates, and therefore, has ultimate responsibility for oversight of the subcontractor. In addition, there is nothing in this provision that would preclude a State from requiring such a certification if it so chooses.

Moreover, we do not review subcontracts and normally do not become involved in the relationship between MCOs and PHPs and their subcontractors, with the exception of physician incentive rule arrangements, which must be disclosed. The law imposes requirements on MCOs, not on their subcontractors. We do not believe that we should be involved because the MCO or PHP (with whom there is a direct relationship) is ultimately responsible that requirements are met. Therefore, we will not in this final rule with comment period require public access to subcontracts. However, public access to subcontracts is subject to State procedures and policies governing their disclosure.

Comment: Several commenters requested clarification on the definition of subcontractor. The commenters questioned whether we intended for this provision to apply to individual providers or solely to organizations. One commenter expressed the view that if an individual physician/provider is considered to be a subcontractor, the requirement for annual recredentialing would be unreasonable. Another commenter suggested that we give States the flexibility to define subcontractor as it applies to these provisions, while other commenters recommended that we define the term so that these provisions would apply solely to organizations.

Response: Any entity, whether an individual or organization, that is not an employee of the organization, but who assumes responsibility on behalf of the MCO or PHP, would be considered to be a subcontractor. While we are not specifically defining subcontractor, we do intend for it to include any non-employee individuals or organizations within the MCO's or PHP's network.

Comment: One commenter believes the requirement that the MCO subject each subcontractor's performance to formal review on an annual basis is unnecessarily prescriptive. The commenter notes that there is considerable overlap between this requirement and the provider credentialing requirements, and that States should have flexibility in this area.

Response: The intent of this provision was not to require recredentialing once a year. Proposed § 438.330 was designed to hold MCOs and PHPs accountable for the availability and adequacy of all covered services delivered through their subcontracts. As a result of this comment, we have revised § 438.230(b)(3) of the final rule with comment period to require that the MCO or PHP monitor the subcontractor's performance on an ongoing basis, and subject it to formal review according to a periodic schedule established by the State, consistent with industry standards or State laws and regulations.

Comment: One commenter expressed the view that the proposed rule did not go far enough in protecting an enrollee's rights when Medicaid services are delegated to subcontractors. The commenter believed that the enrollee has the right to know what to expect of a subcontractor, and that the State should be much more involved in making sure the subcontractor complies with the requirements of the contract and State and Federal law. The commenter recommended that, at a minimum, all subcontracts should be directly monitored by the State with the

monitoring procedures applicable to the MCO also applied to subcontractors.

Response: Section 438.230(a) of the final rule with comment period requires that the MCO or PHP oversee, and be held accountable for, any functions and responsibilities that it delegates to any subcontractor. Therefore, it is the MCO's or PHP's responsibility to ensure that its subcontractors are in compliance with all applicable laws, including those identified under § 438.100 (Enrollee Rights). It is the sole responsibility of the MCO or PHP to ensure that the delegated function is performed in accordance with applicable contractual requirements. However, there is nothing in this provision that precludes States from monitoring subcontracts if they so choose.

Comment: One commenter recommended that regulatory language be revised so that it is the same as that used in the Medicare+Choice regulations. The commenter believes that this will reduce the regulatory burden on managed care organizations that contract under both programs. The commenter recommends that the Medicaid final rule with comment period require that subcontractors comply with all applicable Medicaid laws, regulations, and our guidance.

Response: For the most part, the requirements contained in the Medicare regulations for subcontractors are reflected in the Medicaid regulatory language. However, in response to this comment, we have added a new provision at § 438.6(l) to require that all subcontracts fulfill the requirements of part 438 that are appropriate to the service or activity delegated under the subcontract.

Comment: One commenter suggested that the final rule with comment period address the obligation of States and MCOs to certain subcontractors, specifically Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs). They recommended that the rule reflect the statutory requirement that MCOs that enter into contracts with FQHCs and RHCs are required to provide payment that is not less than the level and amount of payment which would be made for services from a provider which is not an FQHC or RHC. These commenters also believed that the final rule with comment period should reflect the requirement that States directly compensate FQHCs and RHCs if they receive less compensation than that to which they are entitled. The commenters believe that an FQHC's or RHC's ability to provide high quality services, such as HIV services, in a managed care environment depends upon linkages with MCOs that include adequate compensation.

Response: The rules cited by the commenter are ''transitional'' in nature, as the payments provided for thereunder are to be phased out over the next several years. We do not believe it appropriate to promulgate regulations that will be obsolete in a relatively short period of time. Moreover, we do not believe regulations are necessary, as the statutory requirements are straightforward and self-implementing, and we have provided guidance to all States on FQHCs and RHCs, through State Medicaid Director Letters on April 21, 1998, October 23, 1998, and September 27, 2000. We will continue, as necessary, to clarify FQHC and RHC payment policies.

Comment: One commenter expressed the view that subcontractual relationships may not be advantageous between Indian Health Service (IHS) and tribally operated programs and MCOs, if they are only reimbursed at a capped rate that does not give them the ability to recoup the costs of providing services in reservation communities located in rural and isolated locations. However, the commenter believed that some contracts may be desirable in communities where a local relationship with an MCO provider provides a network of support services not available in the Indian health care system. Another commenter cited a Memorandum of Agreement between IHS and HCFA, and Federal legislation, which each provide that IHS is compensated at a special rate, and that tribally operated programs may also choose to be compensated at the IHS rate. Furthermore, services furnished by these entities are entitled to a 100 percent Federal matching rate. The first commenter requested that we require that IHS or tribal providers operating as subcontractors be allowed to bill States or their fiscal intermediaries directly for American Indian Medicaid beneficiaries. The second commenter recommended that IHS, tribal providers, and urban Indian clinics receive payment for services to IHS beneficiaries who are also Medicaid beneficiaries from States or their fiscal intermediaries directly and not be required to bill MCOs, regardless of whether the facility is a subcontractor or providing ''off-plan'' services.

Response: As also noted in section II. H. below, policies concerning IHS or tribal providers, the rates paid to such providers, or the Federal matching applicable to such providers, are unaffected by, and are outside the scope of, this rulemaking.

12. Practice Guidelines (Proposed § 438.336)

Proposed § 438.336 required that States ensure that each MCO and PHP develop or adopt and disseminate practice guidelines that met standards set forth in proposed § 438.336(a), which required that the guidelines: (1) Be based on reasonable medical evidence or a consensus of health care professionals; (2) consider the needs of MCO and PHP enrollees; (3) be developed in consultation with contracting health care professionals, and (4) be reviewed and updated periodically. MCOs and PHPs were required under proposed § 438.336(b) to disseminate the guidelines to providers and enrollees where appropriate, or when they request them. Proposed § 438.336(c) required that decisions with respect to utilization management, enrollee education, coverage of services, and other areas be consistent with the guidelines.

Comment: Several commenters requested clarification of the regulatory language requiring MCOs and PHPs to ''develop'' (or adopt) practice guidelines. One commenter assumed that § 438.336 did not require the development of ''new'' practice guidelines, but only that if practice guidelines currently exist, they should be disseminated according to the language in this section. Another commenter was unclear if the provision required MCOs to adopt guidelines, or required MCOs, if using practice guidelines, to use them in accordance with this section.

Other commenters requested that MCOs be allowed to ''develop'' their own practice guidelines instead of ''utilizing'' existing practice guidelines developed by governmental agencies. Some commenters believed that practice guidelines should not be required. These commenters believed a blanket requirement for practice guidelines in all disease management areas is unwise, as not all areas have developed guidelines. Also, the commenters noted that the Medicare+Choice regulations do not mandate the development of guidelines.

Response: We realize that the words ''develops'' and ''development'' were misleading in that they appeared to suggest that we were encouraging MCOs and PHPs to develop their own practice guidelines, instead of using those already established by expert panels. We have removed those words from § 438.236 of the final rule with comment period. Since a number of practice guidelines already exist for a variety of clinical areas, we do not specify how

many or which practice guidelines MCOs and PHPs must adopt. Rather, each MCO and each PHP will need to establish a process for identifying and reviewing guidelines that are relevant to the health conditions of its enrolled population and implement a process, in conjunction with its providers, for the adoption and implementation within the MCO or PHP. This is consistent with industry standards in the private sector. NCQA's 1999 accreditation standard QI8, ''Clinical Practice Guidelines,'' states, ''The MCO is accountable for adopting and disseminating practice guidelines for the provision of acute and chronic care services that are relevant to its enrolled membership.''

Comment: Multiple commenters recommended that the final rule with comment period specifically mention or require MCOs to use the following specified Federal Practice Guidelines: (1) Federal ''Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents,'' (2) Federal ''Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection,'' and (3) the ''USPHS/IDSA Guidelines for the Prevention of Opportunistic Infections in Persons with Human Immunodeficiency Virus,'' and update as appropriate.

Several commenters felt this section should be clearer and more specific to the unique health care needs of children, for example, specifically referencing the American Academy of Pediatrics (AAP) immunization guidelines.

One commenter believed that MCOs should be required to report on compliance with scientifically grounded clinical practice guidelines where they exist for persons with disabilities.

Response: Many evidence-based practice guidelines exist that would be beneficial for MCOs and PHPs to adopt as tools for improving the quality of health care provided to enrollees. Because of the growing number of such guidelines, the variation in the strength of the evidence base supporting these guidelines, and the need for ongoing review and updating of guidelines, we are reluctant to single out a subset of practice guidelines as superior to all others and preferentially require adherence to them in this regulation. We do, however, reference the Adult and Pediatric Guidelines for use of Antiretroviral Agents in Treatment of HIV Disease as examples of the type of guidelines that should be adopted. We did not specifically require that the guidelines be adopted due to the reasons stated above. However, we have referenced HIV guidelines in the text of § 438.236(b) as examples of guidelines that could be adopted consistent with this final rule with coment period, to reflect our strong belief that adherence to the HIV guidelines is essential to providing quality HIV care. We would continue to hold this position as long as the guidelines continue to meet the criteria in § 438.236(b). In addition to the guidelines referenced in the regulations text, we also strongly recommend that MCOs and PHPs adopt the following HIV guidelines if they continue to meet the criteria in § 438.336(b): USPHS/IDA Guidelines for Prevention of Opportunistic Infections in Persons Infected with HIV, Public Health Task Force Recommendations for the Use of Antiretroviral Drugs in Pregnant Women Infected with HIV–1 for Maternal Health and Reducing Perinatal HIV–1 Transmission in the United States, and US Public Health Service Recommendations for Human Immunodeficiency Virus Counseling and Voluntary Testing of Pregnant Women. We did not include references to any immunizations schedules, because current law requires State Medicaid agencies to provide all immunizations recommended by the Advisory Committee on Immunization Practices as part of the EPSDT program.

Comment: One commenter expressed the view that practice guidelines should take into consideration the needs of populations with special health care needs. One other commenter believed that a lack of medical evidence cannot be taken as a sign of a lack of efficacy. People with disabilities have limited access to clinical trials, and would suffer if practice guidelines based on clinical proof of efficacy were needed to ensure coverage. One commenter felt that guidelines should not be required to be based on ''reasonable medical evidence,'' because in some specialty areas, including mental health, there is not an established base of published clinical trial outcomes. The commenter also noted Federal case law, that requires the provision of appropriate treatment, even if the treatment is not supported by clinical studies.

Two commenters agreed that MCOs should use practice guidelines that are evidence-based and developed by clinicians with training and expertise in a field, but they believed that some guidelines are not developed in an empirical framework, and if implemented, could jeopardize both children's access to and types of treatments received.

One commenter agreed that practice guidelines can be helpful, but found that the area of mental health has not developed sufficient guidelines for all courses of treatment. The commenter believed that use of guidelines in the area of mental health may result in the denial of treatment as new treatment methods are developed.

Response: Some commenters have interpreted the regulation as requiring practice guidelines to be based on clinical trials, and were concerned about the potential lack of clinical trials including populations with special health care needs. In fact, this regulation does not require the use of practice guidelines for all conditions, or restrict the use of guidelines to those based on clinical trials. Section 438.236(b)(1) of the final rule with comment period requires that the guidelines be based on ''reasonable clinical evidence or a consensus of health care professionals in the particular field,'' which does not necessitate that a clinical trial have been conducted; for example, guidelines for Perinatal Care, developed by the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists.

The commenters are also concerned over the lack of practice guidelines for some conditions, such as mental health, and fear that treatment may be denied. The regulation does not specify the number of practice guidelines that must be adopted, nor does it mandate for which conditions practice guidelines must be developed. The lack of practice guidelines for a particular condition does not provide a basis for an MCO or PHP to fail to treat conditions for which there is no guidance.

Comment: Two commenters suggested that we only permit practice guidelines developed by licensed health care providers in a particular field. Another commenter wanted to give greater weight to the requirements that guidelines based on ''reasonable medical evidence or a consensus of health care professionals in the particular field (§ 438.336(a)(1)),'' and that they ''consider the needs of the MCO's enrollees (§ 438.336(a)(2))'' than the requirement that they be developed ''in consultation with contracting health care professionals (§ 438.336(a)(3)).'' The commenter believed that guidelines developed in accordance with § 438.336(a)(3) could lead to ''garden variety'' practice guidelines. One commenter believed that professional specialty organizations have adopted many national standards and practice guidelines that should be used.

Response: Because there is variation in the evidence base that supports all medical interventions, we believe we must be flexible and accept the use of guidelines developed both by clinical evidence or a consensus of health care professionals in the particular field. We

have replaced the word ''reasonable'' with the words ''valid and reliable'' to better describe the type of clinical evidence that should serve as a basis for practice guidelines that MCOs and PHPs are to adopt. The language we have used in the proposed rule and final rule with comment period at § 438.236 is consistent with industry standards.

Comment: One commenter suggested that practice guidelines be based on reasonable ''clinical'' evidence instead of reasonable ''medical'' evidence. Two commenters believe that if medical evidence does not exist, it may be due to the rarity of the disease, inadequate research infrastructure, or the fact that people with disabilities do not have as much access to clinical trials.

Response: We agree with the commenters. The term ''medical'' typically refers to actions and treatments related to physician practices, while ''clinical'' extends to health care researchers, as well as other health care providers, such as dentists, pharmacists, and nurses. Because of this, in response to this comment, we have substituted ''clinical'' for ''medical'' in § 438.236(b)(1). By replacing ''medical'' with the broader term, ''clinical,'' we are also being more consistent with the following examples. The Institute of Medicine (IOM) discusses practice guidelines in the context of ''clinical practice.'' For example, ''Practice guidelines must include statements about when they should be reviewed to determine whether revisions are warranted, given new clinical evidence or professional consensus (or the lack of it).'' The IOM also points out that two of the key attributes of practice guidelines include ''clinical applicability'' and ''clinical flexibility.''

One source of clinical practice guidelines on a variety of topics and that can help interested parties compare different practice guidelines on the same topic is the Agency for Healthcare Research and Quality's (AHRQ) National Guideline Clearinghouse, available at www.AHRQ.gov.

Comment: One commenter believed that MCOs should be required to report on compliance with scientifically grounded clinical practice guidelines where they exist for persons with disabilities. The same commenter also believed that the regulation should require that the amount, duration, and scope of coverage for covered benefits be reasonably sufficient to achieve the purpose of the service.

Response: We have decided not to require reporting on, or State monitoring of, compliance with the guidelines adopted by each MCO and PHP due to excessive cost and administrative burdens. Instead we have chosen to emphasize the adoption and dissemination of evidence-based and widely accepted practice guidelines by MCOs and PHPs to their providers. We also believe that compliance with those practice guidelines adopted by States and MCOs and PHPs can be monitored through the quality assessment and performance improvement project requirements in § 438.240.

The commenter's second concern about the amount, duration, and scope of coverage for covered benefits was addressed in the response to comments on § 438.310.

Comment: One commenter believed that MCOs need to require their providers to use practice guidelines through a MOA or linkage agreements.

Response: We do not believe it is appropriate for the regulation to specify how MCOs and PHPs are to promote adherence to the guidelines by their contracted providers. We note that the state-of-the-art of information dissemination, technology transfer, and changing provider practice patterns is complex and continues to be the subject of much study.

Comment: One commenter believed that decisions about medical care should be based on medical necessity and medical judgement, and that these may not in individual cases, be consistent with the guidelines. Several commenters stated that practice guidelines are guidelines only, and should not restrict access and should be consistent with individual needs.

Many commenters expressed a concern that no requirement exists requiring individual coverage decisions to conform to government practice and care guidelines, especially in the area of HIV/AIDS treatment.

One commenter expressed a concern regarding how MCOs contracting with Medicaid will apply EPSDT standards and guidelines to children being served, and specifically to children with special health care needs.

Response: Our intent is not to substitute practice guidelines for professional judgement in the care of individuals. Practice guidelines are guidelines, not mandates, and should be applied consistent with the needs of the individual.

Comment: One commenter expressed a concern that MCOs will not reimburse subcontractors for services that are not recognized as medically necessary, or not consistent with nationally recognized practice guidelines.

Response: As noted above, there are many evidence-based practice guidelines that would be helpful to MCOs and PHPs in undertaking efforts to improve the quality of health care provided to enrollees. However, we are not prescribing a uniform set of guidelines that must be used, or specifying that guidelines must be used whenever they are available. Rather, we are requiring that MCOs and PHPs consider relevant guidelines and choose those they find appropriate. Because it is not practical for an MCO or PHP to focus its quality assessment and improvement efforts simultaneously on all areas for which there are practice guidelines, it is not our expectation that MCOs and PHPs will adopt practice guidelines for all areas of treatment.

For those clinical areas for which an MCO or PHP has adopted a clinical practice guideline, if an enrollee requests services that contradict the practice guideline, the MCO or PHP may have grounds for withholding the services or refusing to pay for the service. Similarly, if an MCO or PHP found a requested service not to be medically necessary, the MCO or PHP would have grounds for withholding the service or refusing to pay for the service. However, there are two means of recourse for beneficiaries who believe that they have been inappropriately denied a service based on a practice guideline. First, the enrollee may appeal the denial of services on an individual basis. Second, the enrollee may request that the Medicaid agency review the guideline to see that it meets the regulation requirements that guidelines be evidence-based and up-to-date. We believe this will protect enrollees from the misuse of practice guidelines.

Comment: One commenter believed that guidelines should also be disseminated to enrollee representative, advocates, and the general public. Several commenters agree that enrollees, as well as the public, should have a right to obtain a copy of the practice guidelines.

In contrast, many other commenters voiced concern over the dissemination of guidelines to anyone other than appropriate providers. Some stated that the dissemination of guidelines intrudes on the practice of medicine and exceeds BBA requirements. One commenter believed that the administrative effort and expense would be too high if guidelines were to be disseminated ''as appropriate.'' Two commenters were unclear about the meaning of ''as appropriate.'' One commenter stated that disclosure of practice guidelines to enrollees may present problems around inclusion of proprietary information directly related to the conduct of business between providers and the MCO. Two commenters question the

value/usefulness of guidelines being disseminated to individual enrollees, as the information may be too confusing for them to comprehend. Finally, several commenters agree that guidelines should be disseminated to practitioners, but not to enrollees. These commenters believed the provider could give the guidelines to the enrollee as part of a treatment plan.

One commenter feared that the requirement to disseminate guidelines to all providers may result in MCOs collecting or creating guidelines in cases where medical outcomes are uncertain, expert preferences are mixed, or no justification is needed when following a treatment option. Another commenter believed that guidelines should only be disseminated to providers affected by the guidelines.

Response: Concerns over the dissemination of practice guidelines fell into two opposing views. Some commenters believed that guidelines should be available not only to enrollees, but also to enrollee representatives, advocates, and the general public. Other commenters believed that the current dissemination language is too broad, and that it would create a burden on MCOs to have to disseminate guidelines to all providers and all enrollees. Others were simply unclear as to what the words disseminate ''as appropriate'' entailed. We believe that guidelines should be disseminated to all providers who are likely to deliver the type of care that is the subject of the guideline (e.g. an MCO need not disseminate guidelines on childhood immunizations to its adult specialty surgeons). We also believe that enrollees with particular health concerns; e.g., asthma, may reasonably want to know if an MCO or PHP has adopted any particular guidelines on asthma care (such as those promulgated by the National Institutes of Health), and if so, would want to receive a copy of the guidelines. To clarify this section, and the intentions of the regulatory language regarding dissemination, we are revising the regulation at § 438.236(c)to read as follows: ''Each MCO and PHP disseminates the guidelines to all affected providers, and upon request to enrollees and potential enrollees.''

13. Quality Assessment and Performance Improvement Program (Proposed § 438.340)

Proposed § 438.340 required each MCO and PHP that contracts with a State Medicaid agency to have an ongoing quality assessment and performance improvement program, and specified the basic elements of such a MCO and PHP program. Under proposed § 438.340(b), MCOs and PHPs were required to: (1) Achieve minimum performance levels on standardized quality measures, using standard measures required by the State; (2) conduct performance improvement projects; and (3) have in effect mechanisms to detect both underutilization and overutilization of services. Proposed § 438.340(c) provides for minimum MCO and PHP performance levels to be established by the State. Proposed § 438.340(d) established criteria for performance improvement projects, requiring, among other things: (1) the State to establish contractual obligations for the number and distribution of projects among specified clinical and non clinical areas; and to specify certain non clinical focus areas to be addressed by performance improvement projects; (2) that each MCO and each PHP assess its performance for each project based on systematic, ongoing collection, and analysis off valid and reliable data on one or more quality indicators; (3) that each MCO's and each PHP's interventions result in improvement that is significant and sustained over time; and (4) that each MCO and each PHP report the status and results of each project to the State agency as requested. Proposed § 438.340(e) required the State to review, at least annually, the impact and effectiveness of each MCO's and each PHP's quality assessment and performance improvement program; and authorized the State agency to require each MCO and each PHP to have in effect a process for its own evaluation of the impact and effectiveness of its quality assessment and performance improvement program.

Comment: Several commenters believed that States could be faced with the loss of FFP when MCOs fail to achieve minimum performance levels, since meeting these levels is a requirement under proposed § 438.340(b)(1), and section 1903(m) of the Act requires that requirements under section 1932 of the Act be met as a condition for FFP. These commenters believed that this would give States an incentive to set performance levels that are low enough to be easily achieved. The commenters felt that the States needed the flexibility to make exceptions for MCOs and providers with high-risk patient caseloads.

Response: We would not expect to deny FFP to any State that establishes a Quality Assessment and Performance Improvement Program that meets the requirements in the regulations, even if an individual MCO or PHP might not achieve required performance levels in a single instance. Therefore, we do not agree that States will establish low minimum performance levels because of fear of loss of FFP. States are responsible for judging MCO and PHP performance in meeting the levels. We intend that the minimum performance levels be set at levels that can realistically be achieved. We require States to consider data and trends in managed care and fee-for-service in setting the levels. This is key to the process of quality improvement that we establish in this regulation.

Comment: One commenter believed that phase-in of full compliance with the imposed standards, and ongoing improvement over time should be allowed.

Response: As stated above, we believe that these regulations allow for flexibility. We believe that all MCOs and PHPs should be responsible for measuring their performance using standard measures set by the State, meet State-established minimum performance levels and conduct performance improvement projects. These are basic elements of a quality improvement program.

Comment: Several commenters were concerned that the proposed rule did not expressly require States to study care across the spectrum of enrolled populations, or to establish minimum quality measures relevant to all enrollees.

Response: For performance improvement projects, the regulation specifies four clinical areas that must be addressed over time. We intend that these areas (that is, prevention and care of acute and chronic conditions, high-volume services, high-risk services, and continuity and coordination of care) to apply to all enrolled populations. We do not specify that States must use measures of performance that address all conditions affecting all enrollees, because the state-of-the-art and limitations on resources do not allow this. However, in response to this comment, and other comments discussed in section II. C. above, we have added a provision at § 438.240(c)(2)(ii)(A) that permits us to specify standardized quality measures to be used by MCOs and PHPs. This provides us with the opportunity to specify measures for subpopulations of Medicaid enrollees and we could use this authority if a State failed to address certain subpopulations of enrollees. In addition, also in response to this and other comments, we have added at § 438.240(b)(4) a requirement that MCOs and PHPs must have in effect mechanisms to assess the quality and

appropriateness of care furnished to enrollees with special health care needs.

Comment: Several commenters believed that minimum performance levels should not be set below established compliance levels, for example in EPSDT, even if the State/MCOs are well below these standards at present.

Response: While we permit States to set minimum performance levels for their MCOs and PHPs, this authority does not diminish the responsibility of States to meet performance levels established by law, such as conducting EPSDT screening and providing EPSDT services.

Comment: Several commenters believed that the Federal government should develop over time performance measures, and set minimum performance levels, based on an aggregation of data submitted by the MCOs.

Response: We agree with this comment. In the final rule with comment period, in response to this comment and other comments discussed in section II. C. above, we have added a provision (§ 438.204(c)) that requires States to include among their strategies, performance measures and levels prescribed by us. This does not reduce the State's authority to set minimum levels for MCOs and PHPs. We expect that States will pass on to MCOs and PHPs responsibility to meet Federally-established performance levels in order for the States to meet their own targets.

Comment: One commenter read proposed § 438.340(c)(2)(i) to imply that States cannot impose standards on MCOs in addition to those specifically allowed by this regulation. The commenter also believed that proposed § 438.340(c)(6), which allows States to require the MCO to undertake performance projects specific to the MCO, and to participate annually in statewide performance improvement projects, could be read to prevent the State from being able to go further. The commenter suggested deleting §§ 438.340(c)(2)(i) and (c)(6).

Response: Section 438.240(c)(2)(i) of the final rule with comment period permits States to choose how many performance measures and performance measurement projects to require from their MCOs and PHPs. It sets as a minimum requirement that MCOs and PHPs measure, report to the State, and conduct performance improvement projects (PIPs). This regulation does not prohibit a State from imposing standards in addition to those specifically provided for in the regulation. Neither does it prohibit the State from imposing a greater number or diversity of performance improvement projects specific to a given MCO or PHP or on a statewide basis.

Comment: One commenter believed that the level of detail for quality assessment and performance improvement left little flexibility for States to accommodate the special needs of newly formed MCOs that may have limited resources and experience with such activities required during their initial contract period.

Response: States have considerable flexibility in determining how many projects an MCO or PHP must conduct, the areas to be addressed by the projects, the scope of the projects, and the amount of improvement expected. We believe this latitude is sufficient for States to address the circumstances of new MCOs or PHPs and those with fewer resources than others.

Comment: Several commenters were concerned that prospectively determined, quantifiable quality improvement goals could be difficult for MCOs and PHPs to achieve, as they do not control all factors impacting such improvement. They believed that circumstances outside the control of the MCO could make it difficult or impossible to complete a study and collect clean data. These commenters felt that States needed flexibility to accommodate these problems appropriately, without facing sanctions, when noncompliance occurs as a result of factors beyond the control of the MCO.

Response: As stated in the responses to several comments above, we believe these regulations provide States with considerable flexibility to set requirements for their MCOs and PHPs. States also have flexibility in deciding when sanctions should be imposed on MCOs and PHPs. Also, while we agree that some factors that affect quality improvement may be outside of the MCO's or PHP's control, we believe that many factors are within the control of MCOs or PHPs, and that MCOs and PHPs should be held accountable for quality improvement.

Comment: Several commenters believed that we should require States to allow MCOs sufficient time to implement programs and systems. They were concerned about the total administrative burden being imposed by the proposed rule (for example, the requirement that MCOs maintain health information systems that collect, analyze, integrate, and report necessary data).

Response: We do not agree that States should be able to postpone the Quality Assessment and Performance Improvement (QAPI) provisions to give MCOs or PHPs the time to develop programs and systems. MCOs and PHPs now have the responsibility to monitor care, and to do this requires that they have programs and data that can be used to measure their performance.

Comment: One commenter did not believe new requirements on MCOs should be imposed unless specific additional funding covering the costs of such requirements is made available.

Response: In this final rule with comment period we are replacing the upper payment limit on payments to MCOs and PHPs with a different mechanism to contain managed care costs. This new method will allow for additional costs to be considered in setting capitation rates including the costs of complying with QAPI requirements.

Comment: Another commenter wanted us to review existing QI projects that MCOs are conducting as part of HEDIS reporting and NCQA accreditation, so as not to duplicate measures and increase administrative costs.

Response: The relationship in Medicaid is between the State and the MCO or PHP, not between us and the MCO or PHP. In establishing these requirements, nothing in the regulation prohibits States from considering other QI projects their MCOs are conducting, and we would encourage States to do so.

Comment: Several commenters believed that State agencies should consider historical MCO and FFS Medicaid performance data and trends to determine the appropriateness of quality measures. They also believed that performance levels adopted by States should be reasonably attainable. They asked that the following preamble language be inserted into the regulation text, ''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 FFS Medicaid performance data and trends.''

Response: Section 438.240(c)(2)(ii)(B) of the final rule with comment period provides that States should ''consider data and trends for both the MCOs and PHPs and fee-for-service Medicaid in that State,'' in setting minimum performance levels. This addresses the issues of achievability and equity.

Comment: Several commenters believed that a predefined percentage, like QISMC's standard of a 10 percent reduction in deficient care, would stifle creative approaches to QI. They also object to the 10 percent standard because it is inconsistent with NCQA's

''meaningful'' standard for improvement, based on effort. The same commenters also believed that the 10 percent standard could cause MCO not to pursue QI projects for which a 10 percent reduction was difficult to predict. The commenters would like to see the defined percentages removed from the preamble, and in its place have NCQA's ''meaningful'' improvement standard inserted.

Response: The 10 percent reduction rule from QISMC is in the preamble as an example only and is not a requirement. However, we believe that the true test of quality improvement is measurable improvement. This requires that a numeric benchmark or percentage improvement goal be in place. Therefore, we do not agree that a standard of ''meaningful'' improvement is sufficient. The regulation does not require the use of the 10 percent reduction standard. States have the discretion to establish specific numeric, objective improvement levels themselves.

Comments: Many commenters believed that without specific instructions from us, stating that MCOs must identify and monitor care delivered to populations with special health care needs enrolled in an MCO, it is unlikely that results from QAPI will reflect the experiences of these groups. They also believed that HEDIS for Medicaid does not include many measures specific to children or adults with special health care needs. The commenters would like to see specific quality assurance activities and outcome measures, focusing on the various populations with special health care needs, to be developed in conjunction with advocates and experienced providers in these areas.

Response: We agree that populations with special health care needs should not be left out of MCO and PHP quality assessment and performance improvement activities. Section 438.240(d)(2) of the final rule with comment period requires that performance measurement and quality improvement projects address the entire Medicaid enrolled population in an MCO or PHP to whom the measure is relevant. The regulation also requires that all enrolled populations be measured over time. As discussed above, we have added provisions permitting the Secretary to specify annual quality measures and performance improvement project topics for MCOs and PHPs. Through this mechanism, we have the authority to direct States, MCOs, and PHPs to address subgroups of enrollees should the States fail to do so. To make explicit the requirement that populations with special health care be included in MCO and PHP quality assessment and performance improvement activities, we have added a new item at § 438.240(b)(4) requiring that MCOs and PHPs have in effect mechanisms to assess the quality and appropriateness of care furnished to enrollees with special health care needs. We note however that more effective and plentiful quality indicators to measure the quality of care delivered to individuals with special health care needs are still needed.

Comment: One commenter believed that in addition to reporting performance measures, States or medical auditors should also target and access medical records to study overall treatment of specified conditions and adherence with treatment protocols.

Response: We do not agree that we should require States (in addition to using performance measures and quality assessment and performance improvement projects) to separately review medical records to study overall treatment of specific conditions and monitor the use of treatment protocols. While States are free to undertake this activity, we believe that the elements of State quality assessment and performance improvement strategy will be sufficient to monitor health care quality (including adherence to treatment protocols).

Comment: One commenter favored outcomes measured through both process indicators and ''quality of life'' indicators.

Response: The term performance measure, as we are using it, provides the option for States to use process and outcome measures, including quality of life indicators.

Comment: A commenter recommended a requirement that HEDIS be the standardized tool for QAPI, instead of leaving this up to States.

Response: We believe that the choice of performance measures and measurement tools should be left to the discretion of individual States. Many States now use a number of HEDIS measures; however, we note that HEDIS as a measurement set has limitations and may not serve the complete needs of States or fully address the Medicaid population.

Comment: A commenter believed that the statement, ''projects are representative of the entire spectrum of clinical and non-clinical areas,'' should be qualified so that projects are not required to cover the entire spectrum every year, but should focus on one area each year, as long as the subject varies over time.

Response: The proposed rule did not, and the final rule with comment period does not, require that all areas be addressed each year. States may specify the number of projects its MCOs and PHPs must conduct, and the requirement would be met if the State requires only one project. We have clarified the final rule with comment period to state at § 438.240(d)(3) that States must require each MCO and each PHP or more to initiate one or more performance improvement projects per year.

Comment: One commenter asked if a successful NCQA review would be acceptable in lieu of the required yearly audit, since this would save administrative efforts and expense.

Response: As discussed above in section II. C., while section 1932(c)(2) of the Act provides for external quality review (EQR) requirements to be met based on other accreditations, there is no such authority for the requirements under section 1932(c)(1) of the Act (as is the case with respect to similar requirements under the Medicare+Choice program).

Comment: A commenter was concerned about the fact that many subpopulations served by an MCO were small in number, and believed it may be difficult to produce any meaningful results for quality assurance and performance measurement. The commenter asked if aggregate results of a performance project across several MCOs of a national company would be acceptable.

Response: States are accountable for the quality of care for their Medicaid beneficiaries, and must be permitted to set the requirements for the MCOs and PHPs with which they contract. Therefore, we will not modify the regulation to permit MCOs or PHPs to aggregate data across States.

Comment: Several commenters wanted States to publish performance measurement tools and results of assessments. The commenters were concerned that no requirement exists that requires MCOs to provide information about quality assurance programs to enrollees and potential enrollees in Medicaid.

Response: While we have not provided in this final rule with comment period for the provision of information on MCO or PHP quality measures, this will be provided for in the final EQR regulation, as it is required under section 1932(c)(2)(A)(iv) of the Act.

Comment: Several commenters believed that self-reported quality measures should be subject to external validation by the State, and that State-

defined measures and performance improvement projects should be required to use audited data.

Response: This type of external review is provided for in section 1932(c)(2) of the Act, which is being implemented in a separate rulemaking.

Comment: Some commenters did not believe that the use of the word benchmark in the preamble discussion of proposed § 438.340(d)(9) was clear. Yet they believed that benchmarking is one of the key terms for QI, and needs to be expanded in the final rule with comment period.

Response: We agree that the term ''benchmarks'' can have many connotations, and have deleted it from the final rule with comment period.

Comment: A commenter requested that we include a definition of ''high-volume'' or ''high-risk'' services. The commenter believed this should be defined to require the review of mental health services, and did not believe that mental health services would be considered high-volume or high-risk without these services being expressly included in the definition.

Response: We have chosen not to define ''high-volume'' or ''high-risk'' services, as they differ relative to individual MCOs or PHPs and the populations they serve. For example a PHP behavioral health carve-out would only include mental health services. We believe States are in the best position to define this for their MCOs and PHPs.

Comment: One commenter urged that cultural competence be included as a nonclinical area of performance measurement in the regulation.

Response: We agree that cultural competence is a nonclinical area that may be a topic of a performance improvement project. In response to this comment, in § 438.240(d)(5)(iii) of the final rule with comment period, we have added ''cultural competence'' as a non-clinical area.

Comment: Several commenters asked that we establish a process for detailed discussions with MCOs to better understand the operational issues associated with implementing the proposed standards of the regulation. Two of the commenters desired discussions with us to define short- and long-term goals for Medicaid managed care quality oversight and to arrive at a focused strategy. For example, they believed that HEDIS was undermined by the ability of States to establish an independent system of quality improvement strategies.

Response: We are working to provide technical assistance tools to the States. In turn, the States will be able to work with MCOs and PHPs, and MCOs and PHPs will have an opportunity to provide public input to the quality strategy in their respective State.

Comment: A commenter believed that more ''horizontal'' lines of communication regarding performance improvement and measurement needed to occur, in addition to the current ''vertical'' lines of communication between the States, MCOs, and HCFA. For example, they would like to see communication take place across MCOs and across State agencies.

Response: We agree that communication across organizational components is of considerable value, and this function is currently addressed through membership organizations, such as the American Public Human Services Association (APHSA). These organizations can assist with the exchange and gathering of information through conferences and publications.

14. Health Information Systems (Proposed § 438.342)

Section 1932(c)(1)(iii) of the Act requires States 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 the population enrolled under the contract, and that includes requirements for provision of quality assurance data to the State, by MCOs using the data and information set that the Secretary has specified for use under the Medicare+Choice program, or such alternative data as the Secretary approves, in consultation with the State.

In proposed § 438.342, we provided that the State ensure that each MCO and PHP maintain a health information system that collects, analyzes, integrates, and reports data that can achieve the objectives of this part. Under the proposed rule, we specified that the system should provide information on areas including, but not limited to, utilization, grievances, disenrollments and solvency. Furthermore, we proposed that the State ensure through its contracts with MCOs and PHPs that each MCO and PHP be required to: (1) Collect data on enrollee and provider characteristics, as specified by the State, and on services furnished to enrollees; (2) ensure that the 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; and (3) make available all collected data to the State and HCFA. An MCO or PHP was permitted to use any method or procedure for data collection, so long as it could demonstrate that its system achieves the objectives of this standard.

Comment: Several commenters believed that the regulation should specifically require appropriate acquisition of data by MCOs concerning race, ethnicity, sex, age, disability, and primary language. These commenters believed that without the collection of such data, compliance and enforcement with civil rights laws including Title VI and the ADA would be difficult.

Response: All of the above, with the exception of age and sex, are explicitly addressed in this final rule with comment period. Information on disability will be captured through the initial and ongoing assessment provisions of § 438.208. Primary language spoken is addressed in the language requirement of § 438.10(b). As discussed previously, race and ethnicity are addressed in § 438.204(b)(1)(iii). However, sex and age are fundamental pieces of demographic information that are essential if MCOs and PHPS are to be able to comply with the information system requirements in § 438.242. Age and sex are such routinely collected demographic information, that we do not believe it necessary to expressly mandate their collection in the regulation.

Comment: Several commenters urged that the timing and costs associated with implementing the regulations be evaluated. These commenters suggested that we allow more time to comply with the regulation, because of millennium activities that are utilizing the majority of State and MCO resources. Several other commenters questioned how funding for this activity would occur, as they did not believe they had the resources to meet the requirements.

Response: Given the passage of time since January 1, 2000, ''Y2K'' activities should no longer be utilizing State systems resources. We will work with States to assist them in implementation of this final rule with comment period. As for the funding for implementing the requirements, new Medicaid State agency system development design and implementation is funded at 90 percent and maintenance to existing systems is matched at 50 percent.

Comment: Several commenters questioned the logic of including solvency information in the same system as enrollee-specific data such as utilization, grievances and disenrollments. These commenters did not believe solvency information should

be included as a mandatory element of a health information system. The commenters believed that a State's current standards for reporting and format should be sufficient.

Response: We agree that this is not the appropriate place to capture solvency information. In response to this comment, we have removed the reference to solvency from § 438.342(a).

Comment: Several commenters found the requirement that MCOs make all collected data available to both the State and HCFA excessive and redundant since the State must also submit data to us. The commenters noted that it is the MCO's business to manage their population and to report required data to the State. Duplicative reporting requirements could increase the administrative expenses of MCOs, and make contracts with State Medicaid programs less attractive to commercial HMOs.

Response: We agree that it is burdensome to request all information to be sent to both the State and to HCFA. In response to this comment we have provided in § 438.242(b)(3) of this final rule with comment period that MCOs and PHPs make all collected data available to the State as required in subpart D, and to us upon request.

Comment: Several commenters recommended that we establish national data collection standards for States to use for the collection of encounter data, EPSDT, and network information. These commenters specified that these standards should be based on current data elements that could be systematically produced by providers, and captured by MCOs and PHPs.

Response: We desire to have consistency of information, and to have national standards in those cases where it makes sense to do so. However, we must also balance that desire with providing States with the necessary flexibility to implement their individual Medicaid programs. We are working on several initiatives to standardize data collection on a national level. The Health Insurance Portability and Accountability Act (HIPAA) requires us to work toward the goals recommended by several of the commenters.

E. Grievance Systems (Subpart F)

Background

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

In this subpart, we proposed regulations that lay out the required elements of the grievance system required under section 1932(b)(4) of the Act, and how it interfaces with the State fair hearing requirements in section 1902(a)(3) of the Act; describing what constitutes a notice (that is, the first step in the grievance system); addressing complaints and grievances, including timeframes for taking action; the process for actions; how grievances are to be handled; and how enrollees are to be notified of the resolution of grievances. In addition, the proposed rule provided for expedited resolution of grievances and appeals in specific circumstances; addressed the requirement for continuation of benefits; included the requirement that MCOs and PHPs clearly and fully inform enrollees of the entire system so that they are aware of it and how to use it; specified what materials must be provided when notifying an enrollee, and the requirements for those materials; and lay out the requirements relating to record keeping, monitoring, and the consequences of noncompliance.

1. Statutory Basis and Definitions (Proposed § 438.400)

Definitions of terms that would apply for purposes of proposed subpart F are found in § 438.400 of the proposed rule, in that the following terms have the indicated meanings:

Complaint was defined as any oral or written communication made by or on behalf of an enrollee to any employee of either the MCO, PHP, its providers, or to the State, expressing dissatisfaction with any aspect of the MCO's, PHP's, or provider's operations, activities, or behavior, regardless of whether the communication requests any remedial action.

Enrollee was defined for purposes of subpart F, as an enrollee or their authorized representative.

Governing body was defined as the MCO's or PHP's Board of Directors, or a designated committee of its senior management.

Grievance was defined as a written communication, submitted by or on behalf of a Medicaid enrollee expressing dissatisfaction with any aspect of the MCO's, PHP's, or providers's operations, activities, or behavior that pertains to the following: (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 provided for under the proposed rule.

Comment: Some commenters questioned HCFA's statutory authority to promulgate the detailed requirements in proposed subpart F, given the limited amount of text in section 1932(b)(4) of the Act.

Response: As noted above, these rules are based only in part on section 1932(b)(4) of the Act. We believe that those portions of subpart F that address an MCO's internal grievance system constitute a reasonable implementation of authority under section 1932(b)(4) of the Act. This rule is also based on our general authority under section 1902(a)(4) of the Act, and on the State fair hearing requirements in section 1902(a)(3) of the Act, that prior to this final rule with comment period have not been implemented in regulations that apply to managed care enrollees. We believe that the requirements in subpart F of this final rule with comment period are warranted in order to ensure that MCOs have an effective and useful internal grievance process, as required under section 1932(b)(4) of the Act, and in order to ensure that MCO and PHP enrollees have access to the same State fair hearing process that fee-for-service enrollees have under subpart E of part 431. This final rule with comment period applies the general rights in section 1902(a)(3) of the Act to managed care enrollees both in MCOs and PHPs. In the case of PHPs, the requirements in subpart F are based both on section 1902(a)(3)of the Act and, in the case of longstanding PHP regulations, they are generally on our broad authority under section 1902(a)(4) of the Act to specify methods necessary for proper and efficient administration. In the case of MCOs, we are also implementing the requirements in section 1932(a)(4) of the Act, and setting forth what we believe is necessary to adequately meet these requirements as we have interpreted them. The analysis of key court decisions has also guided the development of these final regulations, just as the Supreme Court's *Goldberg* v. *Kelly* decision was incorporated in the State fair hearing regulations under part 431, subpart E to which the MCO and PHP grievance system is linked.

Comment: Some commenters believed that while we took case law into account in proposed subpart F, HCFA did not go far enough to protect

Medicaid managed care enrollees' rights in the following three areas: (1) Continuation of benefits; (2) direct access to State fair hearings; and (3) time frames for action.

Response: We have carefully considered all comments on these three issues and address each issue below in the context of our discussion of regulation language that pertains to the issue. In general, we recognize that we have a responsibility to protect Medicaid enrollees and ensure their rights. To meet this responsibility, we have established a set of Federal protections that apply to Medicaid enrollees regardless of their State of residence. This will ensure a minimum degree of consistency with the level of protection afforded Medicare beneficiaries. States may choose to add to these protections by exceeding the minimum levels required by this regulation.

In developing these regulations, we relied heavily on the Consumer Bill of Rights and Responsibility (CBRR). We also examined the grievance procedures of many States, and considered all comments on these issues. We have carefully documented, tracked, and analyzed each decision we have made with respect to our consideration of commenters' suggestions in light of the guiding principles in the CBRR.

Comment: We received comments that suggested that we specify a different grievance process for enrollees with addiction or mental health issues or, at a minimum, make specific mention of these concerns in the regulation, and adopt the principles of the Model Managed Care Consumer Protection Act proposed by the President's Commission on Model State Drug Laws. Under this Act, the patient, family, or program must be permitted to appeal directly outside the MCO or PHP. These commenters also suggested that there be a separate office responsible for the addiction and mental health grievance process and to advocate for patients and families.

Response: We do not agree that there should be separate grievance processes, procedural requirements, or offices based on diagnosis-specific or population-specific criteria. The grievance system set forth in this regulation is designed to address the needs of all Medicaid enrollees, including those with special health care needs. PHPs providing mental health or substance abuse services are also subject to these provisions, that we believe adequately protect individuals with these conditions.

Comment: Many commenters strongly recommended that we eliminate the ''complaint'' category set forth in the proposed rule, while others supported the broad definition of ''complaint'' as separate from ''grievances'' subject to a State fair hearing, but recommended changes to better distinguish these categories. The comments advocating the elimination of a separate complaint category are first presented below followed by the comments supporting retention of the two categories but recommending changes related to these categories.

In support of eliminating separate categories, one commenter contended that it has been well documented that Medicare+Choice organizations misidentify what should be appeals under the Medicare+Choice appeals system as ''grievances,'' are not subject to external administrative and judicial review under that system. The commenter believed that HCFA should eliminate the ''complaint'' level, because the commenter saw it as the equivalent of ''grievances'' under Medicare+Choice, and in order to avoid confusion and prevent the potential mishandling of appeals. One commenter noted that under the proposed rule, an MCO or PHP could fail to acknowledge an appeal and provide the required notice to enrollees simply because the enrollees failed to ''use the magic words'' when filing their dispute.

Another commenter believed that because the NPRM does not require that complaints be monitored and tracked as closely as grievances, MCOs and PHPs have an incentive to categorize a dispute as a complaint. The commenter stated that this could benefit the MCO or PHP because complaints would not be reflected in the MCO's or PHP's performance ratings, and MCOs and PHPs should not be given the authority to decide whether an issue is a complaint or grievance.

Another commenter expressed the view that a complaint process does not protect the enrollee and, therefore, should be deleted from the regulation. This commenter believed that MCOs and PHPs would be able to resolve complaints on a more informal basis through the customer service department, while enrollees' rights to a formal appealable grievance would remain.

One commenter noted that many States have a single definition for a ''grievance'' in order to avoid confusion for MCOs, PHPs and enrollees. The commenter felt that this simplifies reporting and facilitates the resolution of a complaint. One commenter said that all issues should be tracked as grievances whether submitted orally or in writing. Another said that enrollees should be able to address any problem that they have with the MCO, PHP, or a provider without getting trapped or confused by a labeling and tracking process. Several commenters said the documentation of all complaints as well as grievances should be required.

A commenter felt that allowing both an informal complaint and a formal grievance process has led to confusion of enrollees, MCOs and PHPs, as well as to inappropriate transfers and unnecessary delays. This commenter believed that there have been many instances of MCOs and PHPs re-classifying grievances as ''complaints'' in order to evade review or to slow the dispute resolution process, and that an enrollee's rights may hinge on this classification process.

One commenter believed that enrollees should be given the right to request expedited resolution of complaints and these should be treated in the same manner as grievances were under the proposed rule, for when expedited resolution is requested by the enrollee or the provider.

One commenter noted that under existing fee-for-service regulations, all disputes are dealt with in a uniform manner and all that is required to obtain a hearing is a ''clear expression by the applicant or recipient, or his authorized representative, that he wants the opportunity to present his case to a reviewing authority.'' According to this commenter, this [42 CFR 431.201] definition allows for differences in presentation of disputes and does not require beneficiaries to refer to rules and definitions when presenting them. In the commenter's opinion, many beneficiaries do not have the capacity to distinguish between a ''complaint'' and a ''grievance.''

Other commenters agreed that there should be distinct categories for complaints and grievances subject to appeal, but suggested changes to how these categories are defined and the provisions applying to each. These comments follow.

One commenter believed that complaints that are not resolved to the beneficiary's satisfaction within 30 days after filing should automatically become appealable grievances.

Another commenter stated that if the complaint process is not eliminated, it should be regulated to the same extent as the grievance process was under the proposed rule. The commenter suggested that the regulation should provide more guidance on how complaints are to be handled. The regulation should also specify who distinguishes a complaint from a grievance and the qualifications of this

decision-maker. The distinction between a complaint and grievance, as used in the proposed rule, needed to be clarified with examples, in the commenter's view. Matters do not always squarely fit within one category.

One commenter said that the terms ''complaint'' and ''grievance'' should be clarified in the regulation, and that the complaint process would address those communications that were not grievances under the proposed rule. The commenter provided examples of topics that would likely be addressed as complaints in this process for example, waiting times, operating hours, demeanor of health care personnel, and the adequacy of facilities.

A commenter noted that the preamble's characterization of complaints differs from the regulatory definition. The commenter stated that the regulation defines complaints but includes no guidance on how they are to be handled. One commenter noted that the preamble says that complaints include problems involving waiting times and operating hours. However, the commenter noted, if a beneficiary must wait three weeks for an appointment during limited afternoon hours, this clearly is an availability and quality problem which should be defined as an appealable grievance.

One commenter believed that the distinction made in the proposed rule between complaints and grievances was subjective and suggested that the proposed rule's requirement that grievances be in writing would greatly reduce the number of disputes handled through the grievance process, because of the difficulty enrollees may have in filing a written appeal. The commenter further noted that some problems require immediate response, which a telephone communication allows.

One commenter thought that grievances which result from unresolved complaints should apply only to unresolved complaints that are related to service delivery or treatment. This commenter believes that appeals should be available only for ''actions'' (that is, the denial, reduction, or termination of services), and that frivolous complaints not resolved to the enrollee's satisfaction should not be entitled to a State fair hearing. This commenter was concerned that the proposed regulation opens up the State fair hearing process to virtually any expression of dissatisfaction with the operation of the MCO or PHP.

A final commenter recommended that we use the terms used in the Medicare+Choice regulations to simplify MCO and PHP documentation, and MCO and PHP enrollee education. According to the commenter, consistent use of terms would also make life easier for providers and for enrollees who participate in both the Medicare and Medicaid programs.

Response: We agree with the commenters who were confused by the way the term ''grievance'' was used in the proposed rule, particularly in light of Medicare+Choice's use of the term ''grievance'' as a complaint that is not subject to external review or a State fair hearing. Our use of the term ''grievance'' in the proposed rule was based on the fact that the Congress, in section 1932(b)(4) of the Act, referred to an internal ''grievance procedure under that an enrollee could challenge a denial of payment or coverage.'' The Congress used the term ''grievance'' to refer to a type of appeal that under the Medicare+Choice program was subject to appeal and was under that program's terminology not a grievance. It was for this reason that we used the term ''complaint'' to refer to the type of problem labeled a ''grievance'' in the Medicare+Choice program. In order to adopt an approach more consistent with Medicare's (to avoid confusion for organizations that participate in both programs). In this final rule with comment period, we are deleting the use of the word ''complaint,'' and using the term ''grievance'' to refer to the same types of enrollee problems. Also, in this final rule with comment period, like in the Medicare+Choice program, we establish two mutually exclusive categories: (1) a ''grievance,'' that is not subject to the State fair hearing process (called a ''complaint'' in the proposed rule), and (2) an ''appeal,'' that is subject to a State fair hearing (encompassed in the term ''grievance'' in the proposed rule). Because the Congress employed the term ''grievance procedure'' in section 1932(c)(4) of the Act, we continue to use the term ''grievance system'' to refer to the overall grievance and appeal system provided for in subpart F.

Specifically, in response to the above comments, we have in this final rule with comment period: (1) dropped the definition of ''complaint;'' (2) changed the definition of ''grievance'' to roughly track the definition of ''complaint'' used in the proposed rule; and (3) added a new definition of ''appeal'' to § 438.400 so that grievance and appeal are two mutually exclusive categories. We agree with the commenters favoring the employment of two distinct categories because we believe that certain disagreements between the MCO or PHP and its enrollees should have a higher standard of review, and should be subject to a State fair hearing if the MCO or PHP decision is adverse to the enrollee. The term ''appeal'' also is used by most States for State fair hearing requests. In this final regulation, the term ''appeal'' is used to refer to requests for an MCO or PHP hearing, as well as, for a State fair hearing. As just noted, it is also the term used in Medicare and will reduce the burden on MCOs and PHPs for educating providers and dually-eligible enrollees.

To clearly distinguish between a grievance and an appeal, in this final rule with comment period, we have added a definition of ''action'' as the event that entitles an enrollee to file an appeal and defined a grievance as involving a matter other than an action. An action includes the following: (1) the denial or limited authorization of a requested service; (2) the reduction, suspension, or termination of previously authorized services; (3) the denial of payment, in whole or in part for a service, for a resident of a rural area with only one MCO or PHP; (4) the denial of a Medicaid enrollee's request to exercise their right to obtain services out of network; (5) the failure to either furnish, arrange or provide for payment of services in a timely manner; and (6) the failure of an MCO or PHP to resolve an appeal within the timeframes provided in the regulation. In addition, for a State agency, the denial of a Medicaid enrollee's request to disenroll is an action.

In response to comments that we should set out additional requirements for MCOs and PHPs when they are addressing complaints (now called grievances), we have added several requirements. In this final rule with comment period, we require that MCOs and PHPs ensure correct classification of grievances. We also provide examples of grievance issues in the regulation text (in a parenthetical in the revised definition of grievance). We specify maximum timeframes for MCOs and PHPs to dispose of grievances. We provide in § 438.406(a)(7)(ii) that grievances involving clinical issues and those regarding denials to expedite resolution of appeal be decided by a health care professional with appropriate clinical expertise. We also provide that while grievances are not subject to review at the State fair hearing level, they are subject to further review by the State at the request of the enrollee. We also provide that MCOs and PHPs must work with the State to dispose of grievances if the State considers the MCO or PHP response to be insufficient. In addition, the State must monitor these processes and incorporate that monitoring into its overall quality improvement strategy.

Overall, we believe that this new approach will streamline the grievance and appeal process, eliminate confusion on the part of enrollees and providers, be more consistent with Medicare, and provide protection for enrollees.

Comment: Some commenters believed that the grievance and appeals provisions should apply to PCCMs, as well as, to MCOs and PHPs.

Response: We do not agree with the commenter's suggestion that the grievance and appeal provisions should apply to PCCMs. PCCMs are often individual physicians or small group practices and can not be expected to have the administrative structure to support a grievance process. Because PCCMs that are not capitated (capitated PCCMs would be subject to subpart F as PHPs) are reimbursed through the fee-for-service system, they are subject to the State fair hearing process described in 42 CFR 431 Subpart E. Moreover, as noted above in section II. D. with respect to the quality requirements in section 1932(c)(1) of the Act, the Congress made a conscious decision in section 1932(b)(4) of the Act to apply the grievance requirements only to MCOs in that section, notwithstanding the fact that other requirements in section 1932 of the Act apply to PCCMs. We believe it would be inconsistent with Congressional intent to apply grievance requirements to PCCMs. In the case of PHPs, the Congress was silent in section 1932 of the Act. We believe that because PHPs are paid on a risk basis like MCOs and have a financial incentive to deny care like MCOs, grievance and appeal protections are as important for PHP enrollees as they are for MCO enrollees.

Comment: One commenter urged that grievances and appeals be classified according to the type of denial (for example, a clinical determination should be subject to appeal). The commenter stated that this differentiation is important because denials of service may have a critical impact on the patient's health, unlike denials of payment and general grievances.

Response: In this final rule with comment period (§ 438.400(b)) the definition of ''action'' distinguishes what is subject to appeal from what is addressed as a grievance. In addition, we also distinguish between grievances involving quality of care issues and other grievances. Section 438.406(a)(7)(ii) of this final rule with comment period provides that grievances involving a clinical issue or a grievance of a denial of a request for expedited appeal must be decided by a health care professional who has appropriate clinical expertise in treating the enrollee's condition or disease.

2. General Requirements (Proposed § 438.402)

Proposed § 438.402 stated the general requirements of the MCO and PHP grievance system, and required MCOs and PHPs to have a grievance system that includes a complaint (now referred to as grievance) process, a grievance (now called appeal) process, and a link to the State's fair hearing system. Proposed § 438.402 required the MCO and PHP to—

- Base its complaint (now grievance) and grievance (now appeal) process on written policies and procedures that, at a minimum, meets the conditions set forth in this subpart.
- Obtain the State's written approval of the grievance (now appeal) policies and procedures before implementing them.
- Provide for its governing body to approve and be responsible for the effective operation of the system;
- Provide for the governing body to review and resolve complaints (now grievances) and grievances (now appeals) unless it delegates this responsibility to a grievance committee.
- Provide through its grievance (now appeal) process clearly explained steps that permit the enrollee to appeal to the MCO, PHP, and to the State.
- Allow the enrollee a reasonable time to file an appeal, include for each step timeframes that take into consideration the enrollee's health condition and provide for expedited resolution of grievances (now appeals) in accordance with § 438.410, not substitute for the State's fair hearing system.
- Permit enrollees to appear before the MCO and PHP personnel responsible for resolving the grievance (now appeal), and provide that, if the grievance (now appeal) resolution decision is wholly or partly adverse to the enrollee, the MCO or PHP 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 for—

++A standard resolution, no later than 30 days after receipt of the grievance (now appeal) or the expiration of any extension; and

++An expedited resolution, no later than 24 hours after reaching the decision.

Additionally, the State must either permit the enrollee to request a State fair hearing on a grievance (now appeal) at any time, or provide for a State fair hearing following and MCO or PHP adverse decision on the matter that gave rise to the grievance (now appeal).

Comment: Given the provision in proposed § 438.402(a) requiring a link between the grievance system under section 1932(b)(4) of the Act and the State fair hearing system, the right under proposed § 438.402(d) to a fair hearing (either directly, or following an adverse MCO or PHP decision), and language in the preamble to the proposed rule requesting comments on whether fair hearing timeframes should be revised, several commenters were prompted to comment generally on the State fair hearing process. Many of these commenters recommended substantial revisions to HCFA's State fair hearing regulations, and requested that HCFA convene a meeting to discuss proposed changes to those recommendations. The commenters agreed that the State fair hearing process needs to be revised, but there was no consensus on how it should be revised. Several commenters wanted Medicaid to adopt the same standards for the State fair hearing process that were proposed for the MCO and PHP internal grievance process. Other commenters wanted an expedited State fair hearing. Commenters suggested various timeframes which ranged from 24 hours to 15 days. Finally, one commenter wanted HCFA to eliminate extensions for State fair hearings provided for in the Medicaid manual.

Response: We have decided to postpone consideration of major modifications to the State fair hearing regulations generally and to develop an NPRM to propose changes to the State fair hearing rules. At that time we will also review the provisions in the Medicaid Manual related to fair hearings. We will consider using the negotiated rule-making process in developing this NPRM.

In response to these and other comments, however, this final rule with comment period does require, under §§ 438.408(j)(3)(ii) and 431.244(f)(2), expedited State fair hearings when a service has been denied and a delay in receipt of that service could jeopardize the enrollee's health. States must conduct a State fair hearing and issue a final decision on these cases as expeditiously as the enrollee's health condition requires, but no later than 72 hours from receipt of the appeal.

Comment: Several commenters requested modifications to the State fair hearing regulations to allow MCOs and PHPs to become a party to the hearing. The commenters believed that the MCO or PHP should have an opportunity to present its position on the dispute at the hearing. Other commenters noted that

several States have not recognized MCOs and PHPs as parties to State fair hearing.

Response: We agree that MCOs and PHPs should be parties to the State fair hearing and in response to this comment, have provided for this in the final rule with comment period at § 438.408(j)(2). As parties to the hearing, we believe it is clear that MCOs and PHPs are subject to the hearing decision. As parties to the hearing it will also be clear that an MCO or PHP can present its position at a State fair hearing which we think is appropriate because the MCO or PHP will be liable for providing and paying for a service if the State fair hearing officer overturns the decision.

Comment: Several commenters noted that some State fair hearing officers do not believe that they have jurisdiction over MCOs and PHPs and believe they lack authority to order MCOs and PHPs to take a particular action. These commenters believed it would be very helpful for the regulations to provide that both the agency and the State fair hearing officer have authority to order the MCO or PHP to provide a required service or perform a corrective action, including reimbursing for services.

Response: We agree with commenters that State fair hearing officers should have jurisdiction over Medicaid MCOs and PHPs. As just noted, we have provided at § 438.408(j)(2) that MCOs and PHPs are parties to a State fair hearing appealing their decisions. With this addition, we think it will be clear that the presiding officer of the proceeding has jurisdiction over a party to the hearing.

Comment: One commenter recommended that an expedited State fair hearing be available to Medicaid beneficiaries who are not enrolled in managed care. The commenter noted that increasingly, fee-for-service arrangements use prior authorization processes, and as in managed care, the care under review may be urgently needed.

Response: While we believe there is merit in the commenter's suggestion from a policy perspective, we are not amending the State fair hearing regulations to provide an expedited hearing in fee-for-service situations, because the proposed regulation addressed Medicaid managed care, not the fee-for-service delivery system. We plan to develop an NPRM to revise the State fair hearing regulations as they pertain to fee-for-service and managed care. When this NPRM is published, the public will be invited to comment on these proposed rules. In this final rule with comment period we revise the State fair hearing regulation only to provide an expedited timeframe for resolution of appeals involving MCO or PHP denials of services in situations that require expedited resolution. This matter was put before the public in our proposed rule.

Comment: Several commenters recommended that HCFA establish more specific standards for the State fair hearing processes, including specific standards regarding the qualifications of hearings officers. Commenters were concerned with State use of hearing officers who lack adequate understanding of clinical issues when a hearing involves a denial based on lack of medical necessity.

Response: We have not addressed this concern in this final rule, comment period. As with judicial review, the presiding officer is usually not medically trained. It is the responsibility of both parties to explain the matter in a way that can be understood by the adjudicator. Parties may retain experts to present technical issues. In addition, as provided in section 431.420, provides that if the hearing officer finds it necessary, they may order an independent medical assessment to be performed at State expense.

Comment: Several commenters recommended that we require States to consult with beneficiaries, advocates, and the State MCAC when developing State grievance requirements.

Response: In § 438.202(c) we require that States provide for the input of beneficiaries and stakeholders in the development of their quality strategies. Grievance and appeal procedures must be addressed as part of State quality strategies. This provides an opportunity for beneficiary and stakeholder input. We are not specifying the mechanisms States must use to receive input. Therefore, States may, but are not required to, consult with their MCAC on grievance requirements.

Comment: Several commenters supported the requirement in proposed § 438.402(b)(3) that the MCO and PHP grievance process must be approved by the MCO's or PHP's governing body. Other commenters were concerned that requiring the governing body to approve and be responsible for the operation of the process was unnecessary and inefficient. They believed that the State should determine whether MCOs and PHPs have appropriate staff to handle the grievance process.

Response: Our intent is to ensure the involvement of individuals with authority to direct corrective action should systemic changes be required. The regulations at § 434.32, that this regulation replaces, required that the MCO ensure the participation of individuals with authority to require corrective action. We retain this requirement in this final rule with comment period. The actual processing of grievances and appeals can be delegated to a grievance committee of less senior employees.

Comment: Several commenters thought that the 90-day period for filing appeals following the notice of action was burdensome to MCOs and PHPs, because MCOs and PHPs need more timely filing by enrollees in order to assess their potential payment liabilities. Another commenter noted that § 431.221 of the current regulation, that is cited in proposed § 438.402(c)(1)(ii) provides that the State must allow for a reasonable time, not to exceed 90 days for beneficiaries to file an appeal. One commenter implied that the proposed rule states that the State must allow a minimum of 90 days for filing of appeals is inconsistent with the current regulation and that application of the proposed rule would result in different standards for managed care and fee-for-service appeals.

Response: Our intent in the NPRM was to mirror the filing timeframes for the State fair hearing, that is, a reasonable amount of time up to 90 days. This is reflected in the parenthetical in proposed § 438.402(c)(1)(ii) stating ''as provided under the fair hearing process at proposed § 431.221.'' Our reference to 90 days was incorrect because it did not reflect the fact that the regulation we intended to incorporate provided for ''up to'' 90 days. We therefore have revised this final rule with comment period to mirror § 431.221. In addition, we have incorporated in the regulation the longstanding policy at § 2901.3 of the Medicaid Manual that beneficiaries be given a minimum of 20 days to file an appeal. We believe that this policy more specifically defines the requirement in the current regulation that beneficiaries be given ''a reasonable amount of time'' to file an appeal. We believe that placing this requirement in this final rule with comment period will increase public awareness of this standard.

In the notice of action, MCOs and PHPs must include information on the deadline for filing an appeal. Further, in States that do not require that enrollees appeal first through the MCO or PHP grievance system, the notice of action must also state that the enrollee may appeal directly to the State for a fair hearing.

Comment: We received several comments concerning the manner in

which grievances and appeals may be filed.

One commenter recommended that an enrollee be permitted to submit a grievance or appeal either orally or in writing. If the decision is made to require that grievances and appeals be submitted in writing, the commenter urged that MCOs and PHPs be required to provide assistance in the process. The commenter believed that requiring Medicaid enrollees to submit grievances and appeals in writing may deprive some beneficiaries of their rights if they are not proficient in English, have little formal education or a low level of literacy, or have disabilities that prevent or make writing difficult.

Another commenter suggested that staff designated to receive and resolve grievances or appeals (proposed § 438.406(a)) be charged with reducing to writing any oral request for official review or remedial action. The commenter felt that the regulations should require MCOs and PHPs to record oral grievance and appeal requests.

One commenter suggested that we clarify whether the enrollee or the MCO or the PHP must put in writing the request for expedited resolution. Another commenter noted that the requirement for written confirmation of an oral request for expedited resolution can be a barrier to an enrollee who has severe and persistent mental illness, and who is in a period of cognitive deficit. This commenter recommended that an oral request should be allowed to suffice in this circumstance.

One commenter stated that we should delete all reference to oral requests because information received orally may be misconstrued. Another commenter stated that the regulation should include language requiring MCOs and PHPs to record oral grievances.

Response: For standard appeals, as is the case for State fair hearing requests, in this final rule with comment period, we are providing in § 438.402(c)(2) that enrollees may start the appeal clock with an oral request but must follow it with a written request. A written appeal best documents the issue being appealed. This requirement cannot be used to limit enrollees' rights. MCOs and PHPs are required in § 438.406(a)(3) to provide reasonable assistance to enrollees who file grievances or appeals, including assistance with the completion of forms. Our requirement should not preclude Medicaid enrollees with legitimate claims from pursuing those claims because of language or physical barriers. In expedited situations, this final rule with comment period provides that the enrollee is not required to place the appeal in writing. In § 438.410(c)(3) we require that MCOs and PHPs record all expedited oral appeals in writing.

Comment: Some commenters interpreted the NPRM to require that all denials of service authorization be automatically transferred to the MCO and PHP grievance system for processing as an appeal. They believed that a requirement would be too burdensome.

Response: We did not intend that all service authorization denials automatically become appeals. Proposed § 438.402(c)(1)(i) provides for the ''enrollee to appeal'' to the MCO and to the State. Even the expedited appeal process under proposed § 438.410 provided in paragraph (a)(1) apply only when ''an enrollee makes the request''. In this final rule with comment period, we continue to provide that the enrollee must appeal service authorizations denial.

Comment: We received many and varied comments on proposed § 438.402(c)(4), that required MCOs and PHPs to forward information to the State on appeal decisions that were adverse to the beneficiary (in whole or part).

Several commenters believed that the regulation should not only require the transfer of information to the State, but that this should automatically start the process for a State fair hearing.

Similarly, several commenters thought that HCFA should provide that a denial of a request for expedited appeal be automatically appealed to the State agency for a fair hearing. Several commenters noted that the 90-day limit for completion of the State fair hearing would be difficult to meet unless the State starts the fair hearing process upon receipt of the information from the MCO or PHP. Other commenters felt that this requirement would create an overwhelming amount of paperwork and that States would prefer to receive the information at the time a State fair hearing is requested. Several commenters thought that the 24-hour turnaround timeframe for an MCO or PHP to forward the paperwork for an expedited hearing decision is too short and unrealistic given holidays. Several commenters believed that a complex system would be costly and prone to error. One commenter supported the practice of one State that requires MCOs to report only those grievances that are unresolved after 30 days, noting that the State reviews other grievances as part of the annual MCO audit process. One commenter thought that beneficiaries should have to affirmatively request a State fair hearing and that this is sufficient to guarantee the appeal rights of enrollees. One commenter noted that the States are already able to get this type of information through the audit process.

Response: We have revised the requirement for MCOs and PHPs to automatically forward information to the State on appeal decision adverse to the beneficiary to require this only in the case of decisions that are expedited. For these cases, we believe that it is necessary for the State to receive the file and supporting documentation so that it can begin the State fair hearing process as soon as an appeal is filed. Because we have included a requirement for States to expedite the fair hearing process in these cases and decide the appeal within 72 hours of receiving the request, it is essential that they not lose time by needing to request the appeal file from the MCO or PHP. Also, because of the requirement for an expedited fair hearing, we continue to require that the file be forwarded within 24 hours.

For standard appeals, we have removed the requirement that the file be forwarded automatically. We are persuaded by the comment that this requirement would be burdensome on MCOs, PHPs, and States, and is not necessary to protect beneficiaries. In this final rule with comment period, we require MCOs and PHPs to forward within 72 hours files requested by the State. States will request these files upon receipt of a request for a fair hearing or for a standard appeal.

Comment: Several commenters expressed the view that in proposed § 438.402(c), HCFA has taken an important step by recognizing the need for uniform timeframes across managed care programs, and that setting timeframes recognizes the need for MCOs and PHPs to conclude their reviews promptly. However, these commenters recommended that the final rule with comment period should explicitly provide that MCOs and PHPs must resolve appeals within a timeframe that would allow the State agency to proceed with a State fair hearing, if applicable, and ensure a final decision within 90 days of the initial appeal. The commenter believes that this is needed so that beneficiaries, States, and MCOs and PHPs will clearly understand that the timeframe for final administrative action is not affected by the appeal process at the MCO and PHP level. One commenter expressed the opposite view and requested that the regulations clarify that the time allowed for State fair hearing decisions under 42 CFR 431.244(f) does not begin until a Medicaid beneficiary requests a State fair hearing following the conclusion of the MCO and PHP appeal process. This

commenter expressed the opinion that if both the MCO and PHP appeal process and the State fair hearing process are to have sufficient time to meet all the requirements imposed on each of them, then both should not have to be completed in the time allowed for one.

Response: We believe that it is important to maintain a total maximum time period for appeals to be resolved at the MCO and PHP level and by the State at the fair hearing level. However, we recognized that the 90-day timeframe for the completion of both reviews discussed in the preamble of the proposed rule is not workable because the time allowed the MCO or PHP to complete action (30 days with a possible 14 day extension), together with the time allowed by the State for a beneficiary to file a fair hearing request (up to 90 days), may exceed 90 days. Therefore, in this final rule with comment period, we have retained a total of 90 days for consideration of an appeal, but we are providing that this period be interrupted between the time the MCO issues its notice of decision and the beneficiary files for a State fair hearing. We provide that the State has 90 days to complete the State fair hearing process minus the number of days taken by the MCO or PHP to resolve the initial appeal. In addition, in order to ensure that MCO and PHP review does not unduly delay the appeal process, we have provided that if an MCO or PHP does not complete its review within the required timeframes that this becomes an adverse action.

Comment: Several commenters agreed with our statement that the MCO and PHP grievance process is not a substitute for the State fair hearing process.

Response: We agree with the commenter that it is critical that all beneficiaries, including those enrolled in MCOs or PHPs, have access to the State fair hearing process rights provided for under section 1902(a)(3) of the Act.

Comment: Several commenters wanted specific mention of members' right to a second opinion, and would like that right mentioned in adverse action notices. The commenters believed that members should have a right to out-of-plan, unbiased second opinions.

Response: In response to this and other comments, we explicitly provide in § 438.206(d)(3) of this final rule with comment period for the right to a second opinion in the network, or outside the network if an appropriate provider is not available within the network, and this right is referenced in § 438.100(b)(3). We do not provide the right to a second opinion out of network if there is another provider within the network qualified to provide a second opinion. We believe that this is consistent with the concept of holding the MCO or PHP accountable for services to their enrollees. This final rule with comment period provides that enrolles must be informed of the right to a second opinion as part of enrollment information and we therefore, do not believe it is necessary to require that it be included in the notice of action.

Comment: Several commenters supported allowing the State to choose whether to require that enrollees exhaust MCO and PHP grievance procedures prior to appealing to the State for a fair hearing. Other commenters believed that the regulations should not permit States to require the exhaustion of the internal MCO and PHP grievance process prior to permitting access to the State fair hearing process. These commenters felt that requiring the exhaustion of an MCO's and PHP's internal grievance process would inevitably lead to delays, confusion about timing, and a denial to the right to a timely State fair hearing. Commenters also believed that the internal MCO and PHP process was not impartial because the MCO or PHP has a financial interest in the outcome. Finally, one commenter argued that forcing individuals with disabilities to navigate the administrative procedures of the grievance process would be inconsistent with the provisions of the Americans with Disabilities Act (ADA), because in this commenter's view, the ADA prohibits requiring qualified individuals with disabilities to complete administrative processes that cannot be directly linked to the provision of the services offered.

Response: We continue to believe that a State should be permitted to require Medicaid managed care enrollees to exhaust MCO and PHP appeal remedies prior to accessing the State fair hearing process. This not only gives the MCO or PHP an opportunity to reconsider its decision, if the decision is reversed, it reduces the burden on the fair hearing system. We do not understand the commenter's contention that requiring exhaustion in the case of people who have disabilities necessarily would violate the ADA. While we would agree that exhaustion would not be required in the case of a claim under the ADA itself, the exhaustion requirement at issue here involves an appeal of an ''action'' (for example, a denial of payment or coverage). It is true that the ADA requires that reasonable accommodations be made for people who have disabilities in the conduct of the MCO or PHP level grievance process, and the extent of an obligation is based on the facts and circumstances of the individual case. It is not clear, however, why it would be any more of a burden for an individual who has a disability to file an appeal with their MCO or PHP than it would be to file a request for a State fair hearing. If anything, it might be easier, because the enrollee would have an existing relationship with the MCO or PHP. MCOs and PHPs should be aware of their obligations under the ADA to accommodate people who have disabilities in the grievance process. We do not believe that requiring enrollees who have disabilities to use the same process as other enrollees violates the ADA.

Comment: One commenter questioned HCFA's statutory authority for the requirement that the State fair hearing process be available to review MCO and PHP determinations. This commenter noted that the BBA does not mention the State fair hearing process and infers that the Congress intended that the MCO and PHP appeal process alone address enrollee appeals. Another commenter believed that open access to State fair hearings essentially would negate the grievance procedures within an MCO or PHP.

Several commenters applauded HCFA for providing detailed guidance to MCOs and PHPs on establishing grievance processes. One commenter felt that there also is currently little, if any, link between the MCO and PHP appeal process and the State fair hearing process. Beneficiaries are informed of both options, but are not advised as to whether they must exercise these options in a particular order or whether one ''trumps'' the other. One commenter believed that allowing the State to choose to provide a fair hearing only after running the course of the MCO's and PHP's grievance system could be the equivalent of denying a fair hearing, which is a beneficiary right. This commenter stated that better mechanisms to coordinate simultaneous participation in both the MCO and PHP and State systems should be devised.

Response: As discussed above, the requirements in subpart F are based only in part on the internal grievance requirements in section 1932(b)(4) of the Act. To the extent these regulations apply to the MCO internal grievance process, they are grounded on section 1932(b)(4) of the Act. To the extent these regulations involve the State fair hearing process, however, including the requirement that MCO and PHP internal grievance processes interface with the

State fair hearing process, they are based on the fair hearing requirements in section 1902(a)(3) of the Act. The State fair hearing process guarantees all Medicaid beneficiaries an independent hearing. At the time the original fair hearings regulations were promulgated, beneficiaries were not enrolled in managed care arrangements as they are today. Even if the BBA had never been enacted, there would have been a need to promulgate regulations applying the fair hearing rights that all beneficiaries have in the managed care context. We took the opportunity to do so in the proposed rule implementing the grievance requirements in section 1932(b)(4) of the Act. We believe that these regulations are clearly authorized. With respect to the commenter's argument that allowing States to require exhaustion could be ''the equivalent'' of denying a fair hearing, which is a beneficiary right, this is clearly not the case. As noted above, in cases that exhaustion is required, if the MCO or PHP does not favorably resolve the case by the timeframe provided, the case is automatically forwarded to the State for a fair hearing, and a decision must be made within the same 90-day timeframe that would apply if the fair hearing was requested directly. States should work with MCOs, PHPs, and enrollees to ensure that enrollees understand the linkage between the MCO and PHP grievance processes and the State fair hearing process.

Comment: Several commenters thought that the proposed regulations should preserve beneficiaries' State fair hearing rights, not expand them to include appeals from unresolved complaints, that these commenters saw as a burden on State fair hearing systems. They requested that proposed § 438.402(d) be amended to restrict the right to a State fair hearing to enrollees appealing MCO and PHP decisions denying, reducing, or terminating medical care for an enrollee. Other commenters requested that HCFA confirm that the State fair hearing process applies only to issues that involve claims for services or denials of coverage. These commenters noted that current regulations at § 431.200 provide that the hearing right arises when the ''Medicaid agency takes action to suspend, terminate, or reduce services.'' In the commenter's view, quality or access grievances that do not also involve the denial of services should not be appealed through the State fair hearing process and should be pursued through the MCO's and PHP's internal grievance process or with the External Quality Review Organization with which the State contracts. These commenters also stated that medical treatment decisions made by providers should not be subject to the State fair hearing process.

Response: We agree that the scope of issues subject to the State fair hearing process should not be as broadly defined as in the NPRM. This final rule with comment period specifies that actions, as defined in the regulation, are subject to appeal at the MCO or PHP, and to the State for a fair hearing. This includes a denial of a service, a limitation on receipt of a service, or the reduction, suspension, or termination of a service. We recognize that a provider may deny a requested service for a variety of reasons, including that the provider does not believe the service is medically appropriate for the enrollee. However, because of the financial arrangement that provides a capitated payment to an MCO or PHP for services provided to an enrollee, we believe that the enrollee needs to have recourse through an appeal if a requested service is not provided.

Comment: One commenter contended that the option for the State to require exhaustion at the MCO and PHP level or allow for direct appeal to a State fair hearing could be interpreted to allow an enrollee to file an appeal after the conclusion of the 90-day timeframe for filing.

Response: As discussed above, this final rule with comment period clearly provides that the enrollee has a reasonable time period specified by the State, not less than 20 days and not to exceed 90 days, to file an appeal with the MCO or PHP, or with the State following an unsuccessful appeal to the MCO or PHP, or initially with the State if the State does not provide for exhaustion. If an enrollee does not file an appeal with the MCO, PHP or State, the enrollee would have waived their right to an appeal.

Comment: Several commenters asked for clarification on how Medicare-Medicaid dual eligible enrollees would access the Medicare and Medicaid external hearing processes.

Response: As in the fee-for-service system, dually eligible Medicare-Medicaid beneficiaries have the appeal rights provided for under both programs, to the extent the particular program has paid for the service in question. If a dually-eligible enrollee is enrolled in a Medicare+Choice plan, then the Medicare+Choice appeals process would apply to benefits covered under that program, including otherwise non-Medicare benefits covered under the Medicare+Choice plan. When a dually eligible beneficiary is enrolled in a Medicaid MCO or PHP, and is denied a service covered by Medicare, the beneficiary similarly has Medicare appeal rights, as well as Medicaid rights to the extent that Medicare applies a different standard from Medicaid. In the case of an MCO or PHP denial of a Medicaid service not covered by Medicare, the appeal rights in subpart F apply. In all cases, the notice of action will inform the beneficiary of how to file an appeal.

Comment: Commenters requested that HCFA amend the language in the regulation to say that the MCO and PHP must ''have,'' rather than ''provide for,'' a link to the State fair hearing process.

Response: In this final rule with comment period at § 438.402(a) we define ''grievance system'' as including the MCO and PHP grievance and appeal processes, and access to the State's fair hearing system. We believe this change clearly establishes the link from the MCO and PHP processes to the State fair hearing process.

Comment: Several commenters asked that HCFA require States to allow providers the right to challenge MCO and PHP decisions on behalf of enrollees.

Response: Section 1932(b)(4) of the Act expressly requires that MCOs have a grievance procedure in place under that an enrollee ''or a provider on behalf of an enrollee'' can ''challenge the denial of coverage or payment'' by an MCO. We agree with the commenters that States are required to allow providers the right to do so, on behalf of an enrollee. In response to this comment, we have added at § 438.402(c)(1) a provision to permit the provider to file a grievance or appeal or request a State fair hearing on behalf of an enrollee with the enrollee's written consent. This condition that the enrollee provide written consent for the provider to act on their behalf reflects policy communicated in a letter to the State Medicaid Directors dated February 20, 1998 that stated, the enrollees' consent is needed if a provider submits an appeal on their behalf. We note that enrollees may be financially liable for the costs of services when provided as a continued benefit during appeal. Therefore, it is important that enrollees understand the possible implications of an appeal and consent to the appeal.

Comment: Commentators urged that HCFA require States to establish a system for administrative appeals that providers could appeal adverse network selections, payments, or other administrative actions that directly affect providers but that only indirectly affect beneficiaries.

Response: The Congress spoke to issues involving MCO relationships with subcontracting providers in provisions: (1) regulating physician incentive arrangements in section 1903(m)(2)(A)(x) of the Act, (2) prohibiting discrimination based on licensure in section 1932(b)(7) of the Act, prohibiting restrictions of provider-enrollee communications in section 1932(b)(3) of the Act, and in section 1932(b)(4) of the Act providing for a provider to file a grievance on behalf of an enrollee. We believe that if the Congress had intended that providers have specific appeal rights under Federal law, these would have been provided for in section 1903(m) or section 1932 of the Act. We believe that this is best left for providers and MCOs or PHPs to negotiate. However, this regulation does not prohibit a State from granting providers the right to challenge MCO and PHP decisions affecting them.

Comment: One commenter suggested that if a decision to deny an item or service is reversed, the MCO or PHP should be required to review all similarly situated beneficiaries and make the item or service available to them as well, regardless of whether the beneficiaries have filed appeals.

Response: We believe that decisions on appeals are so fact-specific that it would not be practical to apply an across the board rule. However, where a State requires MCOs and PHPs to extend the benefit of a hearing decision or court order to individuals in the same situation as those directly affected by the decision or order. Under § 431.250(d), FFP may be claimed for such expenditures.

3. Notice of Intended Action (Proposed § 438.404)

Under proposed § 438.404, MCOs and PHPs were required to provide enrollees timely written notice of a decision to deny, limit, reduce, delay or terminate a service, within timeframes specified in § 438.310, and in the notice explain the action the MCO or PHP intends to take, the reasons for the action, any laws and rules that support the action, the enrollee's right to file a grievance with the MCO or PHP, the enrollee's right to request a State fair hearing, the circumstances under which expedited grievance review is available and how to request it, how to file grievances (called complaints in proposed § 438.404), appeals (called grievances in proposed § 438.404), and State fair hearing requests; that if an appeal is filed, the enrollee has a right to appear in person before the MCO or PHP personnel assigned to resolve the appeal; the circumstances under which benefits will continue pending resolution, how to contact the designated office described in § 438.406(a), and how to obtain copies of enrollee's complete records.

Comment: We received many comments regarding notice to enrollees. Several commenters believed that a strict application of this principle would be burdensome, especially if applied to the following: (1) Prescription drugs; (2) decisions of primary care physicians (PCPs) made without involvement of the MCO or PHP utilization control unit; (3) MCO and PHP decisions to authorize a limited number of visits; and (4) denials of payment to a specialist when the visit was without a referral by a PCP. One commenter pointed out that denials are typically the result of provider administrative issues involving coding practices, contractual fee schedules, and timely filing. The commenter recommended that the regulation not require that notice be sent to members as a result of provider administrative issues.

One commenter found this provision fairly consistent with current Medicaid fee-for-service requirements, except for the requirement to give notice of a ''delay of service.'' This commenter expressed concern that a notice would be required when a utilization management representative asks for additional information or tests prior to approving a service, as this would confuse the member and create an administrative burden for the MCO or PHP. Several commenters strongly agreed that notice should be provided in all instances when an enrollee's authorization is denied or limited or a service already provided to the enrollee is reduced, terminated, suspended, or delayed.

Several commenters wanted the definition of grievance in the proposed rule (containing grounds for a grievance now included in the definition of ''action'' in this final rule with comment period) to be expanded to include a determination by the MCO or PHP to deny a service because the MCO or PHP believes that the service is not included in its contract. Similarly, the commenters wanted a State's denial of a service included if the State's reason for denial is because the service is to be provided by the MCO or PHP.

Response: In this final rule with comment period, we define ''action,'' and specify that notice must be sent to enrollees any time an action occurs. We believe that it is an essential enrollee protection that they be sent a notice of all actions, including those that the commenter believes to be burdensome to the MCO and PCP. We define ''action'' as a denial or limitation of a service authorization request; a reduction, suspension, or termination of a service previously authorized; a denial of payment for a service by an MCO, PHP, or its providers; the failure to furnish, arrange, or provide for payment in a timely manner; or a decision by the State not to grant an enrollee's request to disenroll from the MCO or PHP. In addition, an action includes, for residents of rural areas with only one MCO or PHP, the denial of an enrollee's request to go out of plan. Actions may be taken by the MCO, PHP, or its providers.

The terms ''deny or limit'' apply when the service requested by the enrollee or provider on behalf of the enrollee is not yet authorized or referred by either the MCO's or PHP's primary care physician, or otherwise authorized by the MCO or PHP in whole or in part. Under this final rule with comment period, a notice of service denial must be sent to the enrollee even if the MCO or PHP believes that its contract does not require that it provide the service. Without this requirement, the enrollee would have no recourse if the MCO or PHP denied the service in error. In this final rule with comment period, we have deleted the reference to a ''delay'' in service. We provide in § 438.210 that requested services must be approved or denied within 14 days. A request not acted on within this timeframe is considered a denial and a notice of denial must be sent to the enrollee. Extensions to the 14-day time period to act on a service authorization can be requested by the enrollee or by the MCO or PHP when taking additional time is in the best interest of the enrollee. The terms ''reduction, suspension, or termination of services or denial of payment'' are the same as the traditional fee-for-service definitions of those terms, that is, when a service has been authorized or is being provided and the MCO, PHP, or its provider reduces the number or frequency of the service, stops providing the service prior to the end of the time that was originally authorized, stops providing the service for a period of time, or refuses to pay for a covered or authorized service. The final two criteria in the definition of an action give managed care enrollees a remedy when the State denies a request for disenrollment or the State, MCO or PHP denies the request of an enrollee who is enrolled in a single rural MCO or PHP to go out-of-plan.

Comment: Some commenters contended that MCOs and PHPs do not always know when their providers deny

services, making it difficult for them to comply with the notice requirements.

Response: MCOs and PHPs must have a system in place to identify these situations, and to ensure that notice is provided. In this final rule with comment period, we allow providers of MCOs and PHPs to provide only general information in the notices they give to enrolles. When this option is chosen, the MCO or PHP must send the enrollee another notice that provides information specific to the enrollee's situation. (See § 438.404(d)(2)). To meet this requirement, MCOs and PHPs will need to have systems in place to find out from their providers when an enrollee has been denied a service or had a service reduced, suspended, or terminated.

Comment: Several commenters believed that Medicaid beneficiaries do not file grievances and appeals very often because of the complex requirements imposed by States, MCOs and PHPs. These commenters further stated that a system established to facilitate resolution of grievances or appeals should ensure that beneficiaries are encouraged to voice their dissatisfaction without fear of reprisal or consequences of any kind.

Response: To ensure beneficiary rights to appeal, in response to this comment, in this final rule with comment period at § 438.404(b), we specify what must be included in the notice of action. This includes information about the right to appeal, how to file an appeal, how to obtain assistance with filing, and that filing an appeal will not negatively affect the way enrollees are treated by MCOs, PHPs, their providers, or the State.

Comment: Several commenters were concerned that enrollees' rights to notice may be violated if HCFA did not prohibit States from delegating responsibility for State fair hearing notices to MCOs and PHPs. They believed that until States, MCOs, and PHPs can better ensure timeliness in processing appeals as well as full constitutional protections, there should be no delegation of the State's responsibility for providing a due process notice to beneficiaries.

Response: We have not accepted this recommendation because we believe that States may find MCO or PHP issuance of State fair hearing notices the most efficient and timely way to get the information about State fair hearing rights to enrollees when an action is taken by the MCO or PHP.

Comment: Several commenters requested that § 438.404 be amended to specifically address situations in which an MCO or PHP intends to deny, limit, reduce, delay, or terminate a service, or deny payment for a service in whole or in part.

Response: The current appeal notice requirements require a notice any time there is an ''action'', that can include the reduction of services for a Medicaid-eligible individual. Similarly, the notice requirements in this regulation apply when MCOs or PHPs intend to deny, limit, reduce, suspend, or terminate a service, or deny payment for a service in whole or in part. The terms ''reduce'' and ''limit'' were included in the notice requirements to cover instances in which already authorized services or requested services, respectively, were decreased or diminished in part.

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

Response: We believe that the expiration of an approved number of visits does not constitute a termination for purposes of notice and continuation of benefits. When a prescription (including refills) runs out and the enrollee requests another prescription, this is a new request not a termination of benefits. In these circumstances, the MCO or PHP would not need to send a notice or continue benefits pending the outcome of an appeal or State fair hearing. If the enrollee requests a re-authorization that the MCO or PHP denies, the MCO or PHP must treat this request as a new request for service authorization and provide notice of the denial or limitation. However, in this situation, if the enrollee appeals the action, benefits would not be continued.

Comment: Several commenters pointed out that HCFA exclusively relies on a written notice to meet the enrollees' needs. They found this policy insufficient, given language, literacy, and disability barriers. Other commenters noted that some States require MCOs and PHPs to send notices by certified mail, and believed that this was very costly, and often unsuccessful in reaching enrollees.

Response: We recognize that Medicaid beneficiaries often face language, literacy, and disability barriers. To address this issue, we have applied the information requirements found at § 438.10, including the language requirements in § 438.410(b) to the notice requirements. We also require that MCOs and PHPs mail notices to an authorized representative designated by the enrollee. We are not requiring States to provide notice in formats other than in writing, except in the case of notices about expedited hearings, that must be provided orally due to time considerations. In this final rule with comment period, we do not prohibit States from setting additional requirements for MCOs and PHPs concerning notices.

Comment: One commenter believed that HCFA has underestimated the true burden associated with MCO and PHP notices.

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

Comment: One commenter requested that we adopt the notice timeframes in part 431, subpart E for the situations covered by those sections, and allow States to set other notice timeframes. Several commenters disagreed with the use of a 10-day notice period prior to the date of action. They found that period to be too long because the medical condition of the enrollee may require quicker action. They also suggested that HCFA disregarded the exceptions to the 10-day rule set forth in § 431.213(h). That regulation allows for notice to be sent on the date of the action when a change in the level of medical care is prescribed by the beneficiary's physician. This exception should be interpreted to give MCO's and PHP's the flexibility to give notices, in specified cases, immediately prior to the action being taken.

Response: This final rule with comment period does not change the current regulation at § 431.213 and is consistent. Under § 438.404(c)(1) of this final rule with comment period, timeframes for notices for the reduction, suspension, or termination of previously authorized services are governed by the State fair hearing regulations found in 42 CFR 431 subpart E. While some MCOs and PHPs may find the advance notice requirement inappropriate, there are exceptions to advance notice, that allow notice to be given on the date of the action (see § 431.213). These exceptions would cover situations that a provider believes an immediate change in care is appropriate for the health

condition of the enrollee, for example, the reduction in dosage of a prescription drug.

Comment: We received several comments regarding the elements of a notice. Several commenters suggested that the written notice requirements of proposed § 434.404 be modified to mirror the existing State fair hearing regulations. Other commenters pointed out that HCFA is requiring a great deal of information in the notices required under proposed § 434.404. They suggested deleting some of the requirements. One commenter believed that information on continuation of benefits should be provided if a service is terminated or reduced. Commenters requested that information be provided in the notice about how to contact the MCO or PHP to receive help in filing an appeal. One commenter requested that the rule require MCOs and PHPs to notify the enrollee of their right to expedited review.

Several commenters wanted the content and time line requirements clarified in the notice and a full explanation to be provided of the laws and rules that support the action, rather than a citation to a particular statute or regulation. These commenters requested clarification that the enrollee has a right to obtain other relevant information germane to the resolution of the enrollee's issue. These commenters further requested a clarification that notices must specify the reasons or criteria used in determining that the request was not medically necessary.

Response: We agree that notices given by MCOs and PHPs should, at a minimum, contain the information required by the State fair hearing notices. We have provided for this in this final rule with comment period. However, we have retained the requirements specified in the NPRM concerning the content of the notice, including information about the circumstances under which an enrollee may receive expedited review, and the reason for the action. We believe that requiring the inclusion of the reason for the action will provide the enrollee with information to understand why it occurred, and help the enrollee to decide whether to appeal. We made one change to the NPRM requirements to remove the requirement that the notice specify that the enrollee may appear before the person assigned by the MCO or PHP to resolve the appeal, as we have deleted this requirement for MCOs and PHPs in this final rule with comment period.

In response to the commenter who favored inclusion of information in the notice about continuation of benefits when benefits are being terminated or reduced, we have added a requirement that the notice state that an enrollee may be held liable for payment for services if the enrollee requests continuation of benefits during appeal. This provides the enrollees with a more complete picture of what the continuation of benefits provision means to them. We also agree with the commenter favoring a requirement that the notice contain information on how to obtain assistance from the MCO or PHP in filing an appeal, and have provided for this in § 438.404(b)(8) of this final rule with comment period.

Comment: Several commenters believed that we should require MCOs and PHPs to provide enrollees with copies of their records within 24 hours of the request and, if the member (or authorized representative) is unable to pick up the copies, that they be mailed the next business day.

Response: In § 438.224 we provide that MCOs and PHPs must ensure that enrollees may request and receive a copy of their medical records and information. MCOs and PHPs should allow members to obtain copies of their medical records in a timely manner to allow the enrollee to submit information in support of their appeal. However, we have not accepted the commenter's suggested deadline, as we believe that this would be impractical and create too great a burden for MCOs and PHPs. We believe that States should have the flexibility to decide whether to establish deadlines in this area.

Comment: Several commenters believed that the notice should explain that the enrollee may be represented by counsel or a legal representative during the grievance process and include the address and phone number for free legal assistance. They noted that the right to be represented by counsel is required under the *Goldberg* v. *Kelly* ruling and that this right is given to fee-for-service Medicaid beneficiaries in the State fair hearing process.

Other commenters believed that it is sufficient to provide enrollees information regarding free legal services in a Medicaid brochure or other enrollee notification materials. Another stated that providing this information on a routine basis would be burdensome and that it may not be accurate because assistance is not available in all areas.

Response: In response to these comments at § 438.404(b)(1) of this final rule with comment period, we provide that the notice must inform the enrollee of the right to represent themselves or to use legal counsel, a relative, a friend, or other spokesperson. We do not believe it is necessary to require that the notice itself include information about free legal assistance, and we leave it to States to decide how this information is to be made available to beneficiaries.

Comment: Several commenters urged us to require each State to develop a uniform notice to be used by MCOs and PHPs. They contended that requiring use of a State-developed uniform notice is a simple, common sense way to assure consistency in the grievance and State fair hearing process across MCOs and PHPs, and would best protect the constitutional rights of the beneficiary.

Response: We believe that due process and notice requirements can be observed without requiring each State to develop a uniform notice for MCO and PHP use. States are expected to review MCO and PHP notices to ensure that all required elements, including those listed in § 431.200 et seq., are included. Nothing in our regulations prohibits States from developing a uniform notice for use by their MCOs and PHPs if they choose.

Comment: Several commenters suggested that the notice should explicitly inform the beneficiary that filing an appeal or State fair hearing request would not affect the way the member is treated by the provider, MCO, PHP, or the State.

Response: In response to this comment, we have provided under § 438.404(b)(11) of this final rule with comment period that the notice must inform the enrollee that filing an appeal or requesting a State fair hearing (where an enrollee is permitted to do so directly) will not negatively affect or impact the way the MCO or the PHP and their providers, or the State agency, treat the enrollee.

Comment: Several commenters believed that providing for an in-person hearing before the MCO or PHP would significantly increase the time and expense involved, without substantially improving the quality of the system. They also questioned if this requirement is realistic for appeals that are expedited. Finally, commenters noted that the appearance of disgruntled enrollees before MCO and PHP personnel may pose a security risk to MCO and PHP staff.

Response: We agree that due process does not require an in-person hearing at the MCO and PHP. However, we believe that enrollees should have an opportunity to present evidence and allegations of fact or law related to the issue in dispute, in person as well as in writing. In this final rule with comment period (§ 438.406(b)(4)), we provide enrollees the opportunity to present their cases in person but do not require a formal hearings process. We have also

removed the requirement that the in-person presentation must be before the decision maker for the MCO or PHP. We do this because of the burden this would place on MCOs and PHPs. Appeals requiring expedited resolution, MCOs and PHPs must notify enrollees of the limited time available for them to appear in person.

4. Handling of Complaints (Grievances) (Proposed § 438.406)

Proposed § 438.406 set forth how grievances or appeals (called complaints and grievances in the proposed rule) must be handled. The general requirement for handling grievances and appeals required MCOs and PHPs to have an adequately staffed office, acknowledge receipt of each grievance and appeal, give enrollees any assistance with completing forms or taking other steps necessary to obtaining resolution at the PHP level, and conduct appeals using impartial individuals who were not involved in any previous level of review. Proposed § 438.406(d) required that in the case of a denial based on lack of medical necessity, the individual must be a physician with appropriate expertise in the field the encompasses the enrollees condition.

Comment: One commenter advocated deleting proposed § 438.406 altogether. Other commenters believed that requirements should be added to those in § 438.406. Among the suggested additions, one commenter wanted the regulation to prohibit MCOs and PHPs from using internal appeal timeframes and procedures to avoid the medical decision process, or to discourage or prevent members from receiving medically necessary care in a timely manner. Another commenter asked that we include a clear explanation of the role of personnel provided by the MCO or PHP to advocate for the enrollee, provide customer service, or assist in resolving grievances. Another suggested that we require MCOs and PHPs to give consumers written notice of a hearing and a description of the hearing procedures, at least fifteen days in advance. One suggested that we require MCOs and PHPs to hold internal hearings at mutually convenient times. Another said we should require MCOs and PHPs to postpone hearings at the request (for just cause) of the enrollee. When enrollees have cause, one commenter wanted us to provide that enrollees need not appear at a hearing and that the hearing be conducted in the same manner regardless of the consumer's presence. Another asked that we forbid all ex parte discussions. One commenter wanted us to require MCO and PHP staff to attempt, whenever possible, to resolve grievances informally pending a decision, but that resolution should not permit the MCO or PHP to consider the grievance ''withdrawn'' in order to evade State review. Another asked that formal rules of evidence not be used, but rather that enrollees be allowed to submit written information in support of their claims, arrange for a physician or other expert to testify on the enrollee's behalf, and compel the appearance of MCO or PHP staff to answer questions concerning the dispute. Commenters believed that if the MCO or PHP has an attorney present at the hearing, the role of the attorney should be to ensure that a fundamentally State fair hearing takes place and all issues in dispute are adequately addressed. The attorney should not, in these commenters' view, be permitted to argue the MCO or PHP position in the dispute. These commenters believed that consumer representatives should be trained and certified by the State on a periodic basis, that MCOs and PHP should be required to document how they select the consumer representatives on the internal hearing committee, and that this selection process should be approved by the State on a yearly basis.

Response: The proposed rule did not propose to require a formal hearing at the MCO and PHP level. We believe that commenters misconstrued the provision in the proposed regulation concerning the in-person appearance of the enrollee to be a requirement for a formal hearing. This was not our intent. The proposed rule only addressed the presentation of evidence by the enrollee in person to the MCO or PHP. We do not believe a hearing is necessary at the MCO and PHP level and therefore, do not require it in this final rule with comment period. Because we did not propose a hearing and are not providing for a hearing before the MCO or PHP in this final rule with comment period, we are not addressing the comments relating to the nature of a hearing. We believe that the provisions remaining in this section strike an appropriate balance between proscribing sufficient provisions to protect beneficiaries and retaining some flexibility for MCOs and PHPs to design, with State approval, the procedures for their appeal processes.

Comment: One commenter was concerned that proposed § 438.406(b) did not specify a time period within that the MCO or PHP must transmit its acknowledgment of receipt of a grievance or appeal. The commenter believed that an enrollee who files a grievance or appeal needs to know in a timely manner whether the MCO or PHP has received it. Consequently, the commenter suggested that § 438.406(b) indicate that the MCO or PHP must acknowledge receipt within a specified time period, perhaps 24 hours after receiving a grievance or appeal. One commenter believed that the regulation was intended to require the MCO or PHP to acknowledge receipt of grievances or appeals in writing.

Response: We require MCOs and PHPs to acknowledge the receipt of grievances and appeals, but we do not specify that the acknowledgments be in writing, nor do we specify the timeframes in which they must be provided. We believe that requirements would be burdensome for MCOs and PHPs. States, at their option, may consider adding these requirements.

Section 438.416(b) of this final rule with comment period requires that MCOs and PHPs track the date of acknowledgment and report it to the State as part of the annual disclosure report under § 438.416(d). State monitoring should include tracking this activity.

Finally, if the appeal was oral and is not expedited, the acknowledgment must tell the enrollee that although the timeframe for resolution has begun, the appeal must be submitted in writing. The MCO or PHP must assist the enrollee with the written request, if asked.

Comment: Several commenters requested that HCFA modify the language in proposed § 438.406(c) to change the requirement that MCOs and PHPs must provide enrollees ''any assistance'' to ''reasonable assistance'' with the completion of forms or other procedural steps in the grievance process. These commenters were concerned that the phrase ''taking other steps necessary to obtain resolution of the grievance'' may require the MCO or PHP to pay for a second opinion on the disputed service in order to ''obtain resolution.'' Other commenters wanted this provision clarified so that MCOs and PHPs would not be required to pay for attorney representation or other unreasonable assistance.

Other commenters urged that the following be required elements of MCO and PHP assistance to beneficiaries during the grievance process: (1) A toll-free number with adequate interpreter capability including TTY; (2) outreach to beneficiaries with limited English proficiency, in accordance with Title VI of the Civil Rights Act of 1964; (3) an ombudsman program; and (4) a State established consumer assistance program to assist enrollees (especially homeless persons) to navigate the grievance process.

Response: In response to the above comment, we have revised the language to require MCOs and PHPs to provide ''any reasonable assistance'' for the completion of forms or other procedural steps in the grievance and appeal process. Also in response to the above comments, we have deleted the phrase ''to obtain resolution of the complaint or grievance at the MCO level,'' as we do not intend for this provision to require MCOs and PHPs to do more than assist enrollees during the grievance process.

In response to the above suggestions to specify required elements of assistance, in § 438.406(a)(3) of this final rule with comment period, we require MCOs and PHPs to make interpreter services available to enrollees, as well as, toll-free numbers that have adequate TTY/TTD and interpreter capability. By including these as examples of types of assistance required to meet certain needs, we do not intend that other reasonable assistance need not be given. We believe, for example, that MCOs and PHPs are required by this provision to provide reasonable assistance to meet other needs of enrollees, and assisting enrollees who have low-literacy abilities.

In this section, we do not address outreach to beneficiaries with limited English proficiency, but we note that the information requirements in § 438.10(b) and (c), in the section on Notice of Action (§ 438.404), and in the section on Information about the Grievance System (§ 438.414) require that information and assistance be provided to these enrollees.

The remaining comments relate to State responsibilities. This section addresses MCO and PHP requirements. We have not revised § 438.404 to address these points.

Comment: One commenter urged HCFA to create an affirmative duty of the provider to assist the enrollee in registering an appeal.

Response: We do not agree that the provider should be required to assist the beneficiary in filing a grievance or an appeal. We believe that this is appropriately the responsibility of the MCO and PHP, and we are requiring in this regulation that they provide this assistance. They are free, however, to use their contracting providers to provide this assistance on their behalf.

Comment: Several commenters commended HCFA for specifying that individuals making decisions on appeals must not have been involved previously in the claim, but requested that § 438.406 omit the word ''impartial'' when referring to individuals employed by a MCO or PHP who serve as decision makers. These commenters believed that MCO and PHP employees involved in appeal decisions can never be impartial.

Response: The requirement is that the MCO and PHP decision makers not have played a role in the original decision. Therefore, the term ''impartial'' is unnecessary and in response to this comment, we have removed it in § 438.406(a)(7) of this final rule with comment period.

Comment: Several commenters requested that enrollees receive access to hearings presided over by independent panels of clinical peer professionals. One commenter believed that enrollees should be able to seek review by an external panel and receive a de novo determination if the decision denies or limits a covered benefit, denies payment of services deemed not medically necessary or experimental, involves services that exceed a significant threshold, or puts the patient's life or health in jeopardy.

Response: The regulations provide for external review through the State fair hearing process that is available to all beneficiaries as required under section 1902(a)(3) of the Act. These regulations link the internal grievance procedures required under section 1932(b)(4) of the Act with the existing State fair hearing process that implements section 1902(a)(3) of the Act. Under the State fair hearing process, Medicaid beneficiaries are guaranteed due process through an independent hearing meeting the standards set forth in the Supreme Court's *Goldberg* v. *Kelly* decision. While the hearing officer is not required to be a health professional, we would expect medical evidence to be presented by clinicians to support an enrollee's appeal.

While the State fair hearing provides beneficiaries with an independent review of their appeals and is a beneficiary right that cannot be denied, we are aware that some States have established independent panels to review MCO and PHP decisions unfavorable to enrollees, and have made these available to Medicaid managed care enrollees. This regulation does not prohibit use of this review process by Medicaid enrollees. However, any process cannot be substituted for the grievance process and fair hearing process that is required under this final rule with comment period and the regulations at 42 CFR part 431, subpart E. If an enrollee chooses to appeal through the grievance and State fair hearing process, the decisions under this process would be controlling over any inconsistent determination made by another State body.

Comment: We received several comments concerning our decision, stated in the preamble, not to require the establishment of ombudsman programs. One commenter suggested that an enrollment broker may effectively serve as an initial unbiased contact for grievances and appeals and assist beneficiaries through the grievance process or refer them for appropriate assistance from an ombudsman or other outside source. One commenter suggested that States should establish centralized advocacy and customer service programs available to all citizens enrolled in MCOs (not just Medicaid enrollees).

Several commenters requested that ombudsman programs be established and have sign language, interpreters, and TTYs. The commenters stated that the need for an external agency, as an ombudsman program, is well proven and should be required by the regulation.

Commenters noted that the Medicaid population includes individuals with limited education, linguistic and cultural barriers to care, and frequent negative experiences in accessing entitlements and challenging bureaucratic institutions. They stated that enrollees should have designated points of contact to receive counseling on grievances or appeals if managed care is to be successful as a quality health delivery system for the Medicaid program.

Response: We encourage States to establish consumer assistance programs to assist enrollees in navigating the grievance and appeal system. After careful consideration, we have decided not to include a requirement that MCOs, PHPs, or State agencies establish ombudsman programs to assist beneficiaries. We believe that each State agency should establish its own approach to how enrollees obtain assistance during the grievance process, including the State fair hearing process. We require that MCOs and PHPs assist enrollees in completing forms and taking other procedural steps. Other assistance could be provided through a more comprehensive ombudsman program. We encourage States, MCOs, and PHPs to work with the ombudsman programs currently operating through State Medicaid Agencies, Departments on Aging, and Insurance Commissioners. In many instances, States may be able to expand existing State ombudsman programs with few additional resources. As noted in 42 CFR 431.250, FFP is available for transportation costs and other expenses of Medicaid enrollees during the appeals process.

Comment: One commenter pointed out that the word ''contracts'' in the first paragraph of the preamble to proposed § 438.406 should be ''contacts''.

Response: This commenter is correct. However, because this language did not appear in proposed regulations text, and the preamble to this final rule with comment period controls the meaning of the final regulations, no action was required in response to this comment.

Comment: Several commenters suggested that all appeals be filed by enrollees on a form developed by the State. They further suggested that MCOs and PHPs submit these to the State Medicaid agency, and that the Medicaid agency log in the appeals and return them to the MCO and PHP within 72 hours.

Response: We do not agree with this suggestion. We are not requiring use of a State-developed form for filing appeals, as this would require that enrollees obtain these forms, possibly delaying the process, and may be an impediment to enrollees wishing to file appeals. We note that States may wish to develop forms to guide and assist enrollees in filing appeals. However, their use must be at the option of the enrollee. As for filing appeals with the State, we are aware that a similar process is required by the State of Tennessee. We are concerned that the central log-in system used by that State agency would not work well in other States. A log-in procedure would require a well-developed infrastructure that could be costly and burdensome to many States, and that would add another layer (and, even under the commenter's proposal add 72 hours) to the appeals process. Furthermore, we believe that other parts of this rule will result in many of the same benefits noted by advocates of the approach used by Tennessee. For example, under § 438.416, we require that MCOs and PHPs keep a log of grievances and appeals and that its contents be reported to the State. This will provide the State the same information obtained through the commenters' suggested approach. Additionally, State on-site reviews can monitor appeal processes to determine if MCOs and PHPs are meeting required timeframes.

Comment: Several commenters requested that the person investigating the grievance should receive training on the Medicaid statute, regulations, and contractual provisions; on confidentiality and patient protections; and on the grievance process.

Response: We agree that MCOs and PHPs should provide this training to their personnel. States should consider making this a requirement of their MCOs and PHPs. However, we do not think it necessary to require specific MCO and PHP training programs in Federal regulations.

Comment: Several commenters urged that this final rule with comment period require that grievances and appeals involving application of medical standards should be reviewed by an appropriately trained physician.

Response: This final rule with comment period at § 438.406(a)(7)(ii) provides that the individual making a decision must be a health professional; with appropriate clinical expertise in treating the enrollee's condition or disease for—(1) an appeal of a denial that is based on lack of medical necessity, (2) a grievance regarding denial of expedited resolution of an appeal, and (3) a grievance or appeal that involves clinical issues.

Comment: Several commenters pointed out that the NPRM referred to ''physicians'' when describing individuals with appropriate medical expertise to make decisions on grievances and appeals concerning clinical issues. They noted that other health care professionals, not just physicians, are competent to make decisions and commonly perform these services in the private market. They stated that Medicaid beneficiaries are best served by having service denials reviewed by qualified health care professionals with appropriate expertise.

Response: We agree that health providers, other than physicians, may be appropriate to make decisions when the area of expertise required is other than a physician (for example, a dentist). In § 438.406(a)(7)(ii) of this final rule with comment period we have removed the term ''physician'' and replaced this with ''health care professionals who have the appropriate clinical expertise in treating the enrollee's condition or disease.''

5. Grievance (Appeal): Resolution and Notification (Proposed § 438.408)

Proposed § 438.408 required MCOs and PHPs to investigate each appeal (called grievance in the proposed rule) to base the decision on the record of the case, including any MCO or PHP hearing provided under § 438.402(c)(3), and relevant program laws, regulation and policies; and to resolve each as expeditiously as the enrollee's health condition requires, within State established time-frames, but no later than 30 days after it receives the appeal. The MCO or PHP would be permitted to extend the 30 day timeframe by up to 14 days if the enrollee requests the extension, or if the MCO or PHP justifies a need for additional information on how the delay is in the interest of the enrollee. For an appeal that requires an expedited resolution under § 438.10, proposed § 438.408(a)(3) required that it be resolved as expeditiously as the enrollee's health condition requires, within timeframes established by the State, but no later than 72 hours after it receives the appeal. The MCO or PHP again would be permitted to extend the timeframe by up to 14 days if the enrollee requests the extension, or if the MCO or PHP justified a need for additional information or how the delay is in the best interest of the enrollee. Proposed § 438.408 also set forth requirements for notification if the decision is adverse or partially adverse to the enrollee. For a standard resolution the timeframe was no later than 30 days after it received the appeal, and for an expedited resolution, no later than 24 hours after it reaches the decision. The content of the notice must include the name of the MCO or PHP contact, the results of the appeal and the date competed, 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, circumstances under which benefits would continue if a State fair hearing request was filed, and the potential for enrollee liability for services furnished during the pending appeal if an adverse decision is reached.

Comment: One commenter believed that HCFA underestimated the burden associated with the grievance system timeframes.

Response: We address the burden imposed by this provision elsewhere in this preamble, in the section titled Collection of Information Requirements.

Comment: Several commenters believed that extensions to the appeals timeframes benefit the MCOs and PHPs more than the enrollee, and recommended that we eliminate them.

Response: We believe that extensions may be necessary to provide additional time to decide appeals when information necessary to the decision cannot be obtained in time to meet the timeframes, and that extensions may be in the enrollee's interest In expedited cases, however, we agree with the commenter that giving MCOs and PHPs the discretion to extend timeframes may be problematic because this is by definition a case that the enrollee's health is at risk. Therefore, we believe that unless the enrollee actually has determined that an extension is in their interests and requests an extension, there should be no extensions in expedited cases, and we accept the commenters' recommendation that

extensions be eliminated to this extent. In this final rule with comment period, therefore, for appeals that are expedited, only the enrollee may request an extension. This is an added protection for enrollees who are appealing to receive services without which their health may be jeopardized.

Comment: Several commenters strongly favored the adoption of standardized timeframes for Medicaid that conform with those for Medicare.

Response: We have retained the same timeframes for Medicaid that are used for Medicare. Appeals must be resolved as quickly as the enrollee's health condition requires, or no later than 30 days for standard appeals, and 72 hours for expedited appeals. As under the Medicare+Choice program, we permit 14 day extensions for both standard and expedited appeals when requested by the enrollee. In the case of a standard appeal a 14-day extension may also be obtained if the MCO or PHP justifies to the State Medicaid agency that it is in the enrollee's interests. As noted in response to the previous comment, we have eliminated extensions in expedited cases unless requested by the enrollee.

In response to the above comment favoring the adoption of Medicare timeframes, we are extending the extent to which this final rule with comment period follows Medicare timeframes by providing in §§ 438.408(j)(3)(ii) and 431.244(f)(2)(ii) and (iii), for an expedited State fair hearing in cases of expedited appeals. Specifically, we require that the State fair hearing decision be made within 72 hours, that is the same timeframe used for Medicare for expedited appeals to the Center for Health Dispute Resolution (CHDR), the current Medicare contractor for external independent review under Medicare+Choice. The fair hearing process is the Medicaid counterpart of CHDR review, in that in both cases it is the first ''independent'' and ''external'' review of a managed care organization's decision.

Comment: Comments on standardized timeframes differed. Some commenters believed that consistent timeframes are especially important in expedited appeals when the enrollee's health condition needs to be taken into consideration. Other commenters supported the adoption of standardized timeframes, but called for them to be shorter. One commenter believed that the timeframes in the proposed rule might violate Constitutional due process because the timeframes outlined do not adequately protect beneficiaries.

Other commenters criticized the standardized timeframes. Several commenters found the timeframes unreasonable, unrealistic, subjective, and too prescriptive and asked for more State flexibility to set timeframes. One commenter wanted the timeframes to begin when all documentation is received from providers. One commenter noted that most States already have expedited timeframes and changing these requirements may be confusing for beneficiaries and may not provide any additional protections to enrollees. One commenter found the extensive and varying timeframes for resolutions confusing and believed that it would be difficult to administer.

Response: We continue to believe that the regulation should establish timeframes for steps in the internal appeal process and that an expedited timeframe is necessary when the use of standard timeframes may jeopardize the enrollee's health. This is an important beneficiary protection and is necessary to ensure that the overall timeframe of 90 days for a decision at the State fair hearing (excluding the time the beneficiary takes to file for a State fair hearing) can be met in all cases. In § 438.408(a) we provide for States to establish timeframes that ''may not exceed'' the timeframes specified in this final rule with comment period. States may establish shorter timeframes.

Comment: Several commenters believed that mandatory timeframes might be difficult to meet if enrollees fail to submit timely information, or are not available for an in-person presentation to the MCO or PHP. These commenters asked that a limit be placed on the number of days MCOs and PHPs are responsible for providing continued services pending final determination.

Response: We believe that the timeframes included in the regulation will result in timely decisions on appeals. Enrollees must be informed of the timeframes, and provided an opportunity to present evidence and appear in person before an MCO or PHP representative. However, if they do not provide information to support their appeal, the MCO or PHP is responsible for deciding the appeal on the basis of available information within the timeframes set out. Continuation of benefits for already authorized services must continue throughout these periods until the final decision at the MCO, PHP, or State is made, whichever is later. Given the limits on timeframes for decision in this rule, we do not believe that ''time limits'' are necessary. We note that there are no such limits under fee-for-service Medicaid.

Comment: Several commenters thought that MCOs and PHPs should be required to receive written approval from the State before extending the timeframes.

Response: We are not requiring that MCOs and PHPs receive prior approval from the State for extensions, as we do not believe that this would be practical, given the number of cases and the timeframes involved. However, States are required to monitor MCO and PHP use of extensions and may require that MCOs and PHPs provide justification for any extension.

Comment: Several commenters believed that the enrollee should be forwarded a concurrent copy of the MCO's or PHP's written request given the opportunity to respond to the MCO's or PHP's request for a time extension, and provided a concurrent copy of the State's response. One commenter warned that requiring prior approval would be burdensome.

Response: We agree that enrollees should be informed when an MCO or PHP grants an extension, and in response to this comment have provided for this in § 438.408(d)(2) of this final rule with comment period. The MCO or PHP notice must include the reasons for the delay and inform the enrollee of the right to file a grievance if the enrollee disagrees with the decision to extend the timeframes. We do not believe that this requirement will unduly burden MCOs and PHPs, as we believe that most appeals will be decided within the time period allowed before an extension is needed. We note that our decision to not permit MCOs or PHPs to extend the timeframe for an expedited appeal absent a request by an enrollee is also responsive to the commenters' concerns about an enrollee being informed of extensions and having the opportunity for input.

Comment: One commenter requested that we require the MCO or PHP to give a written justification to the enrollee whenever the MCO or PHP extends the 14-day timeframe, and that a copy be included in the case file. Another commenter noted that the MCO or PHP does not need to obtain prior approval before granting itself an extension, and as currently drafted, the enrollee appears to have no recourse other than to file a grievance with the MCO or PHP, even in situations when the enrollee's life may be jeopardized. They believe that due process and fundamental fairness require MCOs and PHPs to provide notice to the enrollee, and that the enrollee should have the right to object and have the dispute immediately decided by an impartial decision maker. A delay in decision making constitutes a delay in providing the service. and is subject to Constitutional requirements

and *Goldberg* v. *Kelly* in this commenter's view.

One commenter also requested that physicians (in addition to enrollees) should have a right to request a 14-day extension.

Response: We agree that MCOs and PHPs, upon granting themselves an extension, should notify the enrollee in writing of the extension and of the enrollee's right to file a grievance if the enrollee disagrees with an extension of the timeframes. We do not believe that providers need to be given the right to seek an extension. The provider is associated with the MCO or PHP that can grant itself an extension in a non-expedited case if the standard is met. The MCO or PHP must also provide justification for the extension to the State, if required. We note that the commenter's concern about ''situations when the enrollee's life may be jeopardized'' by an MCO or PHP-initiated extension has been addressed by our decision to eliminate the opportunity for the MCO or PHP to extend the deadline in expedited cases absent an enrollee request.

Comment: One commenter believed that the timeframes should begin when the appeal initially is made, not when it is submitted in writing.

Response: We agree that timeframes should begin when the enrollee first appeals the action, regardless of whether the appeal is made orally or in writing. When setting the timeframe for resolving appeals in § 438.406(b)(3) of this final rule with comment period, we refer to the date that the MCO or PHP first ''receives'' an oral or written appeal as the point that the time for resolving the appeal has begun. We note, however, that the enrollee must follow a standard oral appeal for a request with a written request.

Comment: Several commenters recommended that the timeframe for making a decision on a request to authorize a service should be less than the 14 days proposed.

Response: We continue to believe that 14 days is an appropriate outer limit for the time allowed for an MCO or PHP to authorize a service. We have retained the provision of the NPRM that requires this decision to be make more quickly if required by the enrollee's health needs. In addition, in this final rule with comment period, when a determination is made that a case meets the standards for an expedited appeal, the MCO or PHP must decide an appeal of this decision no later than 72 hours after the appeal is filed.

Comment: One commenter agreed with our decision stated in the preamble to the proposed rule not to require MCOs and PHPs to automatically resolve any dispute in the enrollee's favor that the MCO or PHP did not resolve within a defined timeframe. Other commenters supported requiring that appeals be resolved automatically in the favor of the enrollee if not completed within a specific time period. These commenters reported ongoing problems of MCOs and PHPs denying services for months while multiple requests for information are made.

Several commenters reported that some State laws provide safeguards when decisions on medical care are not made within required timeframes, including deeming the failure to make a timely decision an adverse decision subject to appeal or automatic approval of the service.

Several commenters pointed out that in HCFA's Medicare+Choice regulations, the failure of a Medicare+Choice organization to meet initial determination and reconsideration timeframes is automatically considered an adverse decision and automatically referred to the next level of review.

Response: We are not requiring that appeals be resolved automatically in the favor of the enrollee if not completed within a specific time period. Instead, non-compliance will be considered an adverse decision, and automatically referred to the next level of review (the State fair hearing process). For service authorization requests, an MCO or PHP not completing authorizations within the specified timeframes would be required to send a notice of adverse action explaining the enrollee's appeal rights. As the commenters noted, this is consistent with Medicare's policy for reconsiderations not acted upon within the required timeframes. That is, the Medicare+Choice organization's failure to act is considered an affirmation of its adverse decision and the file must be sent to the independent entity for an independent outside review. This first level of independent review under Medicare+Choice is analogous to fair hearing review under this final rule with comment period.

Comment: One commenter asked that the words ''title of staff person'' be substituted for ''name of staff person'' to protect MCO and PHP staff members from possible retaliation by enrollees.

Response: We agree and have changed ''name'' to ''title'' in this final rule with comment period.

6. Expedited Resolution of Grievances and Appeals (Proposed § 438.410)

Proposed § 438.410 required that each MCO and PHP establish and maintain an expedited review process for appeals (called grievances in the proposed rules) and set forth requirements for the resolution of expedited grievances and appeals including, responses to oral or written requests if the MCO or PHP determines, or the provider indicates that the time for a standard resolution could seriously jeopardize the enrollees's life, health, or ability to regain maximum function.

Comment: Some commenters applauded our inclusion of an expedited grievance process similar to that under Medicare+Choice and-then-proposed the Department of Labor regulations. Others argued for State flexibility and contended that prescriptive Federal requirements preclude States from taking into account other expedited processes that they have implemented with respect to clinical aspects of appeals, for example, preauthorizations.

Response: We believe that expedited resolution is necessary to ensure that appeals of situations that potentially place an enrollee's health in jeopardy are not delayed. The Consumer Bill of Rights and Responsibilities (CBRR) and beneficiary advocates have both recommended the adoption of expedited procedures. Although States have historically instituted different processes to protect beneficiaries, HCFA believes that standardized expedited appeal processes are needed to protect beneficiaries in a capitated health care delivery system.

Comment: One commenter requested that ''retain function'' be added to the criteria for expedited grievances and appeals. The commenter stated that retention of less than full function is often the goal for beneficiaries with long-term disabilities who cannot expect to regain full function but should be protected against further loss of function. Other commenters wanted the expedited process to apply when the enrollee has significant pain or side effects, and for children with special health care needs.

Response: In response to this comment, we have revised the language for expedited appeals to include all instances for which the time needed for standard resolution could ''seriously jeopardize the enrollee's life or health, or the ability to attain, maintain, or regain maximum function.'' With this revision, the Medicaid criteria are more inclusive than those for Medicare. We believe that these criteria are sufficient to address situations that the enrollee is in significant pain or is having significant side effects. Finally, we do not agree that children with special health care needs should automatically receive expedited appeals in all cases

solely on the basis of being in that category. We believe that the criteria we have established will ensure that expedited appeals will be available when they are needed.

Comment: Several commenters suggested that the regulations allow the beneficiary to obtain an expedited review based on the beneficiaries' own attestation that the standard for expedited review has been met. They believed that MCOs and PHPs should not be given control over the situation because their financial arrangements with physicians may provide an incentive to deny services. One commenter supported the ability of an enrollee to obtain an expedited resolution if the enrollee obtains the support of a physician.

Response: We do not agree that an enrollee's attestation should be sufficient to require an expedited appeal. The enrollee may not be objective in this determination or may not have the knowledge to draw a correct conclusion. It is not clear what would preclude enrollees under this approach from attesting that the standard is met in every case simply to get faster action on all appeals. We are including in this final rule with comment period a provision that if a provider makes the request, or supports the enrollee's request for expedited review, the review must be expedited. We believe this sufficiently protects enrollees.

Comment: Several commenters noted that the rule should prohibit retaliation by the MCO or PHP against physicians who support their patients' requests for expedited appeals.

Response: We intend that providers who advocate on behalf of their patients should be protected against retaliation by MCOs and PHPs in all circumstances. In response to this comment, we expressly prohibit any retaliation in § 438.402(b)(5) of this final rule with comment period.

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

Response: We are aware that some Medicaid enrollees may not have telephones. Nevertheless, MCOs and PHPs must make reasonable efforts to notify enrollees orally of decisions not to expedite the appeal and follow up with a written notice within two calendar days. MCOs and PHPs should request information from enrollees about how and where they can be contacted.

Comment: Several commenters recommended that the State Medicaid agency be required to hear all expedited appeals and issue decisions within specified timeframes. One commenter recommended we include a requirement that decisions be made within 24 hours; another suggested two days.

Response: This final rule with comment period requires the State to conduct a fair hearing and make its decision within 72 hours for service authorization denials that meet the criteria for expeditious handling. We have limited this requirement to initial denials of authorization for a service because in the case of a decision to reduce or terminate benefits, benefits continue through the State fair hearing decision. The enrollee's health is protected during the time it takes for the State fair hearing decision to be made. We have chosen to use the same 72-hour standard that applies to MCO or PHP review in expedited cases because we do not believe it would be reasonable to expect the State to complete review of all expedited cases in 24 hours. We also note that this 72-hour timeframe is employed in Model guidelines established by the National Association of Insurance Commissioners (NAIC), in Department of Labor regulations governing Retirement Income Security Act (ERISA) health plans, and at both the Medicare+Choice organization and independent external review levels in the Medicare+Choice program.

Comment: Several commenters pointed out that proposed § 438.410 (c)(2) allowed a physician to request an expedited appeal. They suggested that we broaden this provision to allow other health care professionals to make these requests.

Response: We agree that all health care professionals who provide services to Medicaid beneficiaries should be permitted to request expedited appeals. As discussed above, we have made this change in this final rule with comment period.

7. Information About the Grievance System (Proposed § 438.414)

Proposed § 438.414 required that MCOs and PHPs provide information about the grievance system to enrollees, potential enrollees (as provided by the State), and all providers at the time they enter into a contract with the MCO and PHP. It also specified that the content of the information include a description of the grievance process that is developed or approved by the State, and that it include the following: (1) specification of what constitutes grounds for a complaint (now grievance) grievance (now appeal) or State fair hearing; (2) an explanation of how to file for each; (3) an explanation of the assistance available; (4) toll-free numbers (with TTY and interpreter capability) for enrollees to register grievances and appeals; (5) titles and telephone numbers of persons responsible for the functioning of the grievance process and with authority to require corrective action; (6) assurance that filing an appeal or requesting a State fair hearing will not negatively affect or impact the way the MCO or PHP, their providers, or the State agency treat the individual; and (7) information on how to obtain care or services during the grievance or fair hearing processed. Section 438.414 also requires that the MCO or PHP to provide enrollees and potential enrollees with aggregate information regarding the nature of enrollee appeals and their resolution.

Comment: One commenter believed that we underestimated the true burden associated with MCO and PHP grievance information requirements.

Response: We address the issue of burden in the Burden Statement to this final regulation.

Comment: Several commenters requested that we explicitly require notices and information about the grievance system to be written at a fourth grade level, translated into prevalent languages, and accessible to persons with hearing and sight impairment.

One commenter requested us to require MCOs, PHPs, and PCCMs to use at least one of the following reference materials: (1) Fry Readability Index; (2) PROSE: The Readability Analyst; (3) Gunning FOG Index; or (4) McLaughlin SMOG Index.

Response: In this final rule with comment period, we require that notices meet the formatting and language requirements at § 438.10. We believe that it is appropriate that we include a general requirement for material to be written in easily understood language and formatted likewise. We also provide that material must be translated into the prevalent languages in the MCO's or PHP's service area. In the preamble to the proposed rule, we provided examples of standards States can use to determine prevalence. We are not requiring that material be written at a specific grade level because no single level is possible or appropriate for all material.

Comment: One commenter believed that additional State flexibility was necessary regarding how and when information should be distributed to enrollees. Another commenter asked for more clarification about the detail of the information that must go to all enrollees

and the time that information must be sent. One commenter requested that States develop standard language that MCOs and PHPs be required to use in their member handbooks. Several commenters supported the amount of detail in the regulation regarding information because it ensures that information about beneficiary protections is provided more uniformly to enrollees.

Response: We are not mandating that States require the use of standard language because, we believe that States should be permitted to decide this based on State circumstances. With respect to the timing of the provision of information, § 38.10(d), (e), and (f) set forth requirements as to when information about the grievance system must be provided to enrollees and potential enrollees. With respect to the information on grievances and appeals addressed in § 438.414, for enrollees, § 438.10(e)(1) requires that this information (referenced in § 438.10(e)(2)(x)) be provided within a reasonable time after the MCO or PHP receives notice of enrollment, and once a year thereafter. In the case of potential enrollees, § 438.10(f)(7) requires that the information described in paragraphs (d) and (e) of § 438.10 (including the grievance information described in § 438.10(e)(2)(x)) be provided only upon request. In § 438.414(a)(1) and (3), we require MCOs and PHPs to provide information about the grievance system to enrollees, and to providers and subcontractors (at the time of entering into a contract). In section 438.414(a)(2), we require that the State, a State contractor, or MCOs and PHPs provide this information to potential enrollees. In § 438.404 we require that information about the grievance system be sent to enrollees as part of the notice of action.

Comment: One commenter believed that the State fair hearing process should be explained clearly to enrollees at the time of enrollment, and annually thereafter. Several commenters asked that MCOs and PHPs be required to give enrollees information on the right to be represented by counsel, and the availability of free legal assistance. One commenter requested that beneficiaries be informed of their rights during the grievance process at every stage.

Response: We have revised this regulation to clarify that the beneficiary's State fair hearing rights must be explained, including the fact that enrollees have the right to represent themselves, or be represented by legal counsel, a relative, a friend, or other spokesperson. We do not require MCOs and PHPs to inform beneficiaries about the availability of free legal counsel. This is consistent with the current policy in fee-for-service. In the State Medicaid Manual (SMM 2900.3), we require States to maintain a list of available free legal services and to notify beneficiaries of their right to legal assistance, including free legal assistance. States may, at their option, require MCOs and PHPs to maintain copies of this list and make it available to enrollees.

Comment: Several commenters thought that we should require MCOs and PHPs to provide grievance, appeal, and State fair hearing information to potential enrollees, upon request, and to enrollees upon initial enrollment, and whenever the grievance system is changed by the MCO, PHP, or the State. Several commenters wanted aggregate information on grievances and their resolution to be given to consumers as part of their initial and annual enrollment choice information. Several commenters wanted grievance data to be available to the general public, as well as, to enrollees and potential enrollees. One commenter encouraged us to have consistent requirements for Medicaid and Medicare.

Response: As noted above, we require the State to ensure that information on grievances and appeals is provided to potential enrollees upon request, either by the State or its contractor (for example, an enrollment broker), or by the MCO or PHP. MCOs and PHPs also are required to provide this information to enrollees at the time of enrollment, and annually thereafter. Information will also be provided as part of notices of actions. We believe that this will provide enrollees with the information they need to exercise their rights.

We agree with the commenter that MCOs and PHPs should provide aggregate information on grievances and appeals to enrollees, potential enrollees, and the general public upon request. In response to this comment, § 438.414(d) of this final rule with comment period provides that aggregate information be released to the public upon request.

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

Response: In § 438.414(a)(3) of this final rule with comment period, we specify that this information must be provided to subcontractors as well as to contractors.

8. Recordkeeping and Reporting Requirements (Proposed § 438.416)

Proposed § 438.416 required that MCOs and PHPs comply with specified record keeping requirements, that also had to be done in compliance with confidentiality requirements in § 438.324. Specifically, MCOs and PHPs were required to—

- Maintain a log of all grievances and appeals (called complaints and grievances in the proposed rule).
- Track each appeal until its final resolution.
- Record any disenrollment and the reason for it, even if it occurs before the appeal process is complete.
- Retain the records of grievances and appeals (including their resolution) and disenrollments for three years, and make them accessible to the State or if any litigation, claim negotiation, audit or other action is started before the end of this three year period, the MCO or PHP must retain the records until completion of the action and resolution of the issues, if later than three years.
- Analyze the collected information and prepare and send to the State a summary as often as the State requests, but at least annually—

++ The number and nature of all complaints and grievances.

++ The timeframes within which they were resolved, and the decisions.

++ A listing of all grievances that have not been resolved to the satisfaction of the affected enrollee.

++ The number and nature of grievances for which the MCO or PHP provided expedited resolution, and the decisions.

++ Trends relating to a particular provider or a particular service.

Comment: One commenter believed that HCFA underestimated the true burden associated with MCO and PHP record keeping and reporting requirements.

Response: We address the issue of burden in the section of the preamble titled Collection of Information Requirements.

Comment: Several commenters suggested that the State be allowed to determine the specific data elements to collect on grievances and appeals, and how and when reports are to be submitted to the State. Other commenters supported the inclusion of the elements included in the proposed rule.

Response: We believe that a minimum set of data should be available from all MCOs and PHPs to facilitate monitoring. We have changed this final rule with comment period to remove the requirement in proposed § 438.416(e)(3) that MCOs and PHPs submit a list of all appeals not resolved to the satisfaction of the enrollee. We believe that this requirement is unnecessary now that MCOs and PHPs will be required to forward all appeals not resolved to the

satisfaction of the enrollee to the State for a fair hearing. We note that States have the flexibility, at their option, to set record keeping and reporting requirements in addition to these Federal minimums. For example, States may establish a minimum number of categories of grievances and appeals that MCOs and PHPs must report (for example, delays in receiving referrals, delays in access to specialists or services, dissatisfaction with quality of care, and waiting times for appointments).

Comment: Several commenters wanted the regulation to specify that MCOs and PHPs should collect and report information on the number and nature of requests for expedited review.

Response: We agree that we should require that MCOs and PHPs collect and report information on the number of requests for expedited review, and in response to this comment have provided in § 438.416(b) of this final rule with comment period that grievances and appeals must be classified in terms of whether the disposition was standard or expedited. We have retained the requirement in proposed § 438.416(e)(1) (now § 438.416(d)(1)) that information be reported on the ''nature of all grievances and appeals,'' whether expedited or standard.

Comment: Several commenters wanted grievances to be tracked, sorted by type, number and resolution, and reported to the same extent as appeals. They believed that this would be useful in identifying problems with education and outreach.

Response: This final rule with comment period requires that grievances, as well as appeals, be tracked and reported. In response to the comment favoring additional tracking, we have added a requirement to the regulation that MCOs and PHPs must track and report on the time frames for acknowledging to the enrollee the receipt of grievances and appeals.

Comment: Several commenters objected to the requirement in proposed § 438.416(c) that MCOs and PHPs record any disenrollments and the reason for them, because these commenters believed that the State controls the disenrollment process and maintains data regarding disenrollments. Therefore, these commenters believed that States, not MCOs and PHPs, should be required to maintain disenrollment records. One commenter noted that requiring the collection of disenrollment information is good and that it should also be classified

Response: We have removed the requirement for an MCO or PHP to ''record any disenrollment and the reason for it'' from the proposed provisions at § 438.416 because this was duplicative of the requirement at proposed § 438.342(a) that the State ensure that each MCO and PHP maintain a health information system that collects, integrates and reports data on areas including disenrollments. However, in response to this comment, we recognize that there is a distinction between disenrollments from an MCO or PHP due to loss of Medicaid eligibility and other disenrollments initiated by the enrollee of the MCO or PHP. Given that information regarding disenrollments due to loss of Medicaid eligibility is not typically known by MCOs or PHPs, in response to this comment, we have modified the reference to disenrollment in § 438.242 to refer to ''disenrollment for other than loss of Medicaid eligibility.''

Comment: One commenter requested that we clarify that the regulation requires MCOs and PHPs to provide the State only with information about grievances and appeals of Medicaid enrollees, not all enrollees.

Response: We believe that the regulation is clear that this information must be supplied only for Medicaid enrollees, as it references grievance and appeal mechanisms that are only available to enrollees.

Comment: We received several comments regarding the annual disclosure of information. One commenter believed that annual disclosure of aggregate data was appropriate, but that reporting trends relating to a particular provider or particular service was not. Commenters urged us not to require such information to be reported. They were very concerned that these reports would have a detrimental effect on existing quality improvement and peer review processes.

Response: We agree that Federal reporting of trends relating to particular providers may not be appropriate, and in response to this comment have deleted this requirement from this final rule with comment period. States, at their option, may develop provider grievance and appeal profiling requirements consistent with State laws.

Comment: Several commenters asked that State Medicaid agencies and ombudsman programs have access to MCO and PHP logs. In addition, commenters urged that the regulation require States to provide members of the public, upon request, with MCO and PHP summaries. Another commenter recommended that HCFA require MCOs and PHPs to identify trends on grievances and appeals for particular enrollee sub-populations. One commenter wanted the regulation to require MCOs and PHPs to computerize their grievance and appeal logs and report to the State on a quarterly rather than annual basis.

Response: States have the authority to require that MCOs and PHPs make available to the State grievance and appeal logs or other MCO and PHP grievance system documents. In the final regulation we are requiring that States must make information on MCO and PHP grievances and appeals available to the public. We do not agree that we should be more prescriptive in the regulation about reporting requirements. States, at their option, may require MCOs and PHPs to provide ombudsman programs access to grievance and appeal logs, to include information about all systemic issues that emerged from grievances and appeals, to report on their response to systemic problems, to report grievance and appeal data on particular subpopulations of enrollees including persons with special needs, to computerize logs, or to report on a more frequent basis. In designing their quality strategies, States should consider what additional information they or others will need to support those strategies.

9. Continuation of Benefits Pending Resolution of a State Fair Hearing Decision (Proposed § 438.420)

Proposed § 438.420 set forth requirements for MCOs and PHPs, in the case of an appeal from the termination or reduction of services currently being provided to continue services upon a timely appeal while the MCO or PHP considers the appeal, and through the end of any State fair hearing. As used in this section, ''timely'' means filing on or before the time limit specified by the State and communicated in the notice of intended action, or before the effective date of the MCO's or PHP's proposed action, whichever is later. Although the benefit is to be continued during the resolution process, enrollees who lose their appeal at either the plan or State fair hearing levels will be liable for the cost 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.

Comment: Commenters expressed concern that the regulation may be read to permit benefits to be stopped after the appeal to the MCO or PHP, but before the State fair hearing.

Response: We intend for benefits to continue through the enrollee's final appeal at the State fair hearing when requested by the enrollee. Section 438.420(d)(1) of this final rule with

comment period makes it clear that benefits must continue without interruption, if elected by the enrollee, through the conclusion of the State fair hearing process if the case is not favorably resolved at the MCO or PHP level.

Comment: One commenter thought that requiring continuation of benefits through the State fair hearing decision was inappropriate because the enrollee may be liable for payment for services provided during this period if the appeal is ultimately denied at the State fair hearing.

Response: We provide that enrollees must request to have benefits continue during the appeal process because of their potential financial liability in the event that they are unsuccessful. In § 438.404(b)(7) of this final rule with comment period, we require that the notice of action inform the enrollee of the potential financial liability for services continued during appeal. Likewise, in § 438.408(g)(4)(iii), we require a written notice to the enrollee that the enrollee may request that benefits be continued and of the potential financial liability if the benefits continue.

Comment: We received many comments regarding enrollees' rights to continuation of benefits during the MCO and PHP appeal process. Several commenters thought that the regulations should include a provision to require MCOs and PHPs to continue benefits when the appeal involves services that are being terminated or reduced. Several commenters felt that continuation of benefits pending resolution of an appeal or State fair hearing without financial risk, is one of the most important protections needed for managed care enrollees.

Several commenters were opposed to extending continuation of benefits to the MCO and PHP appeal process. One contended that this requirement would have significant cost implications. Another believed that benefits should be continued only at the point when an enrollee requests an external fair hearing.

One commenter thought that requiring MCOs and PHPs to continue benefits would place them in an untenable position with their providers, compromising their ability to manage care and cost. They expressed concern that this provision may damage managed care programs and believed it unnecessary given the requirement of expedited review of appeals in cases in which a delay could jeopardize health.

One commenter argued that requiring continuation of benefits during an MCO or PHP appeal, as opposed to a State fair hearing, was not consistent with this commenter's interpretation of the statute and case law. It appeared to this commenter that a beneficiary would obtain double benefits in this situation. The commenter requested clarification to explain the duration of continuation of benefits when they are provided during the MCO and PHP appeal process. The same commenter also felt that continuation of benefits would make it difficult for the State to track the case and determine the beneficiary's eligibility for continuation of benefits at the point of the State fair hearing.

Response: Because we allow States to require exhaustion of the MCO and PHP appeal before receiving a State fair hearing, we believe that, in order for the right to continued benefits during a fair hearing to be meaningful, that continuation of benefits must begin with the filing of the appeal and continue until the State fair hearing decision. Continuation of benefits at the MCO and PHP level thus is not a ''double'' benefit, but part of the same longstanding right to continuation of benefits that has existed for Medicaid beneficiaries when services are reduced or terminated.

As in fee-for-service, under managed care, the right to continuation of benefits is not exercised without financial risk to the beneficiary of payment for services provided should he or she lose the appeal. The enrollee may choose not to request continuation of benefits because of the potential liability. The notice of adverse action must include an explanation of this choice.

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

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

It is not clear why the last commenter believes that providing continued benefits through the fair hearing level is inconsistent with the statute or case law. We believe that it simply gives MCO and PHP enrollees the same Medicaid fair hearing rights that all other enrollees have under the program. To the extent that we are aware of case law on this issue, courts have supported continuation of benefits in the managed care context.

Comment: One commenter requested that this section should make clear that re-authorization of a service at a lower level than previously received, or a denial of re-authorization, is a termination or reduction of the service requiring the continuation of benefits pending appeal.

Response: We believe that the expiration of an approved number of visits does not constitute a termination for the purposes of notice and continuation of benefits. If an enrollee requests re-authorization for services and the MCO or PHP denies the request or re-authorizes the services at a lower level than requested, the MCO or PHP must treat this request as a new service authorization request and provide notice of the denial or limitation. The MCO or PHP is not obligated to provide continuation of benefits in this circumstance. This policy is consistent with that in fee-for-service.

Comment: One commenter objected to requiring MCOs and PHPs to cover the service pending appeal if the enrollee is no longer eligible for Medicaid and there is no emergency.

Response: The policy for continuation of benefits does not apply when an enrollee loses Medicaid eligibility.

Comment: We received many comments regarding the requirements in proposed § 438.420(b) that a MCO or PHP physician with authority under the MCO or PHP contract must have authorized the enrollee's services in order for them to be continued.

Several commenters believed that benefits should be continued in all cases in which a dispute involves a service covered under the Medicaid State plan. They argued that conditioning continuation of benefits on the benefits having been authorized was inconsistent with constitutional due process requirements. They contended that the rule could lead to an interruption in services when services are prescribed by an out-of-plan emergency room physician or by an out-of-network provider who is treating a Medicaid beneficiary because the MCO or PHP does not have an available provider in the network; the MCO or PHP pays for the service although it is prescribed by an out-of-network provider; a beneficiary is receiving out-of-network family planning services; or an enrollee, while continuously eligible for Medicaid, either changes MCOs or PHPs or joins an MCO or PHP (from fee-for-service or PCCM) during a course of treatment.

Several commenters recommended that the regulation be amended to trigger continued services regardless of whether the provider requests the

service. They contended that there is a direct financial conflict of interest between a provider employed by a MCO or PHP (or contracting with a MCO or PHP) and the patient. These commenters also said that MCO and PHP doctors base treatment decisions, in part, on MCO and PHP guidelines and receive bonuses if they meet performance goals that may include utilization criteria.

Response: For continuation of services to apply, the services must have been previously authorized. This final rule with comment period uses the term ''authorized provider'' rather than ''MCO or PHP physician'' to address some of the concerns expressed by the commenters. We note, with respect to the example of emergency services cited by the commenters, that in section 1932(b)(2)(A)(ii) of the Act, the Congress has provided MCOs with the right to decide whether to authorize out of network ''post-stabilization services'' once an emergency medical condition has been stabilized. The Congress contemplated that services would only be covered by Medicaid if authorized by the MCO, or covered under the post-stabilization guidelines in cases in which the MCO does not respond timely to a request for coverage authorization. To the extent the MCO or PHP does not authorize continued services by a non-network provider, it must assume responsibility for the services through a network provider, so there would be no interruption in needed services.

Where services were not covered in the first place because they were not authorized or covered as emergency services or post-stabilization services, there could be no ''right'' to continuation of coverage, even if the services would be covered under the State plan for a beneficiary not enrolled with an MCO or PHP. We therefore disagree with the commenters who suggested that it violated due process to require MCOs and PHPs to provide continuation of services only when the services in question were authorized in the first place.

However, if services are covered under Medicaid, under this final rule with comment period, benefits must be continued if the beneficiary timely appeals a decision to terminate, reduce or suspend the services, regardless of whether or not the beneficiary is enrolled in a MCO or PHP. We note that this includes instances in which the services were begun by a provider under the fee-for-service system, but a MCO or PHP made a decision to terminate, reduce, or suspend them. These beneficiaries' rights to continued care are addressed under regular fee-for-service rules, and it is the State that is obligated to ensure that these rights are enforced. States should specify in their contracts with MCOs and PHPs whether the MCO, PHP, or the State will assume financial responsibility for these services under these circumstances. We note that § 438.62(b) requires that States have a mechanism in effect to ensure continued access to services when an enrollee with ''ongoing'' health care needs is transitioned from fee-for-service to managed care.

Benefits must be continued by the MCO or PHP in the following situations, (this assumes that the benefits are included in the MCO or PHP contract): (1) the MCO or PHP pays for services prescribed out-of-plan; (2) services are prescribed by an outside specialist who is treating the enrollee with the MCO's or PHP's knowledge and consent; (3) family planning services are being received from a provider who is not part of the MCO or PHP network, and family planning services are covered under the MCO or PHP contract; and (4) in rural areas, where individuals are, by law, permitted to seek out-of-network services/providers, for example when the service or provider is not available within the MCO or PHP. If the benefit is not included in the MCO or PHP contract, the State must pay to continue the benefits.

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

The commenters noted that the existing regulation at 42 CFR 431.230(b) provides for the possibility of recoupment, yet benefits are continued when an appeal is filed timely. The commenters found no reason to change this long-standing rule for beneficiaries who are receiving services through an MCO or PHP.

Response: We do agree with the commenters view that beneficiaries should not be required to specifically request continuation of benefits. We continue to believe that beneficiaries should have to request continuation as they may be held liable for services if the final decision is not in their favor. We have provided that enrollees be notified that they may incur a financial liability if their appeal is unsuccessful. As in the case of the fee-for-service regulations, benefits will only be continued if the enrollee files a timely appeal. This is a ''prerequisite'' to obtaining them which has been upheld in the courts as consistent with due process.

Comment: Several commenters expressed concern that beneficiaries may request continuances of State fair hearings, and extend the period during which benefits will continue. They recommended that the final regulation specify the grounds on which an enrollee may request a hearing continuance. If a continuance is granted for reasons other than good cause, these commenters believed that the MCO or PHP should not be obligated to continue to provide services during the period of the continuance.

Response: We do not agree that we should specify when a State fair hearing officer may grant a continuance, as we believe that this should be left to the hearing officer's discretion, as is the case under fee-for-service Medicaid. The State Medicaid Manual at 2900 permits the State fair hearing officer to grant one continuance of up to 30 days.

Comment: Several commenters recommended that we establish parameters for the liability of MCOs and PHPs for care provided pending the outcome of the hearing. Commenters wanted to work with HCFA to develop this provision. They stated that MCOs and PHPs should be compensated appropriately if they are required to provide services, and the hearing decision upholds the MCO's or PHP's determination.

Some commenters believed that it would be unrealistic to assume that an MCO or PHP would be able to collect payment for services from an enrollee if the final decision is not in their favor. They noted that Medicaid beneficiaries generally do not have the financial resources to pay, and MCOs and PHPs thus should be able to recoup payment from a provider, with the provider then billing the enrollee. They believed that this process would add to the administrative burden of the MCO or PHP and the provider.

One commenter recommended that MCOs and PHPs should be paid their costs for providing services during the hearing process if the enrollee is unsuccessful at the State fair hearing and the MCO or PHP is unsuccessful in collecting from the enrollee.

Another commenter recommended that MCOs and PHPs be reimbursed on a fee-for-service basis for services provided during the time taken for the appeal and State fair hearing.

One commenter asked that this section be amended to limit the responsibility of enrollees for services provided that are the subject of the appeal, rather than all services provided during this time period.

Several commenters were concerned that MCOs and PHPs would use the requirement that enrollees be told of their potential liability for payment for services continued to intimidate enrollees from using the grievance process. These commenters noted that, under the fee-for-service system, States seldom try to recover the cost of services from a beneficiaries, but under a managed care system, the MCOs and PHPs are more likely to attempt recovery to avoid financial losses.

Response: States, in their contracts with MCOs and PHPs, have the flexibility to determine what entity is responsible to cover costs of services continued through an appeal. We believe that States are in the best position to decide what entity should pay. They may prefer to take this into account in setting capitation rates for MCOs and PHPs or may prefer to pay for these services directly.

The current requirement in the Medicaid fee-for-service program is that beneficiaries who lose their appeal at the State fair hearing level are liable for the costs of the services continued during the appeal. Enrollees must be told of their potential liability in order for them to make an informed choice about whether or not to accept continued services. Section 438.408(i)(4) of this final rule with comment period thus requires written notice of this potential liability, and the option to refuse continued benefits. Enrollees are not liable for all services provided during this time period, but only for services continued because of their appeals. We have clarified the language on this point in the regulation (§ 438.420 (e)). FFP is available to States for payments for services continued pending a State fair hearing decision. Likewise, if the MCO or PHP is unable to collect from the enrollee after a good faith effort, FFP is available to the State under § 431.250(a) for payments for services continued pending a hearing decision.

10. Effectuation of Reversed Grievance Resolutions (Proposed § 438.421)

Proposed § 438.421(a) provided that if the MCO or PHP decides an appeal (called a grievance in the proposed rule) in favor of the enrollee, the MCO or PHP was required to authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 30 calender days after the date the MCO or PHP receives the request for reconsideration. Furthermore, under proposed § 438.421(b), if the MCO's or PHP's decision on a appeal was reversed under the State fair hearing process, the MCO or PHP must authorize or provide the disputed service as expeditiously as the enrollee's health condition requires within time frames established by the State, but no less than 60 calendar days from the date the MCO or PHP receives notice reversing the MCO's or PHP's decision to deny.

Comment: Several commenters disagreed with the time frames in the proposed rule for providing a service, which depended on whether the beneficiary won the appeal at the MCO or PHP (30 days to provide the service), or at the State fair hearing (60 days to provide the service). Another commenter believed that the time frames should take into consideration the appropriateness of the procedure or treatment for the individual, as there may be cases in which providing the service within 30 days may not be clinically appropriate for the enrollee. The commenter further noted that external factors for example, scheduling and bed availability may affect the time frame for providing treatment. Several commenters supported the elimination of time frames because in the view of these commentators, beneficiaries with successful appeals should not have to wait at all following the decision.

Response: We agree that MCOs and PHPs should remove barriers to receipt of the services and take into account the needs of the individual. Therefore, in response to the above comments, we are eliminating the time frames in proposed § 438.421 (§ 438.424 in this final rule with comment period), and requiring that the services be provided as soon as required to meet the needs of the beneficiary. This is consistent with the State fair hearing policy in 42 CFR 431.246.

Comment: One commenter asked that we hold States, MCOs, and PHPs financially responsible for the cost of services inappropriately withheld if the enrollee obtains them outside the network and their appeal is upheld. The commenter believed that failure to provide for this remedy could encourage States, MCOs, and PHPs to refuse expensive care until after an appeal is resolved.

Response: We agree with these commenters. In response to this comment, we have provided in § 438.424(b) of this final rule with comment period that the State, MCO, or PHP must pay for services denied to an enrollee when the enrollee received the services and later won an appeal of the denial.

11. Monitoring the Grievance System (Proposed § 438.422)

In proposed § 438.422, we required the MCO, PHP, and the State to use the grievance and appeal logs (called complaint and grievance logs in the proposed rule) and annual appeal summary required under § 438.416 for contract compliance and quality monitoring. At a minimum, proposed § 438.422 required that the contract between the State and the MCO or PHP require that logs be reviewed and summarized for trends in grievances and appeals by provider or by service, and the requirement that MCOs and PHPs conduct follow up reviews, report results to the State, and take corrective action when necessary.

Comment: One commenter requested that HCFA either define the term ''undesirable trend'' or delete the term.

Response: We agree that the term ''undesirable trend'' is vague. We now require in § 438.426(b) that when the MCO or PHP identifies through trends in the data collected in § 438.416(b) that systemic changes are needed, the MCO or PHP must investigate, report the results to the State, and take corrective action.

Comment: One commenter requested that we mandate that States conduct random reviews of service denial notifications to ensure that MCOs and PHPs are notifying members in a timely manner.

Response: We agree that States should monitor service denial notifications to ensure that MCOs and PHPs are notifying members in a timely manner. This should be an integral part of each State's Quality Improvement Strategy and contract compliance monitoring. We believe that States are in the best position to determine the timing for this monitoring.

Comment: Several commenters requested that we modify this section to require States to require MCOs and PHPs to take corrective action if numerous grievances are filed concerning the same issue.

Response: As part of the State's quality strategy, which includes monitoring MCO and PHP grievances and appeals, States are required to take corrective action when needed to remedy problems.

Comment: Several commenters felt that the requirement to identify trends by provider constitutes a serious breach under State law of the peer review processes and legal privileges. They believed that these issues can be monitored appropriately by the States without requiring reports.

Response: We agree that Federal requirements that require MCOs and

PHPs to report on undesirable trends relating to providers is not appropriate, and we have revised the rule to delete this requirement. States, at their option, may develop provider grievance and appeal profiling requirements that are consistent with State laws concerning peer review.

12. Consequences of Noncompliance (Proposed § 438.424)

Comment: We received many comments that this section confused readers, particularly with respect to the types of sanctions States could impose on MCOs and PHPs.

Response: We have eliminated this proposed section from this final rule with comment period. This section was intended to emphasize the importance of MCOs' and PHPs' compliance with the provisions of this Subpart. It did not convey any authority or responsibility to the States, MCOs, or PHPs.

F. Certifications and Program Integrity Protections (Subpart H)

Background

We believe it is important for MCOs to develop effective internal controls to fight fraud and abuse and to ensure quality of health care services to Medicaid beneficiaries. Administrative and management procedures, including a compliance plan, address specific areas of concern or potential areas of risk for MCOs. It is in the best interest of MCOs, State agencies, and HCFA to make a commitment to an effective administrative and management arrangement that will significantly aid in the elimination of fraud and abuse.

By requiring certification of the accuracy of data used to determine payments, of information contained in contracts, proposals, and other related documents submitted to State agencies, and of administrative and management procedures designed to prevent fraud and abuse, we are working to promote program integrity, protect Medicaid managed care enrollees, and protect Medicaid government funds.

Subpart H of proposed part 438, Certifications and Program Integrity Provisions, contains safeguards to promote program integrity within Medicaid managed care programs. We have proposed that these rules apply only to MCOs, as they were not made applicable to PHPs under proposed § 438.8.

Proposed § 438.600 sets forth the statutory basis for the requirements in subpart H, which is based on section 1902(a)(4) of the Act. Proposed § 438.600 permits us to find methods of administration that are ''necessary for proper and efficient administration'' of the plan. The requirements in subpart H are also based on section 1902(a)(19) of the Act, which requires that States provide safeguards necessary to ensure that eligibility will be determined and to provide services in a manner consistent with simplicity of administration and the best interests of recipients.

Proposed § 438.602 requires that when State payments to an MCO are based on data submitted by the MCO, which include enrollment information and encounter data, the MCO must, as a condition for receiving payment, attest to the data's accuracy, completeness, and truthfulness. Proposed § 438.606 requires that an entity seeking an MCO contract have administrative and management arrangements or procedures designed to prevent fraud and abuse, which include reporting to the State, HCFA, or OIG (or both) credible information on violations of laws by the MCO or its subcontractors or enrollees. In the case of enrollee's violations, this proposed requirement only applies if the enrollee's violations pertain to his or her enrollment, or to provision or payment for health services.

Proposed § 438.608 sets forth a separate certification requirement, requiring that MCOs certify the accuracy, completeness, and truthfulness of information in contracts, requests for proposals, and other related documents specified by the State.

Comment: One commenter suggested that the program integrity requirements in subpart H apply to all MCOs/primary care case managers (PCCMs), not just MCOs.

Response: We agree with the commenter that the requirements in subpart H should have applicability beyond MCOs. The commenter suggested that primary care case managers should be subject to these requirements. We agree with this recommendation to the extent the PCCM is paid on a risk basis as the MCOs that were the subject of subpart H. In this case, payments may also be based on encounter data submitted by the entity, and the same types of incentives and potential for fraud and abuse apply. However, in the case of a PCCM paid a fixed monthly case management fee, payments for services furnished to an enrollee are paid under the existing State plan payment process, which is subject to existing fraud and abuse protections that apply generally to providers that bill Medicaid. In order to identify only those PCCMs and other non-MCO entities that are paid on a risk basis, we are revising § 438.8 to require that PHPs comply with the program integrity requirements in subpart H.

Comment: One commenter requested clarification as to whether subpart H applies only to MCOs operated under a State plan option or to both those operated under a State plan option and those operated under a waiver program.

Response: The requirements of subpart H apply to MCOs, whether the MCO or PHP operates under a waiver program, a mandatory managed care program, or a voluntary program.

Comment: Several commenters believe that requiring certification of data as 100 percent accurate and complete is unworkable and not customary. The commenters suggested that this provision does not recognize the impossibility of meeting an absolute standard, that this provision should be changed to correlate with more commonly accepted standard language on certifications and to correlate with the language adopted by the Medicare+Choice program.

Response: We recognize that requiring attestation that data is 100 percent accurate may not be feasible. We believe that it is important to ensure accurate data submissions. Because this information may directly affect the calculation of payment rates, we are amending the regulation to be consistent with the current language being adopted in the Medicare+Choice provisions; that is, we will require that attestations be ''based on best knowledge, information, and belief.'' We have restructured and recodified some of the provisions of proposed subpart H. The revised certification requirement containing the Medicare+Choice language is now in § 438.606(b). These certifications will assist HCFA, State agencies, and OIG in combating fraud and abuse and in investigating and prosecuting suspected cases of fraud as authorized by the False Claims Act.

Comment: One commenter believes that the relationship between the submission of data and Medicaid payments is neither clear nor uniform and that there may be a tenuous connection between the State's reliance on the substance of the data and its payments to the MCO. The commenter also believes that certification of data fails to address incentives for underutilization and permits Medicaid payment for coverage of services that the MCO may not actually be providing. This commenter recommended that the MCO's payments be based upon filing a ''claim'' for these payments, certifying the data on which payments may be based, and whether the MCO substantially meets its contract requirements.

Response: Not all States base payments to MCOs on encounter data or on enrollment data submitted by the MCO. In this case, the certification requirement in proposed § 438.604(a) would not apply as it only applies to data when payments are based on the data. If it is not clear that there is a connection between given data and payment, those data may not have to be certified. We believe it is important that data are certified as accurate, at least to the best of the MCO's belief, if payment to that MCO will be based on these data. Submission of data that are complete and accurate will provide the State with information needed to set actuarially sound capitation rates. We disagree with the commenter that underutilization is not addressed at all, as encounter data can be used by States to identify and address underutilization and the potential for payments made for services not furnished. While we do not require States to collect encounter data from MCOs, we believe this is becoming a State requirement. It is unclear how the commenter's first recommendation concerning basing payment on filing a claim and certifying data associated with the claim relates to the commenter's concern for underutilization or how the recommendation differs from the requirements in subpart H. We agree with the commenter that MCOs should be required to certify that services are being provided in substantial compliance with their contracts, since under § 438.802(c) of this final rule (discussed in section II.H of this final rule) FFP is only available in contract payments if the MCO is in substantial compliance with its contract. We have revised §§ 438.604 and 438.606 to provide for this certification.

Comment: Several commenters believe the data should be certified by the Chief Executive Officer (CEO) or the Chief Financial Officer (CFO) whom they believe would have actual knowledge of the accuracy, completeness, and truthfulness of the data and believe that this requirement would force the MCOs to establish procedures and protocols to ensure that the information is correct. These commenters believe that problems arise when the person signing the certification may not have direct information concerning these facts, and that the CEO or CFO should certify the accuracy of the data on a document, a requirement similar to that in the Medicare+Choice program.

Response: We agree with these commenters that an accountable individual such as the CEO or CFO should sign the certification, and we accept the commenters' suggestion that the Medicare+Choice requirement be adopted. Under § 422.502(l) of the Medicare+Choice regulations, certifications must be signed by ''the CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer.'' We have adopted this language in § 438.606(a)(2) of this final rule.

Comment: Several commenters urged that related entities, contractors, or subcontractors that generate these data should be required to certify the accuracy, completeness, and truthfulness of the data.

Response: We agree with these commenters, and we are providing (1) in § 438.602 that an MCO ''and its subcontractors'' must comply with the certification requirements in subpart H; and (2) in §thnsp;438.606(a)(1) that MCOs must require subcontractors to certify the data they submit to MCOs if the data are used in determining the MCO's payment.

Comment: Another commenter believes that the large majority of data on which payment is based is determined by the State agency and not by the MCO. Regardless of the billing data submitted by the plan, the commenter believes the State determines the payment to the MCO based on information within the State system and the certification of the accuracy of the data should be applied equally to the State agency.

Response: The purpose of the certification requirement with respect to data submitted to the State by the MCO is to ensure that MCOs do not submit false or inaccurate data that might result in inappropriate higher payment amounts. It is a protection for the State and HCFA against being defrauded, or paying an MCO more than the amount to which it should be entitled. The State has no incentive to pay more than the amount dictated by accurate information, and has existing incentives to use accurate data. A major purpose of the certification requirement is to facilitate possible cases under the False Claims Act. States are not subject to the False Claims Act. States are subject to detailed requirements in § 438.6(c) requiring that payments are accurate and appropriate. We do not believe that States should have to certify data. However, if payment is based solely on State data, and an MCO does not submit any data upon which its payment is based an MCO would not have to sign certifications under subpart H.

Comment: One commenter believes that data integrity is critical but was still unclear on certification requirements.

Response: We believe that this final rule clearly spells out which data must be certified (§ 438.604), who must certify the data (§ 438.606(a)), and to which data the certifying individual is attesting (§ 438.606(b)). We believe that the requirements of these regulations are clear. We believe that imposing more detailed requirements than already set forth in this final rule would be overly prescriptive and that States should have flexibility in applying these requirements.

Comment: One commenter believes that the State Medicaid Fraud Control Units (MFCUs) should be added to the list of parties to whom the MCO must submit the reports required in § 438.606.

Response: We did not identify the MFCUs as a recipient of the reports on the violations of law because States are already required under 42 CFR 455.21 to refer to the MFCU all cases of suspected provider fraud, including such materials as records or information kept by the State Medicaid Agency or its contractors, computerized data stored by the Agency, and any information kept by providers to which the State Medicaid Agency is authorized access. States already have established relationships with MFCUs relative to referring cases of suspected fraud and abuse. We believe this requirement is already sufficiently addressed, and we have not revised this aspect of the proposed rule.

Comment: One commenter suggested that administrative and management arrangements or procedures should include specific plans for the method by which the MCO intends to discover and discourage fraud and abuse and that these specific plans should be submitted to the State Medicaid Agency for review and prior approval before execution of any contract. The commenter believes that specific plans would eliminate subjective determinations by each MCO of that which constitutes effective arrangements and management procedures.

Response: We believe that it is appropriate to allow States flexibility in determining their requirements for MCOs in this regard. We also note that States may have laws that govern this authority, and we wish to respect those laws.

Comment: One commenter noted differences between the language in proposed § 438.606 requiring only that MCOs have a process for reporting violations of law and language in §422.501(b)(3)(vi) of the Medicare+Choice interim final rule published on June 28, 1998 requiring that Medicare+Choice organizations have a comprehensive compliance plan

that includes an ''adhered-to'' process for reporting credible information to HCFA and/or OIG. The commenter recommended that HCFA adopt the Medicare+Choice language in §422.501(b)(3)(vi). The commenter believes consistency between Medicare and Medicaid will reduce the regulatory burden on managed care plans that elect to participate in both programs by eliminating any uncertainty as to what standard of conduct applies. A few commenters raised concerns about the general requirement that MCOs have ''administrative and management arrangements or procedures designed to guard against fraud and abuse.'' Instead of imposing Federal requirements in this area, such as self-reporting, the commenter believes the rule should allow States to take the lead in working with MCOs to combat fraud and abuse in the Medicaid program.

Response: We agree with the first commenter that maintaining consistency with Medicare+Choice will eliminate unnecessary burden on plans and that administrative and management procedures that include a compliance plan will work toward that end. We have included a compliance plan that includes the same elements as those listed in the Medicare+Choice final rule published on June 29, 2000 (65 FR 40170). We disagree with the second commenter that there should be no Federal requirements, but, consistent with the commenter and consistent with the Medicare final rule, which deleted the mandatory self-reporting requirement in§422.501(b)(3)(vi)(H), we have deleted this requirement. The Medicaid MCO requirements and Medicare+Choice requirements are now consistent on this issue.

Comment: A few commenters raised concern over the term ''credible'' information. One commenter believes the word ''credible'' should be replaced with the standard contained in § 455.15, specifically that if there is ''reason to believe that an incident of fraud or abuse has occurred,'' MCOs are required to report this to the State. One commenter believes the word ''credible'' should be eliminated entirely so that MCOs are not penalized for reporting in good faith information that is later found not to be credible.

Response: We have deleted the Federal self-reporting requirement containing the word ''credible,'' so these comments are moot.

G. Sanctions (Subpart I)

Section 1932(e)(1) of the Act requires, as a condition for entering into or renewing contracts under section 1903(m) of the Act, that State agencies establish intermediate sanctions that the State agency may impose on an MCO that commits one of six specified offenses: (1) Failing substantially to provide medically necessary services; (2) imposing premiums or charges in excess of those permitted; (3) discriminating among enrollees based on health status or requirements for health care services; (4) misrepresenting or falsifying information; (5) failing to comply with physician incentive plan requirements; and (6) distributing marketing materials that have not been approved or that contain false or materially misleading information. In the case of violation number 6, the statute imposes sanctions against PCCMs as well as MCOs. Proposed § 438.700 contains the above provisions from section 1932(e)(1)of the Act.

In section 1932(e)(2) of the Act, the Congress provided specific sanction authority under which State agencies may impose civil money penalties in specified amounts for specified violations, take over temporary control of an MCO, suspend enrollment or payment for new enrollees, or authorize enrollees to disenroll without cause. These provisions are reflected in proposed § 438.702(a). Given the extraordinary nature of the sanction of taking over management of an MCO, we proposed in § 438.706 that this sanction be imposed only in the case of ''continued egregious behavior,'' in situations in which there is ''substantial risk'' to enrollee health, or when the sanction is ''necessary to ensure the health of enrollees.''

Although these sanctions are referenced in section 1932(e)(1) of the Act as sanctions to be imposed on MCOs and on PCCMs only in the case of marketing violations, section 1932(e)(2)(C) of the Act refers to a ''managed care entity,'' while paragraphs (D) and (E) that follow refer to ''the entity'' and provide for suspension of enrollment or suspension of payment after the date the Secretary notifies ''the entity'' of a determination that it has violated ''section 1903(m) or * * * section [1932].'' While only an MCO could violate section 1903(m) of the Act, a PCCM could violate requirements of section 1932 of the Act that apply to MCOs and PCCMs generally or to PCCMs specifically. In proposed § 438.702(b)(2), we interpret the foregoing language to mean that the sanctions in sections 1932(e)(2)(D) and (E) of the Act are available in the case of a PCCM that violates ''any requirement'' in section 1932 of the Act. The general intermediate sanction authority in paragraphs (D) and (E) of section 1932(e)(2) of the Act is reflected in § 438.702(b)(1) with respect to MCOs. In light of the foregoing interpretation, paragraphs (b)(4) and (b)(5) of § 438.702 use the term MCO or PCCM rather than MCO only, even though the only ''determinations'' that apply to PCCMs are terminations under proposed § 438.700(a)(6) (marketing violations) or the general violations of section 1932 of the Act that are addressed in § 438.702(b)(2). Under the codification in the proposed rule, these latter determinations technically are not ''determinations under § 438.700,'' and are not included under paragraphs (b)(4) and (b)(5) of § 438.702. As recodified in this final rule, these determinations are addressed in § 438.700(d).

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

Section 1932(e)(4) of the Act authorizes State agencies to terminate the contract of any MCO or PCCM that fails to meet the requirements in sections 1932, 1903(m), or 1905(t) of the Act. This authority is implemented in proposed § 438.708. Under section 1932(e)(4)(B) of the Act, before terminating a contract, the State is required to provide a hearing. Proposed § 438.710 sets forth this hearing requirement as well as procedures for the hearing. Under section 1932(e)(4)(C) of the Act, enrollees must be notified of their right to disenroll immediately without cause in the case of any enrollee subject to a termination hearing. Proposed § 438.722 reflects this provision.

Section 1932(e)(5) of the Act contains a general requirement that States provide ''notice'' and ''such other due process protections as the State may provide'' in the case of sanctions other than terminations, which are governed by section 1932(e)(4)(B) of the Act. Section 1932(e)(5) of the Act also provides that ''a State may not provide a managed care entity with a * * * hearing before imposing the sanction'' of temporary management. Proposed § 438.710(b) reflects this statutory language.

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

The new sanction authority in section 1932(e) of the Act represents the first time that the Congress has granted Medicaid sanction authority directly to State agencies. Under section 1903(m)(5) of the Act, which the Congress has left in place, HCFA has authority to impose sanctions when Medicaid-contracting MCOs commit

offenses that are essentially the same as those identified in section 1932(e)(1) of the Act. In proposed § 438.730, we retain the existing regulations implementing section 1903(m)(5) of the Act, which is currently codified at § 434.67.

Comment: A few commenters recommended that we add the requirement: ''States shall develop criteria to guide them in their determinations of when and how to use specific sanctions individually or in conjunction with each other.''

Response: While section 1932(e) of the Act mandates that States establish intermediate sanctions, it grants States flexibility to determine which sanctions to impose and when to impose them, stating that State sanctions ''may include'' those identified in section 1932(e)(2) of the Act and that the State ''may impose'' these sanctions. We believe that the Congress intended to give States discretion and flexibility in this area. While we would expect that most States would establish specific criteria to guide their exercise of sanction authority, we believe it should be a State decision whether or to what extent it imposes sanctions. We are not including the suggested Federal criteria requirement.

Comment: One commenter suggested that we provide expressly in subpart I that sanctions be imposed for violations of proposed § 438.100, which require that contracts specify what services are included in the contract and require that States make arrangements for those not covered through the contract. The commenter believes that this would help ensure access to all Federally mandated benefits and services, including nurse-midwifery services.

Response: The Congress intended that States have flexibility in imposing sanctions, requiring only that States have sanctions in place for the specific violations in paragraphs (i) through (v) of section 1932(e)(1)(A) of the Act. Our authority under section 1903(m)(5) of the Act is similarly limited. Even under our broad interpretation of paragraphs (D) and (E) of section 1932(e)(2) of the Act, under which States may impose intermediate sanctions for any violation of sections 1903(m) or 1932 of the Act, the sanctions suggested by the commenter would not be provided for since neither of these sections mandate the inclusion of the contract terms required under proposed § 438.100(a) or impose the obligation on States under proposed § 438.100(b). If services that are included in the contract are not provided, sanctions are authorized under § 438.700(a)(1).

Comment: One commenter supported the provisions in subpart I but suggested that misrepresentation to any member of the public should also be cause for sanction.

Response: Sections 438.700(b)(4) and (5) allow States to impose sanctions on MCOs for misrepresenting or falsifying information that they furnish to HCFA, the State, an enrollee, potential enrollee, or health care provider. This provision implements section 1932(e)(1)(A)(iv) of the Act, which specifies these entities. It is not clear how a misrepresentation to a member of the public who is not a provider, enrollee, or potential enrollee would be relevant. We believe that this list covers any individual, government agency, or entity that could be affected by a misrepresentation. States are free to develop, under State law, a policy to require sanctioning for misrepresentation to any member of the general public.

Comment: One commenter had serious concerns about what the commenter perceived to be the absence of adequate Federal, as opposed to State, standards on the rights to be afforded to MCOs to contest sanctions. Although this aspect of the rule reflects section 1932(e)(5) of the Act, which leaves the decision on what due process protections to provide to MCOs to the States, the commenter believes that States should be encouraged to provide MCOs the same procedural protections that HCFA has provided to Medicare+Choice organizations before HCFA imposes sanctions.

The commenter was also concerned about potential conflicts between the intermediate sanctions required under the Act and the provisions of State law. This commenter also applauded the proposed rule allowing MCOs to be sanctioned for not providing medically necessary services to Medicaid enrollees. Regarding discrimination among enrollees on the basis of health status or need for health care services, the commenter recommended that all health insurance policies fulfill the following requirements: (1) no waiting periods for enrollment; (2) no limitation of coverage or reimbursement because of severe chronic or common recurring illnesses; (3) no premium rate increases based on experience only on community rating; and (4) guaranteed renewability and portability.

Response: The statute requires timely written notice, a hearing before terminating an MCO contract, and in the case of other sanctions for ''such other due process protections as the State may provide.'' The commenter recognizes that the Congress has expressly granted States the discretion to determine what procedures to afford to MCOs in the case of intermediate sanctions and civil money penalties. We agree with the commenter that States should be encouraged to consider offering the types of procedures offered to Medicare+Choice organizations under the Medicare regulations. We do not agree that there is a risk of conflict between the intermediate sanctions authority in subpart I and provisions of State law, because these sanctions have to be established only if State law does not cover the specified situations. With regard to the commenter's suggestion concerning discrimination, we believe that the regulations address these issues. In the case of the ''waiting period'' issue, § 438.6(c)(1) requires that enrollees be accepted in the order in which they apply without restrictions. With respect to the issues of coverage limits or premium increases based on a health condition, § 438.6(c)(1) addresses the provision prohibiting discrimination based on health status or need for health services. Section 438.6(c)(1) also addresses the issue of renewability to the extent that the individual remains Medicaid eligible and the contract remains in place. Since Medicaid only covers people who meet financial eligibility requirements, it is impossible to guarantee renewability. ''Portability'' of Medicaid benefits is similarly impossible.

Comment: A commenter suggested that subpart I should address the issue of inadvertent balance billing of Medicaid enrollees. There are no guidelines that would enable the State agency or contracting MCOs to differentiate minor technical violations from those that should result in sanctions and fines of several thousand dollars. The regulations should develop criteria to guide this kind of decision making and to protect MCOs from arbitrary State action.

Response: Under section 1932(e) of the Act, imposition of sanctions is almost entirely at a State's discretion, other than termination and temporary management rules. We believe that States are in the best position to develop criteria for when they will impose sanctions for balance billing violations, which could be sanctioned under section 1932(e)(1)(A)(ii) of the Act and § 438.700(b)(2) (codified at § 438.700(a)(2) in the proposed rule) as ''charges on enrollees'' in ''excess of'' the charges permitted under title XIX.

Comment: A commenter stated that section 438.700, which specifies the basis on which States may impose intermediate sanctions on an MCO, should include discrimination based on race, ethnicity, or language. This would

be in keeping with Title VI of the Civil Rights Act which states that ''no person in the United States shall, on ground of race, color or national origin, be excluded from participation, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.'' Several of the commenters stated that the omission of Title VI requirements from the list of sanctionable activities reduces the likelihood that MCOs will comply with cultural competency requirements. It is also very important that the rules strengthen the requirements for both State Medicaid agencies and their managed care plans to collect data regarding the race/ethnicity of the enrollees and the care of patients with limited proficiency and/or low literacy. The commenter recommended amending proposed § 438.700(a)(3) (recodified at § 438.700(b)(3) in this final rule) to read, ''Acts to discriminate among enrollees on the basis of their health status, race, color or national origin, or requirements for health care services.''

Response: Section 438.700(b)(3) reflects the language in section 1932(e)(1)(A)(iii) of the Act, which addresses only discrimination based on health status. Since § 438.700(b) reflects the specified violations for which the Congress in section 1932(e)(1)(A) of the Act said States must have sanctions, we believe that we do not have authority under section 1932(e) of the Act to add additional grounds. The civil rights law cited by plaintiffs has its own enforcement provisions, which are administered by the HHS Office for Civil Rights. We believe that it is appropriate to inform MCOs of their obligations under this and other civil rights laws and have required under revised § 438.6(d)(4) that contracts expressly reflect these obligations. Also, § 438.100(d) specifies that the State must require MCOs to comply with Title VI of the Civil Rights Act and other civil rights laws. In addition to the Federal enforcement remedies under civil rights laws, States are free to impose sanctions on an MCO that denies services on the basis of race, color, or national origin, or establish their own rules under State law.

Comments: In general, several commenters wanted the regulation to be clear that States have the authority to impose sanctions for violations beyond those that are listed in the regulation. These commenters do not believe that the six violations listed in this section should be seen as exhaustive and that States should not be precluded from establishing and imposing separate State sanctions or from imposing other types of sanctions. These commenters believe that while our intent may have been clear in the preamble, we should set forth our policy with respect to sanctions in the regulations text. Specifically, the commenters stated that it is unclear whether the regulations allow States to broaden the parameters for imposing sanctions on MCOs or limit the States to the basis set forth in the Act and the regulations. States have made progress in developing their own protections and responses to hold MCOs accountable and should not be preempted by Federal law from using them. They stated that we recognized this concept in the preamble of the proposed rule and suggested that we incorporate this concept into the actual regulations text. They believe that the six offenses outlined in the regulation should not be the only offenses that would permit imposition of sanctions. There are numerous offenses that MCOs could commit that could affect both the integrity of the Medicaid program and the quality of care that Medicaid enrollees receive, for example, failure by the plan to submit accurate data or failure to achieve State defined quality improvement standards. The commenters believe that we should not limit a State's ability to enforce its contract and should instead give States the explicit authority to impose sanctions if an MCO performs unsatisfactorily as found during an annual medical review or audit or if an MCO does not provide complete data to a State or Federal regulator. Recommended solutions provided by the commenters included the following:

- Add a paragraph (a)(7) to § 438.700 stating that sanctions can be used for violations of 1903(m) and 1932 of the Act;
- Add a new paragraph (c) to § 438.700 that specifies: ''State agencies retain authority to provide for additional sanctions under State law or regulation that address both these specified areas of noncompliance as well as additional areas of noncompliance. Nothing in this regulation prevents State agencies from exercising that authority;''
- Add a new paragraph (a)(7) § 438.700 that allows States to impose sanctions for any breach of contract not mentioned in paragraphs (a)(1) through (a)(6);
- Amend § 438.700(a) to specify that the sanctionable violations include, but are not limited to, the specified violations;
- Add to § 438.700(a), after the word ''determination,'' ''based on findings from onsite survey, enrollee, or other complaints, financial audits, or any other means.'' This language clarifies that the State is authorized to act based on findings it has made, regardless of the source of the original information. Broad authority for the State to sanction on the basis of complaints provides enrollees with assurances that the State can hold the entity accountable for specific acts of noncompliance that enrollees or their advocates bring to the State's attention but that might not be evident on an onsite survey.

Response: We agree with the commenters that the sanctions in subpart I do not prevent States from imposing any other sanction they wish under State law, and that the regulations should clearly state that this is the case. We are adopting the commenter's suggested regulations text in a new paragraph (b) in § 438.702. We also agree that it would be useful to clarify that these sanctions may be imposed based on information obtained through enrollee complaints, audits, onsite surveys, or any other means and have added the commenter's suggested language to § 438.700(a).

We disagree with the commenters' suggestions that the list of sanctions in proposed § 438.700(a) be broadened or that the regulations provide for imposing the full range of possible sanctions in the case of any violation of section 1932 or 1903(m) of the Act. To the extent that a State is relying not on any State law, but solely on the affirmative authority enacted by the Congress in section 1932(e) of the Act, this authority is necessarily limited to that provided by the Congress. While we have broadly interpreted paragraphs (D) and (E) of section 1932(e)(2) of the Act to permit suspension of enrollment or payment for any violations of 1903(m) and 1932 of the Act (see § 438.700(d)) and the above discussion of proposed § 438.702(b), section 1932(e) of the Act does not contain authority to impose any of the other sanctions in section 1932(e)(2) of the Act for violations other than those enumerated in section 1932(e)(1)(A)(i) through (v) of the Act.

Comment: One commenter argued that we should amend § 438.700(a) to apply to PCCMs as well as to MCOs. This commenter does not believe there was a compelling argument for applying most sanctions only to MCOs. The commenter argued that PCCMs that fail to provide medically necessary services, misrepresent information provided to HCFA, the State, an enrollee, potential enrollee, or health care provider, or impose excessive premiums or charges on enrollees should be subject to sanctions. Another commenter strongly advised HCFA against drawing a

distinction between MCOs and PCCMs in granting the States authority to impose sanctions for inappropriate behavior. Other commenters also believe that the final rule should provide additional authority to impose sanctions on all MCOs and PCCMs and specifically suggested that the final rule gives States the authority to—

- Require noncompliant MCOs or PCCMs to submit a corrective action plan;
- Temporarily and permanently withhold capitation payments and shared savings in response to unsatisfactory MCO or PCCM performance during an annual medical review or an audited review;
- Make adjustments in MCO or PCCM payments;
- Mandate payment for medically necessary treatment;
- Recoup the cost of State payment for out-of-plan care from a noncompliant MCO or PCCM; and
- Arrange for the provision of health care services by third parties at the cost and expense of the delinquent MCO or PCCM.

These commenters believe that Medicaid beneficiaries in both delivery systems should receive equal protection under the law and that denying States equal authority for imposing sanctions under both delivery systems is not judicious. Conversely, one commenter found applying sanctions to PCCMs problematic because this would hold these entities to a higher standard. California PCCMs currently are not Knox-Keene licensed. This commenter was concerned that this section of the proposed rule may require PCCMs to become Knox-Keene licensed and/or their contracts may have to be amended to reflect the new higher standard.

Response: To the extent a State is relying solely on the Federal authority provided by the Congress as its authority to impose a sanction, this authority is limited to that which the Congress provided. With respect to the violations enumerated in paragraphs (i) through (v) of section 1932(e)(1)(A) of the Act, all but the marketing violations are limited to MCOs. We have already interpreted paragraphs (D) and (E) of section 1932(e)(2) of the Act broadly to permit the sanctions in those paragraphs to be imposed on PCCMs in the case of any violation of section 1932 of the Act. We do not believe that section 1932(e) of the Act can reasonably be interpreted to provide authority for the types of sanctions suggested by the commenter. Because most PCCMs are paid on a fee-for-service basis, they do not have the same incentives to deny medically necessary services that MCOs do. States may provide for sanctions against PCCMs under their own State sanction laws. With respect to the commenter concerned about applying sanctions to PCCMs, the Congress provided for this in section 1932(e) of the Act, and we do not believe that this application is inappropriate or would subject PCCMs to the Knox-Keene Act.

While States are free to adopt the specific additional enforcement strategies suggested by the commenter in the bullet points above, these strategies cannot be included in regulations implementing section 1932(e) of the Act, since there is no reasonable reading of the provisions of section 1932(e) of the Act that would authorize those remedies.

Comment: One commenter believes that HCFA should specify additional grounds for imposing intermediate sanctions and suggested that the final regulations explicitly state that States may impose sanctions when an MCO fails to comply with the grievance regulations of this part. States would be more likely to impose these intermediate sanctions rather than the options provided for in § 438.424.

Response: The sanction authority provided for by the Congress in section 1932(e) of the Act is limited. Section 1932(e) of the Act sets forth the minimum set of violations that must be subject to sanction and provides Federal authority to impose sanctions for these violations. We cannot expand on this authority by regulation. We have clarified in the preamble, and now in § 438.702(b), that States are free to impose sanctions under State law that go beyond those authorized by the Congress in section 1932(e) of the Act, including sanctions for failing to comply with grievance requirements. To the extent that an MCO violates the grievance requirements or regulations implementing section 1932(b)(4) of the Act, States could impose the limited sanctions provided for under paragraph (D) and (E) of section 1932(e)(2) of the Act and § 438.700(b).

Comment: One commenter believes that we should amend § 438.700(a)(1) to refer expressly to the failure to provide medically necessary ''items'' as well as services, since this term is included in section 1932(e)(1)(A)(i) of the Act. Alternatively, the commenter suggested that we use the term ''benefits'' rather than ''services,'' since the commenter believes that the former term would include services and items. For example, prescription drugs and durable medical equipment may not be considered ''services.''

Response: We do not use the term ''items'' in our regulations because the term ''services'' as used in the regulations includes covered ''items'' as well. While only the Medicare regulations expressly specify that ''services'' includes '' items'' (§ 400.202), section 1905(a) of the Act uses the term ''care and services'' to encompass all services or items for which Medicaid payment may be made. References in the regulations to ''services'' include covered ''items'' as well.

Comment: A few commenters were confused regarding our role in the sanction area. These commenters are unclear as to whether HCFA would be making sanction determinations, either at the request of the State or independently. The commenters are opposed to HCFA making sanction determinations without the involvement of the State.

Response: Under § 438.730 of the final rule, previously codified at § 434.67, we may impose sanctions on an MCO based on the recommendation of the State. Under paragraph (e) of § 438.730, we also retain the right to act independently with respect to sanctions. This is consistent with section 1903(m)(5) of the Act, which grants us the authority to impose sanctions against an MCO. This Federal authority was not affected by the new BBA sanction provisions in section 1932(e) of the Act. While we would not expect to impose sanctions without the involvement of the State, we believe that the regulations should reflect the fact that the Congress has authorized us to do so.

Comment: One commenter believes that additional consumer protections were needed with regard to the right to disenroll without cause when sanctions are imposed and that States should be required to educate enrollees on the circumstances that allow them to disenroll automatically. Another commenter requested that HCFA clarify that a State is free to suspend default enrollment, leaving beneficiaries to make an affirmative decision whether to enroll. Several other commenters suggested that HCFA further clarify this provision and give States the option of suspending all enrollment, not just default enrollment. According to the commenters, this clarification would not only provide States with greater flexibility but would also permit greater choice for Medicaid beneficiaries.

Response: Under § 438.702(a)(4) of the final rule, the State may suspend all new enrollment, including default enrollment, as an intermediate sanction. The State is not precluded from establishing other types of intermediate sanctions that are not included in the

regulation. With respect to the suggestion concerning information provided to enrollees, § 438.56(c) requires that information on an enrollee's disenrollment rights be provided annually, including the circumstances under which a beneficiary can disenroll ''for cause.''

Comment: Several commenters requested clarification that States still have the flexibility to establish civil money penalties beyond those listed in the regulation. One commenter specifically mentioned that the amounts of the civil money penalties seemed high but that they would not be problematic so long as the amounts were not mandatory. Another commenter mentioned that if PCCMs could be sanctioned, there should be a regulatory ceiling on the amount of the penalty.

Response: The amounts specified in this provision only apply to the extent the State is relying upon Federal law, under section 1932(e) of the Act, as its authority to act. States may, under State law, establish additional civil money penalties that may be more severe than those authorized under section 1932(e)(2)(A) of the Act or § 438.704. With respect to PCCMs, to the extent the State is relying on Federal law as its authority for the establishment of sanctions, the civil money penalties under § 438.704 would be maximum amounts. A State is not precluded from developing additional intermediate sanctions against PCCMs or MCOs, as explicitly noted in § 438.702(b).

Comment: One commenter believes that HCFA should provide additional guidance as to how the amount of the civil money penalty elected, in cases in which States have discretion to choose an amount below a specified maximum, should be related to the purported harm. The commenter believes that HCFA should provide some rationale for assessing money penalties and should discuss this section with the commenter to develop this rationale.

Response: Section 1932(e)(2)(A) of the Act establishes a relationship between the amount of the civil money penalty (as described in § 438.704 of the final rule) and the specific violations to which these penalties apply. In clauses (i) and (ii), ''maximum'' amounts are specified. We believe that by establishing a ''maximum'' amount for these violations, the Congress intended that States have the discretion to decide what amount to impose below these maximum amounts. We are allowing the States to decide the amount they wish to impose in penalties and to establish criteria for cases when particular amounts at or below the specified maximums will be imposed.

Comment: One commenter expressed confusion regarding the maximum penalty that can be imposed under section 1932(e)(2)(A)(iii) of the Act for imposing premiums or charges in excess of those permitted. Under section 1932(e)(2)(A)(iii) of the Act, for this type of violation, the penalty that can be imposed is double the amount of any excess amount charged to an enrollee with half this amount refunded to the overcharged enrollee or enrollees. The commenter asked whether this would be for the one enrollee who reported a $5 overcharge (that is, one $10 amount) or $10 per each enrollee in the plan. Another commenter suggested that the regulation should be changed to provide that it is the MCO's responsibility, not the State's, to return the amount of the overcharge to affected enrollees and that the authority to collect double the amount of the excess charge provides authority to collect more than the $25,000 limit stated in paragraph (a).

Response: Section 438.704(b)(4) of the final rule specifies that for premiums or charges in excess of the amounts permitted under the Medicaid program, civil money penalties may be imposed at an amount representing double the amount of the excess charges. This would be imposed for each instance of the violation and not necessarily calculated using the total number of enrollees in the plan. If all enrollees were charged the excess amount, this amount would be doubled for all enrollees. Since the State imposes and collects the entire fine, we believe that the State ordinarily would reimburse enrollees by distributing half the amount specified in section 1932(e)(2)(A)(iii) of the Act. We would leave it to the State's discretion, however, whether it wishes to reimburse enrollees through the MCO.

With respect to the commenter's last point about the applicability of the authority to impose $25,000 in penalties in cases of overcharges to enrollees, section 1932(e)(2)(A)(i) of the Act permits a civil money penalty of ''not more than'' $25,000 for ''each determination'' under section 1932(a)(1)(A) of the Act, ''except as provided in clause (ii), (iii), or (iv).'' We believe that this language could reasonably be interpreted in two ways. Under one reading, ''except as provided in clause (ii), (iii), or (iv)'' would be interpreted to mean that clause (i) has applicability only when the other three clauses do not apply. Under this interpretation, one would look solely to clause (ii), (iii), or (iv) to determine the amount that could be imposed in civil money penalties when those clauses apply. If the amount under section 1932(e)(2)(A)(iii) of the Act was $10,000, only this amount could be imposed in penalties. The commenter has suggested an alternative reading, under which the ''except as provided'' clause is read as an exception to the $25,000 limit in clause (i). Under this interpretation, civil money penalties of up to $25,000 could be imposed for any determination under section 1932(e)(1)(A) of the Act ''except'' to the extent that an even higher amount is permitted in the cited clauses. The $25,000 amount would, under this reading, constitute a ''floor'' authorized penalty with potentially higher ''ceilings'' under the other clauses. The $100,000 amount provided for under clause (ii) is higher than $25,000 and would constitute an exception to the $25,000 limit. The amount determined under clause (iv) would similarly be higher than $25,000, as long as just two individuals were denied enrollment based on health status (which would result in a penalty of $30,000). Under clause (iii), ''double the excess amount charged'' also could easily exceed $25,000, and thus also constitute an ''exception'' to the $25,000 limit in clause (i). We agree with the commenter that this latter interpretation is the best interpretation of the statute, in that a substantial penalty could be imposed for overcharging enrollees, even if the amount of the overcharge is not substantial. We are providing in § 438.704(b)(4) that States may impose civil money penalties of the ''higher of'' $25,000 or the amount under section 1932(e)(2)(A)(iii) of the Act.

Comment: Several commenters requested that HCFA reconcile the numerous variations between proposed § 438.704 and 42 U.S.C. 1396u2(e)(2)(A). The commenters suggested that the term ''either'' in proposed § 438.704(a) should be eliminated and replaced with the term ''any'' and that the words ''a failure to act'' in proposed § 438.704(a)(1) should be replaced with ''an act or failure to act.'' These changes would make it clear that the State is not being directed to respond to one circumstance at the expense of another and that noncompliance can be applied in both actions and failures to act.

Response: We agree with the commenter's points, and the revised version of § 438.704 does not contain the reference to ''failure to act'' without ''action,'' or the word ''either'' as referenced by the commenter.

Comment: Numerous commenters believe that we were too restrictive in our interpretation of the $100,000 cap for some of the civil money penalties

outlined in the proposed regulation. In the view of these commenters, the MCO should be fined $15,000 for each beneficiary not enrolled as a result of discrimination, plus $100,000. One commenter believes that there should not be a $100,000 cap at all, because in large areas that threshold is quickly met and enforcement could not proceed.

Response: Under section 1932(e)(2)(A)(iv) of the Act, the provision for a $15,000 penalty for each individual denied enrollment under ''a practice'' described in section 1932(e)(1)(A)(iii) of the Act is ''subject to'' section 1932(e)(2)(A)(ii) of the Act. Section 1932(e)(2)(A)(ii) of the Act limits the amount of any penalty for ''a determination under [section 1932(e)](1)(A) to $100,000.'' If section 1932(e)(2)(A)(iv) of the Act were intended to permit penalties in excess of $100,000 for a finding of discrimination under section 1932(e)(1)(A)(iii) of the Act, it would have said ''in addition to'' the amount in clause (ii) of section 1932(e)(2)(A)(ii). Instead, it says that the amount under section 1932(e)(2)(A)(iv) of the Act is ''subject to'' clause (ii). We believe this can only be read to mean that the total amount under clause (iv) is ''subject to'' the limit in clause (ii) and cannot exceed $100,000 per determination of a discriminatory practice. If there is more than one finding of a discriminatory ''practice described in'' section 1932(e)(1)(A)(iii) of the Act, a penalty of up to $100,000 could be imposed for each such finding.

Comment: All of the commenters oppose the required imposition of temporary management in the case of repeated violations. They believe that we should take a flexible approach to this provision, as it is unlikely that States would choose to impose this requirement, and in many instances this requirement would be overly burdensome. Most commenters indicated that States will be more likely to terminate an MCO's contract under these egregious circumstances in which our regulation requires the imposition of temporary management. Commenters stated that, putting aside the practical problems associated with such a remedy, they believe that a plan that is incapable of managing itself would be equally poorly run by temporary management. In the view of these commenters, this plan should have its contract terminated and should not be subject to the imposition of outside management in a probably futile attempt to salvage the operation. Another commenter stated that this provision is of great concern because the State should always have the authority to terminate the MCO's contract if the MCO meets any specified contract termination threshold. Forcing the State to continue a contractual arrangement and payment when the State has determined that termination is the most appropriate course of action strikes this commenter as imprudent. The imposition of temporary management may be very administratively complex if the State MCO licensing agency does not concur with this course of action, particularly when the MCO has lines of non-Medicaid business that would be affected. Requiring the State to work through the complexities of imposing temporary management when this does not appear to be the appropriate response would be very problematic to the State and have potentially negative ramifications for both enrollees and providers. One commenter believes that if it is appropriate for a State government agency to take over the management of a managed care plan, the appropriate agency would be the State Department of Insurance. That agency generally has far more experience in managing troubled insurers and managed care plans. The commenter recommended that HCFA convey these points to State agencies. Another commenter stated that temporary management requires extensive knowledge and should only be used sparingly. The commenter believes that the State should defer to the State insurance commissioner as temporary management should fall under his or her purview. One commenter would favor a change in the regulation to allow temporary management as an option rather than a mandate. Implementing this sanction would place a heavy administrative burden on the State. Although States would have the discretion to impose this sanction on an MCO, it is doubtful this sanction would ever be used. Authorizing the State to take over management of a commercial enterprise seems to go beyond the scope of authority available to the State, while allowing immediate disenrollment of enrollees is quite justified. The commenter also stated that it is not necessary to assume management of the MCO when other sanctions are available, including termination of the MCO's contract. This sanction is overreaching and invades the State's right to determine appropriate sanctions for its plans. Another commenter stated that in the event of continued egregious behavior by an MCO, the State would certainly terminate the contract and reassign enrollees but would not want to be put in the position of managing an MCO. Although this provision is based on statutory language, the commenter urged HCFA to recognize and to minimize the potential conflict with existing State insurance regulations, policies, and processes for monitoring and taking action against financially insecure plans. One commenter recommended that the regulations reflect the decision reached in the preamble, stating that States set the thresholds for egregious actions requiring temporary management and that the contract can be terminated rather than imposing temporary management.

Response: Section 1932(e)(3) of the Act provides that the State shall (regardless of what other sanctions are provided) impose the sanction of temporary management in cases in which an MCO has ''repeatedly'' violated section 1903(m) of the Act. To the extent that the commenters believe that the requirement in § 438.706(b) is inappropriate, their arguments are properly directed at the Congress, since this regulatory provision merely reflects the statutory requirement in section 1932(e)(3) of the Act and has no independent legal effect. We have no authority to alter or delete this requirement. We agree with some of the sentiments reflected in the above comments and intend to give States the maximum flexibility permitted by statute. The regulations permit the State to terminate a contract at any time and to do so rather than imposing temporary management. States are also free to establish a threshold in their State plan or otherwise that would have to be met before an MCO is considered to have ''repeatedly'' committed violations of section 1903(m) of the Act for purposes of the mandatory temporary management requirement in section 1932(e)(3) of the Act. Since the circumstances for each population and MCO vary greatly, we believe it is prudent to work with each State to determine a reasonable threshold. All States will have ample ability to terminate a contract, if they choose, rather than imposing the temporary management requirement.

Comment: Two commenters were concerned over the effect imposition of temporary management would have on the MCO's commercial enrollment. Another noted that, based upon the regulatory language, this provision could apply to an MCO that also has Medicare and/or commercial business. These commenters believe that this sanction provision raises serious practical concerns, especially with the lack of any due process protections other than written notice. One commenter recommended adding a new paragraph (c) to § 438.706 that says the

State shall develop criteria for who can serve as a temporary manager and shall maintain a list of individuals and entities meeting the criteria who are able and willing to serve in that capacity.

Response: We have no authority to change the requirement in § 438.706(b), since it reflects the statutory requirement in section 1932(e)(3) of the Act. States are free to develop the criteria suggested by the commenter or to maintain the list suggested. Since States are free to terminate a contract before it gets to the stage of a mandatory temporary management, and in keeping with our decision to grant States maximum flexibility in complying with section 1932(e)(3) of the Act, we do not accept the commenter's suggestion that these specific approaches be mandated. We note that for those situations in which temporary management would be mandated under whatever criteria the State develops, MCOs would have had ample warning through other intermediate sanctions and corrective action plans. Since States have the authority to terminate a contract instead of imposing temporary management, termination is more likely to be a State's sanction of choice, with MCOs receiving hearings prior to termination. Except for repeated section 1903(m) of the Act violations, the rest of this section is for use entirely at a State's option. Because we believe that States will be unlikely to exercise temporary management under § 438.706, we believe there should be no effect on an MCO's commercial or Medicare enrollment. In the unlikely event that a State takeover of management were to occur, we would expect States to take measures to limit the scope of their control to the parameters necessary to administer the Medicaid contract.

Comment: One commenter encouraged States to take into consideration the unique needs of children when determining the identification of egregious behavior and threats to enrollees and the number of offenses that would require imposition of temporary management.

Response: We encourage States to take the unique needs of children into consideration when determining when temporary management of an MCO is appropriate. We will take this into consideration when working with States that wish to develop thresholds of section 1903(m) of the Act violations.

Comment: One commenter appreciated being given the clear authority to impose temporary management on an MCO. Another group of commenters supported HCFA's guidance in § 438.706(a) regarding when the voluntary imposition of temporary management is appropriate. Voluntary imposition of temporary management is appropriate when the State finds through onsite survey, enrollee complaints, financial audits, or any other means that there is egregious behavior on the part of the MCO, substantial risk to enrollees' health, or the need to impose the sanctions to ensure the health of the MCO's enrollees.

Response: We appreciate the commenters' support and approval.

Comment: Numerous commenters were concerned over their perception of a lack of an adequate opportunity for MCOs to contest a State decision to impose a sanction. The commenters noted that while § 438.710(b) requires that a hearing be provided before a contract is terminated, § 438.710(a) requires in the case of other sanctions only that written notice be provided of the sanction and of any due process requirements that the State elects to provide. One commenter was concerned about a perceived lack of minimum procedures before the State can impose sanctions such as civil money penalties or suspension of new enrollment or payments. Another commenter had serious concerns about the absence of Federal procedural process requirements before the imposition of sanctions on MCOs. Based on the terms of the proposed rule, the State agency would have discretion to impose civil money penalties suspend new enrollment, and suspend payment without giving the MCO and PCCM an opportunity to present its views before the decision maker. One commenter believes that rather than denying the right to a hearing relative to the imposition of temporary management, as provided in section 1932(e)(5) of the Act, the entire concept should be reconsidered. One commenter suggested that minimum procedural safeguards should be included in these regulations but did not specify what these minimum safeguards should be. Another commenter recommended that HCFA require State agencies to ensure some form of procedural due process to be used prior to imposition of sanctions. Two commenters recommended that, at a minimum, MCOs be granted procedural safeguards that are the same or very similar to the procedural safeguards that HCFA has given Medicare+Choice organizations.

Response: We do not prohibit States from establishing the ''due process protections'' that they consider appropriate. As noted earlier, section 1932(e)(5) of the Act provides States with the discretion to make this decision, stating that '' * * * the State shall provide the entity with notice and such other due process protections *as the State may provide,* * * *'' (Emphasis added.) We believe it would be inconsistent with this provision to dictate that specific procedures be employed. We find one area in which our proposed rule goes beyond the requirements of the statute in potentially denying an MCO an opportunity to contest a sanction. Proposed § 438.710(b) of the Act provides that the State could not delay imposition of temporary management ''during the time required for due process procedures, and may not provide a hearing before the imposition of temporary management.'' (Emphasis added.) Section 1932(e)(5) of the Act provides for the State to afford ''due process protections,'' but precludes a State only from providing a ''hearing'' before imposing temporary management. In response to the above concerns, we have revised what is now § 438.706(c) to eliminate the reference to due process protections and to reflect the statute by prohibiting the State only from providing a hearing before imposing temporary management.

Comment: One commenter believes that when a contractor is terminated, adequate notice needs to be given to beneficiaries. The commenter recommended that we require timely notice to beneficiaries when States terminate an MCO or when an MCO withdraws from the program. This notice should include accurate information on options to enable beneficiaries to make informed choices among other available MCOs and PCCMs.

Response: We agree that Medicaid beneficiaries enrolled in an MCO or PCCM that is being terminated should receive timely notice of the termination with information on the options available to the beneficiary once the termination is effective. While the Congress provided in section 1932(e)(4)(C)(i) of the Act for notice to enrollees of a decision to terminate a contract, this notice is provided only when the State exercises its discretion to permit enrollees to disenroll immediately without cause before the termination hearing is completed. Section 1932(e)(4)(C)(i) of the Act clearly provides that States ''may'' provide such notice. We agree with the commenter that if a decision to terminate an MCO is upheld, and a termination is about to take effect, beneficiaries should be notified. Under section 1902(a)(19) of the Act, which requires that States provide safeguards necessary to assure that care and

services are provided in a manner ''consistent with * * * the best interests of recipients,'' we are adding § 438.710(b)(2)(iii) to require that notice of the termination be provided to enrollees of the terminated MCO or PCCM, with information on their options following the effective date of the termination.

Comment: We received one comment that stated that in order to avoid conferring an unintended defense to MCOs that meet the contractual standard for termination of the contract, we should specify that failure of a State to impose intermediate sanctions is no basis for objection or affirmative defense against a contract termination.

Response: States have the authority to terminate an MCO's or PCCM's contract without first having to impose intermediate sanctions, such as civil money penalties. If a State chooses not to impose intermediate sanctions before it terminates an MCO's or PCCM's contract, this action should not be used as an affirmative defense on the part of the MCO or PCCM against contract termination. We do not believe it is necessary or appropriate to make this statement in the regulation text itself.

Comment: Several commenters disagreed with the language in proposed § 438.718(a) that allows a State to terminate an MCO's or PCCM's contract if the MCO or PCCM failed ''substantially'' to carry out the terms of its contract. These commenters argued that the term substantially does not appear in section 1932(e)(4) of the Act, which is implemented in revised § 438.708, and severely restricts State flexibility in protecting Medicaid beneficiaries and the integrity of the Medicaid program. In the commenters' view, the added burden of proving substantial failure to comply is unnecessary and will add layers of litigation when a State seeks to terminate an MCO or PCCM. These commenters recommended removing the word ''substantially.''

Other commenters made the same point about our inclusion of the word ''substantially'' in proposed § 438.708, which implements the obligation in section 1932(e)(3) of the Act to impose temporary management in the case of repeated violations. Although the preamble indicates that we introduced the word ''substantially'' in order to allow States greater flexibility, there is no indication that the Congress intended for there to be greater flexibility in the application of this statutory requirement. These commenters argued that if the Congress had intended flexibility, it would not have made this provision ''mandatory'' in the first place, noted that this provision is the only mandatory requirement that sanctions be imposed, and noted that this provision is triggered only in instances in which the MCO repeatedly failed to meet requirements. These commenters found it difficult to understand why we would take what they considered the only mandatory sanction in the statute and attempt to give States greater flexibility.

Response: We agree that the word ''substantially'' is not used in section 1932(e)(4) or section 1932(e)(3) of the Act, is potentially ambiguous, and could create misunderstanding and enforcement problems. We included this term in proposed §§ 438.718(a) and 438.708 because we did not believe that termination or temporary management would be warranted for violations that are not substantive in nature, such as clerical or non-quality related reporting violations. In response to the above comments, in the final rule, we have changed ''substantially'' to ''substantive'' in both § 438.708(a) and § 438.706(b) as codified at § 438.708 in the proposed rule.

Comment: One commenter believes that the 30-to 60-day time frame for the termination hearing was insufficient and imposed an undue administrative burden. Another commenter recommended that the regulation provide notice of the intent to terminate 60 days before the effective date of the termination. The commenter also believes that the final regulation should establish criteria for when termination should be imposed and notice of when a termination decision has been made. A third commenter argued that this proposed requirement would impose a hardship on States because they are required to set the date and time for a hearing that the provider may not wish to have or be willing to attend. One commenter suggested that the termination notification should inform the MCO of its right to request a hearing and the procedures for doing so by phone or by mail. Upon the receipt of a hearing request, the State would be required to schedule the hearing not fewer than 30 or more than 60 days thereafter, unless the State agency and MCO or PCCM agree in writing to a different date.

Response: Because of legitimate concerns from many different parties, and in light of the fact that the Congress chose to provide States with their own discretion to establish due process protections, we are removing the time frames that were in the proposed rule and allowing the State to develop its hearing process and its timing.

Comment: We received several comments requesting that we require the pre-termination hearings be open to the public, since public disclosure is an important step towards ensuring accountability. These commenters stated that the Supreme Court has recognized the public policy value of having program participants most affected by an enforcement decision participate in an enforcement hearing, citing the Supreme Court's decision in O'Bannon v. Town Court Nursing Center, 447 U.S. 773 (1980). One commenter requested that we clarify who may participate in the hearing and the procedural rules that apply to the hearing. Another commenter recommended that States be required to provide potentially affected enrollees with the following: (1) written notice at least 15 days before the date of the pre-termination hearing and (2) information regarding how enrollees may testify at that hearing. Commenters stated that we should require that this notice be (1) written at no higher than a fourth grade level, (2) translated into the prevalent languages spoken by the population in the service area, and (3) accessible to persons with hearing and sight impairments.

Response: We believe that the above suggestions represent good ideas. With respect to the period prior to a decision following a hearing, the Congress has suggested that States should have discretion whether to notify enrollees of the proposed termination. Under section 1932(e)(4)(C) of the Act, the State ''may'' notify ''individuals enrolled with a managed care entity which is the subject of a hearing to terminate the entity's contract with the State of the hearing.'' We believe it would be inconsistent with Congressional intent to mandate notice at this time. We have required that notice to enrollees be provided if a decision to terminate is upheld in a hearing. Any notice the State sends to enrollees must meet the language and format requirements of § 438.10(b) and (c).

Comment: One commenter stated that sometimes it is necessary for the State to terminate a contract with a PCCM because, the PCCM has left the practice without notifying the State. In that situation, the proposed requirement for notice and hearing before termination would not allow the State to take immediate action and would cause hardship to enrollees whose access to medical care would be greatly hindered.

Response: While a State may not terminate a contract with an MCO or PCCM, unless the State provides a hearing before termination in the situation described by the commenter,

the statutory requirement for pre-termination hearing would not apply because the PCCM would have ''terminated'' the contract. Enrollees would not be adversely affected if the State gives them prompt notice and assists them to enroll in another MCO or PCCM or change to the fee-for-service program.

Comment: Several commenters recommended that we specify that States may inform enrollees of their right to disenroll any time after the State notifies the MCO or PCCM of its intent to terminate. Commenters stated that this section does not make clear at what point in the termination process States are required to notify enrollees. The commenters suggested that we explicitly require MCOs or PCCMs to provide both oral and written notification to enrollees and specify that this may be sent before completion of the hearing process. Steps should be taken to ensure that all people, including individuals with limited English proficiency, limited reading skills, visual impairments, or other disabilities are effectively notified. The final regulation should include adequate safeguards to ensure continuity of care during the time needed for enrollees to select another MCO or PCCM. Other commenters stated that this notification should be mandatory.

Response: Under § 438.722, the State may notify enrollees and authorize them to disenroll without cause at any time after it notifies the MCO or PCCM of its intent to terminate. The notice to enrollees must meet the language and format requirements of § 438.10(b) and (c). Section 438.62 requires the State agency to have a mechanism to ensure continuity of care during the transition from one MCO or PCCM to another or from an MCO or PCCM to fee-for-service. We have not required that notice be oral as well as written.

Comment: The State does not notify HCFA before imposing sanctions or once the sanction has been lifted. Why would HCFA need or want to be notified for each MCO infraction when it never has been in the past and has not needed the information? The commenter recommends that the requirement to notify HCFA of every sanction is not necessary and should be dropped.

Response: We agree that this would be burdensome. It is also unnecessary since we can access this information when needed. This requirement has been removed.

Comment: Many commenters recommended some level of public notification of imposition of sanctions. Some commenters stated that notice of the sanctions should be required to be given to current enrollees, by all enrollment brokers to potential enrollees, and to a newspaper of wide circulation in the area served by the MCO. Public information about the imposition of sanctions will contribute another layer of accountability to the extent members of the public, specifically the Medicaid population, are able to exercise choice among health care providers. Others stated that, although this section is an important provision to assist Federal oversight, enrollees, health care providers, and potential enrollees should also receive timely information concerning the following issues: (1) whether a specific MCO has been sanctioned, (2) the type of sanction, (3) the reason the sanction was imposed, and (4) what steps the enrollee can take to protect himself or herself. The independent enrollment assistant should provide potential enrollees with this information in both oral and written form, and the sanctioned MCO should be required to provide to current enrollees and health care providers in its network timely written information on sanctions. This requirement will ensure public access to critical information on quality of services. The State should also provide this information, upon request, to the general public. These notices should also meet the literacy recommendations discussed previously. Commenters further suggested that we add the following, ''prior to enrollment, the enrollment broker (or other entity conducting enrollment) shall provide each eligible recipient with information regarding which MCOs or primary care case managers have been sanctioned, the types of sanctions, and the reasons for the sanctions. In addition, this information will be publicly available, upon request, from the State.''

Response: In response to this and the preceding comment, we have revised § 438.724 so that, instead of requiring notice to HCFA, it requires States to publish public notice describing the intermediate sanction imposed, the reasons for the sanction, and the amount of any civil money penalty. We specify that the notice must be published no later than 30 days after imposition of the sanction and must appear as a public announcement in either the newspaper of widest circulation in each city with a population of 50,000 or more within the MCO's service area, or the newspaper of widest circulation in the MCO's service area if there is not, within that area, any city with a population of 50,000 or more.

Comment: Section 438.730 authorizes HCFA to impose sanctions directly on MCOs. Although this provision is authorized by the BBA, some commenters urged HCFA, except in extraordinary circumstances, to defer to States on the appropriateness of sanctions. They stated that such an approach is consistent with the roles performed by States and HCFA under the Medicaid program. The commenters were concerned about HCFA making sanction determinations without the involvement of the State and want clarification that sanctions will not be imposed by HCFA without involvement of the State.

Response: We already had sanctioning authority codified by § 434.67, which has been redesignated as § 438.730. We have no plans to deviate from our traditional role of deferring to States on the monitoring of day-to-day MCO or PCCM operations and their appropriateness. The regulation itself makes clear that our involvement would be based on the State's recommendation.

Comment: Several commenters suggested that HCFA should take a more proactive role in ensuring oversight and monitoring. The early implementation of mandatory Medicaid managed care has been plagued with problems. Neither the State nor HCFA has provided adequate oversight to protect beneficiaries. Managed care has clearly not lived up to its promise of providing quality care at lower costs. There is considerable doubt that it ever will. Unlike their wealthier counterparts, Medicaid beneficiaries cannot simply pay out-of-pocket if their managed care plan does not provide the care they need. Health care consumers across the nation are calling for greater accountability and oversight. This is extremely important to Medicaid beneficiaries. The commentors are deeply concerned that HCFA has placed too much of the oversight and enforcement responsibilities on the State Medicaid agencies. The Congress did not revoke HCFA's statutory authority to sanction MCOs or PCCMs. Although the regulations transfer much of this responsibility to the State, beneficiaries have little assurance that the State will adequately protect them, particularly since State Medicaid agencies do not have a good track record of oversight and enforcement. Reports by the GAO and OIG have called for greater Federal oversight and enforcement. This focus makes even less sense with the BBA changes than it did under preexisting authority. Why would a State interested in enforcing compliance recommend that HCFA impose a sanction that the State itself is authorized to impose? Why would a

State not interested in enforcing compliance recommend anything at all to HCFA? The proposed rule lacks any assurance that HCFA will act if the State fails to act. When will HCFA perform these functions, if they are not performed by the State? What would trigger HCFA action or will it be entirely at HCFA's discretion? Will HCFA monitor States' actions or failure to act? The commenters believe that this section should be rewritten to eliminate the State as a recommender of action to HCFA and to emphasize HCFA's independent authority to impose sanctions. As with States, the section should direct that sanctions can be imposed based on findings made through onsite surveys, enrollee complaints, financial audits, or any other means. The regulation should state that HCFA will automatically perform the functions articulated in § 438.730 if an MCO performs any of the following activities: (1) Fails to carry out the terms of its contract; (2) fails to substantially provide medically necessary services that it is required to provide; (3) imposes premiums or charges in excess of those permitted by law; (4) discriminates among enrollees on the basis of health status or requirements for health care services; (5) misrepresents information that is furnished to HCFA, the State, an enrollee, a potential enrollee, or managed care plan; (6) does not comply with physician incentive requirements; (7) distributes, either directly or indirectly, information that has not been approved by the State or that contains false or materially misleading information; (8) engages in any behavior that is contrary to any requirements of section 1903(m) or 1932 of the Act and implementing regulations; (9) places enrollee health at substantial risk; or (10) by virtue of its conduct, poses a serious threat to an enrollee's health or safety or both.

Response: We have always had independent authority to sanction MCOs but not the resources to monitor them individually. Our primary tools to influence State activities with its MCOs have been corrective action plans, specific performance actions, and denials of FFP.

Comment: Several commenters were concerned at the absence of guidelines or criteria that would be used by a State agency in determining the amount of sanctions and urge us to include these guidelines and criteria. There must be standards of reasonableness that would apply to ensure that MCOs are not arbitrarily subjected to sanctions that are excessive in comparison with the nature of the offense in question.

Response: We may not impose standards or criteria because the Federal sanctioning authority is completely a State option (other than temporary management) and we do not set criteria for States using State authority. Any extra requirements could have a chilling effect of discouraging the use of the Federal authority. The monetary amounts specified in § 438.704 are limits, giving MCOs protection against excessive fines. The only mandatory due process protections involve termination of the contract and are contained in the statute.

Comment: One commenter recommended deletion of § 438.730. The commenter stated that if the State believes that an MCO should be sanctioned, it is free to impose that sanction without HCFA involvement. The commenter also pointed out that the sanctions that HCFA may impose are the same sanctions available to the State.

Response: This section is a redesignation of § 434.67, which reflects authority granted through section 1903(m)(5) of the Act, part of the Social Security Act before enactment of the BBA. We have no authority to remove these provisions from the regulations.

Comment: Several commenters believe that HCFA should publicly report the number of times States have recommended that HCFA deny payment and the result of each of the recommendations. This information should then be updated regularly. Requiring that this information be made public and updated on a regular basis will help ensure the State's accountability to recipients and the public at large. Since a similar provision under § 434.67 has existed for several years, they would like HCFA to specify in the preamble the number of times States have recommended that HCFA deny payment and the result of each of the recommendations. They are concerned that this provision has not been implemented to the extent necessary to protect beneficiaries. They believe that information on the number of times States have recommended denial of payment is a critical element in determining how active States have been in monitoring compliance and protecting beneficiaries.

Response: We disagree that sanctions should be publicly reported. The existing longstanding sanction provision at § 434.67 does not require us to report to the public the number of recommendations by States for imposition of sanctions or actions resulting from the recommendations. We do not require regular reporting of sanctions that are imposed on MCOs through provisions of this final regulation because we do not want to discourage State use of sanctions. The preamble to this final regulation is not the appropriate place to report on activity related to the existing regulation.

H. Conditions for Federal Financial Participation (Subpart J)

Subpart J of the proposed rule set forth largely recodified versions of the regulations in part 434, subpart F. These regulations contain rules regarding the availability of Federal financial participation (FFP) in MCO contracts.

1. Basic Requirements (§ 438.802)

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

Comment: One commenter noted that proposed § 438.802(c) represents a more stringent standard than the long-standing standard in § 434.70(b), arguing that the proposed standard is ''much too onerous.'' The commenter noted that under § 434.70(b), FFP could be withheld if an MCO ''substantially fails to carry out the terms of the contract,'' while under proposed § 438.802(c), FFP is based on the MCO and State being ''in compliance'' with the requirements of the contract. The commenter argued that States may hesitate to incorporate special quality initiatives into their contracts anticipating that FFP will be withheld if State or plan (or both) are not in complete compliance.

Response: Like proposed § 438.802, § 434.70(a) provided that FFP was available in contract payments ''only'' for periods that the contract ''is in effect'' and ''[m]eets the requirements of this part,'' specifically including physician incentive plan requirements. Unlike proposed § 438.802, however, § 434.70(a) is also based on FFP on meeting ''appropriate requirements of 45 CFR part 74.'' Proposed § 438.802 dropped this latter condition. Proposed § 438.802 was less stringent than § 434.70. The commenter is focusing not on the contract's compliance with requirements but on the MCO's compliance with the contract. We agree with the commenter that § 438.802(c) imposes a stricter standard than § 431.70(b) and it was not our intent to put States and plans at higher risk of FFP withholding than they were before. In this final rule with comment period,

we have substituted ''substantial compliance'' for ''compliance'' in the Basic Requirements section, both in § 438.802(c) and § 438.802(b), regarding compliance with physician incentive plan requirements.

Comment: Several commenters argued that compliance with ADA and Civil Rights Act requirements should be added to § 438.802.

Response: Entities that contract with Medicaid are required to comply with both the ADA and the Civil Rights Act as well as all other applicable law and Federal regulation. As discussed above, in § 438.6 of this final rule with comment period, we have added language requiring that contracts expressly prohibit MCOs from discrimination based on race, color, or national origin and require compliance with all applicable State and Federal laws.

Comment: A commenter argued that there is an inequity in a system that certain States pay extremely high capitation rates for disabled populations (in which FFP is awarded) but do not provide for a comparable level of FFP to cover equivalent populations in other States. This commenter found general reason for concern about which populations different States are covering and the method by which different States are providing that care (fee-for-service versus managed care).

Response: Section 1902 of the Act requires that States provide medical assistance to certain mandatory groups and provide them with a certain specified minimum level of benefits. However, States have considerable latitude in deciding which other groups to cover and what levels of payment to set for their contracting MCOs, within the parameters of actuarial soundness and the rate setting requirements in § 438.6(c). It is the nature of a State run program for benefits to vary from State to State. However, as discussed above in section II. A, § 438.6(c)(1)(i)(B) requires that payment rates be ''appropriate for the populations to be covered,'' and § 438.6(c)(1)(i)(B)(3)(iv) requires that payment and cost assumptions be ''appropriate for individuals with special health needs.'' We believe that these requirements should ensure that payments are sufficient for disabled enrollees when they are enrolled in managed care contracts.

2. Prior Approval (§ 438.806)

Proposed § 438.806 was based on § 434.71 and provided that FFP was not available in expenditures under contracts involving over a specified financial amount ($1 million for 1998, adjusted by the consumer price index for future years) ''prior approved'' by us.

Comment: Several commenters believe that the $1 million figure for 1998 was too low, and one suggested raising it to a $5 million minimum.

Response: We do not have the authority to raise the threshold amount for required prior approval of contracts, which is stipulated in section 1903(m)(2)(A)(iii) of the Act.

Comment: A commenter suggested that this final rule with comment period clarify (1) that State or county-level purchasers will not be at risk because the State has not obtained the approval required under § 438.806 by the time the contract needs to be implemented and (2) that FFP is available retroactively if approval from the HCFA Regional Office is not secured by the time of the effective date of the contract.

Response: This rule does not change our existing interpretation of the prior approval requirement. For any contract that is implemented without first obtaining approval from the HCFA Regional Office, the State is at risk for FFP in payment for those services should the contract not be approved. The risk facing county-level purchasers is a question of the degree to which a State puts its own counties at risk within the context of State law and regulations. With regard to the related question of FFP retroactive to the effective date of the contract, the revision of § 438.806(b)(1) does not expand the scope of the original regulation. It merely adjusts upward the threshold amount for prior approval, which was $100,000 before the BBA raised the cost.

3. Exclusion of Entities (§ 438.808)

Proposed § 438.808 reflects the limitation on FFP in section 1902(p)(2) of the Act under which FFP in payments to MCOs is based. FFP payments are based on the State excluding from participation as an MCO any entity that could be excluded from Medicare and Medicaid under section 1128(b)(8) of the Act, that has a substantial contractual relationship with an entity described in section 1128(b)(8)(B) of the Act, or employs or contracts with individuals excluded from Medicaid. We received no comments on this section.

4. Expenditures for Enrollment Broker Services (§ 438.810)

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

- The broker is independent of any managed care entity or health care provider that furnishes services in the State in which the broker provides enrollment services.
- No person who is the owner, employee, or consultant of the broker or has any contract with the broker—
  - —Has any direct or indirect financial interest in any entity or health care provider that furnishes services in the State in which the broker provides enrollment services;
  - —Has been excluded from participation under title XVIII or XIX of the Act;
  - —Has been debarred by any Federal agency; or
  - —Has been, or is now, subject to civil monetary penalties under the Act.
- The initial contract or memorandum of agreement (MOA) or memorandum of understanding (MOU) for services performed by the broker has been reviewed and approved by HCFA before the effective date of the contract or MOA.

Comment: Several commenters expressed support for this provision and indicated that it is critical that the broker remain independent and unbiased.

Response: We appreciate the commenters support and agree that this provision is of great help in ensuring that beneficiaries are able to make informed choices.

Comment: One commenter suggested that we allow a ''de minimis'' exception for certain levels of stock ownership, especially in a publicly traded company. The commenter also suggested that HCFA rules preempt similar State rules to avoid excessive application of these rules.

Response: We believe that any degree of ownership, including any amount of stock in an MCO, PHP, or PCCM or other provider, by enrollment broker owners, staff, or contractors may create the potential for bias. That is why we are not providing for exceptions in § 438.810. Although section 1903(b)(4) of the Act and § 438.810 of the regulations set forth conditions that must be met to receive FFP, States have the prerogative to set rules more stringent than the Federal rules.

Comment: Some commenters believe that § 438.810 should include safeguards to protect Medicaid beneficiaries from false and deceptive advertising. A commenter recommended that, when brokers are used to enroll Medicaid beneficiaries into managed care, States should be required to assure that they have

accurate data about the Medicaid eligibles and the availability of MCOs, PHPs, or PCCMs and any subcontracting providers.

Response: We agree that it is important for States to provide enrollment staff with accurate information about Medicaid eligibles and about MCOs, PHPs, or PCCMs and their subcontracting providers. Sections 438.10(d) and (e) require that enrollees and potential enrollees be provided with names and locations of current network providers, including identification of those who are not accepting new patients. It also emphasizes that information must be sufficient to allow an informed decision. We believe that this addresses the expressed concerns. States or enrollment brokers must make efforts to provide the most accurate and current information available. State and broker data systems differ in their capabilities, and provider and eligibility information changes daily. We ordinarily address this issue during pre-implementation review and monitoring of mandatory programs.

Comment: One commenter believes that it is not necessary for us to approve initial enrollment broker contracts or memoranda of understanding because statutory limitations are straightforward, FFP is limited, and brokers must be independent. In this commenter's view, contract approval is not necessary to ensure compliance, since the threat of civil money penalties is sufficient.

Another commenter supported our decision to require prior approval of initial enrollment broker contracts but suggested that we provide additional guidance pointing to minimum qualifications of enrollment brokers.

One commenter acknowledged the need for contract review but suggested that we impose a 30 day time limit for review in order to avoid delaying contract implementation. Once this time had elapsed, the contract would be deemed approved.

Response: We have already reviewed some broker contracts and MOAs/MOUs on a voluntary basis. Much of the current review consists of technical assistance and advice about whether contracts contain legally required provisions, as well as assurances of quality and results of noncompliance. We intend to issue contract review guidelines for our staff.

We will not impose a time limit for review of contracts since it is impossible to assess workloads and the amount of time required for review. Once mandatory contract review is implemented, we will assess the length of time required for review and recommend time frames if necessary.

Comment: One commenter believes that fiscal intermediaries for State Medicaid programs face an inherent conflict of interest, because they are paid to process claims for traditional fee-for-service Medicaid programs, and assisting Medicaid beneficiaries to enroll in a managed care entity poses a threat to these agents' primary source of revenue. In this commenter's view, the intermediaries have a strong incentive to maintain the status quo. The commenter recommended that HCFA's rules should prohibit entities from serving as enrollment brokers for States in which they serve as fiscal intermediaries.

Response: We are aware that some fiscal intermediaries have adapted to the managed care environment by performing enrollment broker functions in some States. This is often convenient for States that already have fiscal intermediary contracts in place. Since enrollment brokering has become an additional line of business for some of these agents, we believe that the incentives for bias toward fee-for-service are minimal. In addition, we anticipate that States desiring to use fiscal intermediaries in the role of enrollment brokers would consider any inherent bias during the selection process.

Comment: One commenter asked about the applicability of this provision to a public entity in which eligibility and enrollment functions might occur in one division and other divisions might be responsible for purchasing or providing some Medicaid covered services. The commenter asked whether State ''conflict of interest'' regulations, if approved by HCFA, would satisfy the intent of this section. The commenter noted that if county government employees conduct enrollment and education, and counties are also directly involved in arranging for or providing Medicaid services directly, FFP would not be payable for the county employee's enrollment services. The commenter suggested that we define ''independent'' in such a way as to allow a county employee to conduct enrollment activities as long as the county has in place adequate safeguards to protect against conflict of interest. For example, if an employee conducting enrollment is employed under a separate division or department and is not subject to supervision or discipline by a separate division or department that conducts purchasing or operates an MCO, the commenter recommended that this be considered acceptable.

Response: The managed care enrollment function is an administrative function of the State. The State may choose to contract out this function, have it done by the State or local staff, or even allow MCO staff to perform this function. The example of a county eligibility employee performing enrollment activities when the county also provides services would violate § 438.810, thus precluding payment of FFP for the enrollment activities. The Medicaid eligibility function must always be performed by State or local staff. This function cannot be contracted out to other entities. If MCO, PHP, or PCCM enrollment is contracted out to an enrollment broker, defined as an entity or individual that performs choice counseling and/or enrollment activities, the broker may not have any connection to or interest in any entity or health care provider that provides coverage of services in the same State. An enrollment broker might be a public or quasi-public entity with a contract or MOA/MOU with the State or county. In this situation, this entity may not furnish health care services in the State. For example, a State may not contract with or have an MOU with a county health department to do managed care enrollment or choice counseling because the health department provides health services. A community organization that provides health services in the State, for example, an organization providing health care to homeless individuals, may contract or subcontract to perform outreach and education, but not enrollment and choice counseling functions. An MCO, PHP, PCCM, or other health care provider that provides services in a State may not also have an interest of any sort in an organization performing Medicaid enrollment or choice counseling. This restriction is based upon the statutory language contained in section 1903(b)(4) of the Act.

In § 438.810(b)(1) of this final rule with comment period, we have clarified that an enrollment broker would not meet the test for independence if it is an MCO, PHP, PCCM or other health care provider, or owns, or is owned by an MCO, PHP, PCCM, or other health care provider in the State in which the broker operates.

A State's conflict of interest regulations ordinarily address situations in which a State or local officer, employee, or agent has responsibilities related to the awarding of contracts. Conflicts of interest involving Medicaid officials have long been prohibited under sections 1902(a)(4)(C) and (D) of the Act. This language prohibits conflict of interest by current or former State and local officers, employees, or independent contractors responsible for

the expenditure of substantial amounts of funds under the State plan. The conflict of interest language in § 438.58 applies to State and local officers and employees and agents of the State who have responsibilities relating to MCO contracts or the default enrollment process. Conversely, it specifically prohibits conflict of interest in any Medicaid managed care contracting activities, including enrollment broker contracting. Section 438.810 specifically addresses situations in which a relationship between a health care provider and an individual or entity responsible for choice counseling or enrollment may be biased by that relationship. While conflict of interest provisions would be expected to be in place in the State, § 438.810 covers an additional situation in which potential conflict of interest might influence a Medicaid recipient's choice of plan.

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

Proposed § 438.812 was transferred in its entirety from previous §§ 434.74 and 434.75 and was unchanged in the proposed rule. Proposed § 438.812 provides that States receive Federal matching for all costs covered under a risk contract at the ''medical assistance'' rate, while under a nonrisk contract only the costs of medical services are matched as ''medical assistance,'' and all other costs are matched at the administrative rate.

Comment: One commenter believes that we should provide additional guidance on what constitutes the ''furnishing of medical services'' as described in § 438.812(b)(1). The distinction between what is administrative and what is a medical service is becoming less clear in this commenter's view.

Response: We do not believe additional clarification in the regulations text is necessary. The costs of medical services are the payments made to providers for furnishing services covered under the contract. In the case of fee-for-service Medicaid, this would be the State plan payment amounts. These costs could either be in the form of payments to providers (fee-for-service, per diem, or capitation) or ''salary'' in the case of an employee. Administrative costs would include member services, claims processing, coverage decisions, and other activities that would be matched as administrative costs under fee-for-service Medicaid.

Comment: One commenter noted that the proposed rule discussion of § 438.812 did not address the Federal medical assistance percentage (FMAP) that States receive for services provided to American Indians by the Indian Health Service (IHS) and tribally operated programs. The commenter believes that the regulation should specifically address how the special matching rate for eligible IHS services will be applied and the State role in assuring that standards are met.

Response: We agree that the FMAP rate for services provided to Indians by IHS or tribally operated programs applies whether the IHS or tribal facility operates in fee-for-service or managed care. There is no need to change this regulation since, when applicable, this special FMAP rate is the ''medical assistance'' rate in that case. The regulation differentiating FMAP rates for risk and nonrisk contracts would not prohibit or in any way modify the matching rate that is required for IHS or eligible tribal facilities. Section 438.812 simply recodifies longstanding regulations and does not involve or affect HCFA policy on the application of the FMAP for IHS services in the managed care context.

In response to this and other comments received, we want to reemphasize that tribal and IHS providers are not necessarily required to be licensed by a State as long as they meet the State's or MCO's qualifications. We believe that the definition of provider in § 400.203 will ensure that these providers are not inappropriately excluded from participation in Medicaid managed care programs.

6. Condition for Federal Financial Participation (FFP) in Certain Contract Arrangements (§ 438.814)

As discussed in detail in section II. A of this regulation, this new section reflects the condition for FFP in contracts that contain incentive arrangement or risk corridors. As described in new § 438.6(c)(5) on rate setting for risk contracts, FFP is only available in these contracts to the extent that payments do not exceed 105 percent of the payment rate determined to be actuarially sound.

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

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

1. Guaranteed Eligibility

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

Comment: One commenter observed that the provision in the proposed rule is inconsistent, authorizing guaranteed eligibility for individuals enrolled in any MCE (MCO or PCCM) in the introductory text of the section, while limiting the authority to MCOs elsewhere.

Response: Using both terms in the proposed rule was an inadvertent error. We have clarified this issue by using the terms MCO and PCCM throughout the final rule, as intended by the BBA.

2. Definition of PCCM Services (Proposed § 440.168)

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

Proposed § 440.168(a) set forth the definition of primary care case management services, for case

management related services that include ''location, coordination, and monitoring of primary health care services,'' that are provided under a contract between the State and either (1) an individual physician (or, at State option, a physician assistant, nurse practitioner, or certified nurse-midwife), or (2) a group practice or entity that employs or arranges with physicians to furnish services. Proposed § 438.168(b) provided that PCCM services may be offered as a voluntary option or on a mandatory basis under section 1932(a)(1) or a section 1115 or 1915(b) waiver.

Comment: One commenter expressed concerns about any form of required case management.

Response: Current law, through freedom of choice waivers under sections 1915(b) and 1115 of the Act, has for many years permitted States to require that Medicaid beneficiaries obtain their care through PCCM programs. Section 4702 of the BBA provided States additional flexibility by adding PCCM services to the list of optional Medicaid services. This allows States, at their option, to provide quality health care services and to enhance access to Medicaid beneficiaries through an arrangement that has proven to be cost effective to the Medicaid program. In addition, this section sets forth new requirements for contracts between primary care case managers and the State agency that provide important protections for beneficiaries and ensure access to quality health care. We believe that these protections, along with other beneficiary protections provided for in this final rule, adequately address the commenter's concerns.

3. Timeliness of Provider Payments (Proposed § 447.46)

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

Comment: One commenter objected generally to the requirements in proposed § 447.46, while another argued that the provision for developing a mutually agreed upon alternative payment schedule between an MCO and provider would not resolve the issue of timely payments. This commenter recommended that the timely payment provisions should provide that payments must be made in a manner consistent with State law, or, in the absence of a State requirement, in accordance with requirements in Federal regulation. This commenter did not believe that MCOs should be free to negotiate alternative arrangements. Another commenter contended that delayed payments for both managed care and fee-for-service programs have long been a problem in State Medicaid programs. This commenter felt that physicians, hospitals, and health systems should be paid for the covered services they provide to Medicaid beneficiaries in a timely manner, and that chronic payment delays by Medicaid programs and plans discourage physician and provider participation, are disruptive to the patient-physician relationship, and could adversely affect patient access. This commenter recommended that HCFA adopt a standard that would require payment to health care providers within 14 days for uncontested claims which are filed electronically and within 30 days for paper claims which are uncontested. In addition, the commenter recommended that for capitated payment systems, HCFA should require MCOs to make capitated payment to physicians and providers shortly after the beneficiary's enrollment, and also promulgate a standard time frame for payments by States to physicians and other providers of services under Medicaid fee-for-service programs.

Response: Congress was very specific in section 1932(f) to incorporate the standards set forth in section 1902(a)(37)(A), and provide that parties could also agree to an alternative payment schedule. We do not have the discretion to change the timeframes in section 1902(a)(37)(A), or to eliminate the right to negotiate an alternative schedule, as these are mandated by statute. We note that if an alternative payment schedule is established, it must be stipulated in the contract according to § 447.46(c)(3). The statute does not address the timing of capitation payments, which we believe should be negotiated between the parties.

4. Miscellaneous Preamble Comments

a. Effective Date of the Final Rule

In the proposed rule, we stated our intention to make the final rule effective 60 days following publication. However, those provisions which must be implemented through contracts would be effective for contracts entered into or revised on or after 60 days following the effective date, but no longer than 12 months from the effective date.

Comment: Several commenters asked us to clarify or revise the proposed effective date. In particular, the commenters were concerned that adequate time was not allowed for implementing the many changes proposed in the regulation. One commenter suggested that HCFA give States an additional year from final publication of the regulation to bring contracts into compliance. Another commenter recommended that HCFA consider allowing States at least 120 days to implement the final regulation.

Response: In recognition of the significant changes within this final rule, we have set the implementation date of this final rule to take effect 90 days following publication. Although we believe that it is important to provide BBA protections as soon as possible, we believe that changing the effective date will help to ease the State burden of implementing these provisions. Further, those provisions of the final rule that must be implemented through contracts with MCOs, PHPs, HIOs or enrollment brokers must be reflected in contracts entered into or revised on or after 90 days following the publication date, but no longer than 12 months from the effective date. Because a substantial number of the provisions of the final rule are implemented through contract revisions, the effective date for many provisions will be delayed in many States. Of course, some provisions in this final 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.

b. Absence of FQHC and RHC Provisions in the Proposed Rule

Comment: Several commenters requested that HCFA address the new FQHC and RHC reimbursement requirements set forth in section 4712(b) of the BBA. One of the commenters was concerned that unless these provisions were included in the regulation there would be no mechanism to ensure State

and MCO compliance. The commenter acknowledged that HCFA had undergone a process to inform State Medicaid Directors of their new obligations under the BBA through a series of letters. However, without this requirement in the regulation, the commenter was concerned that both MCOs and States would disregard the Federal statutory protections intended to preserve FQHCs and RHCs as vital Medicaid providers. Moreover, the commenter argued that regulations have the force of law, whereas States have challenged in the past whether they are legally bound by guidance in letters to State Medicaid Directors. By placing these requirements in its regulations, the commenter believed that HCFA could ensure that States or MCOs that fail to comply with BBA's requirements would be subject to sanctions by HCFA. The remaining commenters questioned HCFA's interpretation of the FQHC/RHC statutory provision and believe that this area should be clarified in regulation and open to public comment.

Response: This rulemaking primarily implements Chapter 1 of Subtitle H of the BBA, titled ''Managed Care.'' The provisions relating to FQHC/RHC payment are set forth in Chapter 2, ''Flexibility in Payment of Providers,'' and thus arguably are outside the scope of this rulemaking. Even if this rule were the appropriate vehicle for regulations implementing these FQHC/RHC provisions, we do not believe that such regulations would be warranted. The rules in question are ''transitional'' in nature, as the 100 percent cost payments described will eventually be phased out over the next several years. We do not believe it appropriate to promulgate regulations that will be obsolete in a relatively short period of time.

Moreover, we do not believe regulations are necessary, as the statutory requirements are straightforward and self-implementing, and HCFA has provided guidance to all States, through State Medicaid Director Letters on April 21, 1998 and October 23, 1998, on FQHCs and RHCs. We disagree with the commenter that there is no ''enforcement mechanism'' for these requirements. The requirements in question, as interpreted by HCFA in State Medicaid Director Letters, are fully enforceable. A State that fails to fulfill its obligations under section 1902(a)(13)(C)(ii) to make required quarterly supplemental payments to FQHCs/RHCs that subcontract with MCOs would be subject to a compliance enforcement action under section 1904. If an MCO fails to comply with section 1903(m)(2)(A)(ix) by paying at least what it pays other providers, HCFA would disallow Federal financial participation (FFP) in payments under the MCO's contract. Thus, the FQHC/RHC requirements in question are self-implementing and fully enforceable. HCFA's interpretations of these requirements are also enforceable, and entitled to deference from courts.

c. General Comments on the Proposed Rule

Comment: Several commenters supported HCFA in its implementation of the BBA, and were pleased to see the proposed rule reflect many of the recommendations from the Consumer's Bill of Rights and Responsibilities (CBRR). These commenters also believed that the proposed rule was a thoughtful implementation of the BBA provisions, which adequately reflected the intent and hope of the Congress and provides functional guidance to States without becoming overly burdensome or demanding. Other commenters believed that the regulation is a positive step toward improving quality for Medicaid beneficiaries in managed care and that the regulation is brief, simple and written at a readable level.

However, several other commenters criticized HCFA for creating regulations that they perceived as overly burdensome that did not allow sufficient State flexibility. These commenters also argued that the proposed regulations went beyond the statutory intent and authority of the BBA, and that the regulations would lead to increased administrative costs for Medicaid MCOs. These commenters believed that HCFA was micro-managing its approach to Medicaid managed care, and the proposed regulations, if finalized, would make it increasingly difficult for State Medicaid agencies to provide access to quality health care through MCOs, since MCOs would not be willing to participate. Another commenter believed that the proposed regulations did not reflect the approach of a purchaser, but the approach of a unilateral regulator particularly with respect to the CBRR and other beneficiary protections.

Response: The regulation was developed to provide States with an appropriate level of flexibility that we believe to be consistent with necessary beneficiary protections. Thus, State flexibility had to be balanced against statutory requirements of the BBA, and a Presidential directive that required Medicaid program compliance to the extent permitted by law, with the recommendations in the CBRR. In response to specific comments regarding the over-prescriptiveness or burden of certain provisions, we have made some changes to promote even greater flexibility, and also added requirements in response to other commenters. Further, the regulation has been designed to provide a framework that allows HCFA and States to continue to incorporate further advances for oversight of managed care, particularly as it pertains to beneficiary protection and quality of care. With respect to HCFA's statutory authority, we summarize each provision of the effected regulations followed by our response.

Comment: In general, a few commenters were concerned that what they believe to be over-prescriptiveness of the regulation would result in MCOs leaving the Medicaid managed care market. These commenters believed that the prescriptive mandates of the regulation would limit and hinder negotiations with MCOs, because of the additional requirements that would have to be met for Medicaid members as opposed to commercial members. As a result, the commenters argued that these requirements would be administratively burdensome for MCOs. In addition, the commenters believed that the financing of these administrative requirements was so inadequate MCOs would be forced out of the Medicaid market due to financial reasons.

Response: We will be reviewing this issue as we are also concerned about the continued viability of MCOs in the Medicaid managed care market. However, we also recognize the importance of quality care and consumer protections for Medicaid beneficiaries enrolled in Medicaid managed care and are unwilling to sacrifice these very necessary protections. In this final rule we have also revised the upper payment limit requirement, which may result in increased levels of funding for MCOs.

d. Beneficiary Protections in FFP

Comment: Commenters expressed concern that the proposed rule did not extend its numerous beneficiary protections to the fee-for-service (FFP) delivery system, and that many of the protections within the regulation have no corollary protections in FFP. The commenters noted that in FFP Medicaid, there were no rights afforded to providers who will coordinate care, nor was there adequate quality assurance activities, information on participating providers, or detailed grievance procedures. The commenters believed that the proposed regulation makes it difficult to make meaningful comparisons between FFP and managed care. Another commenter felt that the proposed rule did not adequately

recognize that managed care is not the only system that States will be using to provide health services to beneficiaries, as many States will continue to operate a FFP system. The commenter believed that it is the clear intent of Federal legislation that all Medicaid beneficiaries should receive the same protections and advantages without respect to the type of provider that is under contract. Therefore, in the commenters opinion, the regulations that apply to MCOs should also apply to the State Medicaid agencies in their operation of FFP systems.

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

e. Use of Examples in the Preamble

Comment: Some commenters were concerned over the use of examples in the preamble to the September 29, 1998 Notice of Proposed Rule Making (NPRM) and the potential applicability of these examples in a court of law. These commenters requested that HCFA clarify that the examples in the preamble to the proposed rule would not be standards enforceable by law. They believed that the use of examples could lead to unintended interpretations of the final rule. One commenter suggested that HCFA make a clear statement ''that the preamble that accompanied the proposed rule was intended to spark discussion, not provide guidance for further interpretations.''

Response: The examples provided in the preamble to the NPRM were intended to be just that, examples. They were included in the preamble discussion to provide options for States when implementing the provisions within the proposed rule. We did not include these examples in the regulation text itself, as they were intended to be illustrative in nature and States always retain the flexibility to deviate from these examples.

f. Consistency with Medicare

Comment: Several commenters disagreed with our guiding principle that, where appropriate, we would promote consistency with the Medicare+Choice program in developing this regulation. One commenter argued that the Medicaid statute is not designed to promote consistency with Medicare. The commenter did not believe that consistency between Medicare and Medicaid is a valid reason to deviate from the principle of State flexibility. The commenter believed that Title XIX provides Federal funds for various State medical assistance programs that are to be administered by States within broad Federal rules, and noted that those Federal rules, as found in Title XIX, contain no general requirement for consistency with Medicare. The commenter further noted that the preamble to the proposed rule also states that ''the regulations were written to support State agencies in their role as health care purchasers * * * and * * * to provide State agencies with the tools needed to become better purchasers.'' The commenter found this to be a ''paternalistic'' approach, which in the commenter's view was inconsistent with the nature of the Medicaid program as one administered by States within broad Federal rules. Portions of the proposed regulations intended to ''support'' States as health care purchasers, but which do not implement any requirement under Title XIX, should in the commenter's view be issued as guidance or advice to States, not as additional requirements in Federal regulations. Finally, the commenter found the ''uniform national application'' of ''best practices,'' as defined by HCFA, to be inconsistent with the nature of the Medicaid program as one administered by States within broad Federal rules.

Several other commenters, however, supported the guiding principle of consistency with the Medicare+Choice program, and believed that it would help relieve the administrative burdens imposed on MCOs, because to the extent that the Medicare and Medicaid programs are consistent with each other, administrative efficiencies result. The commenters also felt that establishing uniform industry standards was beneficial not only to MCOs and primary care case managers, but also for consumers receiving services and providers who contract with those MCOs or primary care case managers to deliver health care services. The commenters commended HCFA for recognizing that while it is imperative that there be consistency and uniform application of standards, some areas require a unique approach by States; as a result, the commenters support HCFA's efforts to allow States the flexibility in developing such programs.

Response: It was our intent to create consistency with Medicare+Choice program requirements in order to ensure that the managed care industry would not have to comply with multiple sets of standards. However, where there was a clear need for State flexibility or where consistency with the Medicare+Choice program was not appropriate for Medicaid managed care, we deviated from Medicare+Choice policy. We believe that this final rule effectively balances the need for flexibility and consistency, while providing States with the broad tools they need to become more efficient purchasers of health care. As we developed this final rule, we continued to work with our Medicare colleagues to coordinate changes to provisions in this final rule that had counterparts in the Medicare+Choice regulations. While we have promoted uniform national application of knowledge and best practices learned, the Medicaid statue has always given States the flexibility to design their own Medicaid programs.

g. Applicability of BBA Provisions to Waiver Programs

Section 4710(c) of the BBA provides that nothing in the managed care provisions of the BBA (Chapter 1 of subtitle H) shall be construed as affecting the terms and conditions of any waivers granted States under section 1915(b) or 1115 of the Act. The Conference Report on the BBA clarifies that this exemption is intended solely for waivers that are approved or in effect as of August 5, 1997 (the date of enactment). We indicated in the preamble to the proposed rule that we interpreted this exemption to apply to 1915(b) waivers only for the period of time for which a waiver has been approved as of August 5, 1997, at which time the State would be required to comply with the BBA provisions. In the case of waivers under section 1115 demonstration projects approved as of August 5, 1997, the terms and conditions are similarly ''grandfathered'' under section 4710(c) of the Act only for the period of time for which the waivers were approved as of August 5, 1997. However, unlike section 1915(b) waivers, these demonstration projects are subject to another BBA provision that affects the applicability of BBA managed care provisions. Section 4757 of the BBA added a new section 1115(e), providing for a three year

extension of demonstrations if certain conditions are met. If a section 1115 demonstration approved on or before August 5, 1997 is renewed under the terms of section 1115(e), the terms and conditions that applied on the last day approved under the original demonstration remain in effect during the three year extension period. Thus, if terms inconsistent with the BBA managed care provisions were still in effect by virtue of section 4710(c), these terms were extended for three years if there an extension was granted under section 1115(e).

Comment: Many commenters felt that HCFA's interpretation of section 4710(c) as applicable only for periods for which waivers were approved on August 5, 1997 was inconsistent with the commenters' view of the intent of this provision. These commenters felt that States had developed specific provisions of their waivers and demonstrations to address specific issues within the State, doing so in consultation with all appropriate stakeholders, and that to require changes in the programs now would result in confusion for enrollees and providers, disruptions in the delivery system, and increased administrative costs for both the States and health plans.

Response: We disagree with the commenters' view of this provision. Language in the Conference Report on the Balanced Budget Act of 1997 specifically states the intent of Congress as limiting the exemption contained in section 4710(c) to waivers ''either approved or in effect'' as of the date of enactment. Since section 1915(b) waivers are specifically limited by statute to no more than 2 years and section 1115 demonstration waivers are typically granted for periods of no more than 5 years, the waiver which is ''approved'' or ''in effect'' as of the date of enactment expires at some point thereafter. While States may request renewals of section 1915(b) waivers for up to 2 years, these additional waiver periods cannot be seen to have been ''approved'' or ''in effect'' on August 5, 1997. This is similarly the case with respect to standard extensions of a section 1115 demonstration approved after August 5, 1997. As explained above, however, in this latter case, a totally separate provision of the BBA created section 1115(e) of the Act, that requires the terms and conditions in effect on the date before a section 1115 demonstration would otherwise expire be extended for three years. Section 1115 demonstrations that do not qualify for an extension under the authority in section 1115(e)(1) do not maintain the same exemption, and would be subject to all BBA provisions in effect at the time of the expiration of the 1115 authority approved as of August 5, 1997 (in the absence of new waiver or matching authority under section 1115(a) exempting a State from BBA requirements).

We have provided some flexibility to States in phasing in BBA requirements by permitting exemptions for any provisions 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, rather than limiting the exemption solely to specific ''Special Terms and Conditions'' negotiated between HCFA and the States. We believe that HCFA has balanced the need to implement important beneficiary protections contained within the BBA with the flexibility that States need to effectively phase-in these requirements in programs designed to meet specific needs within the State.

Comment: Some commenters felt that the terms and conditions agreed to by HCFA and the State should continue to be the applicable rules under which a waiver program is operated.

Response: As indicated above, not only the special terms and conditions, but any other policies, procedures or protocols approved by HCFA will remain in effect for the period the State is entitled to an exemption under this provision. With the exception of section 1115 demonstrations extended under section 1115(e) of the Act, we believe that Congress limited this exemption to the time period of the waiver approved or in effect as of August 5, 1998.

Comment: Several commenters argued that the BBA provisions were intended to apply to managed care programs established under State plan amendments authorized by section 1932(a) of the Act, and should not apply at all to waiver programs.

Response: The BBA provisions on managed care in sections 4701 through 4710 of the BBA that are limited in their application to mandatory managed care under the State plan contain a specific reference to that section of the Act. Both the definition of PCCM services in section 1905(t) (in section 1905(t)(3)(F)), and section 1903(m)(2)(A), in the case of MCOs, require compliance with applicable provisions in section 1932. Thus, when a provision in section 1932 applies to an MCO or MCE, and is not limited to a program under section 1932(a)(1), it applies regardless of the authority under which the managed care program in which they participate operates. Thus, these provisions apply to all types of managed care—voluntary or mandatory, State plan or waiver.

Comment: Some commenters felt that HCFA inappropriately limited this exemption by applying it only to provisions that were ''specifically addressed'' in approved State documents, rather than to the entire waiver program.

Response: We believe that we have adopted a broad interpretation of the applicability of section 4710(c). Section 4710(c) states that the managed care provisions shall not be construed to affect the ''terms and conditions'' of waivers. As noted above, this could have been interpreted to apply only to provisions set forth in actual formal ''terms and conditions.'' We have interpreted this to refer to anything addressed in the State's approved waiver materials. In such cases, no determination need be made as to whether the State's policy or procedures meet or exceed the BBA requirement during the duration of the waiver period approved as of August 5, 1997 (or an extension under section 1115(e) in the case of a section 1115 demonstration). We note that the BBA contains provisions such as fraud and abuse protections, some of the quality provisions, a prudent layperson's definition of emergency, and the extension of guaranteed eligibility to PCCMs, which would not usually be addressed in a State's waiver materials. We believe it is important to implement these provisions which can provide beneficiary protections beyond that already provided for in a State's waiver.

Comment: One commenter questioned the impact of this exemption on a State which is phasing-in a waiver on a county-by-county basis, where parts of the State would be exempt from BBA requirements, while other parts of the State would be subject to them.

Response: A State that is phasing-in a waiver which was approved prior to August 5, 1997 maintains exemptions from the BBA for the whole service area of its waiver program as it is implemented, not merely the areas which were implemented prior to that date. The language in the Conference Report provides the exemptions for any waiver which is ''approved or in effect.''

Comment: One commenter believed that HCFA should provide additional clarification as to how this exemption from BBA provisions applies to section 1115 demonstrations.

Response: HCFA Regional Offices have been working with section 1115 States to identify those areas that need to come into compliance with BBA provisions. These decisions will have to be on a State-by-State basis, determined

by the specific provisions in effect in each State's waiver program. Once HCFA has determined which BBA provisions apply and which do not apply, the exemptions will remain in place until the current approved period of the waiver expires, or if it is extended under section 1115(e), the end of the three year extension. At this time States will need to come into compliance with all BBA provisions that are currently in effect. The only exception is for a State that receives an extension of its section 1115 authority under section 1115(e)(1) which, as indicated above, requires the same terms and conditions to be in place when the waiver is extended for up to three years.

Comment: One commenter felt that the BBA provisions should be applied immediately to all new and existing waiver programs.

Response: Section 4710(c) provides that nothing in the BBA provisions on managed care ''shall be construed as affecting the terms and conditions of any waiver . . . under section 1115 or 1915(b) of the Social Security Act.'' We believe that this language precluded us from applying these provisions in an inconsistent manner with such waiver terms and conditions.

h. Comments Relating to American Indians and Alaskan Native Populations

Comment: We received several comments that specifically addressed the relationship of the proposed regulation to the American Indian and Alaskan Native (AI/AN) populations. Most of the commenters were concerned that the tribal health care systems would be drastically impacted by the proposed regulation. Because of this impact, one commenter recommended that the Indian Health Service (IHS) and the tribal system be exempted from the proposed regulations, and that we consult with IHS and tribal organizations before including them in the proposed regulations. Another commenter indicated that States should recognize the inherent sovereignty of Indian Tribes and Nations and the special status of health programs for American Indians under Federal law. This commenter recommended that States implementing Federal programs need to develop a consultation policy that ensures tribal participation in developing health care programs. Another commenter stated that the proposed regulation showed concern for consumer protection in general, but gave little attention to the specific needs and circumstances of AI/AN consumers and Indian health providers. In the commenter's opinion, the best way to ensure that this happens is to require States to engage in meaningful tribal consultation. Several other commenters specified that the proposed rule does not mention or discuss the special relationship that exists between the United States and its indigenous peoples, namely American Indians, Alaskan Natives, Aleuts, Eskimos and Native Hawaiians. These commenters believed that it is important to specifically include language that acknowledges this relationship and allows the Federal government to provide services for these groups. This would be done not on the basis of race or ethnicity, but rather upon the Federal government's historical relationship with native peoples and their governments who live in areas which are not portions of States of the United States but who have had affinities to these areas long before these States came to be part of the United States. The commenters also noted the importance of including language in the final rule that recognized the trust responsibilities of the Federal government to indigenous peoples and their respective tribes in developing program standards, including defining cultural competence, enrollment policies and procedures, marketing, access, grievances, quality assurance and sanctions for MCOs providing health services to their peoples and not the States.

Response: While we are aware of, and concerned about, the impact of this final rule on IHS and tribal health systems, we are not exempting them from its application when they operate as Medicaid managed care entities or subcontract with Medicaid managed care entities. First, there is no basis in the statute for such an exemption. We also believe that Medicaid beneficiaries who use such systems are entitled to the protections and safeguards embodied in this rule whether or not they use IHS and tribal systems. We do however understand that IHS and tribal health systems have unique circumstances, and we have consulted with IHS and tribal governments on many issues. These consultations have resulted in some adjustments to the rule. We will continue the consultation process as we interpret and implement this final rule to ensure that we address the concerns of IHS and tribal health systems. We do not believe, however, that this rulemaking is an appropriate vehicle to address the full range of Federal treaty relationships with tribal groups cited, since its scope is limited to the Medicaid managed care provisions in Chapter 1 of Subtitle H of the BBA.

Comment: One commenter strongly suggested that efforts be made by Tribal, Federal and State officials to implement the IHS/HCFA Memorandum of Agreement (MOA). The commenter believed that MOA provisions for 100 percent FMAP for tribally operated facilities should be honored under any State managed care system in the views of this commenter. The commenter believed that States operating Medicaid managed care programs should carve out IHS and tribal programs as Medicaid providers eligible for the ''pass-through'' reimbursement. Another commenter stated that Indian health facilities should be paid by Medicaid for every visit in which Medicaid covered services are provided to a Medicaid beneficiary. This would apply to the Indian Health Service direct service facilities, tribally operated facilities, and urban Indian clinics, collectively known as the I/T/U. The commenter believed that the I/T/U should be paid by Medicaid at a rate that covers the cost of delivering services, considering that there is little opportunity to shift costs to other third party payers. The commenter further stated that barriers to participation should be eliminated for AI/AN populations for health care programs that receive any Federal funding. Recognizing the limitations in funding, the commenter believed that resources should be used to the maximum extent for direct patient care and prevention activities while keeping administrative functions as efficient as possible.

Response: As discussed above in the discussion of comments on Subpart J section II. H., issues of Federal matching funding levels are outside the scope of the proposed rule or this final rule, which has no effect on matching rates for services furnished by IHS or tribal facilities. We note that the commenter is mistaken in suggesting that the cited MOA requires any particular payment levels to IHS or tribal facilities (and further note that it does not address urban Indian facilities at all). We recognize, however, that IHS and tribal health systems and providers may have unique circumstances in contracting with such programs. We intend to continue to work with IHS and the tribes to minimize barriers to participation in Medicaid managed care programs, and to address the matching rate issues raised by the commenters.

i. Miscellaneous Comments

Comment: One commenter recommended that the final rule address the administration of non-emergency MCO transportation services. The commenter believed (based on recommendations made by HCFA's Transportation Technical Advisory Group) that coordination with

transportation agencies and other human service providers increased the efficiency of the transportation system, helped control costs, and can provide better service to Medicaid and non-Medicaid users of the transportation system. The commenter noted that it is in the interest of the community, State, and the health care and transportation industries to develop coordinated networks of transportation. Further, according to the commenter, States should have the ability to operate their non-emergency transportation services with Federal matching funding comparable to the optional medical service match to improve the States' capacity to coordinate transportation services, thereby saving Medicaid related costs while supporting the existing public transportation network.

Response: The issue of non-emergency transportation services is not an issue that is unique to managed care. This regulation only pertains to the Medicaid managed care provisions in the BBA, and thus, non-emergency transportation is beyond the scope of this regulation and the statute it implements.

Comment: One commenter disagreed with the deletion of the requirement that no more than 75 percent of enrollees in risk contracts be eligible for Medicare or Medicaid. Although it is not clear why this would be the case, the commenter apparently believed that this deletion would result in MCOs decreasing the numbers of Medicaid beneficiaries.

Response: First, the 75/25 enrollment requirement is a limit on the percentage of enrollees eligible for Medicaid, and therefore there is no reason to believe it would result in decreased Medicaid enrollment. Any changes that resulted from its elimination would presumably increase Medicaid enrollment. More importantly, this change was made by Congress in the BBA, and we thus had no discretion in this rulemaking to retain it. We note that this requirement was previously used as a rough ''proxy'' to ensure quality services by requiring that an MCO attract commercial customers. This ''proxy'' has been replaced in the BBA with more direct quality requirements implemented in this final rule.

Comment: We received one comment urging that the proposed rule deal with the effects on Medicaid of the law prohibiting ''public benefits'' going to individuals who are not citizens or permanent residents.

Response: This subject is outside the scope of this rulemaking.

Comment: A few commenters suggested that HCFA require State agencies to consult with beneficiaries and the physician community at all stages of the planning and implementation of new managed care initiatives. The commenters believed that physician organizations can offer significant input into the development of professional standards effecting patient care delivery, evaluating the adequacy of provider networks, and assessing quality of care delivered. Further, the commenters believed that we should continuously monitor and evaluate State experiences with physician participation and serve as a clearinghouse of information for States on successful strategies.

Response: We realize that public and physician consultation are important factors in the development of Medicaid managed care initiatives and encourage stakeholder input at all stages of managed care development. However, we are not requiring a specific requirement for stakeholder involvement since States, based on the uniqueness of their Medicaid managed care programs, are in the best position to determine how this involvement should be structured. Each State is required to have a Medical Care Advisory Committee (MCAC) established for the purpose of advising the Medicaid agency about health and medical services. This committee, by regulatory definition, is required to include physicians and beneficiaries. We encourage States to continue to use the MCAC as a mechanism for obtaining input on managed care issues. Likewise, under § 438.302, we are requiring public consultation in development of the State's quality strategy, though we are not specifying the structure of this consultation.

Comment: One commenter expressed concern with the lack of discussion in the preamble and proposed regulation text of requirements or directions to States regarding long term care services and support delivered by MCOs. The commenter believed that this was of particular concern since the elderly and people with disabilities account for the majority of Medicaid spending.

Response: While long-term care services were not explicitly addressed in the regulation, we believe the regulation was written in such a manner to encompass all the types of services delivered under managed care including long-term care. Long-term care issues were considered in discussions during the development of the final regulation.

Comment: Several commenters were concerned with what they believed to be a lack of clarity and specificity in the proposed rule concerning children and children with special health care needs. These commenters believed that the final rule should be more specific on child health requirements separate from adult health requirements, since children have distinct medical and developmental health care needs. The commenters also stated that the proposed rule offered no special protection for children with special health care needs. One commenter stated that when Congress enacted section 1932(a)(2)(A) of the Act, it intended that HCFA develop standards and protections for special needs children above and beyond the managed care standards and protections provided to all beneficiaries. The commenter further indicated that because children with special health care needs are the most vulnerable, it was essential that HCFA provide specific regulations that protects these children in managed care environments.

Response: We agree that children, and particularly children with special health care needs, have unique needs that differ from the adult population. While this final rule establishes a general framework for States to use when developing managed care programs to serve all of its enrolled populations, as discussed in section II. D. above, it also takes into account and implements recommendations set forth in HCFA's report to Congress on special needs beneficiaries required under section 4705(c)(2) of the BBA. We note that section 1932(a)(2)(A) specifically exempts special needs children from being mandatorily enrolled in the State Plan Option for Medicaid managed care. In addition, under 1915(b) waivers HCFA has established new interim criteria that States must meet when establishing programs for children with special health care needs. These criteria require additional reporting and monitoring for children with special health care needs. And finally, the terms and conditions for 1115 waiver programs also contain specific areas that address the needs of these types of children.

Comment: One commenter was concerned about the impact of Medicaid managed care on the nation's dental schools and other hospital-based or allied dental education programs. The commenter urged HCFA to recognize the special role of dental education institutions in serving the Medicaid population and to use the regulations to strengthen the Medicaid program by improving access to dental prevention and treatment services. Finally, this commenter recommended that the proposed regulations be revised to amplify the specific requirements of law related to the access of diagnostic,

preventive and treatment services for children under Medicaid's EPSDT program. The commenter was specifically concerned about the impact of managed care on the utilization rate for children's dental services.

Response: We recognize the importance of the nation's dental schools and other hospital-based dental education programs in serving the dental needs of the Medicaid population. At this time, we do not believe it is necessary to develop a separate regulation to address access to dental prevention and treatment services. This final rule is designed to address access issues related to all Medicaid managed care services. For example, an MCO that delivers dental services to Medicaid beneficiaries must comply with the access requirements in the regulation. The MCO must ensure that it offers an appropriate range of services and that it maintains a network of providers that is sufficient to meet the needs of its enrollees. Further, according to § 438.206(a), each State must ensure, through its contract with an MCO, that all of the covered services are accessible for all the beneficiaries enrolled with the MCO. We are also optimistic that managed care will facilitate increased utilization in the area of dental services.

Comment: Several commenters recommended that HCFA develop a final rule which ensures that States, MCOs and PCCMs will develop Medicaid managed care programs that protect the rights of enrollees who are homeless, promote their access to an appropriate range of services, and improve the quality of care available to them.

Response: We believe this final rule protects the rights of all beneficiaries, including persons who are homeless. For example, § 438.206 requires that the delivery network meet the needs of the population served and that access to services be guaranteed, while under § 438.100 all beneficiaries must be treated with dignity and respect. We recognize that persons who are homeless face unique difficulties in receiving information needed to make appropriate choices among MCO or PCCM options due to transience, lack of mailing address, and other circumstances. Under § 438.56(d)(2)(i), persons who are homeless, and who have been automatically assigned at their initial enrollment into an MCO or PCCM, may disenroll and re-enroll with a different MCO or PCCM at any time. We believe this will give persons who are homeless the opportunity to learn more about managed care when they need medical services and make the most effective choice of MCOs or PCCMs at that time.

Comment: One commenter recommended that there should be some form of consumer assistance programs to help enrollees navigate the managed care system.

Response: We agree that there must be adequate and appropriate consumer assistance programs available to enable beneficiaries to navigate the managed care system. We also agree that it is a State's responsibility to ensure that consumer assistance is available to its beneficiaries. However, because consumer assistance can be accomplished in many different ways, and should be designed by each State to meet the unique characteristics of its managed care population and program, we are not imposing a Federal requirement for this. Some States already use toll free hotlines for consumer assistance, while others have developed ombudsman programs. We do require that MCOs must give enrollees reasonable assistance they need in completing forms or other procedural steps in the grievance process.

Comment: Several commenters believed that the regulation should clearly respond to the special needs of medically vulnerable beneficiaries with acute, chronic and disabling conditions and contain specific definitions of these diagnoses, as well as clear definitions of ''mental illness'' and ''addictive disorders'' so that coverage for these conditions are included under the service plan. One commenter recommended the inclusion within all Medicaid mental health managed care benefit packages of psychosocial rehabilitative services, self-help services and peer supports, and other non-medical services designed to help consumers improve their level of functioning, increase their ability to live independently and cope with ongoing symptoms and side effects of medications. Further, the commenter contended that States should be required to establish the methodology necessary to measure the prevalence of chronic mental illness, acute mental illness, or substance abuse per county, taking into account the predicted health care needs of the population to be enrolled. Another commenter believed that the regulation should incorporate a requirement that each Medicaid managed care behavioral health plan name and provide a full continuum of addiction treatment services in the network including: hospital and non-hospital detoxification, hospital and non-hospital rehabilitation, short and long term rehabilitation, outpatient, partial hospitalization services and treatment for the family. This commenter also recommended that a particular university be given a strong role in review of these provisions, and that this role should be written into regulation.

Response: The regulation was intended to address needs and protections for all Medicaid beneficiaries in managed care. The information requirements at § 438.10 require that the State must, directly, or through the MCO, PHP, or PCCM, provide information on any benefits to which the beneficiary is entitled under the Medicaid program, but that are not covered under the MCO, PHP, or PCCM contract, and specific instructions on where and how to obtain those benefits, including how transportation is provided. Further, we are not identifying specific types of treatment and services in the regulation for one type of service category. Each State has the flexibility to determine the services that will be covered under their own State Medicaid program. This regulation pertains only to the delivery of services, not the benefits provided under the State's Medicaid program. With respect to the last comment on the role of a specified university, we do not believe it would be appropriate to grant an outside private body government oversight authority.

Comment: One commenter suggested that MCO, PHP, and PCCM contracts should specify the services that the entity is responsible to provide, and that the State should be required to make arrangements for providing other State plan services, and give beneficiaries written information on how to obtain them.

Response: As noted above in section II. C., § 438.210(a) requires that contracts specify the services the entity is required to provide, and § 438.206(c) requires that if an MCO contract does not cover all of the services covered under the State plan, the State must make available those services from other sources and instruct all enrollees on where and how to obtain them, including how transportation is provided. Further, the information requirements under § 438.10 require that the State must, directly or through the MCO, PHP, or PCCM, provide to Medicaid beneficiaries information on any services to which they may be entitled under the Medicaid program, but that are not covered under the MCO PHP, or PCCM contract and specific instructions on where and how to obtain those services, including how transportation is provided.

Comment: One commenter recommended that a new paragraph should be included (titled ''Americans with Disabilities Act'') to require that each MCO must ensure that: (1) the physical and mental disabilities of enrollees and potential enrollees are reasonably accommodated, including flexible scheduling, extra assistance and specialized staff training; (2) enrollees with disabilities receive services in the most integrated setting appropriate to their needs, including community based services to enable them to live in community settings instead of institutions or residential treatment facilities; (3) no eligibility criteria, service authorization procedures, utilization review practices or other methods of administration are employed that defeat or substantially impair, with respect to individuals with disabilities, accomplishment of the objectives of the State's medical assistance program; and (4) qualified individuals with disabilities be provided services, benefits and aids that are as effective in affording equal opportunity to obtain the same result, to gain the same benefit or to reach the same level of achievement as that provided to others.

Response: We do not feel it is necessary to add a separate provision as other areas of the regulation respond to this issue. Section 438.100 requires that the State must ensure that each MCO and PHP comply with any and all Federal laws pertaining to enrollee rights, including the Americans with Disabilities Act. Further, § 438.6(f) requires that all contracts must comply with all applicable State and Federal laws and regulations, including Title VI of the Civil Rights Act of 1964; Title IX of the Education Amendments of 1972 (regarding education programs and activities); the Age Discrimination Act of 1975; the Rehabilitation Act of 1973; and the Americans with Disabilities Act.

Comment: One commenter was concerned with what will happen to people with mental retardation should an MCO, PHP, or PCCM withdraw from the Medicaid market. The commenter stated that if a Medicaid MCO or PHP leaves the Medicaid market, there must be protections in place to ensure continuing access to medically necessary services for individuals with mental retardation and other disabilities who critically need access to these health and health related services and supports to live in the community.

Response: It is the State's ultimate responsibility to ensure access to Medicaid covered services. In the event that an MCO or PHP withdraws from the Medicaid market, the State must ensure that services are delivered to all Medicaid beneficiaries either through another Medicaid MCO or PHP, or through fee-for-service arrangements.

Comment: One commenter found it disturbing that managed care consumer protections and quality measures for the Medicare population have more ''teeth'' than those required for Medicaid. The commenter felt that this perceived distinction in the requirements of Medicare managed care and Medicaid managed care continues what the commenter believed to be ongoing discrimination against people who are poor and disabled.

Response: It was our intent to create consistency with the Medicare+Choice requirements to lessen the impact that multiple regulatory and administrative standards exert on the managed care industry. However, where there was a clear need for greater beneficiary protection or where consistency with the Medicare+Choice program was not appropriate for Medicaid managed care, we deviated from the Medicare+Choice policy. We believe that this final rule balances the need for flexibility and consistency, while providing States with the broad tools necessary to become better purchasers of health care. We believe that this final rule contains protections for enrollees that are equal to or exceed those in the Medicare+Choice final rule. This includes sanction and civil money penalty authority similar to that in the Medicare+Choice rule. We thus disagree with the commenter's premise about the Medicare+Choice rule having more ''teeth.''

Comment: Several commenters urged HCFA to provide special attention to the effect of these regulations on people with disabilities. The commenters believed that the regulations must provide specific protections for special needs populations, such as those with spinal cord injury or dysfunction when enrollment in Medicaid managed care is mandatory. One commenter believed a methodology should be developed which would allow States to inventory disabled populations on a per county basis in order to ensure that adequate numbers of providers, especially specialists, would be available to serve the enrolled special needs population.

Response: The regulation was intended to address the needs and protections for all Medicaid beneficiaries in managed care, including persons with disabilities. The regulation was written in a manner to establish a general framework for States to use when developing managed care programs to serve all of its enrolled populations. We believe the regulation allows greater access to quality health care services delivered through managed care arrangements for persons with disabilities. As noted above in section II. C., § 438.206(d) requires that MCOs and PHPs take into account the anticipated enrollment of persons with special health care needs in establishing their provider network, and must have the appropriate numbers and ''types'' of providers in terms of training and experience to meet these needs. We believe these provisions directly address the commenters' concerns.

Comment: One commenter suggested that the final regulation make clear that all States are free to adopt more rigorous standards of consumer protections in Medicaid managed care.

Response: The consumer protections in this regulation were not designed to prevent States from developing more rigorous standards. States retain the flexibility to develop more restrictive consumer protection provisions that go beyond those contained in this regulation.

Comment: Several commenters noted that the issue of low physician participation in Medicaid does not appear to have been addressed in the proposed rule, and believed that this has always been a concern under the Medicaid program. Some of the commenters believed that because of inadequate funding and administrative requirements, physicians have minimized their participation in the Medicaid program. These commenters believed that financial incentives may be an appropriate mechanism to entice physician participation. On the other hand, a commenter felt that financial incentives that may prevent the delivery of medically necessary services may be partially controlled by prohibiting any financial incentives. Another commenter recommended that in addition to physician incentive plans that place physicians at substantial financial risk for services they do not provide, having to conduct enrollee surveys, and provide adequate and appropriate stop loss protection, HCFA should also state that financial risk will reside with the plan in instances where a plan decision results in a limit on the services provided. Finally, one commenter felt that there was a need to develop financial incentives for managed care plans to compete on the basis of quality rather than the basis of price. This commenter believed that it is important for Medicaid managed care regulations to establish rewards for MCOs based on quality, not merely cost reductions.

Response: The general issue of relatively low levels of physician participation in the Medicaid program is

outside the scope of this rulemaking. We note, however, that levels of participation in managed care settings have been higher than under fee-for-service Medicaid, and that a managed care enrollee is ensured access to a primary care provider under this final rule. Thus, to the extent managed care is involved, physician participation is guaranteed under this final rule to the extent necessary to meet access requirements. Specifically, § 438.207 requires that each MCO and PHP must ensure that it 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 MCO's or PHP's service area. Further, under § 438.214, the State must ensure that each MCO and PHP have a process for formal selection and retention of providers that does not discriminate against those that serve high risk populations or specialize in conditions that require costly treatment. With respect to financial incentives for MCOs and PHPs, these are addressed in § 422.6(c)(5) as part of the discussion of actuarially sound rates. See section II. A. above. Beyond these limits, we believe States should have flexibility in this area. With respect to financial incentives for individual physicians, § 438.6(h) requires that MCO and PHP contracts provide for compliance with the physician incentive plan requirements.

Comment: One commenter wrote to express concerns regarding the quality of care delivered by a particular managed care program. The commenter was concerned about the introduction of managed care for persons with disabilities and persons with chronic conditions. The commenter contended that they were misled by their health plan, and the organization denied and reduced care when not appropriate.

Response: We anticipate that the new consumer protections, quality provisions and grievance system requirements in this final rule will work to alleviate problems in the areas addressed by the commenter.

Comment: One commenter believed that the final rule should maintain an adequate safety net to guarantee the continued viability of Medicaid managed care and to allow for reasonable alternatives. The commenter cautioned States moving towards mandatory managed care that they must avoid the tendency to make the area fit MCOs rather than the MCOs address the area. The commenter felt that ''cookie cutter'' approaches will not work in large rural States, and it might be difficult to develop health plan networks in rural areas.

Response: We recognize that States are unique and have different needs for their enrolled populations. This final rule was designed to maintain State flexibility as much as possible, so that States can implement managed care programs that meet the needs of their beneficiaries.

VI. Collection of Information Requirements

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

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

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

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

The following information collection requirements and associated burdens are subject to the PRA. For purposes of this requirement, we incorporated pertinent managed care data from the 1999 Medicaid enrollment report. As of June, 1999, there were 375 managed care organizations (MCOs) (this includes 2 HIOs that must adhere to the MCO requirements of this regulation), 37 primary care case management systems (PCCMs), 412 managed care entities (MCOs and PCCMs combined), and 129 prepaid health plans (PHPs). There were a total of 24,470,583 beneficiaries enrolled in these plans (some beneficiaries are enrolled in more than one plan) in forty-eight States and the District of Columbia (Wyoming and Alaska do not currently enroll beneficiaries in any type of managed care).

A. Section 438.6 Contract Requirements

1. Section 438.6(c) Payments Under the Contracts

a. Requirement

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

b. Burden

We believe that the burden of providing additional information to support the actuarial soundness of a State's capitation rates will be offset by the elimination of the UPL requirement. States will no longer be required to extract fee-for-service (FFP) data and manipulate that data by trending and other adjustments in order to establish a FFP equivalent for purposes of comparison to capitation rates.

2. Section 438.6(i)(2) Advance Directives

a. Requirement

This paragraph requires that MCOs and PHPs (States may determine that it is inappropriate to require this of some PHPs) provide adult enrollees with written information on advance directives policies and include a description of applicable State law.

b. Burden

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

B. Section 438.8 Provisions That Apply to PHPs

Section 438.8(a) Contract Requirements

a. Requirement

This section imposes most of the contract requirements contained in § 438.6 on PHPs, including advance

directives (in most instances) and physician incentive plan requirements.

2. Burden

PHPs have not previously been required to maintain written policies and procedures with respect to advance directives. This requires the PHP to provide written information to enrollees of their rights under this provision and the PHP's policies with respect to the implementation of those rights. We project 8 hours for each of the 129 PHPs to establish this policy and 2 minutes per enrollee for provision of this information, and acceptance of this right to each of approximately 8.1 million individuals enrolled in PHPs. The total time for this would be 271,032 hours.

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

We are basing our projections of burden upon information published in the **Federal Register** on March 27, 1996 and December 31, 1996 (61 FR 13445 and 61 FR 69049) which contained the original regulatory provisions on physician incentive plans for Medicare and Medicaid HMOs. Based on those assumptions, we believe no more than one third of the approximately 130 PHPs use incentive or risk payment arrangements with their subcontracting providers. Affected PHPs would be required to provide detailed responses to State surveys regarding their payment mechanisms and amounts. At the projected 100 hours per response for approximately 43 PHPs the total burden would be 4300 hours. For those PHPs with substantial financial risk, there are other requirements such as stop loss insurance and beneficiary surveys. We believe there would be minimal additional burden as a result of these requirements (because many already comply with these requirements) and that this would apply to no more than one fourth of those PHPs with risk or incentive payments, or a total of 11. We estimate an additional 10 hours per plan for a total of 110 hours. Altogether, we estimate 4,410 hours of burden through imposition of this requirement on PHPs.

C. Section 438.10 Information Requirements

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

a. Requirement

In summary, § 438.10(b), (d) and (e) state that each State, MCO, PHP, and PCCM must furnish information to enrollees and potential enrollees, to meet the requirements of this section. Paragraph (b) requires that the State notify enrollees and potential enrollees, and require each MCO, PHP, and PCCM to notify its enrollees and potential enrollees that oral interpretation and written information are available in languages other than English and how to access those services. The basic information listed in paragraph (d) and (e) of this section must be provided to each enrollee or to any potential enrollee upon request, by the MCO or PHP (unless the State chooses to furnish it directly), within a reasonable time after it receives from the State notice of the beneficiary's enrollment. This information must be provided on an annual basis thereafter, the MCO or PHP must notify enrollees of their right to obtain this information upon request. The information that must be provided includes the following:

Information for potential enrollees

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

Information specific to each MCO and PHP serving an area that encompasses the potential enrollee's service area must be provided. This includes information on benefits covered; cost sharing if any; service area; names, locations, and telephone numbers of current network providers, including at a minimum information on primary care physicians, specialists, and hospitals, and identification of providers that are not accepting new patients; and benefits that are available under the State plan but are not covered under the contract, including how and where the enrollee may obtain those benefits, any cost sharing, and how transportation is provided.

Information for enrollees

The State must give each enrollee written notice of any change (that the State defines as ''significant'') in the information specified at least 30 days before the intended effective date of the change and make a good faith effort to give written notice of termination of a contracted provider, within 15 days after receipt or issuance of the termination notice, to each enrollee who received his or her primary care from, or was seen on a regular basis by, the terminated provider.

Required information:

- Kinds of benefits, and amount, duration, and scope of benefits available under the contract; enrollee rights as specified in § 438.100.
- Procedures for obtaining benefits, including authorization requirements.
- Names, locations, and telephone numbers of current network providers, including information at least on primary care physicians, specialists, and hospitals, and identification of providers that are not accepting new patients.
- Any restrictions on the enrollee's freedom of choice among network providers.
- The extent to which, and how, enrollees may obtain benefits, including family planning services, from out-of-network providers.
- The extent to which, and how, after-hours and emergency coverage are provided.
- Policy on referrals for specialty care and for other benefits not furnished by the enrollee's primary care provider.
- Cost sharing, if any.
- Grievance, appeal, and fair hearing procedures for enrollees, including time-frames, required under § 438.414(b).
- Any appeal rights that the State chooses to make available to providers to challenge the failure of the organization to cover a service.
- Any benefits that are available under the State plan but are not covered under the contract, including how and where the enrollee may obtain those benefits, any cost sharing, and how transportation is provided. The State must furnish information about how and where to obtain the service.
- Information on how to obtain continued services during a transition, as provided in § 438.62.
- The rules for emergency and post-stabilization services, as set forth in § 438.114.
- Additional information that is available upon request, and how to request that information.

At least once a year, the MCO or PHP, or the State or its contracted representative, must notify enrollees of their right to request and obtain the information listed above.

In addition, § 438.10(f) requires that information related to the licensure, certification, and accreditation status of MCOs, PHPs, and their providers be

furnished to each enrollee and each potential enrollee.

b. Burden

We believe the burden placed on States, MCOs, PHPs, and enrollment brokers as a result of this requirement is the time associated with modifying the content of existing information materials, as well as the time associated with distributing the materials to enrollees as specified by the regulation. We estimate that it will initially take 12 hours for each MCO or PHP to modify existing information materials to conform with the requirement above. We further estimate that there are approximately 375 MCOs and 129 PHPs, equating to an initial modification burden of approximately 6,048 hours. After the initial modification, we estimate that it will take MCOs and PHPs approximately 4 hours each to annually update the information materials, equating to an annual total burden of approximately 2,016 hours.

We expect that it will take MCOs, PHPs, or States approximately 5 minutes per enrollee to mail the initial packet, for an estimated 20.2 million enrollees. The total burden associated with this requirement is approximately 1,683,000 hours, approximately 3,340 hours per MCO or PHP, or 34,000 hours per State.

We similarly estimate that it annually will take MCOs, PHPs, or States 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 2,020,000 enrollees and potential enrollees. The annual mailing burden associated with this requirement is estimated to be 2,020,000 individuals multiplied by 5 minutes per person, for a total burden of approximately 168,300 hours (approximately 330 hours per MCO or PHP, or 3,400 hours per State).

Finally, we estimate that it will annually take MCOs, PHPs, or States 5 minutes per enrollee to notify enrollees of their right to receive information. Five minutes multiplied by an estimated total enrollee population of 20,200,000 individuals equates to an annual burden of approximately 16,830,000 hours or approximately 3,300 hours per MCE or PHP or 33,400 hours per State.

2. Section 438.10(g)

a. Requirement

Section 438.10(g) requires that each primary care case manager (PCCM) (and PHPs that operate like PCCMs) provide similar types information to potential enrollees including information on provider names and locations, benefits, grievance procedures, and procedures for obtaining services during the appeals process.

b. Burden

The burden associated with this requirement is the amount of time required by States or their contracted representative to mail the required information to potential enrollees. We believe that it will take the 30 States approximately 5 minutes per enrollee to mail this information. We estimate that there are a total of approximately 4,274,000 PCCM enrollees, and that 10 percent of those enrollees will request this information. This equates to an annual burden of 5 minutes multiplied by 427,400 enrollees, or approximately 35,600 hours (approximately 962 hours per primary care case manager).

3. Section 438.10(h)

a. Requirement

In summary, § 438.10(h) states that if a State plan provides for mandatory MCO, PHP, or PCCM enrollment under section 1932(a)(1)(A) of the Act, the State or its contracted representative must provide information in a comparative, chart-like format, to potential enrollees and at least once a year thereafter. The information must include the MCO's, PHP's or PCCM's service area, the benefits covered under the contract, any cost sharing imposed by the MCO, PHP, or PCCM 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 States (for example those not yet captured in the above provisions) is the length of time associated with creating the comparative chart. We estimate that it will take States approximately 4 hours each to create the comparative chart. We further estimate that approximately 8 States per year will avail themselves of the State Plan Option, for a total annual burden of approximately 32 hours.

D. Section 438.12 Provider Discrimination Prohibited

a. Requirement

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

b. Burden

The burden associated with this requirement is the time it takes the MCO or PHP to draft and furnish the providers with the requisite notice. We estimate that it will take an hour to draft and furnish any given notice. We estimate that on average each MCO and PHP will need to produce 10 notices per year for a total of 5,040 hours.

E. Section 438.50(b) State Plan Information

a. Requirements

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

b. Burden

The burden associated with this section includes the time associated with developing the process for public involvement, including annual updates. We estimate that it will take 40 hours per State to develop the process for, and involving, the public for a total burden of 1960 hours (48 States and D.C.). We estimate that ensuring ongoing public involvement will take another 20 hours per State annually for a total annual burden of 980 hours.

F. Section 438.56z Disenrollment: Requirements and Limitations

1. Section 438.56(b)

a. Requirement

All MCO, PHP, and PCCM contracts must—

(1) Specify the reasons for which the MCO, PHP, or PCCM may request disenrollment of an enrollee;

(2) Provide that the MCO, PHP, or PCCM may not request disenrollment because of a change in the enrollee's health status, or because of the enrollee's utilization of medical services, diminished mental capacity, or uncooperative or disruptive behavior resulting from his or her special needs; and

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

b. Burden

The burden of submitting this supporting documentation when MCOs, PHPs, or PCCMs request disenrollment of beneficiaries would be two hours per request. We calculate that approximately one-tenth of one percent of enrollees (24,470) would be affected, or 43 per MCO, PHP, or PCCM annually. The total burden would be 48,940 hours, or 87 hours per MCO, PHP, or PCCM.

2. Section 438.56(d)(1)

a. Requirement

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

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, if they choose to use the written format. We estimate that it will take approximately 10 minutes per enrollee to generate a written disenrollment request. We estimate that approximately 5 percent of MCO, PHP, and PCCM enrollees will request that they be disenrolled from an MCO, PHP, or PCCM. Approximately one-fourth of the enrollees will choose a written rather than an oral request. This equates to an annual burden of approximately 10 minutes multiplied by 306,000 affected enrollees (one-fourth of the 1,221,000 enrollees requesting disenrollment), or approximately 51,000 hours.

3. Section 438.56(d)(3)

a. Requirement

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

b. Burden

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

Of the 1,221,000 affected enrollees, we calculate that one-fifth (244,000) will not be approved. If each notice takes 15 minutes to produce, the total burden would be 61,000 hours. Of the 244,000 enrollees not approved, we calculate that three-fourths (183,000) will involve the State requesting information from the MCO, PHP, or PCCM justifying the denial. At one hour per request, the total burden on MCOs, PHPs, or PCCMs would be 183,000 hours.

We estimate that the MCOs, PHPs, and PCCMs will need to produce notices for the remaining four-fifths of enrollees requesting disenrollment (977,000) and the States to approve the request for disenrollment. As this notice will probably be a short form letter, with attachments as necessary, we believe that it will take ten minutes per request to send out the notices, or an annual burden of 163,000 hours.

G. Section 438.102 Enrollee-Provider Communications

a. Requirement

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

b. Burden

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

H. Section 438.114 Emergency Services

a. Requirement

Section 438.114(b) states that at the time of enrollment and at least annually thereafter, each MCO, PHP, and State (for PCCMs) 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.

a. Burden

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

I. Section 438.202 State Responsibilities

a. Requirement

Each State contracting with an MCO or PHP must have a strategy for assessing and improving the quality of managed care services offered by the MCO or PHP, document the strategy in writing and make it available for public comment before adopting it in final, and conduct periodic reviews to evaluate the effectiveness of the strategy at least every three years. Each State must also submit to HCFA a copy of the initial strategy and a copy of the revised strategy whenever significant changes are made. In addition, States are required to submit to HCFA regular reports on the implementation and effectiveness of the strategy, consistent with the State's own periodic review of its strategy's effectiveness, but at least every three years.

b. Burden

The burden associated with this section is limited to those States offering managed care through MCOs or PHPs (49) and includes the time associated with developing the proposed strategy, publicizing the proposed strategy, incorporating public comments, submitting an initial copy of the strategy to HCFA prior to its implementation and whenever significant changes are made, and submitting regular reports on the implementation and effectiveness of the strategy at least every three years. We estimate that it will take 40 hours per State to develop the proposed strategy for a total burden of 1960 hours. We estimate that publicizing the proposed strategy will take 2 hours per State for a total burden of 98 hours. We estimate that incorporating public comments for the final strategy will take another 40 hours per State for a total burden of 1960 hours. We estimate it will take one hour per State to submit an initial copy of the strategy to HCFA and whenever significant changes are made for a total of 49 hours. We estimate it will take 40 hours per State to create and submit a report on the implementation and effectiveness of the strategy. We assume that these reports will be submitted at least every three years for a total annual burden of 653 hours.

K. Section 438.204 Elements of State Quality Strategies

a. Requirement

In this final rule we have added a new requirement at § 438.204(b)(1)(iii) that a State identify the race, ethnicity, and primary language spoken by each MCO

and PHP enrollee and report this information to each MCO and PHP in which each beneficiary enrolls at the time of their enrollment.

b. Burden

We believe that most States currently track race and ethnicity data in their eligibility systems. If States do not, minor changes in their software will be needed. With respect to primary language of enrollees, there will likely be additional programming needed for all States. We estimate that this would require 2 hours of programming for each of the 49 jurisdicitons for a total of 98 hours.

L. Section 438.206 Availability of Services

a. Requirement

Paragraph (c) of this section requires that if an MCO, PHP, or PCCM contract does not cover all of the services under the State plan, the State must make those services available from other sources and provide to enrollees information on where and how to obtain them, including how transportation is provided.

b. Burden

The burden associated with this requirement is the time it takes to provide the information. This burden of this requirement is included in the general disclosure requirements in § 438.10.

M. Section 438.207 Assurances of Adequate Capacity and Services

a. Requirement

Section 438.207 requires that each MCO and PHP must submit documentation to the State, in a format specified by the State and acceptable to HCFA, that it has the capacity to serve the expected enrollment in its service area in accordance with the States' standards for access to care and meets specified requirements.

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

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

b. Burden

We believe that MCOs and PHPs already collect and provide this information to State agencies as part of their customary and usual business practices and that the only additional burden on MCOs and 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 the 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 of 20 hours multiplied by 504 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 burden to the State for an annual burden of approximately 5 minutes multiplied by 502 MCOs and PHPs, or approximately 42 hours.

In this final rule we have added requirements to the types of assurances that MCOs and PHPs must provide (for example assurances that the MCO or PHP has policies and practices to address situations where there are: (1) unanticipated needs for providers with particular types of experience; and (2) unanticipated limitations on the availability of such providers. In addition, we have added new requirements under § 438.206(d) that when establishing and maintaining provider networks, each MCO and PHP must consider the anticipated enrollment with respect to persons with special health care needs and the experience of providers required to furnish contracted services. Documentation to support assurances by each MCO and PHP that they have considered the anticipated enrollment of persons with special health care needs and have recruited or are in the process of recruiting experienced providers is part of the assurances that must be provided to the State. We do not believe that it is customary, or part of the ususal business practice of MCOs and PHPs to collect data that includes totals for projected enrollment of persons with special health care needs and their specialized provider requirements. We estimate that obtaining information on: (1) the numbers and types of persons with special health care needs that could be anticipated to enroll in the MCO or PHP; (2) the types of experienced providers they would require; (3) the experience of the existing providers in the MCO's or PHP's network; and (4) the numbers and types of additional experienced providers needed, would require an estimated 40 hours of work for each of the 504 MCOs and PHPs for a total estimated burden of 20,160 hours.

N. Section 438.240 QualityAssessment and Performance Improvement Program; Performance Improvement Projects

a. Requirement

Section 438.240(c) states that each MCO and PHP must annually measure its performance using standard measures required by the State and report its performance to the State. In this final rule we have added a requirement that the State must include any minimum performance measures and levels specified by HCFA. In addition to using and reporting on measures of its performance, in § 438.240(d)(3) States are to ensure that each MCO and PHP initiates each year one or more performance improvement projects. In § 438.240(d)(10) each MCO and PHP is required to report the status and results of each such project to the State as requested.

B. Burden

This regulation would require States to require each MCO and PHP to annually produce at least two performance measures. Based on discussions with the 17 States with the largest Medicaid managed care enrollments, all 17 States are already doing so. Because the use of performance measures in managed care has become commonplace in commercial, Medicare and Medicaid managed care, we do not believe that this regulatory provision imposes any new burden on MCOs, PHPs, or States.

With respect to the requirements for performance improvement projects in § 438.240(d), we expect that, in any given year, each MCO and PHP will complete two projects, and will have four others underway. We further expect that States will request the status and results of each MCO's and PHP's projects annually. Accordingly, we estimate that it will take each MCO and PHP 5 hours to prepare its report for each project, for an annual total burden of 30 hours per MCO and PHP. In aggregate, this burden equates to 30 hours multiplied by an estimated 504 MCOs and PHPs, or approximately 15,120 hours.

O. Section 438.242 Health Information Systems

a. Requirement

Section 438.242(b)(2) requires the State to require each MCO and PHP to collect data on enrollee and provider characteristics as specified by the State, and on services furnished to enrollees, through an encounter data system or other such methods as may be specified by the State. Section 438.242(b)(3) states that each MCO and PHP must make all collected data available to the State and to HCFA, as required in this subpart, or upon request.

b. Burden

The above 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.

P. Section 438.402 General Requirements

a. Requirement

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

b. Burden

We estimate that approximately 1 percent of 20.2 million MCO and PHP enrollees (202,000) annually will file a grievance with their MCO or PHP and that approximately .5 percent (101,000) annually will file an appeal. For these cases, we estimate that the burden on the enrollee filing a grievance or appeal is approximately 20 minutes per case. The total annual burden on enrollees is 101,000 hours.

Q. Section 438.404 Notice of Action

a. Requirement

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

b. 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 30 seconds per action to make this notification. We estimate that approximately 5 percent (1,010,000) of the approximately 20.2 million MCO and PHP enrollees will receive one notice of intended action per year from their MCO or PHP (2,004 hours per MCO or PHP) for a total burden of approximately 8417 hours.

R. Section 438.406 Handling of Grievances and Appeals

a. Requirement

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

b. Burden

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

S. Section 438.408 Resolution and Notification: Grievances and Appeals

a. Requirement

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

This section also provides, for expedited appeals, that MCOs and PHPs must submit delayed and adverse appeal decisions to the State fair hearing office along with all supporting documentation.

b. Burden

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

T. Section 438.410 Expedited Resolution of Grievances

1. Paragraph (c)

a. Requirement

Paragraph (c), Requirements for appeals, requires each MCO and PHP to document all oral requests in writing and maintain the documentation in the case file.

b. Burden

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

2. Paragraph (d)

a. Requirement

Section 438.410(d) states that if an MCO denies a request for expedited grievance, it must automatically transfer the request to the standard time frame process and give the enrollee prompt oral notice of the denial and follow up, within 2 working days, with a written letter.

b. Burden

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

U. Section 438.414 Information About the Grievance System

a. Requirement

Sections 438.414(a) and (b) state that each MCO and PHP 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), and (3) all providers and contractors, 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 (6).

In addition, § 438.414(c) states that upon request, the MCO or PHP 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.

(c) Requirements for appeals. Each MCO and PHP must meet the following requirements with respect to appeals:

(1) Establish a convenient and efficient means for an enrollee or a provider to request expedited resolution of an appeal;

(2) Provide expedited resolution of an appeal in response to an oral or written request if the MCO or PHP determines (with respect to a request from the enrollee) or the provider indicates (in making the request on the enrollee's behalf or supporting the enrollee's request) that taking the time for a standard resolution could seriously jeopardize the enrollee's life or health or ability to attain, maintain, or regain maximum function.

(3) Document all oral requests in writing; and

(4) Maintain the documentation in the case file.

b. Burden

These 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.

V. Section 438.416 Recordkeeping and Reporting Requirements

a. Requirement

Sections 438.416 (a) and (c) state that each MCO and PHP must maintain a log of all complaints and grievances and their resolution, and 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.

In addition, § 438.416(d) states that each MCO and PHP must, at least once a year, send to the State a summary that includes the following information, (1) the number and nature of all grievances and appeals, (2) the time frames within which they were acknowledged and resolved, and (3) the nature of the decisions. This material is available to the public upon request under § 438.10.

b. Burden

We estimate that approximately .5 percent of the approximately 20.2 million MCO and PHP enrollees will file a grievance with their MCO or PHP (200 per MCO or PHP). The recording and tracking burden associated with each grievance is estimated to be 1 minute per request (3.4 hours per MCO or PHP), for a total burden of 1,680 hours (1 minute multiplied by an estimated 101,000 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 504 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 2,016 hours total.

W. Section 438.604 Data That Must Be Certified

a. Requirement

When payments from States to MCOs and PHPs are based on data submitted by the MCO or PHP that include, but are not limited to, enrollment information, encounter data, or other information required by the State, the MCO or PHP must attest to such data's accuracy, completeness, and truthfulness as a condition of receiving such payment. Each MCO and PHP must certify that it is in substantial compliance with its contract. Certification is required, as provided in § 438.606, for all documents specified by the State.

b. Burden

While the requirement for MCOs and PHPs (and their contractors) to attest to the accuracy of enrollment information encounter data or other information required by the State is subject to the PRA, as is the requirement for MCOs and PHPs to certify the accuracy, completeness, and truthfulness of all information provided in contracts, requests for proposals, or other related documents specified by the State, the burden associated with these requirements is captured during the submission of such information. Therefore, we are assigning one token hour of burden for this requirement.

X. Section 438.710 Due Process: Notice of Sanction and Pre-termination Hearing

1. (a) Due Process: Notice of Sanction and Pre-Termination Hearing

a. Requirement

Section 438.710(a) states that before imposing any of the sanctions specified in this subpart, the State must give the affected MCO or PCCM written notice that explains the basis and nature of the sanction. Section 438.724 also requires all intermediate sanctions to be published in a newspaper in order to notify the public.

b. Burden

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

2. (b)(1) Due Process: Notice of Sanction and Pre-Termination Hearing

a. Requirement

Section 438.710(b)(1) states that before terminating an MCO's or PCCM's contract, the State must give the MCO or PCCM written notice of its intent to terminate, the reason for termination, and the time and place of the hearing.

b. Burden

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

Y. Section 438.722 Disenrollment During Termination Hearing Process

a. Requirement

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

b. Burden

States already have the authority to terminate MCO or PCCM contracts according to State law and have been providing written notice to the MCOs or PCCMs. States are now given, at their discretion, the option of notifying the MCO's or PCCM's enrollees of the State's intent to terminate the MCO's or PCCM's contract. While it is not possible to gather an exact figure, we estimate that 12 States may terminate 1 contract per year. We estimate that it will take States 1 hour to prepare the notice to enrollees, for a total burden of 12 hours. In addition, we estimate that it will take States approximately 5 minutes per beneficiary to notify them of the termination, equating to a burden of 5 minutes multiplied by 12 States multiplied by 40,080 beneficiaries per MCO or PCCM, for a burden of approximately 40,080 hours. The total burden of preparing the notice and notifying enrollees is 40,096.

Z. Section 438.810 Expenditures for Enrollment Broker Services

a. Requirement

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

b. Burden

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

We have submitted a copy of this proposed rule to OMB for its review of the information collection requirements described above. These requirements are not effective until they have been approved by OMB.

If you comment on these information collection requirements, please mail copies directly to the following: Health Care Financing Administration, Office of Information Services, DHES, SSG, Attn: Julie Brown, HCFA–2001–F, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850; and Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Brenda Aguilar, Desk Officer.

VII. Provisions of the Final Rule

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

Part 400—Introduction; Definitions

Section 400.203

We have revised this section to include three new provisions. First, we specify that *PCCM* stands for primary care case manager. Second, we specify that *PCP* stands for primary care physician. Third, we have revised the definition of *provider* to clarify that, for the fee-for service program, it means any individual or entity furnishing Medicaid services under an agreement with the Medicaid agency and for the managed care program, it means an any individual or entity that is engaged in the delivery of health care services and is legally authorized to do so by the State in which it delivers the services.

Part 430—Grants to States for Medical Assistance

Section 430.5

We have revised this section by removing the definition of *clinical laboratory,* moving the definition of *authorized representative* to this section from § 438.2, and moving the definitions of *capitation payment, federally qualified HMO, health insuring organization, nonrisk contract, prepaid health plan,* and *risk contract* from this section to § 438.2. We have revised the definition of *authorized representative* to provide that the term will be defined by each State consistent with its laws, regulations, and policies.

Part 431—State Organization and General Administration

Section 431.200

We have revised paragraph (c) to include a reference to section 1819(f)(3) of the Act.

Section 431.201

We have defined service authorization request to mean a managed care enrollee's request for the provision of a Medicaid-covered service.

Section 431.244

We have revised paragraph (f) regarding time frames for State fair hearings to include a requirement for an expedited hearing for certain service authorization requests. We have redesignated paragraph (g) as (h) and included a new paragraph (g) which permits States to allow a hearing officer to grant an extension of the time frames under certain circumstances.

Part 434—Contracts

Section 435.212

We revised this section to replace ''HMO,'' wherever it appears, with ''MCO and PCCM'' rather than ''MCO.''

Section 435.1002

We revised paragraph a to include a reference to § 438.814.

Part 438—Managed Care Provisions

Subpart A—General Provisions

Section 438.2

We have revised this section by moving the definition of *authorized representative* to § 430.5 and moving the definitions of *capitation payment, federally qualified HMO, health insuring organization, nonrisk contract, prepaid health plan,* and *risk contract* from § 430.5 to this section. We have revised the definition of *capitation payment* to clarify that the State agency makes the payment regardless of whether the particular recipient receives services during the period covered by the *payment,* rather than a *fee.* We have clarified the definition of health insuring organization (HIO) so that it does not appear to require that an HIO's subcontractors be capitated. Since we have decided to specify within each regulatory provision, whether it applies to MCOs, PHPs, and/or PCCMs, we no longer use the term managed care entity, and have deleted that definition. We have revised the definition of *nonrisk contract* to clarify that the term refers to a contract under which the contractor is not at financial risk for changes in utilization or for costs incurred under the contract that do not exceed the upper payment limits specified in § 447.362 of this chapter. In addition, under a nonrisk contract, the contractor may be reimbursed by the State at the end of the contract period on the basis of the incurred costs, subject to the specified limits. Finally, we have clarified the definition of PHP to indicate that PHPs may be reimbursed by any non-state plan methodology, not just capitation.

Section 438.6

We have revised this section to include a new paragraph (a) that provides for regional office review of all MCO and PHP contracts including those that are not subject to the prior approval requirements in § 438.806. We are making significant revisions to paragraph (c). We have extended the rate setting requirements to all risk contracts. We are removing the requirement that rates not exceed the upper payment limit (UPL) set forth in § 447.361 and substituting an expanded requirement for actuarial soundness including certification of capitation rates by an actuary. We specify data elements to be included in the methodology used to set capitation rates and require States to consider the costs for individuals with chronic illness, disability, ongoing health care needs, or catastrophic claims in developing rates. We also require States to provide explanations of risk-sharing or incentive methodologies and impose special rules, including a limitation on FFP, in contracts utilizing some of these arrangements. These changes are being made as a Final Rule with a 60-day period for submission of comments.

We have revised paragraph (d) to clarify that the provision applies to MCOs and PHPs, not MCEs. Paragraph (i)(2) is revised to clarify that MCOs and PHPs are not required to provide adult enrollees with oral information on advance directives.

Section 438.8

We have revised paragraph (a) to provide that the requirements for advance directives specified in § 438.6 apply to all PHPs except where the State believes that they are not appropriate, for example, if the PHP contract only covers dental services or non-clinical services such as transportation. We have also expanded the PHP requirements to include compliance with the physician incentive plan rules and all of the State

responsibility provisions of Subpart B (except for the State plan provisions in § 438.50).

Section 438.10

We have revised this section to include the substantive requirements from § 438.318. We have also made several minor wording and organizational changes that served to clarify the requirements of this section. We have clarified how these rules apply to PHPs, whereby PHPs that have PCCM contracts are subject to the rules governing PCCMs, but all other PHPs are subject to the rules governing MCOs.

In paragraph (c), we have clarified that informational material must be available in alternative formats and in a manner that takes into consideration special needs, such as visual impairment or limited reading proficiency. In addition, paragraph (c) provides that the State and MCE must provide instructions to enrollees and potential enrollees regarding how they may obtain information in an appropriate format.

We have revised paragraph (d) to require the State or its contracted representative to provide information to potential enrollees regarding which populations are excluded from enrollment, subject to mandatory enrollment, or free to enroll voluntarily.

We have included a new provision in paragraph (e)(1)(ii), which requires an MCO to inform enrollees regarding any significant changes in any of the information that was furnished to them. The MCO must furnish the information within 90 days after the effective date of the change. We have included regulatory language in paragraph (e)(2) requiring the information provided to enrollees to include names and locations of current network providers, including information at least on primary care physicians, specialists, and hospitals, and identification of providers that are not accepting new patients. In paragraph (e)(3), we have revised the annual notice requirement to provide that at least once each year, the MCO, the State or its contracted representative must notify enrollees of their right to request and obtain specified information.

In paragraph (g), we have clarified that the time frames for furnishing information are the same for both PCCMs and MCOs.

We have revised paragraph (f) to provide that enrollees and potential enrollees may request and receive information on requirements for accessing services, including factors such as physical accessibility.

Section 438.12

We have revised paragraph (b) to permit different reimbursement amounts for the different specialties or for the same specialty.

Subpart B—State Responsibilities

Section 438.50

We have revised this section by including paragraph (b)(4), which requires the State plan to specify the process that the State uses to involve the public in both the design and the initial implementation of the program and the methods it uses to ensure ongoing public involvement once the State plan has been implemented. We have also revised the language in paragraph (a) to clarify that the provisions of this section do not apply to programs that have mandatory managed care enrollment pursuant to a waiver under either section 1115 or section 1915(b) of the Act. We have moved the requirements regarding limitations on enrollment and default enrollment from § 438.56 to this section so that they are only applicable in State plan managed care programs.

Section 438.52

We have revised the definition of ''rural'' area in paragraph (a) to eliminate the State's option to use definitions other than any area outside an ''urban area'' as defined in § 412.62(f)(1)(ii). We have revised the exception for rural area residents in paragraph (c) to clarify that an enrollee must be permitted to obtain services from an out of network provider if the provider is the main source of a service to that individual. We also require that, in rural areas, an enrollee must be permitted to obtain services from an out of network provider if he or she needs related services, not all related services are available within the network, and the enrollee's primary care provider or another provider determines that receiving the services separately would subject the enrollee to unnecessary risk.

Section 438.56

We have moved the requirements regarding limitations on enrollment and default enrollment from this section to § 438.50. We have revised paragraph (a) to provide that the provisions of this section apply to all managed care arrangements whether enrollment is mandatory or voluntary and whether the contract is with an MCO, a PHP, or a PCCM provider.

We have revised paragraph (b) to require that all MCE contracts must specify the reasons for which the MCO, PHP, or PCCM may request disenrollment of an enrollee. The contracts must also provide that the MCO, PHP, or PCCM may not request disenrollment because of a change in the enrollee's health status, or because of the enrollee's utilization of medical services, diminished mental capacity, or uncooperative or disruptive behavior resulting from his or her special needs except where the behavior impairs the ability of the MCO, PHP, or PCCM to furnish services to this enrollee or others.

In paragraph (c), we have clarified that an enrollee may request disenrollment without cause in four instances:

- During the 90 days following the date of the recipient's initial enrollment, or the date the State sends the recipient notice of the enrollment, whichever is later.
- At lease once every 12 months thereafter.
- Upon automatic reenrollment, if the temporary loss of Medicaid eligibility has caused the recipient to miss the annual disenrollment opportunity.
- When the State imposes an intermediate sanction, as specified in § 438.702(a)(3)

We have revised paragraph (d) to permit an enrollee to submit either an oral or a written request for disenrollment. In subparagraph (d)(2), we have significantly revised the provisions relating to ''for cause'' disenrollment. We identify three circumstances that would constitute cause under the final rule:

- The enrollee was homeless (as defined by the State) or a migrant worker at the time of enrollment and was enrolled in the MCO, PHP, or PCCM by default.
- The plan does not, because of moral or religious objects, cover the service the enrollee seeks.
- The enrollee needs related services to be performed at the same time, not all related services are available within the network, and the enrollee's primary care provider or another provider determines that receiving the services separately would subject the enrollee to unnecessary risk.

In subparagraph (d)(iv), we recognize that the enrollee may cite other reasons for requesting disenrollment that could constitute ''cause'' under the rule, including poor quality of care, lack of access to services covered under the contract, or lack of access to providers experienced in dealing with an enrollee's special health care needs.

In paragraph (e), we clarify the time frames for disenrollments to provide that regardless of the procedures followed, the effective date of an approved disenrollment must be no

later than the first day of the second month following the month in which the enrollee or the MCO, PHP, or PCCM files a request.

We have revised paragraph (f) to clarify that if a State restricts disenrollment under this section, it must provide that enrollees are furnished a written notice of their disenrollment rights at least 60 days before the start of each enrollment period. In addition, if a State denies a disenrollment request, it must provide notice to the enrollee of their right to file a request for a State Fair Hearing.

Section 438.60

We have deleted an exception for emergency and post stabilization services from this provision, which had been erroneously included in the NPRM, since duplicate payments are prohibited for these services.

Section 438.62

We have added a new paragraph (b) that requires the State agency to have in effect a mechanism to ensure continued access to services when an enrollee with ongoing health care needs is transitioned from fee-for-service to an MCO, PHP, or PCCM, from one MCO, PHP, or PCCM to another, or from an MCO, PHP, or PCCM to fee-for-service. We require that this mechanism apply at least to the following groups:

- Children and adults receiving SSI benefits.
- Children in Title IV–E foster care.
- Recipients aged 65 or older.
- Any other recipients whose care is paid for under State-established, risk-adjusted, high-cost payment categories.
- Any other category of recipients identified by HCFA.

In addition, we require the State to notify the enrollee that a transition mechanism exists, and provide instructions on how to access the mechanism. We also require the State to ensure that an enrollee's ongoing health care needs are met during the transition period, by establishing procedures to ensure that, at a minimum—

- The enrollee has access to services consistent with the State plan and is referred to appropriate health care providers.
- Consistent with Federal and State law, new providers are able to obtain copies of appropriate medical records.
- Any other necessary procedures are in effect.

Section 438.64

We have deleted this section which required that capitation payments be computed on an actuarially sound basis, and incorporated it into the new § 438.6(c) provisions.

Section 438.68

We have added this new section which requires the State agency to have in effect procedures for educating MCOs, PHPs, or PCCMs and their providers about the clinical and other needs of enrollees with special health care needs.

Subpart C—Enrollee Rights and Protections

Section 438.100

We removed the language relating to benefits and moved the provisions relating to ''Enrollee Rights'' from § 438.320 to this section. We revised the enrollee rights in paragraph (b) to include the following two rights:

- To obtain a second opinion from an appropriately qualified health care professional in accordance with § 438.3206(d)(3).
- To be free from any form of restraint or seclusion used as a means of coercion, discipline, convenience, or retaliation, as specified in other Federal regulations on the use of restraints.

In addition, we have revised three of the enrollee rights to provide that the State must ensure that the enrollee has the right—

- To receive information on available treatment options and alternatives, presented in a manner appropriate to the enrollee's condition and ability to understand. We clarify that if the MCO does not cover a service because of moral or religious objections, then the MCO need not furnish information on where and how to obtain the service, but only on where and how to obtain *information* about the service.
- To participate in decisions regarding his or her health care, including the right to refuse treatment.
- To request and receive a copy of his or her medical records and to request that they be amended or corrected, in accordance with § 438.3224.

We have included a new requirement in paragraph (c) that provides that the State must ensure that an enrollee's free exercise of his or her rights does not adversely affect the way the MCO, PCCM, or PHP, the MCO, PCCM, or PHP's providers, or the State agency treat the enrollee. In paragraph (d), we have revised the list of examples of applicable Federal and State laws for which States must ensure MCO, PCCM, or PHP compliance.

Section 438.102

We have replaced the term ''practitioner'' with ''health care professional'' and revised the definition to mirror the statutory language. We have reorganized the substantive provisions of the section to clarify the requirements. We revised paragraph (c) to include all of the information requirements that apply if an MCO does not provide a counseling or referral service based on moral or religious objections. We have clarified that, if the MCO does not cover a service under this section, then it is not required to inform enrollees and potential enrollees about how and where to obtain the service, but rather how and where to obtain information about a service. In paragraph (d), we require the State to provide information to enrollees on how and where to obtain a service that the MCO does not cover based on moral or religious objections.

Section 438.104

In paragraph (a) we moved the definitions of *choice counseling, enrollment activities,* and *enrollment broker* from this section to § 438.810. We revised the definition of *marketing materials* to mean materials that are produced in any medium, by or on behalf of an MCO, PCCM, or PHP and can reasonably be interpreted as intended to market to enrollees or potential enrollees. We also defined *marketing* to mean any communication from an MCO, PCCM, or PHP, any of its agents or independent contractors, with an enrollee or potential enrollee that can reasonably be interpreted as intended to influence that individual to enroll or reenroll in that particular MCO, PCCM, or PHP's Medicaid product or disenroll from another MCO, PCCM, or PHP's Medicaid product.

In paragraph (b), we have clarified that inaccurate, false, or misleading statements include, but are not limited to, any assertion or statement (whether oral or written) that the beneficiary must enroll in the MCO, PCCM, or PHP in order to obtain benefits or in order to not lose benefits or that the MCO, PCCM, or PHP is endorsed by HCFA, the Federal or the State government, or similar entity. We have also revised two of the provisions in subparagraph (b)(2) in order to clarify that the MCO, PCCM, or PHP contract must provide that the MCO, PCCM, or PHP distributes their marketing materials to its entire service area, as indicated in the contract and that the MCO, PCCM, or PHP does not seek to influence enrollment in conjunction with the sale or offering of any other insurance.

Section 438.108

In § 447.53(e), we now prohibit providers from denying care or services to an individual eligible for the care or services on account of the individual's inability to pay the cost sharing.

Section 438.110

We have moved the provisions related to assurances of adequate capacity and services to § 438.207.

Section 438.114

We have removed the definitions of *emergency medical condition, emergency services,* and *post-stabilization services* and included cross references to the definitions of the same terms in the regulations governing the Medicare+Choice program. We have revised paragraph (c) to provide that the following entities are responsible for coverage and payment of emergency services and post-stabilization services:

- The MCO
- The primary care case manager that has a risk contract
- The State, in the case of a primary care case manager that has a fee-for-service contract.

In paragraph (d), we clarify the specific rules governing coverage and payment for emergency services. We revised paragraph (e) to provide for additional rules that govern emergency services. First, the entity responsible for payment may not limit what constitutes an emergency medical condition based on lists of particular diagnoses or symptoms and it may not refuse to process a claim because it does not contain the primary care provider's authorization number. Second, once a qualified provider determines that an enrollee has an emergency medical condition, the enrollee may not be held liable for subsequent screening and treatment needed to diagnose the specific condition, or stabilize the patient. Third, the attending emergency physician or the provider actually treating the enrollee is responsible for determining when the enrollee is sufficiently stabilized, and that determination is binding on the entities responsible for payment.

We have also revised paragraph (f) to require post-stabilization services to be covered and paid for as provided in the regulations governing the Medicare+Choice program (§ 422.113). We explain that, in applying the Medicare+Choice provisions, reference to ''M+C'' organization'' must be read as reference to the entity responsible for Medicaid payment, as specified in paragraph (c) of this section.

Subpart D—Quality Assessment and Performance Improvement

Note: In the proposed rule, this subpart was subpart E, and the sections were numbered as §§ 438.300 to 438.342. In this final rule, this subpart has been relocated as Subpart D and the sections are numbered as §§ 438.200 to 438.242. Sections referenced herein use the §§ 438.200 to 438.242 numbering of the final rule.

Section 438.202 State responsibilities

In paragraph (b) we require each State contracting with an MCO or PHP to document its quality strategy in writing. In paragraph (c) we require each State to provide for the input of recipients and other stakeholders in the development of the quality strategy, including making the strategy available for public comment before adopting it in final. In paragraph (e) we require the State to update the strategy. In paragraph (f) we require each State to submit to HCFA a copy of the initial strategy and a copy of the revised strategy whenever significant changes are made. In addition, we require the State to submit to HCFA regular reports on the implementation and effectiveness of the strategy.

Section 438.204 Elements of State Strategies

We have revised paragraph (b) to require that the State quality strategy must include procedures for identifying enrollees with special health care needs and assessing the quality and appropriateness of care furnished to those enrollees. We included a new paragraph (c) to require the State quality strategy to incorporate performance measures and levels prescribed by HCFA.

Section 438.206 Availability of Services

We have revised paragraph (d) to clarify that the State must ensure that when each MCO and PHP establishes and maintains its network of providers, each MCO and PHP considers the anticipated enrollment, with particular attention to pregnant women, children, and persons with special health care needs. We have also clarified that each MCO and PHP must consider the training and experience of providers when establishing and maintaining its provider network. In subparagraph (d)(3), we have included a new requirement for MCO and PHP networks (consistent with the scope of the PHP's contracted services) to provide for a second opinion from a qualified health care professional within the network or otherwise arrange for the enrollee to obtain one outside the network at no cost to the enrollee if an additional professional is not currently available within the network. In subparagraph (d)(5) we have added a new requirement that the MCO or PHP must permit an enrollee to access out-of-network providers to receive medical services, if the MCO's or PHP's network is unable to provide the necessary medical services, for as long as the MCO or PHP is unable to provide the services. We have added a new requirement at subparagraph (d)(7) requiring an MCO or PHP to ensure that its providers do not discriminate against Medicaid enrollees. At subparagraph (d)(8) we have added a new requirement that requires the MCO or PHP to require out-of-network providers to coordinate with the MCO or PHP with respect to payment and ensure that the cost to the enrollee is no greater than it would be if the services were furnished within the network. We have moved requirements that MCOs and PHPs must ensure that provider hours of operation are convenient for the enrollees from subparagraph (d)(6) to subparagraph (e)(1)(ii), and have added a requirement that convenience be determined by a State-established methodology, and at least comparable to Medicaid fee-for-service. We have also moved the requirement that services must be available 24 hours a day, 7 days a week, when medically necessary from subparagraph (d)(5) to (e)(1)(iii).

We have moved the requirements relating to initial assessment from this section to § 438.208.

Section 438.207 Assurances of Adequate Capacity and Services

We have created this new section which relocates and adds to the requirements regarding assurances of adequate capacity and services previously located at § 438.110. We have revised paragraph (a) to provide that each MCO and PHP must give assurances to the State (in the NPRM the MCO was to also give assurance to HCFA) that it has the capacity to serve the expected enrollment in its service area in accordance with the State's standards for access to care under this subpart. In paragraph (b), we have required that each MCO and PHP must submit specific documentation that must be in a format specified by the State and acceptable to the HCFA. In subparagraph (b)(4), we have added requirements that each MCO and PHP must document that it has policies and practices in place to address situations in which there is unanticipated need for providers with particular types of experience or unanticipated limitation of the availability of such providers. We revised paragraph (c) to require the submission of the assurance documentation at least once a year as opposed to every two years as stated in the proposed rule. We also added in paragraph (c) circumstances which we believe constitute a significant change in the MCO's or PHP's operation and

which would require the MCO or PHP to resubmit assurances documenting adequate capacity and services. These are: (1) A significant change in the MCO's or PHP's services or benefits; (2) an expansion or reduction of the MCO's or PHP's geographic service area; (3) the enrollment of a new population in the MCO or PHP; and (4) a significant change in the MCO or PHP rates. We also revised paragraph (d) to provide that after the State reviews the documentation submitted by the MCO or PHP, the State must certify to HCFA that the MCO or PHP has complied with the State's requirements for availability of services, as set forth in § 438.206. We have added a new paragraph (e) to provide that the State must make available to HCFA, upon request, all documentation collected by the State from the MCO or PHP.

Section 438.208 Coordination and Continuity of Care

We have made significant changes to the content and organization of this section. As a part of those changes, we have moved section 438.306(e)(2) and (3) pertaining to initial assessment, and pregnancy and complex and serious medical conditions, to this section. We have clarified that the words ''initial assessment'' used in the proposed rule are actually two different functions: screening and assessment. We have also replaced the words ''persons with serious and complex medical conditions'' with the words ''persons with special health care needs.'' In new paragraph (a) we have clarified that the State needs to determine the extent to which requirements pertaining to initial and ongoing screenings and assessments, and primary care are appropriate requirements for PHPs based on the scope of the PHP's services, and the way the State has organized the delivery of managed care services. New paragraph (b) requires the State to implement mechanisms to identify to the MCO and PHP upon enrollment, the following groups:

- Enrollees at risk of having special health care needs, including —
  - ++Children and adults who are receiving SSI benefits;
  - ++Children in Title IV-E foster care;
  - ++Enrollees over the age of 65;
  - ++Enrollees in relevant, State-established, risk-adjusted, higher-cost payment categories; and
  - ++Any other category of recipients identified by HCFA
- Other enrollees known to be pregnant or to have special health care needs
- Children under the age of 2

We have revised paragraph (d) to clarify and expand upon MCO and PHP responsibilities for screening and assessment. In subparagraph (d)(1)(i), we require that for enrollees identified by the State as being at risk of having special health care needs, the MCO (and PHP as determined appropriate by the State) must make a best effort attempt to perform a screening within 30 days of receiving the identification from the State. For any enrollee that the screening identifies as being pregnant or having special health care needs, the MCO (and PHP as determined appropriate by the State) must perform a comprehensive assessment as expeditiously as the enrollee's health requires, but no later than 30 days from the date of identification.

In subparagraph(d)(2), we require that for enrollees under the age of two or other enrollees known by the State to be pregnant or to have special health care needs, each MCO (and PHP as determined appropriate by the State) must perform a comprehensive assessment as expeditiously as the enrollee's health requires, but no later than 30 days from the date of identification.

In subparagraph (d)(3), we require that for all other enrollees, each MCO (and PHP as determined appropriate by the State) must screen them within 90 days from the date of enrollment. For any enrollee that the screening identifies as being pregnant or having special health care needs, each MCO (and PHP as determined appropriate by the State) must perform a comprehensive assessment as expeditiously as the enrollee's health requires, but no later than 30 days from the date of identification.

We have also added a requirement in subparagraph (e) for MCOs (and PHPs as determined appropriate by the State) to implement mechanisms to identify enrollees who develop special health care needs after enrollment in the MCO or PHP and perform comprehensive assessments as expeditiously as the enrollee's health requires, but no later than 30 days from the date of identification.

In subparagraph (f), we have revised the requirements relating to treatment plans. We require that each MCO and PHP must implement a treatment plan for pregnant women and for enrollees determined to have special health care needs. The treatment plan must —

- Be appropriate to the conditions and needs identified and assessed;
- Be for a specific period of time and periodically updated;
- Specify a standing referral or an adequate number of direct access visits to specialists;
- Ensure adequate coordination of care among providers;
- Be developed with enrollee participation; and
- Ensure periodic reassessment of each enrollee as his or her health requires.

In subparagraph (g), we clarify that MCOs and PHPs must use appropriate health care professionals to perform any comprehensive assessments required by this section and develop and implement any treatment plans required by this section. In paragraph (h) and subparagraph (h)(1), we have revised the requirements relating to primary care and over-all coordination to clarify that the MCO (and PHP as determined appropriate by the State) must have a coordination program that meets State requirements and ensures that each enrollee has an ongoing source of primary care appropriate to his or her needs and a person or entity formally designated as primarily responsible for coordinating the health care furnished to the enrollee. In subparagraph (h)(2) we require the MCO or PHP to coordinate the services it furnishes to the enrollee with the services the enrollee receives from any other MCOs or PHPs. In addition, subparagraph (h)(3) requires the MCO's or PHP's coordination program to ensure that the results of its screening and assessment of an enrollee is shared with the other entities serving the enrollee, so that those entities need not duplicate the screening or assessment. Subparagraph (h)(4) requires that in the process of coordinating care, the MCO or PHP ensures that each enrollee's privacy is protected consistent with confidentiality requirements at § 438.224. Subparagraph (h)(5) requires MCOs and PHPs to ensure that each provider maintains health records that meet professional standards and that there is appropriate and confidential sharing of information among providers.

In subparagraph (h)(6), we require each MCO and PHP to have in effect procedures to address factors that hinder enrollee adherence to prescribed treatments or regimens. In subparagraph (h)(7), we require the MCO to ensure that its providers have the information necessary for effective and continuous patient care and quality improvement, consistent with the confidentiality requirements in § 438.224 and the information system requirements of § 438.242.

Section 438.210 Coverage and Authorization of Services

We have revised paragraph (a) to clarify the contract requirements relating to coverage of services. In subparagraph (a)(1), we require that each contract identify, define and specify each service that the MCO or PHP is required to offer. In subparagraph (a)(2), we require that the MCO or PHP make available the services it is required to offer at least in the amount, duration, and scope that are specified in the State plan and can reasonably be expected to achieve the purpose for which the services are furnished. Subparagraph (a)(3) specifies that the MCO or PHP may not arbitrarily deny or reduce the amount, duration, or scope of a required services solely because of the diagnosis, type of illness, or condition and that the MCO or PHP may place appropriate limits on a service on the basis of criteria such as medical necessity or for the purposes of utilization control (provided the services furnished can reasonably be expected to achieve their purpose).

In subparagraph (a)(4), we require the contract to specify what constitutes medically necessary services in a manner that is no more restrictive than the State Medicaid program as indicated in State statutes and regulations, the State plan, and other State policy and procedures. The contract must specify the extent to which ''medically necessary services'' includes services to prevent, diagnose, treat, or cure health impairments, enable the enrollee to achieve age-appropriate growth and development, and enable the enrollee to attain, maintain, or regain functional capacity. Subparagraph (a)(5) requires the MCO or PHP to furnish services in accordance with their contract specifications.

We have revised paragraph (b) to specify that with respect to the processing of requests for initial and continuing authorization of services, each contract must not have information requirements that are unnecessary or unduly burdensome for the provider or the enrollee. We have also included a requirement that any decision to deny a service authorization request or to authorize service in an amount, duration, or scope that is less than requested, be made by an individual who has appropriate expertise in the field of medicine that encompasses the enrollee's condition or disease.

We have revised paragraph (c) to clarify that each contract must provide for the MCO or PHP to notify the requesting provider and give the enrollee written notice of any decision to deny a service authorization request, or to authorize a service in an amount, duration, or scope that is less than requested. We also clarify that the notice must meet the requirements of § 438.404, except that the notice to the provider need not be in writing.

We have revised the time frames for expedited service authorization decisions. In paragraph (e), we require that under specific circumstances, the contract must provide for the MCO or PHP to make a decision as expeditiously as the enrollee's health condition requires but not later than 72 hours after receipt of the request for service.

Section 438.214 Provider Selection

We have changed the name of this section from ''establishment of provider networks'' to ''provider selection.'' We have reorganized this section to clarify the requirements that apply to licensed independent providers (for example, physicians) and other providers. In subparagraph (b)(3), we have created an exception that applies to providers who are permitted to furnish services only under the direct supervision of a physician or other provider and hospital-based providers who provide services only incident to hospital services. The latter exception does not apply if the provider contracts independently with the MCO or PHP or is promoted by the MCO or PHP as part of the provider network. In subparagraph (b)(4) we have added requirements that the initial credentialling application be dated and signed and that applications, updates, and supporting information submitted by the applicant include an attestation of the correctness and completeness of the information. We have added a new requirement in paragraph (d) that specifies that MCOs and PHPs may not employ or contract with providers excluded from participation in Federal health care programs. In addition, we state in paragraph (e) that each MCO and PHP must comply with any additional requirements established by the State.

Section 438.218 Enrollee Information

We have moved the provisions from this section to § 438.10 and clarified that the information requirements that States must meet under § 438.10 constitute part of the State's quality strategy.

Section 438.320 Enrollee Rights

We have moved the requirements regarding enrollee rights to § 438.100.

Section 438.224 Confidentiality and Accuracy of Enrollee Records

We have changed the name of this section from ''confidentiality'' to ''confidentiality and accuracy of enrollee records.'' We have also reorganized this section to clarify the requirements that apply to MCOs and PHPs. We clarify that this section applies to medical records and any other health and enrollment information maintained with respect to enrollees. In paragraph (c) we require MCOs and PHPs to establish and implement procedures that specify for what purposes the MCO or PHP uses the information and to which entities outside the MCO or PHP (and for what purposes) it discloses the information. In paragraph (d), we clarify that MCO and PHP procedures must safeguard the confidentiality of any information (in *any* form) that identifies a particular enrollee. We have revised the requirements of paragraph (e) to provide that MCO and PHP procedures must ensure that originals of medical records are released only in accordance with Federal and State law. We have also revised the requirements for access in paragraph (f) to require that, consistent with applicable Federal and State law, MCO and PHP procedures must ensure that each enrollee may request and receive a copy of his or her records and information and added a requirement that the enrollee may request that they be amended or corrected.

Section 438.228 Grievance Systems

We have added to this section two new paragraphs. Paragraph (b) requires that if the State delegates to the MCO or PHP responsibility for notice of action under subpart E of part 431 of this chapter, the State must conduct random reviews of each MCO and PHP and its providers and subcontractors to ensure that they are notifying enrollees in a timely manner. Paragraph (c) requires the State to establish a process to review, upon request by the enrollee, quality of care grievances not resolved by the MCO or PHP to the satisfaction of the enrollee.

Section 438.230 Subcontractual Relationships and Delegations

We have revised subparagraph (b)(3) to require each MCO and PHP to formally review its subcontractors' performances according to a periodic schedule established by the State, consistent with industry standards or State MCO laws and regulations. In the proposed rule this formal review was to be carried out at least once a year. We have included a new requirement in

subparagraph (b)(5) that, consistent with the requirements in §§ 438.604 and 438.606 pertaining to submission of certain data by the MCO and PHP that must be certified, each MCO and PHP must require subcontractors to provide certifications with respect to the performance of their duties under the contract and submissions that may be related to State payments.

Section 438.236 Practice Guidelines

We have revised the requirements in paragraph (b) to clarify that each MCO and PHP must adopt (as opposed to develop) practice guidelines. We have further revised the regulation to require that the guidelines—

- Are based, in part, on valid and reliable clinical evidence as opposed to ''reasonable medical evidence''; and
- Are reviewed and updated periodically as appropriate.

We include an example of practice guidelines that satisfy the requirements of this section (The Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents and the Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection).

In paragraph (c), we clarify the dissemination requirements by specifying that each MCO and PHP must disseminate the guidelines to affected providers, and upon request to enrollees and potential enrollees.

Section 438.240 Quality Assessment and Performance Improvement Program

We have added additional provisions and made clarifications to this section. We have added in paragraph (a) a provision that HCFA may specify standardized quality measures and topics for performance improvement projects to be required by States in their contracts with MCOs and PHPs. We have added as subparagraph (b)(4) a provision that the State must require each MCO and PHP to have in effect mechanisms to assess the quality and appropriateness of care furnished to enrollees with special health care needs. We have revised subparagraph (c)(1) to clarify that each MCO and PHP must measure its performance annually. We have added in subparagraph (c)(2) a new requirement that the State must, in establishing minimum performance levels for MCOs and PHPs, include any minimum performance levels specified by HCFA.

In subparagraph (d)(2) we clarified that each performance improvement project must represent the entire Medicaid enrolled population to which the measurement specified in paragraph (d)(1)(i) of this section is relevant. In subparagraph (d)(3), we have clarified that the State is to ensure that each MCO and PHP initiates each year one or more performance improvement projects. In subparagraph (d)(4), we have added ''cultural competence'' as a required non-clinical area for MCO and PHP performance improvement projects.

Section 438.242 Health Information Systems

In paragraph (a) we have deleted the requirement that MCO and PHP health information systems should provide information on MCO or PHP solvency. In paragraph (a) we also have clarified that information on Medicaid enrollee disenrollments pertains to disenrollments for other than loss of Medicaid eligibility.

Subpart F—Grievance System

Section 438.400

We have revised the terms used in this section, using ''grievance and appeal'' to replace ''complaint and grievance''. We have added a definition of ''action'' and of ''quality of care grievance''. We have also defined what constitutes an action.

Section 438.402

We have revised this section to include filing requirements as well as general requirements. In the general requirements in paragraph (b), we add that grievances and appeals must be accepted from the representative of the enrollee as well as from the enrollee; that the enrollee or his or her representative is to receive required notices and information; that the MCO or PHP must ensure that punitive action is neither threatened nor taken against a provider who requests an expedited resolution, or supports an enrollee's grievance or appeal; that at the enrollee's request, the MCO or PHP must refer to the State quality of care grievances not resolved to the satisfaction of the enrollee, and the MCO or PHP must require providers to give notice to enrollees of actions. Under the filing requirements in paragraph (c) we add that a provider may file an appeal on behalf of an enrollee with the enrollee's written consent. We clarify that an enrollee has a reasonable time specified by the State, not to exceed 90 days, to file an appeal after the date of an action. We also provide that a appeal may be filed either orally or in writing but that an oral request for standard resolution of the appeal must be followed by a written request. We specify that notice of action for failure to furnish or arrange for a service or provide payment in a timely manner must be provided whenever the entity has delayed access to the service to the point when there is substantial risk that further delay will adversely affect the enrollee's heart condition.

Section 438.404

We have revised paragraph (a) to provide that the notice of action must be in writing and must meet the language and format requirements of § 438.10. In paragraph (b), we specify what must be contained in the notice of action. In this paragraph we have added that the notice must include information on the circumstances under which the enrollee may be required to pay for the costs of services furnished while the appeal is pending and how the enrolees may decline amortization of benefits; that the enrollee has the right to represent himself or herself, to use legal counsel, or to use a relative, or friend or other individual as spokesperson; and that filing an appeal or requesting a State fair hearing will not negatively affect or impact the way the MCO and the PHP and their providers, or the State agency, treat the enrollee. In paragraph (c), we refer to § 438.210 for the time frames that apply to mailing the notice. In paragraph (d), we specify certain notice requirements for subcontractors or providers who are not employees to furnish a notice of action. We also moved to § 438.406 the provision on the right of the enrollee to appear before the MCO or PHP in person and removed the provision that the appearance must be before the person assigned to resolve the grievance.

Section 438.406

We have revised paragraph (a) to clarify that each MCO or PHP must give enrollees any reasonable assistance in completing forms and taking other procedural steps, including providing interpreter services and toll-free numbers that have adequate TTY/TTD and interpreter capability. We also require the MCO or PHP to ensure that the enrollee's communication is correctly classified as a ''grievance'' or an ''appeal'', that each communication is transmitted timely to staff who have the authority to act upon it, and that it is investigated and disposed of or resolved as required. We expanded the provision in the proposed rule concerning the types of appeals that must be decided by a health care professional to include, in addition to denials based on lack of medical necessity, all grievances and appeals that involve clinical issues and grievances regarding a denial to expedite resolution of an appeal. We also clarify that a health care

professional with appropriate clinical expertise, not only a physician, can serve as the decision maker. In paragraph (b), we have included several additional requirements that apply only to appeals, including that the timeframes for resolution of appeals must take account of the enrollee's health condition, that the enrollee and his or her representative have the opportunity to examine the enrollee's case file, and that the enrollee and his or her representative are parties to the appeal.

Section 438.408

In paragraph (a), we added a basic rule that an MCO or PHP must dispose of grievances and resolve appeals as expeditiously as the enrollee's health condition requires within State-established timeframes not exceeding the timeframes specified in this section. We have included in paragraph (b) the provision in paragraph (a)(4) of the proposed rule regarding the basis for decisions. In paragraph (c) we specify the timeframes for disposing of grievances and resolving appeals. We have added timeframes for disposing of grievances, specifying that grievances of a denial of a request to expedite resolution of an appeal must be disposed of within 72 hours of receipt of the grievance. We also added a provision that all other grievances must be disposed of within 90 days. We continue to provide for a 30-day timeframe for resolving appeals that are not expedited. In paragraph (d) we address extensions of timeframes for decisions. In the final rule we eliminated the authority of the MCO or PHP to grant itself an extension when an appeal is expedited. In the final rule we have added a provision that when an MCO or PHP grants itself an extension of the timeframe for decision of an appeal that is not expedited, the enrollee must be given written notice of the reason for the delay and of the enrollee's right to file a grievance with the decision. We added in the final rule the provision in paragraph (e) that the enrollee must be given written notice of the disposition of all grievances filed in writing and of all quality of care grievances. Oral notices can be provided to enrollees who file oral grievances not related to quality of care, unless the enrollee requests a written notice. In paragraph (f) we have added to the final rule that the notice on disposition of a quality of care grievance must include information that the enrollee has the right to seek further review by the State, and how to request it. In paragraph (h) we have revised the requirement of the proposed regulation that the notice of an appeal resolution must include the name of the MCO or PHP contact and now specify that the title of the contact, not the name, must be included. In paragraph (h) we add a requirement that the MCO or PHP must work with the State to dispose of the grievance if the State considers that the MCO or PHP response was insufficient. In paragraph (i) of the final rule we specify that expedited appeals not wholly favorable to the enrollee must be submitted to the State. In paragraph (j) we provide that the timeframe for fair hearing decision is 90 days minus the number of days taken by the MCO or PHP to resolve the internal appeal. The time used by the beneficiary to file for a State fair hearing does not count toward the 90 days. We have added a provision stating that the parties to a State fair hearing are the enrollee and his or er representative, or the representative of the deceased enrollee's estate. Finally, we add that for appeals of service authorization denials that meet the criteria for expedited resolution, the State fair hearing decision must be within 72 hours of receipt of the file.

Section 438.410

In paragraph (a), we retain the requirement from the proposed rule that each MCO and PHP must establish and maintain an expedited review process for grievances and appeals. In paragraph (b), we add to the final rule a requirement for expedited review of certain grievances. In paragraph (c), we describe the requirements that apply to appeals. In the proposed rule we provided for expedited resolution of appeal if non-expedited resolution would jeopardize the enrollee's life or health or the enrollee's ability to regain maximum function. In the final rule we add ''attain and maintain'' maximum function. In paragraph (d), we specify the steps that the MCO or PHP must take if it denies a request for expedited resolution of an appeal. In the final rule we require that the enrollee be notified of the decision within two calendar days. The proposed rule specified the timeframe as two working days. We also specify in the final rule that if the enroll resubmits the request for expedited resolution with a provider's letter of support, the resolution of the appeal will be expedited.

Section 438.414

In this section on information about the grievance system, in the final rule we differentiate between information that must be available with respect to fair hearings from that with respect to grievances and appeals. We added to the required items information about the right of the enrollee to represent himself or herself or to be represented by legal counsel, a friend or relative, or other spokesperson. We also added that information be provided on the fact that benefits will be continued if requested by an enrollee who files an appeal or requests for fair hearing and that the enrollee may be required to pay the cost of services while an appeal is pending if the final decision is adverse to the enrollee. In the proposed rule we provided that benefits would continue only if requested by the enrollee.

Section 438.416

We have added to the reporting requirements that grievances and appeals be tracked according to whether the disposition and resolution was standard or expedited and that a record must be maintained of when grievances and appeals were acknowledged and provide that . We have deleted the requirement to record disenrollments and that the summary submitted to the State include trends by particular providers or services.

Section 438.420

We have revised the provision that for services to be continued they must have been ordered by the MCO or PHP treating physician or another MCO or PHP physician and that the physician is authorized to order services under the MCO or PHP contract. The new requirement is that the services must have been ordered by an authorized provider. The final rule adds in paragraph (d) specifications for the duration of continued or reinstated benefits.

Section 438.421

We have removed this section and moved the provisions relating to effectuation of reversed appeal resolutions from this section to § 438.424.

Section 438.422

We have removed this section and moved the provisions relating to monitoring of the grievance and appeal system from this section to § 438.426.

Section 438.424

We have removed the 30-calendar day and 60-calendar day time periods for providing services originally denied but authorized through an appeal or fair hearing, respectively. We retain as the sole time determinate that the service must be provided as expeditiously as the enrollee's health condition requires. We also add to the final rule a provision that services denied during appeal that were received and are subsequently

authorized must be paid for by the MCO, PHP, or the State, to State policy and regulations.

Section 438.426

We have added this new section and moved the requirements relating to monitoring of the grievance and appeal system from § 438.422 to this section. We also provide in this section that if the summaries of grievances and appeals reveal a need for changing the system, the MCO or PHP must conduct an in-depth review and take corrective action.

Subpart H—Certifications and Program Integrity Protections

Section 438.602

We have revised the name and content of this section to address the basic rule that as a condition for contracting and for receiving payment under the Medicaid managed care program, an MCO and its subcontractors must comply with the certification and program integrity requirements of this subpart.

Section 438.604

We have added this new section to identify the types of data that must be certified. In paragraph (a), we require that when State payments to the MCO is based on data submitted by the MCO, including, but not limited to, enrollment information, encounter data, and other information required by the State, including data in contracts, proposals and other related documents, the State must require certification of the data as provided in § 438.606. In paragraph (b), we require that the certification must ensure that the MCO is in substantial compliance with the terms of the contract, and must be as provided in § 438.606, regardless of whether or not payment is based on data. In paragraph (c), we provide that certification is required for all documents specified by the State.

Section 438.606

We have revised the name and content of this section to address the source, content and timing of certification. In paragraph (a), we provide that subcontractors must certify data that they submit to the MCO and that the MCO certify the data that it submits to the State. One of the following individuals must certify the MCOs data:

- The MCO's Chief Executive Officer (CEO)
- The MCO's Chief Financial Officer (CFO)
- An individual who has delegated authority to sign for, and who reports directly to, the MCO's CEO or CFO.

In paragraph (b), in the case of data and/or other documents specified by the State, we require that the certification must attest to the accuracy, completeness, and truthfulness of the data/documents, based on best knowledge, information, and belief. In paragraph (b), in the case of certification of contract compliance, we require that the MCO attest based on best knowledge, information, and belief that they are in substantial compliance with their contract. In paragraph (c), we require the MCO to submit the certification concurrently with the certified data. In paragraph (c), we require that the MCO submit the certification of substantial compliance when requesting payment.

Section 438.608

We have revised the name and content of this section to include the program integrity requirements. In paragraph (a), we specify that the general rule is that the MCO must have administrative and management arrangements or procedures, including a mandatory compliance plan, that are designed to guard against fraud and abuse. In paragraph (b), we describe the specific requirements that apply to the administrative and management arrangements or procedures, which include:

- Written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable Federal and State standards.
- The designation of a compliance officer and a compliance committee that are accountable to senior management.
- Effective training and education for the compliance officer and the organization's employees.
- Effective lines of communication between the compliance officer and the organization's employees.
- Enforcement of standards through well-publicized disciplinary guidelines.
- Provision of internal monitoring and auditing.
- Provision for prompt response to detected offenses and development of corrective action initiatives relating to the MCO's contract, including specific reporting requirements.

Subpart I—Sanctions

Section 438.700

We have revised paragraph (a) to clarify that States that contract with either MCOs or PHPs must establish intermediate sanctions. We have added a sentence to paragraph (a) specifying that a State's determination may be based on findings from onsite surveys, enrollee or other complaints, financial audits, or any other means. In paragraph (c) we clarify that the intermediate sanctions may be imposed if the State determines that the MCO or PHP distributes directly, or indirectly through any agent or independent contract, marketing materials that have not been approved by the State or that contain false or materially misleading information.

We have moved the requirements that were previously in § 438.702(b) to this section for clarity. In the new paragraph (d) we provide that the intermediate sanctions described in § 438.702(a)(4) and (a)(5) may be imposed if the State determines that an MCO or PHP violates any of the requirements in section 1903(m) of the Act or an MCO or PHP violates any of the requirements of section 1932 of the Act.

Section 438.702

We have revised subparagraph (a)(4) to provide that the State may impose an intermediate sanction that suspends all new enrollment, including default enrollment, after the effective date of the sanction. We have revised subparagraph (a)(5) to provide that the State may suspend payment for recipients enrolled after the effective date of the sanction. We have revised paragraph (b) to specify that State agencies retain authority to impose additional sanctions under State statutes or State regulations that address areas of noncompliance.

Section 438.704

We have revised subparagraph (b)(3) to clarify that the penalty is subject to the overall limit of $100,000 under subparagraph (b)(2). We have also revised subparagraph (b)(4) to clarify that the limit on the penalty is greater of double the amount of the excess charge or $25,000.

Section 438.706

We have revised paragraph (a) to clarify that the State may impose the sanction of temporary management under certain circumstances. We also removed a reference to § 434.67. We have moved the requirements that were previously in § 438.708 to paragraph (b) of this section. That paragraph provides that the State must impose the sanction of temporary management if it finds that an MCO or PHP has repeatedly failed to meet substantive requirements in section 1903(m) or 1932 of the Act, or this subpart. In addition, the State must also grant enrollees the right to terminate enrollment without cause. In

paragraph (c) we specify that the State may not delay imposition of temporary management to carry out due process procedures and may not provide a hearing before imposing this sanction.

Section 438.708

We have revised the name and content of this section to include the requirements relating to termination of an MCO or PHP contract that were previously in § 438.718. We have moved the requirements relating to mandatory imposition of the sanction of temporary management from this section to § 438.706. We have revised terminology in paragraph (a) from ''substantially'' to ''substantive.''

Section 438.710

We have revised the name and content of this section to include the requirements relating pre-termination hearing that were previously in § 438.720. We have revised paragraph (b) by removing the required time frames. Paragraph (b)(2) provides that prior to a pre-termination hearing, the State must give the MCO or PHP written notice of its intent to terminate, the reason for termination, and the time and place of the hearing. In addition, after the hearing, the State must give the MCO or PHP written notice of the decision affirming or reversing the proposed termination and, for an affirming decision, the effective date of termination. We have added a statement at paragraph (b)(2)(iii) that for an affirming decision, the State must give enrollees of the MCO or PHP notice of the termination along with information on their options for receiving care following the effective date of termination.

Section 438.718

We have removed this section and moved the requirements relating to termination of an MCE contract to § 438.708.

Section 438.720

We have removed this section and moved the requirements relating to pre-termination hearing to § 438.710.

Section 438.724

We have revised the name and content of this section to by removing the requirements for providing notice to HCFA of sanctions and by including new requirements for providing public notice of sanctions. In paragraph (a), we provide that the State must publish a notice that describes the intermediate sanction imposed, explains the reasons for the sanction and specifies the amount of any civil money penalty. In paragraph (b), we require the State to publish the notice no later than 30 days after it imposes the sanction. The notice must be a public announcement in either the newspaper of widest circulation in each city within the MCO's or PHP's service area that has a population of 50,000 or more or the newspaper of widest circulation in the MCO's or PHP's service area, if there is no city with a population of 50,000 or more in that area.

Section 438.726

We have added this new section to include the requirement that was previously in § 438.730(g). We require that the State plan must provide for the State to monitor for violation that involve the actions and failures to act specified in this section and to implement the provisions of this section.

Section 438.730

We have revised paragraph (a) to provide that a State agency may recommend that HCFA impose the denial of payment sanction on an MCO with a comprehensive risk contract if the MCO acts or fails to act as specified in § 438.700(b)(1) through (b)(6). Under paragraph (b), we have clarified that if HCFA accepts a State's recommendation, HCFA must convey the determination to the OIG for consideration of possible imposition of civil money penalties under section 1902(m)(5)(A) of the Act and part 1003 of this title. We also explain that, in accordance with the provisions of part 10003, the OIG may impose civil money penalties in addition to, or in place of, the sanctions that may be imposed under this section.

Subpart J—Conditions for Federal Financial Participation

Section 438.802

We have revised paragraph (b) to provide that FFP is available under an MCO or PHP contract only for periods during which the MCO or PHP and its subcontractors are in substantial compliance with the physician incentive plan requirements and the MCO or PHP and the State are in substantial compliance with the requirements of the MCO or PHP contract and of this part.

Section 438.810

We moved the definitions of *choice counseling, enrollment activities, and enrollment broker* from § 438.104 to paragraph (a) of this section. We have also included a new definition of *enrollment services*, which means choice counseling, enrollment activities, or both. We have revised paragraph (b) to include the conditions that enrollment brokers must meet so that State expenditures for their use qualify for FFP. In subparagraph (b)(1), we require that the broker and its subcontractors are independent of any managed care entity or health care provider in the State in which they provide enrollment services. We clarify that a broker or subcontractor is not considered ''independent'' if it is, is owned by, or owns any MCO, PHP, PCCM or other health care provider in the State in which it provides enrollment services. In subparagraph (b)(2), we require that the broker and its subcontractors be free from conflict of interest.

Section 438.814

We have added this new section to prohibit FFP for payments in accordance with risk corridors or incentive arrangements to the extent that these arrangements result in payments that exceed 105% of the approved capitation rates, for the services or enrollees covered by the risk corridor or incentive arrangement.

Part 447—Payments for Services

Section 447.53

We have revised paragraph (e) to specify that no provider may deny care or services to an individual eligible for the care or services on account of the individual's inability to pay the cost sharing.

Section 447.361

This section, which contained the upper payment limit for risk contracts, has been deleted and replaced by expanded requirements for actuarial soundness of capitation rates in new § 438.6(c).

Part 447—Payments for Services

Section 447.53

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Part 447—Payments for Services

Section 447.53

We have revised paragraph (e) to specify that no provider may deny care or services to an individual eligible for the care or services on account of the individual's inability to pay the cost sharing.

VIII. Regulatory Impact Analysis

A. Introduction

We have examined the impacts of this final rule as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits, including potential economic, environmental, public health and safety effects, distributive impacts, and equity. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule meets the criteria of being economically significant because the impact will be over $100 million.

The RFA requires agencies to analyze options for regulatory relief of small entities. This rule implements Medicaid managed care provisions as directed by BBA. The statute does not permit significant alternatives to regulation; however, we have considered ways to reduce burden on small entities.

This final rule with comment period primarily impacts beneficiaries, State Medicaid agencies, enrollment brokers, MCOs, PHPs, and PCCMs. Small entities include small businesses, nonprofit organizations, and other entities that have annual revenues of $5 million or less. Individuals and State governments are not included in this definition. Thus, most of the entities impacted by this regulation do not qualify as small entities. Individual PCCMs and a limited number of small PHPs would be considered small entities for purposes of this regulation.

In publishing this final rule with comment period, we considered regulatory alternatives that would reduce the burden on small entities. Thus, we have decided against imposing additional requirements on PCCMs beyond those specified in the BBA. We also have not applied all MCO requirements to all PHPs. For example, the advance directives requirements do not apply to PHPs that only cover dental or nonclinical services. In addition, PHPs are only required to comply with quality assessment and performance improvement provisions to the extent that they apply services actually provided by the PHP.

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a Metropolitan Statistical Area and has fewer than 50 beds.

We do not anticipate that the provisions in this final rule with comment period will have a substantial economic impact on most hospitals, including small rural hospitals. The BBA provisions include some new requirements on States, MCOs, and PHPs, but no new direct requirements on individual hospitals. The impact on individual hospitals will vary according to each hospital's current and future contractual relationships with MCOs and PHPs. 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 final rule is not expected to have a significant impact on the operations of a substantial number of hospitals.

The Unfunded Mandates Reform Act of 1995 requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an expenditure in any 1 year by State, local and tribal governments, in the aggregate, or by the private sector, of $100 million 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 million or more.

B. Summary of the Final 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 regulation addresses pertinent areas of concern between States and MCOs, PHPs, and PCCMs, including enrollment, access to care, provider network adequacy, and grievance and appeal procedures for beneficiaries.

Specific provisions of the regulation include the following:

- Permitting States to require in their State plan that Medicaid beneficiaries be enrolled in managed care.
- Eliminating the requirement that no more than 75 percent of enrollees in an MCO or PHP be Medicaid or Medicare enrollees.
- Specifying a grievance and appeal procedure for MCO and PHP enrollees.
- Providing for the types of information that must be given to enrollees and potential enrollees, including language and format requirements.
- Requiring that MCOs and PHPs document for the States that they have adequate capacity to serve their enrollees and that States certify this to HCFA.
- Specifying quality standards for States and MCOs and PHPs.
- Increasing program integrity protections and requiring certification of data by MCOs and PHPs.
- Increasing the threshold for prior approval of MCO and PHP contracts from $100,000 to $1 million.
- Permitting cost sharing for managed care enrollees under the same circumstances as permitted in fee-for-service.
- Expanding the managed care population for which States can provide 6 months of guaranteed eligibility.
- Revising the rules for setting capitation rates.

It would be extremely difficult to accurately quantify the overall impact of this regulation on States, MCOs, PHPs, and PCCMs because there is enormous variation among States and these entities regarding their current regulatory and contract requirements, as well as organizational structure and capacity. Any generalization would mask important variations in the impact by State or managed care program type. The Lewin Group, under a contract with the Center for Health Care Strategies, recently completed a study to measure the cost impact of the proposed regulation. The study is the best information we currently have available on the potential incremental impact of the proposed regulation. Further, the study does not include an analysis of the proposed regulation in total, as it only focused on four areas within the proposed regulation: individual treatment plans, initial health assessments, quality improvement porgrams and grievance systems/State fair hearings. While the study's focus is on some of the proposed regulation provisions, of which many have changed, we believe that the overall cost conclusions are relevant to this final rule. In addition to examining the four regulatory requirements, they cited the

need to evaluate the incremental and aggregate effects of the rule; different managed care models (for example, overall enrollment; the Medicare, commercial, and Medicaid mix; geographic location); and State regulatory requirements (for example, State patient rights laws, regulation of noninsurance entities). The Lewin report also points out that many of the BBA provisions were implemented through previous guidance to the States, so the regulatory impact only captures a subset of the actual impact of the totality of BBA requirements.

According to the MCOs included in Lewin's study, many of the proposed provisions are not expected to have large incremental costs. The study mainly focused on the assessment and treatment management components of the regulation, as well as the quality improvement projects. For example, they estimate the incremental cost of an initial assessment (called screening in the final regulation) as ranging from $0.17 to $0.26 per member per month (PMPM), but for an MCO that currently performs an initial assessment, the incremental cost is estimated as $0.03 to $0.06 PMPM. Similarly, the costs of quality improvement projects can vary from $60,000 to $100,000 in the first year (start-up), $80,000 to $100,000 in the second and third years (the intervention and improvement measurement cycle), and $40,000 to $50,000 for the forth and subsequent years (ongoing performance measurement).

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

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

It is clear that all State agencies will be affected by this Medicaid regulation but in varying degrees. Much of the burden will be on MCOs, PHPs, and PCCMs contracting with States, but this will also vary by existing and continuing relationships between State agencies and MCOs, PHPs, and PCCMs. This regulation is intended to maximize State flexibility and minimize the compliance cost to States, MCOs, and PHPs to the extent possible consistent with the detailed BBA requirements. We believe the final 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. This analysis, in combination with the rest of the preamble, is consistent with the standards for analysis set forth by both the RFA and RIA.

C. State Options to Use Managed Care

1. Managed Care Organizations

Under this provision, a State agency may amend its State plan to require all Medicaid beneficiaries in the State to enroll in either an MCO or PCCM without the need to apply for a waiver of ''freedom of choice'' requirements under either section 1915(b) or 1115 of the Act. However, waivers would still be required to include certain exempted populations in mandatory managed care programs, notably SSI populations, 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 States would no longer need to request waiver renewals every 2 years for section 1915(b) of the Act and 5 years for section 1115 of the Act waivers. State agencies may include ''exempted'' populations as voluntary enrollees in State plan managed care programs to maintain parallel waiver programs. Currently, four States use SPAs to require beneficiary enrollment in capitated managed care organizations. In short, the new State plan option provides State agencies with a new choice of method to require participation in managed care. MCOs, PHPs, 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 1115 of the Act waiver may reduce State administrative procedures because it would eliminate the need for States to go through the waiver renewal process. Likewise, we will benefit from a reduced administrative burden if fewer waiver applications and renewals are requested. However, we believe the overall reduction in burden to both States and to us would be small in relation to the overall administrative requirements of the Medicaid program.

2. Primary Care Case Management

Prior to the BBA, many State agencies elected to implement a PCCM system through a freedom of choice waiver under section 1915(b)(1) of the Act. Under the BBA, States may now require beneficiaries to use a PCCM provider under their State plans without the need for a waiver. As of December 2000, five States have chosen this option. Most State agencies, however, have continued to use waiver authority to require enrollment in PCCMs. Therefore, while the BBA provision provides potential for more PCCM programs to come into being, we do not expect expansion of PCCMs to be substantial due to the State plan option. To the extent that the use of PCCMs increases, patients of these providers will benefit from greater continuity of care and patient protections deriving from new and existing standards.

D. Elimination of 75/5 Rule

Prior to the passage of the BBA, nearly all MCOs and PHPs contracting with Medicaid were required to limit combined Medicare and Medicaid participation to 75 percent of their enrollment, and State agencies had to verify enrollment composition as a contract requirement. Elimination of this rule allows MCOs and PHPs to participate without meeting this requirement and eliminates the need for States to monitor enrollment composition in contracting MCOs and PHPs. This will broaden the number of MCOs and PHPs available to States for contracting, leading to more choice for beneficiaries.

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

E. Increased Beneficiary Protection—Grievance Procedures

The BBA requires MCOs to establish internal grievance procedures that permit an eligible enrollee, or a provider on behalf of an enrollee, to challenge the denials of coverage of medical assistance or denials of payment. While these requirements were not previously required by statute, we believe, based on recent State surveys, such as the National Academy for State Health Policy survey of 10 States in 1999, and the American Public Human Services Association survey of 13 States in 1997, that they reflect widespread current practice and, therefore, do not impose significant incremental costs on MCOs, PHPs, or State agencies.

F. 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 MCOs and PHPs. 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 and PHPs, be in a format that can be easily understood by the individuals to which it is directed. We do not believe that these requirements deviate substantially from current practice. Furthermore, there is no way to quantify the degree of burden on State agencies, MCOs, and PHPs for several reasons. We do not have State-specific data on what information States currently provide, or the manner in which they provide it. Variability among States indicates that implementing or continuing enrollee information requirements will represent different degrees of difficulty and expense.

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 and PCCMs to potential enrollees. Currently only eight States have exercised the option to use an SPA to require beneficiary enrollment in managed care. However, for States that do select this option, we do not believe that providing the comparative data in itself represents a burden, as these are elements of information that most States currently provide. The regulation specifies that the information must be presented in a comparative or chart-like form that facilitates comparison among MCOs, PHPs, and PCCMs. This may be perceived as a burden to States that have previously provided this information in some other manner; however, it is our belief that even in the absence of the regulation, the trend is for States, and many accreditation bodies such as the National Committee for Quality Assurance (NCQA), to use chart-like formats. Consequently, enrollees will benefit from having better information for selecting MCOs, PHPs, and PCCMs. Only a few States have opted for SPAs so far, but it is anticipated that more States will participate over the long term. States that participate in the future will benefit from any comparative tools developed by other States.

G. Demonstration of Adequate Capacity and Services

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

Quantifying the additional burden on States, 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 MCOs and PHPs to assure adequate capacity and services. Second, we do not have State-specific information on the manner in which State agencies collect and evaluate documentation in this area. Rather, each State agency has its own documentation requirements and its own procedures to assure adequate capacity and services. This regulation contemplates that States continue to have that flexibility.

Under this regulation, State agencies will determine and specify both the detail and type of documentation to be submitted by the MCO or PHP to assure adequate capacity and services and the type of certification to be submitted to us. Accordingly, variability among State agencies implementing this regulation represents different degrees of detail and expense. Regardless of the level of additional burden on MCOs, PHPs, State agencies, and us, Medicaid beneficiaries will receive continued protections in access to health care under both State and Federal law.

H. New Quality Standards

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

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

addressing how States are to fulfill the statutory requirement for an annual, external quality review (EQR) of each Medicaid-contracting MCO and PHP. (These provisions are addressed in a separate rulemaking). Prior to the BBA, 75 percent Federal financial participation in the cost of these activities was available to States only if the State used a narrowly defined list of entities to perform the quality review. The BBA opened up the possibility for use of a much wider array of entities to perform this function. Further, in HCFA's proposed rule to implement these EQR provisions published on December 1, 1999, we specified that the 75 percent Federal match would also be available to EQR organizations that performed activities necessary for monitoring compliance with these BBA quality requirements for MCOs and PHPs. The BBA also provided that States could exercise an option whereby MCOs that were accredited by a private accrediting organization under certain conditions could be determined to meet certain of the quality requirements specified in this rule, thereby avoiding costs to the State of directly monitoring for compliance with these requirements. In response to this, private accrediting organizations such as the National Committee for Quality Assurance have developed Medicaid accreditation product lines.

In addition, prior to issuance of the proposed rule, we 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 initiatives of State Medicaid agencies and HCFA to promote the assessment and improvement of quality in plans contracting with Medicaid, including:

- The Quality Improvement System for Managed Care (QISMC), an initiative with State and Federal officials, beneficiary advocates, and the managed care industry to develop a coordinated quality oversight system for Medicare and Medicaid that reduces duplicate or conflicting efforts and emphasizes demonstrable and measurable improvement.
- QARI, serving as a foundation to the development of QISMC, highlights the key elements in the Health Care Quality Improvement System (HCQIS), including internal quality assurance programs, State agency monitoring, and Federal oversight. This guidance emphasizes quality standards developed in conjunction with all system participants, such as managed care contractors, State regulators, Medicaid beneficiaries or their representatives, and external review organizations.

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

While we anticipate that many organizations will need to invest in new staff and information systems in order to perform these new quality improvement activities, it is difficult to quantify these financial and operational ''investments,'' as State agencies, MCOs, and PHPs across the country exhibit varying capabilities in meeting these standards. These new quality requirements will present administrative challenges for some State agencies and MCOs; however, PHPs and States have significant latitude in how these requirements will be implemented. Acknowledging that there likely will be some degree of burden on States, MCOs, and PHPs, 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.

I. Administration

1. Certifications and Program Integrity Protections

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

Section 438.602 of the regulation addresses the importance of reliable data that are submitted to States and requires MCOs and PHPs to certify the accuracy of these data to the State. These data include enrollment information, encounter data, or other information that is used for payment determination. For the most part, States reimburse MCOs and PHPs 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 States 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 and PHPs have historically worked closely with States when reporting Medicaid data in order to affirm that the data are accurate and complete. Submitting a certification of validity could take place in a variety of ways and will represent a varying degree of burden for health plans.

Section 438.606 requires MCOs and PHPs to have effective operational capabilities to guard against fraud and abuse. This will result in reporting violations of law by MCOs and PHPs to the State. Providers and health plans have traditionally ensured compliance with Federal and State laws when providing and delivering health care to members. For example, many health plans comply with standards set by the National Association of Insurance Commissioners (NAIC). However, additional resources and procedures will be necessary to have a systematic process for documenting violations and formally notifying the State of these instances.

The requirement for MCOs and PHPs to certify the accuracy and completeness of provider contracts or other documents 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 or PHP, new processes may be necessary to comply with this standard. This requirement may not necessarily result in new mechanisms or resources for MCOs and PHPs but may create the need for more coordination with additional State Medicaid Agency

representatives in the review of provider contracts.

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

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

J. Permitting Same Copayments in Managed Care as in FFP

Under section 4708(c) of the BBA, States may now allow copayments for services provided by MCOs and PHPs 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 or PHP enrollees to realize some savings as a result. However, applying copayments in Medicaid populations may cause States, MCOs, and PHPs to incur overhead costs related to administering these fees that more than offset these savings. This is due to several factors including that copayments are significantly lower for Medicaid beneficiaries than typical commercial copayments, that it is difficult to ensure compliance with these payments, and that collection efforts would be necessary for MCOs or PHPs to obtain all fees due to them. Also, if State agencies take advantage of this option, Medicaid managed care enrollees may defer receipt of health care services and find their health conditions deteriorate such that costs of medical treatment may be greater over the long term. As a result of these variables, it is difficult to predict how many States will take advantage of this new option of permitting copayments for MCO or PHP enrollees.

K. 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 MCOs whose members may have guaranteed eligibility, in that it now includes anyone who is enrolled with a Medicaid managed care organization as defined in section 1903(m)(1)(A) of the Act. Second, it expands the option to include those enrolled with a PCCM as defined in section 1905(t) of the Act. These changes are effective October 1, 1997. To the extent that State agencies choose this option, we expect MCOs, PHPs, and PCCMs in those States to support the use of this provision since it affords health plans with assurance of membership for a specified period of time. Likewise, beneficiaries will gain from this coverage expansion, and continuity of care 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

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

	FY 2000	FY 2001	FY 2002	FY 2003	FY 2004	FY 2005
Federal	40	55	80	115	165	230
State	30	45	60	905	125	175
Total	70	100	140	205	290	405

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 prior to enactment of 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.

L. Financial Impact of Revised Rules for Setting Capitation Payments

This rule replaces the current upper payment limit (UPL) requirement at § 447.361 with new rate-setting rules incorporating an expanded requirement for actuarial soundness of capitation rates as described in detail in § 438.6(c) below. In general, we do not expect a major budget impact from the use of these new rate setting rules. While the new rate setting rules may provide some States additional flexibility in setting higher capitation rates than what would have been allowed under current rules, we believe that the requirements for actuarial certification of rates, along with budgetary considerations by State policy makers, would serve to limit increases to within reasonable amounts. Moreover, the Secretary would retain the authority to look behind rates that appear questionable and disapprove any that did not comply with the new rate setting requirements.

M. Administrative Costs

This regulation requires States to include certain specifications in their contracts with MCOs, PHPs, and PCCMs and to monitor compliance with those contract provisions. It also requires States to take a proactive role in monitoring the quality of their managed care program. These requirements will add some administrative burden and costs to States. The amount of additional administrative cost will vary by State depending on how inclusive current practice is of the new

requirements. In addition, for those States not using like requirements at present, we believe that most would be adopting similar requirements on their own in the future absent this regulation.

The regulation will also increase Federal responsibilities for monitoring State performance in managing their managed care programs. However, no new Federal costs are expected as HCFA plans to use existing staff to monitor these new requirements.

N. Conclusion

This BBA managed care regulation will affect HCFA, States, MCOs, PHPs, PCCMs, providers, and beneficiaries in different ways. The initial investments that are needed by State agencies and MCOs, PHPs, and PCCMs will result in improved and more consistent standards for the delivery of health care to Medicaid beneficiaries. Greater consumer safeguards will result from new quality improvement and protection provisions. Consequently, long term savings will derive from more consistent standards across States, MCOs, PHPs, and PCCMs and increased opportunities for provider and beneficiary involvement in improved access, outcomes, and satisfaction.

O. Federalism

Under Executive Order 13132, we are required to adhere to certain criteria regarding Federalism in developing regulations. We have determined that this final regulation will not significantly affect States rights, roles, and responsibilities. The BBA requires States that contract with section 1903(m) of the Act organizations to have certain beneficiary protections in place when mandating managed care enrollment. This final rule implements those BBA provisions in accordance with the Administrative Procedure Act. This rule also eliminates certain requirements viewed by States as impediments to the growth of managed care programs, such as disenrollment without cause at any time and the inability to amend the State plan without a waiver for mandatory managed care enrollment. We apply many of these requirements to prepaid health plans as set forth in our September 29, 1998 proposed rule. We believe this is consistent with the intent of the Congress in enacting the quality and beneficiary protection provisions of the BBA.

We worked closely with States in developing this regulation. We met with State officials and other stakeholders to discuss opportunities and concerns before the end of the comment period. Throughout the development of the regulation, we consulted with State Medicaid 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 States about the Medicaid provisions of the BBA. We provided this guidance through issuance of a series of letters to State Medicaid Directors. From October 1997 through April 2000, over 50 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 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 also invited public comments as part of the rulemaking process and received comments from over 300 individuals and organizations. Most of the commenters had substantial comments that addressed many provisions of the regulation.

We also received hundreds of comments on every subpart of the final rule, including comments for many States and membership organizations representing States. Many of the recommendations made by commenters have been incorporated into this final rule. For recommendations not accepted, a response has been included in this preamble. Moreover, we discussed technical issues with State experts through technical advisory groups to make certain that the final rule could be practically applied.

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

For the reasons set forth in the preamble, the Health Care Financing Administration is amending 42 CFR Chapter IV 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).

§ 400.203 [Amended]

2. In § 400.203, the following statements are added, in alphabetical order, and the definition of ''provider'' is revised to read as set forth below.

PCCM stands for primary care case manager.

PCP stands for primary care physician.

Provider means either of the following:

(1) For the fee-for-service program, it means any individual or entity furnishing Medicaid services under an agreement with the Medicaid agency.

(2) For the managed care program, it means any individual or entity that is engaged in the delivery of health care services and is legally authorized to do so by the State in which it delivers the services.

PART 430—GRANTS TO STATES FOR MEDICAL ASSISTANCE PROGRAMS

1. The authority citation for part 430 continues to read as follows:

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

2. 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—

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

Representative has the meaning given the term by each State consistent with its laws, regulations, and policies.

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

1. The authority citation for part 431 continues to read as follows:

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

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, 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''.

The additions and revisions read as follows:

§ 431.51 Free choice of providers.

(a) *Statutory basis.* * * *

(4) Section 1902(a)(23) of the Act provides that a recipient enrolled in a primary care case management system or Medicaid managed care organization (MCO) may not be denied freedom of choice of qualified providers of family planning services.

(5) Section 1902(e)(2) of the Act provides that an enrollee who, while completing a minimum enrollment period, is deemed eligible only for services furnished by or through the MCO or PCCM, may, as an exception to the deemed limitation, seek family planning services from any qualified provider.

(6) Section 1932(a) of the Act permits a State to restrict the freedom of choice required by section 1902(a)(23), under specified circumstances, for all services except family planning services.

* * * * *

3. In § 431.55, a sentence is added at the end of paragraph (c)(1)(i) to read as follows:

§ 431.55 Waiver of other Medicaid requirements.

* * * * *

(c) * * *

(1) * * *

(i) * * * The person or agency must comply with the requirements set forth in part 438 of this chapter for primary care case management contracts and systems.

4. Section 431.200 is revised to read as follows:

§ 431.200 Basis and scope.

This subpart—

(a) Implements section 1902(a)(3) of the Act, which requires that a State plan provide an opportunity for a fair hearing to any person whose claim for assistance is denied or not acted upon promptly;

(b) Prescribes procedures for an opportunity for hearing if the State agency takes action to suspend, terminate, or reduce services, or an MCO or PHP takes action under subpart F of part 438 of this chapter; and

(c) Implements sections 1919(f)(3) and 1919(e)(7)(F) of the Act by providing an appeals process for any person who—

(1) Is subject to a proposed transfer or discharge from a nursing facility; or

(2) Is adversely affected by the pre-admission screening or the annual resident review that are required by section 1919(e)(7) of the Act.

§ 431.201 [Amended]

5. In § 431.201, the following definition is added in alphabetical order:

* * * * *

Service authorization request means a managed care enrollee's request for the provision of a service.

6. In § 431.220, the introductory text of paragraph (a) is revised, the semicolons after paragraphs (a)(1), (a)(2), and (a)(3) and the ''and'' after the third semicolon are removed and periods are inserted in their place, and a new paragraph (a)(5) is added, to read as follows:

§ 431.220 When a hearing is required.

(a) The State agency must grant an opportunity for a hearing to the following:

* * * * *

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

* * * * *

§ 431.244 [Amended]

7. In § 431.244, paragraph (f) is revised to read as follows:

* * * * *

(f) The agency must take final administrative action as follows:

(1) Ordinarily, within 90 days from the earlier of the following:

(i) The date the enrollee files an MCO or PHP appeal.

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

(2) As expeditiously as the enrollee's health condition requires, but no later than 72 hours after the agency receives, from the MCO or PHP, the case file and information for any appeal of a denial of a service that, as indicated by the MCO or PHP—

(i) Meets the criteria for expedited resolution as set forth in § 438.410(c)(2) of this chapter, but was not resolved within the timeframe for expedited resolution; or

(ii) Was resolved within the timeframe for expedited resolution, but reached a decision wholly or partially adverse to the enrollee.

(3) As expeditiously as the enrollee's health condition requires, but no later than 72 hours after the agency receives, directly from an MCO or PHP enrollee, a fair hearing request on a decision to deny a service that it determines meets the criteria for expedited resolution, as set forth in § 438.410(c)(2) 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 (HIO)'', ''Health maintenance organization (HMO)'', ''Nonrisk'', ''Prepaid health plan (PHP)'', ''provisional status HMO'', and ''risk or underwriting risk'' are removed.

§§ 434.6 [Amended]

4. In paragraph (a)(1), ''Appendix G'' is removed.

§ 434.20 through 434.38 [Removed]

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

§§ 434.42 and 434.44 [Removed]

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

§§ 434.50 and 434.67 [Removed]

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

8. Section 434.70 is revised to read as follows:

§ 434.70 Conditions for Federal financial participation (FFP).

(a) *Basic requirements.* FFP is available only for periods during which the contract—

(1) Meets the requirements of this part;

(2) Meets the applicable requirements of 45 CFR part 74; and

(3) Is in effect.

(b) *Basis for withholding.* 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).

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

a. Throughout the section, ''HMO'', wherever it appears, is revised to read ''MCO''.

b. The section heading and the introductory text are revised to read as follows:

§ 435.212 Individuals who would be ineligible if they were not enrolled in an MCO or PCCM.

The State agency may provide that a recipient who is enrolled in an MCO or PCCM and who becomes ineligible for Medicaid is considered to continue to be eligible—

* * * * *

3. Section 435.326 is revised to read as follows:

§ 435.326 Individuals who would be ineligible if they were not enrolled in an MCO or PCCM.

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

§ 435.1002 [Amended]

4. In § 435.1002, in paragraph (a), ''§§ 435.1007 and 435.1008'' is revised to read §§ 435.1007, 435.1008, and 438.814 of this chapter,''

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

PART 438—MANAGED CARE PROVISIONS

Subpart A—General Provisions

Sec.
438.1 Basis and scope.
438.2 Definitions.
438.6 Contract requirements.
438.8 Provisions that apply to PHPs.
438.10 Information requirements.
438.12 Provider discrimination prohibited.

Subpart B— State Responsibilities

438.50 State Plan requirements.
438.52 Choice of MCOs, PHPs, and PCCMs.
438.56 Disenrollment: Requirements and limitations.
438.58 Conflict of interest safeguards.
438.60 Limit on payment to other providers.
438.62 Continued services to recipients.
438.66 Monitoring procedures.
438.68 Education of MCOs, PHPs, and PCCMs and subcontracting providers.

Subpart C—Enrollee Rights and Protections

438.100 Enrollee rights.
438.102 Provider-enrollee communications.
438.104 Marketing activities.
438.106 Liability for payment.
438.108 Cost sharing.
438.114 Emergency and post-stabilization services.
438.116 Solvency standards.

Subpart D—Quality Assessment and Performance Improvement

438.200 Scope.
438.202 State responsibilities.
438.204 Elements of State quality strategies.

Access Standards

438.206 Availability of services.
438.207 Assurances of adequate capacity and services.
438.208 Coordination and continuity of care.
438.210 Coverage and authorization of services.

Structure and Operation Standards

438.214 Provider selection.
438.218 Enrollee information.
438.224 Confidentiality and accuracy of enrollee records.
438.226 Enrollment and disenrollment.
438.228 Grievance systems.
438.230 Subcontractual relationships and delegation.

Measurement and Improvement Standards

438.236 Practice guidelines.
438.240 Quality assessment and performance improvement program.
438.242 Health information systems.

Subpart E—[Reserved]

Subpart F—Grievance System

438.400 Statutory basis and definitions.
438.402 General requirements.
438.404 Notice of action.
438.406 Handling of grievances and appeals.
438.408 Resolution and notification: Grievances and appeals.
438.410 Expedited resolution of grievances and appeals.
438.414 Information about the grievance system.
438.416 Recordkeeping and reporting requirements.
438.420 Continuation of benefits while the MCO or PHP appeal and the State Fair Hearing are pending.
438.424 Effectuation of reversed appeal resolutions.
438.426 Monitoring of the grievance system.

Subpart G—[Reserved]

Subpart H—Certifications and Program Integrity Provisions

438.600 Statutory basis.
438.602 Basic rule.
438.604 Data that must be certified.
438.606 Source, content, and timing of certification.
438.608 Program integrity requirements.

Subpart I—Sanctions

438.700 Basis for imposition of sanctions.
438.702 Types of intermediate sanctions.
438.704 Amounts of civil money penalties.
438.706 Special rules for temporary management.
438.708 Termination of an MCO or PCCM contract.
438.710 Due process: Notice of sanction and pre-termination hearing.
438.722 Disenrollment during termination hearing process.
438.724 Public notice of sanction.
438.726 State plan requirement.
438.730 Sanction by HCFA: Special rules for MCOs with risk contracts.

Subpart J—Conditions for Federal Financial Participation

438.802 Basic requirements.
438.806 Prior approval.
438.808 Exclusion of entities.
438.810 Expenditures for enrollment broker services.
438.812 Costs under risk and nonrisk contracts.
438.814 Limit on payments in excess of capitation rates.

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

Subpart A—General Provisions

§ 438.1 Basis and scope.

(a) *Statutory basis.* This part is based on sections 1902(a)(4), 1903(m), 1905(t), and 1932 of the Act.

(1) Section 1902(a)(4) requires that States provide for methods of administration that the Secretary finds necessary for proper and efficient operation of the State Medicaid plan. The application of the requirements of this part to PHPs that do not meet the statutory definition of MCO or to a PCCM is under the authority in section 1902(a)(4).

(2) Section 1903(m) contains requirements that apply to comprehensive risk contracts.

(3) Section 1903(m)(2)(H) provides that an enrollee who loses Medicaid eligibility for not more than 2 months may be enrolled in the succeeding month in the same MCO or PCCM if that MCO or PCCM still has a contract with the State.

(4) Section 1905(t) contains requirements that apply to PCCMs.

(5) Section 1932—

(i) Provides that, with specified exceptions, a State may require

Medicaid recipients to enroll in MCOs or PCCMs;

(ii) Establishes the rules that MCOs, PCCMs, the State, and the contracts between the State and those entities must meet, including compliance with requirements in sections 1903(m) and 1905(t) of the Act that are implemented in this part;

(iii) Establishes protections for enrollees of MCOs and PCCMs;

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

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

(vi) Provides that a State may not enter into contracts with MCOs unless it has established intermediate sanctions that it may impose on an MCO that fails to comply with specified requirements; and

(vii) Makes other minor changes in the Medicaid program.

(b) *Scope.* This part sets forth requirements, prohibitions, and procedures for the provision of Medicaid services through MCOs, PHPs, and PCCMs. Requirements vary depending on the type of entity and on the authority under which the State contracts with the entity. Provisions that apply only when the contract is under a mandatory managed care program authorized by section 1932(a)(1)(A) of the Act are identified as such.

§ 438.2 Definitions.

As used in this part—

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

Comprehensive risk contract means a risk contract that covers comprehensive services, that is, inpatient hospital services and any of the following services, or any three or more of the following services:

(1) Outpatient hospital services.

(2) Rural health clinic services.

(3) FQHC services.

(4) Other laboratory and X-ray services.

(5) Nursing facility (NF) services.

(6) Early and periodic screening diagnostic, and treatment (EPSDT) services.

(7) Family planning services.

(8) Physician services.

(9) Home health services.

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

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

(1) Through payments to, or arrangements with, providers; and

(2) Under a risk contract with the State.

Managed care organization (MCO) means an entity that has, or is seeking to qualify for, a comprehensive risk contract under this part, and that is —

(1) A Federally qualified HMO that meets the advance directives requirements of subpart I of part 489 of this chapter; or

(2) Any public or private entity that meets the advance directives requirements and is determined to also meet the following conditions:

(i) Makes the services it provides to its Medicaid enrollees as accessible (in terms of timeliness, amount, duration, and scope) as those services are to other Medicaid recipients within the area served by the entity.

(ii) Meets the solvency standards of § 438.116.

Nonrisk contract means a contract under which the contractor—

(1) Is not at financial risk for changes in utilization or for costs incurred under the contract that do not exceed the upper payment limits specified in § 447.362 of this chapter; and

(2) May be reimbursed by the State at the end of the contract period on the basis of the incurred costs, subject to the specified limits.

Prepaid health plan (PHP) means an entity that—

(1) Provides medical services to enrollees under contract with the State agency, and on the basis of prepaid capitation payments, or other payment arrangements that do not use State plan payment rates; and

(2) Does not have a comprehensive risk contract.

Primary care means all health care services and laboratory services customarily furnished by or through a general practitioner, family physician, internal medicine physician, obstetrician/gynecologist, or pediatrician, to the extent the furnishing of those services is legally authorized in the State in which the practitioner furnishes them.

Primary care case management means a system under which a PCCM contracts with the State to furnish case management services (which include the location, coordination and monitoring of primary health care services) to Medicaid recipients.

Primary care case manager (PCCM) means a physician, a physician group practice, an entity that employs or arranges with physicians to furnish primary care case management services or, at State option, any of the following:

(1) A physician assistant.

(2) A nurse practitioner.

(3) A certified nurse-midwife.

Risk contract means a contract under which the contractor—

(1) Assumes risk for the cost of the services covered under the contract; and

(2) Incurs loss if the cost of furnishing the services exceeds the payments under the contract.

§ 438.6 Contract requirements.

(a) *Regional office review.* The HCFA Regional Office must review and approve all MCO and PHP contracts, including those risk and nonrisk contracts that, on the basis of their value, are not subject to the prior approval requirement in § 438.806.

(b) *Entities eligible for comprehensive risk contracts.* A State agency may enter into a comprehensive risk contract only with one of the following:

(1) An MCO.

(2) The entities identified in section 1903(m)(2)(B)(i), (ii), and (iii) of the Act.

(3) Community, Migrant, and Appalachian Health Centers identified in section 1903(m)(2)(G) of the Act. Unless they qualify for a total exemption under section 1903(m)(2)(B) of the Act, these entities are subject to the regulations governing MCOs under this part.

(4) An HIO that arranges for services and became operational before January 1986.

(5) An HIO described in section 9517(c)(3) of the Omnibus Budget Reconciliation Act of 1985 (as added by section 4734(2) of the Omnibus Budget Reconciliation Act of 1990).

(c) *Payments under risk contracts.*—

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

(i) *Actuarially sound capitation rates* means capitation rates that—

(A) Have been developed in accordance with generally accepted actuarial principles and practices;

(B) Are appropriate for the populations to be covered, and the services to be furnished under the contract; and

(C) Have been certified, as meeting the requirements of this paragraph (c), by actuaries who meet the qualification standards established by the American Academy of Actuaries and follow the practice standards established by the Actuarial Standards Board.

(ii) *Adjustments to smooth data* means adjustments made, by cost-neutral methods, across rate cells, to

compensate for distortions in costs, utilization, or the number of eligibles.

(2) *Basic requirements.* (i) All capitation rates paid under risk contracts and all risk-sharing mechanisms in contracts must be actuarially sound.

(ii) The contract must specify the payment rates and any risk-sharing mechanisms, and the actuarial basis for computation of those rates and mechanisms.

(3) *Requirements for actuarially sound rates.* In setting actuarially sound capitation rates, the State must apply the following elements, or explain why they are not applicable:

(i) Base utilization and cost data that are derived from the Medicaid population, or if not, are adjusted to make them comparable to the Medicaid population.

(ii) Adjustments made to smooth data and adjustments to account for factors such as inflation, MCO or PHP administration (subject to the limits in § 438.6(c)(4)(ii) of this section), and utilization;

(iii) Rate cells specific to the enrolled population, by:

(A) Eligibility category;

(B) Age;

(C) Gender;

(D) Locality/region; and

(E) Risk adjustments based on diagnosis or health status (if used).

(iv) Other payment mechanisms and utilization and cost assumptions that are appropriate for individuals with chronic illness, disability, ongoing health care needs, or catastrophic claims, using risk adjustment, risk sharing, or other appropriate cost-neutral methods.

(4) *Documentation.* The State must provide the following documentation:

(i) The actuarial certification of the capitation rates.

(ii) An assurance (in accordance with paragraph (c)(3) of this section) that all payment rates are based only upon services covered under the State plan and to be provided under the contract to Medicaid-eligible individuals.

(iii) Its projection of expenditures under its previous year's contract (or under its FFS program if it did not have a contract in the previous year) compared to those projected under the proposed contract.

(iv) An explanation of any incentive arrangements, or stop-loss, reinsurance, or any other risk-sharing methodologies under the contract.

(5) *Special contract provisions.* (i) Contract provisions for reinsurance, stop-loss limits or other risk-sharing methodologies (other than risk corridors) must be computed on an actuarially sound basis.

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

(iii) For all incentive arrangements, the contract must provide that the arrangement is —

(A) For a fixed period of time;

(B) Not to be renewed automatically;

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

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

(E) Not conditioned on intergovernmental transfer agreements; and

(F) Necessary for the specified activities and targets.

(d) *Enrollment discrimination prohibited.* Contracts with MCOs, PHPs, and PCCMs must provide as follows:

(1) The MCO, PHP or PCCM accepts individuals eligible for enrollment in the order in which they apply without restriction (unless authorized by the Regional Administrator), up to the limits set under the contract.

(2) Enrollment is voluntary, except in the case of mandatory enrollment programs that meet the conditions set forth in § 438.50(a).

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

(4) The MCO, PHP or PCCM will not discriminate against individuals eligible to enroll on the basis of race, color, or national origin, and will not use any policy or practice that has the effect of discriminating on the basis of race, color, or national origin.

(e) *Services that may be covered.* An MCO or PHP contract may cover, for enrollees, services that are in addition to those covered under the State plan.

(f) *Compliance with contracting rules.* All contracts under this subpart must:

(1) Comply with all applicable State and Federal laws and regulations including Title VI of the Civil Rights Act of 1964; Title IX of the Education Amendments of 1972 (regarding education programs and activities); the Age Discrimination Act of 1975; the Rehabilitation Act of 1973; and the Americans with Disabilities Act; and

(2) Meet all the requirements of this section.

(g) *Inspection and audit of financial records.* Risk contracts must provide that the State agency and the Department may inspect and audit any financial records of the entity or its subcontractors.

(h) *Physician incentive plans.* (1) MCO and PHP 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 or PHP'', ''State agency'' and ''Medicaid recipients'', respectively.

(i) *Advance directives.* (1) All MCO and most PHP contracts must provide for compliance with the requirements of § 422.128 of this chapter for maintaining written policies and procedures with respect to advance directives. This requirement does not apply to PHP contracts where the State has determined such application would be inappropriate, as described in § 438.8(a)(2).

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

(3) The information must reflect changes in State law as soon as possible, but no later than 90 days after the effective date of the change.

(j) *Special rules for certain HIOs.* Contracts with HIOs that began operating on or after January 1, 1986, and that the statute does not explicitly exempt from requirements in section 1903(m) of the Act are subject to all the requirements of this part that apply to MCOs and contracts with MCOs. These HIOs may enter into comprehensive risk contracts only if they meet the criteria of paragraph (a) of this section.

(k) *Additional rules for contracts with PCCMs.* A PCCM contract must meet the following requirements:

(1) Provide for reasonable and adequate hours of operation, including 24-hour availability of information, referral, and treatment for emergency medical conditions.

(2) Restrict enrollment to recipients who reside sufficiently near one of the manager's delivery sites to reach that site within a reasonable time using available and affordable modes of transportation.

(3) Provide for arrangements with, or referrals to, sufficient numbers of physicians and other practitioners to ensure that services under the contract can be furnished to enrollees promptly and without compromise to quality of care.

(4) Prohibit discrimination in enrollment, disenrollment, and re-enrollment, based on the recipient's health status or need for health care services.

(5) Provide that enrollees have the right to disenroll from their PCCM in accordance with § 438.56.

(l) *Subcontracts.* All subcontracts must fulfill the requirements of this part that are appropriate to the service or activity delegated under the subcontract.

(m) *Choice of health professional.* The contract must allow each enrollee to choose his or her health professional in the MCO to the extent possible and appropriate.

§ 438.8 Provisions that apply to 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 contract requirements of § 438.6, except for the following:

(1) Requirements that pertain to HIOs.

(2) Requirements for advance directives, if the State believes that they are not appropriate, for example, for a PHP contract that covers only dental services or non-clinical services such as transportation services.

(b) The information requirements in § 438.10.

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

(d) The State responsibility provisions of subpart B except § 438.50.

(e) The enrollee rights and protection provisions in subpart C of this part.

(f) The quality assessment and performance improvement provisions in subpart D of this part to the extent that they are applicable to services furnished by the PHP.

(g) The grievance system provisions in subpart F of this part.

(h) The certification and program integrity protection provisions set forth in subpart H of this part.

§ 438.10 Information requirements.

(a) *Basic rules.* (1) Each State or its contracted representative, and each MCO, PHP, or PCCM must, in furnishing information to enrollees and potential enrollees, meet the requirements that are applicable to it under this section.

(2) The information required for all potential enrollees must be furnished by the State or its contracted representative or, at State option, by the MCO or PHP.

(3) The information required for all enrollees must be furnished by each MCO or PHP, unless the State chooses to furnish it directly or through its contracted representative.

(4) PHPs must comply with the requirements of this section, as appropriate. PHPs that contract as PCCMs must meet all of the requirements applicable to PCCMs. All other PHPs must meet all of the requirements applicable to MCOs.

(5) The language and format requirements of paragraphs (b) and (c) of this section apply to all information furnished to enrollees and potential enrollees, such as enrollment notices and instructions, as well as the information specified in this section.

(6) The State must have in place a mechanism to help enrollees and potential enrollees understand the State's managed care program.

(7) Each MCO and PHP must have in place a mechanism to help enrollees and potential enrollees understand the requirements and benefits of the plan.

(8) If the State plan provides for mandatory enrollment under section 1932(a)(1)(A) of the Act (that is, as a State plan option), the additional requirements of paragraph (h) of this section apply.

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

(1) Establish a methodology for identifying the non-English languages spoken by enrollees and potential enrollees throughout the State.

(2) Provide written information in each non-English language that is necessary for effective communication with a significant number or percentage of enrollees and potential enrollees.

(3) Require each MCO, PHP, and PCCM to make its written information available in the languages that are prevalent in its particular service area.

(4) Make oral interpretation services available and require each MCO, PHP, and PCCM to make those services available free of charge to the recipient to meet the needs of each enrollee and potential enrollee.

(5) Notify enrollees and potential enrollees, and require each MCO, PHP, and PCCM to notify its enrollees and potential enrollees—

(i) That oral interpretation and written information are available in languages other than English; and

(ii) Of how to access those services.

(c) *Format.* (1) The material must—

(i) Use easily understood language and format; and

(ii) Be available in alternative formats and in an appropriate manner that takes into consideration the special needs of those who, for example, are visually limited or have limited reading proficiency.

(2) The State must provide instructions to enrollees and potential enrollees and require each MCO, PHP, and PCCM to provide instructions to its enrollees and potential enrollees on how to obtain information in the appropriate format.

(d) *Information for potential enrollees.*—(1) *To whom and when the information must be furnished.* The State or its contracted representative must provide the information specified in paragraph (d)(2) of this section as follows:

(i) To each potential enrollee residing in the MCO's or PHP's service area;

(ii) At the time the potential enrollee first becomes eligible for Medicaid, is considering choice of MCOs or PHPs under a voluntary program, or is first required to choose an MCO or PHP under a mandatory enrollment program; and

(iii) Within a timeframe that enables the potential enrollee to use the information in choosing among available MCOs or PHPs.

(2) *Required information.* The information for potential enrollees must include the following:

(i) General information about—

(A) The basic features of managed care;

(B) Which populations are excluded from enrollment, subject to mandatory enrollment, or free to enroll voluntarily in an MCO or PHP; and

(C) MCO and PHP responsibilities for coordination of enrollee care;

(ii) Information specific to each MCO and PHP serving an area that encompasses the potential enrollee's service area:

(A) Benefits covered;

(B) Cost sharing, if any;

(C) Service area;

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

(E) Benefits that are available under the State plan but are not covered under the contract, including how and where the enrollee may obtain those benefits, any cost sharing, and how transportation is provided. For a counseling or referral service that the MCO or PHP does not cover because of moral or religious objections, the MCO or PHP need not furnish information about how and where to obtain the service, but only about how and where to obtain information about the service. The State must furnish information about where and how to obtain the service.

(e) *Information for enrollees.*—(1) *To whom and when the information must be furnished.* The MCO or PHP must—

(i) Furnish to each of its enrollees the information specified in paragraph (e)(2) of this section within a reasonable time

after the MCO or PHP receives, from the State or its contracted representative, notice of the recipient's enrollment, and once a year thereafter.

(ii) Give each enrollee written notice of any change (that the State defines as ''significant'') in the information specified in paragraph (e)(2) of this section, at least 30 days before the intended effective date of the change.

(iii) Make a good faith effort to give written notice of termination of a contracted provider, within 15 days after receipt or issuance of the termination notice, to each enrollee who received his or her primary care from, or was seen on a regular basis by, the terminated provider.

(2) *Required information.* The information for enrollees must include the following:

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

(ii) Enrollee rights as specified in § 438.100.

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

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

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

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

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

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

(ix) Cost sharing, if any.

(x) Grievance, appeal, and fair hearing procedures for enrollees, including timeframes, required under § 438.414(b).

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

(xii) Any benefits that are available under the State plan but are not covered under the contract, including how and where the enrollee may obtain those benefits, any cost sharing, and how transportation is provided. For a counseling or referral service that the MCO or PHP does not cover because of moral or religious objections, the MCO or PHP need not furnish information on how and where to obtain the service, but only on how and where to obtain information about the service. The State must furnish information about how and where to obtain the service.

(xiii) Information on how to obtain continued services during a transition, as provided in § 438.62.

(xiv) The rules for emergency and post-stabilization services, as set forth in § 438.114.

(xv) Additional information that is available upon request, and how to request that information.

(3) *Annual notice.* At least once a year, the MCO or PHP, or the State or its contracted representative, must notify enrollees of their right to request and obtain the information listed in paragraphs (e)(2) and (f) of this section.

(f) *MCO or PHP information available upon request.* The following information must be furnished to enrollees and potential enrollees upon request, by the MCO or PHP, or by the State or its contracted representative if the State prohibits the MCO or PHP from providing it:

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

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

(3) Other information on requirements for accessing services to which they are entitled under the contract, including factors such as physical accessibility and non-English languages spoken.

(4) A description of the procedures the MCO or PHP uses to control utilization of services and expenditures.

(5) A summary description of the methods of compensation for physicians.

(6) Information on the financial condition of the MCO or PHP, including the most recently audited information.

(7) Any element of information specified in paragraphs (d) and (e) of this section.

(g) *Information on PCCMs and PHPs.*—(1) *To whom and when the information must be furnished.* The State or its contracted representative must furnish information on PCCMs and PHPs to potential enrollees—

(i) When potential enrollees first become eligible for Medicaid or are first required to choose a PCCM or PHP under a mandatory enrollment program; and

(ii) Within a timeframe that enables them to use the information in choosing among available PCCMs or PHPs .

(2) *Required information.*—(i) *General rule.* The information must include the following:

(A) The names of and non-English languages spoken by PCCMs and PHPs and the locations at which they furnish services.

(B) Any restrictions on the enrollee's choice of the listed PCCMs and PHPs.

(C) Except as provided in paragraph (g)(2)(ii) of this section, any benefits that are available under the State plan but not under the PCCM or PHP contract, including how and where the enrollee may obtain those benefits, any cost-sharing, and how transportation is provided.

(ii) *Exception.* For counseling and referral services that are not covered under the PCCM or PHP contract because of moral or religious objections, the PCCM or PHP need not furnish information about how and where to obtain the service but only about how and where to obtain information about the service. The State must furnish the information on how and where to obtain the service.

(3) *Additional information available upon request.* Each PCCM and PHP must, upon request, furnish information on the grievance procedures available to enrollees, including how to obtain benefits during the appeals process.

(h) *Special rules: States with mandatory enrollment.*—(1) *Basic rule.* If the State plan provides for mandatory enrollment under section 1932(a)(1)(A) of the Act, the State or its contracted representative must furnish information on MCOs, PHPs, and PCCMs (as specified in paragraph (h)(3) of this section), either directly or through the MCO, PHP, or PCCM.

(2) *When and how the information must be furnished.* The information must be furnished to all potential enrollees—

(i) At least once a year; and

(ii) In a comparative, chart-like format.

(3) *Required information.* Some of the information is the same as the information required for potential enrollees under paragraph (d) of this section. However, all of the information in this paragraph is subject to the timeframe and format requirements of paragraph (h)(2) of this section, and includes the following for each contracting MCO, PHP, or PCCM:

(i) The MCO's, PHP's, or PCCM's service area.

(ii) The benefits covered under the contract.

(iii) Any cost sharing imposed by the MCO, PHP, or PCCM.

(iv) To the extent available, quality and performance indicators, including, but not limited to, disenrollment rates as defined by the State, and enrollee satisfaction.

§ 438.12 Provider discrimination prohibited.

(a) *General rules.* (1) An MCO or PHP 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. If an MCO or PHP declines to include individual or groups of providers in its network, it must give the affected providers written notice of the reason for its decision.

(2) In all contracts with health care professionals an MCO or PHP must comply with the requirements specified in § 438.214.

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

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

(2) Preclude the MCO or PHP from using different reimbursement amounts for different specialties or for different practitioners in the same specialty; or

(3) Preclude the MCO or PHP from establishing measures that are designed to maintain quality of services and control costs and are consistent with its responsibilities to enrollees.

Subpart B—State Responsibilities

§ 438.50 State plan requirements.

(a) *General rule.* A State plan that provides for requiring Medicaid recipients to enroll in managed care entities must comply with the provisions of this section, except when the State imposes the requirement—

(1) As part of a demonstration project under section 1115 of the Act; or

(2) Under a waiver granted under section 1915(b) of the Act.

(b) *State plan information.* The plan must specify—(1) The types of entities with which the State contracts;

(2) The payment method it uses (for example, whether fee-for-service or capitation);

(3) Whether it contracts on a comprehensive risk basis; and

(4) The process the State uses to involve the public in both design and initial implementation of the program and the methods it uses to ensure ongoing public involvement once the State plan has been implemented.

(c) *State plan assurances.* The plan must provide assurances that the State meets applicable requirements of the following laws and regulations:

(1) Section 1903(m) of the Act, with respect to MCOs and MCO contracts.

(2) Section 1905(t) of the Act, with respect to PCCMs and PCCM contracts.

(3) Section 1932(a)(1)(A) of the Act, with respect to the State's option to limit freedom of choice by requiring recipients to receive their benefits through managed care entities.

(4) This part, with respect to MCOs and PCCMs.

(5) Part 434 of this chapter, with respect to all contracts.

(6) Section 438.6(c), with respect to payments under any risk contracts, and § 447.362 with respect to payments under any nonrisk contracts.

(d) *Limitations on enrollment.* The State must provide assurances that, in implementing the State plan managed care option, it will not require the following groups to enroll in an MCO or PCCM:

(1) Recipients who are also eligible for Medicare.

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

(i) The Indian Health Service; or

(ii) An Indian health program or Urban Indian program operated by a tribe or tribal organization under a contract, grant, cooperative agreement or compact with the Indian Health Service.

(3) Children under 19 years of age who are—

(i) Eligible for SSI under title XVI;

(ii) Eligible under section 1902(e)(3) of the Act;

(iii) In foster care or other out-of-home placement;

(iv) Receiving foster care or adoption assistance; or

(v) Receiving services through a family-centered, community-based, coordinated care system that receives grant funds under section 501(a)(1)(D) of title V, and is defined by the State in terms of either program participation or special health care needs.

(e) *Priority for enrollment.* The State must have an enrollment system under which recipients already enrolled in an MCO or PCCM are given priority to continue that enrollment if the MCO or PCCM does not have the capacity to accept all those seeking enrollment under the program.

(f) *Enrollment by default.* (1) For recipients who do not choose an MCO or PCCM during their enrollment period, the State must have a default enrollment process for assigning those recipients to contracting MCOs and PCCMs.

(2) The process must seek to preserve existing provider-recipient relationships and relationships with providers that have traditionally served Medicaid recipients. If that is not possible, the State must distribute the recipients equitably among qualified MCOs and PCCMs available to enroll them, excluding those that are subject to the intermediate sanction described in § 438.702(a)(4).

(3) An ''existing provider-recipient relationship'' is one in which the provider was the main source of Medicaid services for the recipient during the previous year. This may be established through State records of previous managed care enrollment or fee-for-service experience, or through contact with the recipient.

(4) A provider is considered to have ''traditionally served'' Medicaid recipients if it has experience in serving the Medicaid population.

§ 438.52 Choice of MCOs, PHPs, and PCCMs.

(a) *General rule.* Except as specified in paragraphs (b) and (c) of this section, a State that requires Medicaid recipients to enroll in an MCO, PHP, or PCCM must give those recipients a choice of at least two entities.

(b) *Exception for rural area residents.* (1) Under any of the following programs, and subject to the requirements of paragraph (b)(2) of this section, a State may limit a rural area resident to a single MCO, PHP, or PCCM system:

(i) A program authorized by a plan amendment under section 1932(a) of the Act.

(ii) A waiver under section 1115 of the Act.

(iii) A waiver under section 1915(b) of the Act.

(2) A State that elects the option provided under paragraph(b)(1) of this section, must permit the recipient—

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

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

(A) The service or type of provider is not available within the MCO, PHP, or PCCM network.

(B) The provider is not part of the network, but is the main source of a service to the recipient. (This provision applies as long as the provider continues to be the main source of the service).

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

(D) The recipient's primary care provider or other provider determines

that the recipient needs related services that would subject the recipient to unnecessary risk if received separately (for example, a cesarean section and a tubal ligation) and not all of the related services are available within the network.

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

(3) As used in this paragraph, ''rural area''is any area other than an ''urban area'' as defined in § 412.62(f)(1)(ii) of this chapter.

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

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

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

(d) *Limitations on changes between primary care providers.* For an enrollee of a single MCO, PHP, or HIO under paragraph (b)(2) or (b)(3) of this section, any limitation the State imposes on his or her freedom to change between primary care providers may be no more restrictive than the limitations on disenrollment under § 438.56(c).

§ 438.56 Disenrollment: Requirements and limitations.

(a) *Applicability.* The provisions of this section apply to all managed care arrangements whether enrollment is mandatory or voluntary and whether the contract is with an MCO, a PHP, or a PCCM.

(b) *Disenrollment requested by the MCO, PHP or PCCM.* All MCO, PHP, and PCCM contracts must—(1) Specify the reasons for which the MCO, PHP or PCCM may request disenrollment of an enrollee;

(2) Provide that the MCO, PHP or PCCM may not request disenrollment because of a change in the enrollee's health status, or because of the enrollee's utilization of medical services, diminished mental capacity, or uncooperative or disruptive behavior resulting from his or her special needs (except where his or her continued enrollment in the MCO, PHP or PCCM seriously impairs the entity's ability to furnish services to either this particular enrollee or other enrollees); and

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

(c) *Disenrollment requested by the enrollee.* If the State chooses to limit disenrollment, its MCO, PHP, and PCCM contracts must provide that a recipient may request disenrollment as follows:

(1) For cause, at any time.

(2) Without cause, at the following times:

(i) During the 90 days following the date of the recipient's initial enrollment with the MCO, PHP or PCCM, or the date the State sends the recipient notice of the enrollment, whichever is later.

(ii) At least once every 12 months thereafter.

(iii) Upon automatic reenrollment under paragraph (g) of this section, if the temporary loss of Medicaid eligibility has caused the recipient to miss the annual disenrollment opportunity.

(iv) When the State imposes the intermediate sanction specified in § 438.702(a)(3).

(d) *Procedures for disenrollment.* (1) *Request for disenrollment.* The recipient (or his or her representative) must submit an oral or written request—

(i) To the State agency (or its agent); or

(ii) To the MCO, PHP or PCCM, if the State permits MCOs, PHPs, and PCCMs to process disenrollment requests.

(2) *Cause for disenrollment.* The following are cause for disenrollment:

(i) The enrollee was homeless (as defined by the State) or a migrant worker at the time of enrollment and was enrolled in the MCO, PHP or PCCM by default.

(ii) The plan does not, because of moral or religious objections, cover the service the enrollee seeks.

(iii) The enrollee needs related services (for example a cesarean section and a tubal ligation) to be performed at the same time; not all related services are available within the network; and the enrollee's primary care provider or another provider determines that receiving the services separately would subject the enrollee to unnecessary risk.

(iv) Other reasons, including but not limited to, poor quality of care, lack of access to services covered under the contract, or lack of access to providers experienced in dealing with the enrollee's health care needs.

(3) *MCO, PHP or PCCM action on request.* (i) An MCO, PHP or PCCM may either approve a request for disenrollment or refer the request to the State.

(ii) If the MCO, PHP, PCCM, or State agency (whichever is responsible) fails to make a disenrollment determination so that the recipient can be disenrolled within the timeframes specified in paragraphs (e)(1) of this section, the disenrollment is considered approved.

(4) *State agency action on request.* For a request received directly from the recipient, or one referred by the MCO, PHP or PCCM, the State agency must take action to approve or disapprove the request based on the following:

(i) Reasons cited in the request.

(ii) Information provided by the MCO, PHP or the PCCM at the agency's request.

(iii) Any of the reasons specified in paragraph (d)(2) of this section.

(5) *Use of the MCO, PHP, or PCCM grievance procedures.* (i) The State agency may require that the enrollee seek redress through the MCO, PHP, or PCCM's grievance system before making a determination on the enrollee's request.

(ii) The grievance process, if used, must be completed in time to permit the disenrollment (if approved) to be effective in accordance with the timeframe specified in § 438.56(e)(1).

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

(e) *Timeframe for disenrollment determinations.* (1) Regardless of the procedures followed, the effective date of an approved disenrollment must be no later than the first day of the second month following the month in which the enrollee or the MCO, PHP or PCCM files the request.

(2) If the MCO, PHP or PCCM or the State agency (whichever is responsible) fails to make the determination within the timeframes specified in paragraphs (e)(1) and (e)(2) of this section, the disenrollment is considered approved.

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

(1) Provide that enrollees and their representatives are given written notice of disenrollment rights at least 60 days before the start of each enrollment period.

(2) Ensure access to State fair hearing for any enrollee dissatisfied with a State agency determination that there is not good cause for disenrollment.

(g) *Automatic reenrollment: Contract requirement.* If the State plan so specifies, the contract must provide for automatic reenrollment of a recipient who is disenrolled solely because he or she loses Medicaid eligibility for a period of 2 months or less.

§ 438.58 Conflict of interest safeguards.

(a) As a condition for contracting with MCOs or PHPs, 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 or PHP contracts or the default

enrollment process specified in § 438.50(f).

(b) These safeguards must be at least as effective as the safeguards specified in section 27 of the Office of Federal Procurement Policy Act (41 U.S.C. 423).

§ 438.60 Limit on payment to other providers.

The State agency must ensure that no payment is made to a provider other than the MCO or PHP for services available under the contract between the State and the MCO or PHP, except where such payments are provided for in title XIX of the Act or 42 CFR.

§ 438.62 Continued services to recipients.

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

(b) The State agency must have in effect a mechanism to ensure continued access to services when an enrollee with ongoing health care needs is transitioned from fee-for-service to an MCO, PHP or PCCM, from one MCO, PHP or PCCM to another, or from an MCO, PHP or PCCM to fee-for-service.

(1) The mechanism must apply at least to the following:

(i) Children and adults receiving SSI benefits.

(ii) Children in title IV–E foster care.

(iii) Recipients aged 65 or older.

(iv) Pregnant women.

(v) Any other recipients whose care is paid for under State-established, risk-adjusted, high-cost payment categories.

(vi) Any other category of recipients identified by HCFA.

(2) The State must notify the enrollee that a transition mechanism exists, and provide instructions on how to access the mechanism.

(3) The State must ensure that an enrollee's ongoing health care needs are met during the transition period, by establishing procedures to ensure that, at a minimum—

(i) The enrollee has access to services consistent with the State plan, and is referred to appropriate health care providers;

(ii) Consistent with Federal and State law, new providers are able to obtain copies of appropriate medical records; and

(iii) Any other necessary procedures are in effect.

§ 438.66 Monitoring procedures.

The State agency must have in effect procedures for monitoring the MCO's or PHP's operations, including, at a minimum, operations related to:

(a) Recipient enrollment and disenrollment.

(b) Processing of grievances and appeals.

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

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

(e) All other provisions of the contract, as appropriate.

§ 438.68 Education of MCOs, PHPs, and PCCMs and subcontracting providers.

The State agency must have in effect procedures for educating MCOs, PHPs, PCCMs and any subcontracting providers about the clinical and other needs of enrollees with special health care needs.

Subpart C—Enrollee Rights and Protections

§ 438.100 Enrollee rights.

(a) *General rule.* The State must ensure that—

(1) Each MCO and each PHP has written policies regarding the enrollee rights specified in this section; and

(2) Each MCO, PHP, and PCCM complies with any applicable Federal and State laws that pertain to enrollee rights, and ensures that its staff and affiliated providers take those rights into account when furnishing services to enrollees.

(b) *Specific rights*—(1) *Basic requirement.* The State must ensure that each managed care enrollee is guaranteed the rights as specified in paragraphs (b)(2) and (b)(3) of this section.

(2) An enrollee of an MCO, PHP, or PCCM has the following rights: The right

(i) To receive information in accordance with § 438.10.

(ii) To be treated with respect and with due consideration for his or her dignity and privacy.

(iii) To receive information on available treatment options and alternatives, presented in a manner appropriate to the enrollee's condition and ability to understand. (The information requirements for services that are not covered under the contract because of moral or religious objections are set forth in § 438.10(e).)

(iv) To participate in decisions regarding his or her health care, including the right to refuse treatment.

(v) To be free from any form of restraint or seclusion used as a means of coercion, discipline, convenience or retaliation, as specified in other Federal regulations on the use of restraints and seclusion.

(3) An enrollee of an MCO or a PHP also has the following rights—The right

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

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

(iii) To request and receive a copy of his or her medical records, and to request that they be amended or corrected, as specified in § 438.224.

(c) *Free exercise of rights.* The State must ensure that each enrollee is free to exercise his or her rights, and that the exercise of those rights does not adversely affect the way the MCO, PHP or PCCM and its providers or the State agency treat the enrollee.

(d) *Compliance with other Federal and State laws.* The State must ensure that each MCO, PHP, and PCCM complies with any other applicable Federal and State laws (such as: Title VI of the Civil Rights Act of 1964 as implemented by regulations at 45 CFR part 484; the Age Discrimination Act of 1975 as implemented by regulations at 45 CFR part 91; the Rehabilitation Act of 1973; and Titles II and III of the Americans with Disabilities Act and other laws regarding privacy and confidentiality).

§ 438.102 Provider-enrollee communications.

(a) *Health care professional defined.* As used in this subpart, ''health care professional'' means a physician or any of the following: a podiatrist, optometrist, chiropractor, psychologist, dentist, physician assistant, physical or occupational therapist, therapist assistant, speech-language pathologist, audiologist, registered or practical nurse (including nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, and certified nurse midwife), licensed certified social worker, registered respiratory therapist, and certified respiratory therapy technician.

(b) *General rules.* (1) An MCO or PHP may not prohibit, or otherwise restrict a health care professional acting within the lawful scope of practice, from advising or advocating on behalf of an enrollee who is his or her patient, with respect to the following:

(i) The enrollee's health status, medical care, or treatment options, including any alternative treatment that may be self-administered.

(ii) Any information the enrollee needs in order to decide among all relevant treatment options.

(iii) The risks, benefits, and consequences of treatment or non-treatment.

(iv) The enrollee's right to participate in decisions regarding his or her health care, including the right to refuse treatment, and to express preferences about future treatment decisions.

(2) MCOs and PHPs must take steps to ensure that health care professionals—

(i) Furnish information about treatment options (including the option of no treatment) in a culturally competent manner; and

(ii) Ensure that enrollees with disabilities have effective communication with all health system participants in making decisions with respect to treatment options.

(3) Subject to the information requirements of paragraph (c) of this section, an MCO or PHP that would otherwise be required to provide, reimburse for, or provide coverage of, a counseling or referral service because of the requirement in paragraph (b)(1) of this section is not required to do so if the MCO or PHP objects to the service on moral or religious grounds.

(c) *Information requirements: MCO and PHP responsibility.* (1) An MCO or PHP that elects the option provided in paragraph (b) (3) of this section must furnish information about the services it does not cover as follows:

(i) To the State—

(A) With its application for a Medicaid contract; and

(B) Whenever it adopts the policy during the term of the contract.

(ii) Consistent with the provisions of § 438.10—

(A) To potential enrollees, before and during enrollment; and

(B) To enrollees, within 90 days after adopting the policy with respect to any particular service. (Although this timeframe would be sufficient to entitle the MCO or PHP to the option provided in paragraph (b)(3) of this section, the overriding rule in § 438.10(e)(1)(ii) requires the MCO or the PHP to furnish the information at least 30 days before the effective date of the policy.)

(2) As specified in § 438.10(d) and (e), the information that MCOs and PHPs must furnish to enrollees and potential enrollees does not include how and where to obtain the service excluded under paragraph (b)(3) of this section, but only how and where to obtain information about the service.

(d) *Information requirements: State responsibility.* For each service excluded by an MCO or PHP under paragraph (b)(2) of this section, the State must furnish information on how and where to obtain the service, as specified in §§ 438.10(e)(2)(xii) and 438.206(c).

(e) *Sanction.* An MCO or PHP that violates the prohibition of paragraph (b)(1) of this section is subject to intermediate sanctions under subpart I of this part.

§ 438.104 Marketing activities.

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

Cold-call marketing means any unsolicited personal contact by the MCO, PHP, or PCCM with a potential enrollee for the purpose of marketing as defined in this paragraph.

Marketing means any communication, from an MCO, PHP, or PCCM to an enrollee or potential enrollee, that can reasonably be interpreted as intended to influence the recipient to enroll or reenroll in that particular MCO's, PHP's, or PCCM's Medicaid product, or either to not enroll in, or to disenroll from, another MCO's, PHP's, or PCCM's Medicaid product.

Marketing materials means materials that—

(1) Are produced in any medium, by or on behalf of an MCO, PHP, or PCCM; and

(2) Can reasonably be interpreted as intended to market to enrollees or potential enrollees.

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

(b) *Contract requirements.* Each contract with an MCO, PHP, or PCCM must comply with the following requirements:

(1) Provide that the entity—

(i) Does not distribute any marketing materials without first obtaining State approval;

(ii) Distributes the materials to its entire service area as indicated in the contract;

(iii) Complies with the information requirements of § 438.10 to ensure that, before enrolling, the recipient receives, from the entity or the State, the accurate oral and written information he or she needs to make an informed decision on whether to enroll;

(iv) Does not seek to influence enrollment in conjunction with the sale or offering of any other insurance; and

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

(2) Specify the methods by which the entity assures the State agency that marketing, including plans and materials, is accurate and does not mislead, confuse, or defraud the recipients or the State agency. Statements that would be considered inaccurate, false, or misleading include, but are not limited to, any assertion or statement (whether written or oral) that—

(i) The recipient must enroll in the MCO, PHP, or PCCM in order to obtain benefits or in order to not lose benefits; or

(ii) The MCO, PHP, or PCCM is endorsed by HCFA, the Federal or State government, or similar entity.

(c) *State agency review.* In reviewing the marketing materials submitted by the entity, the State must consult with the Medical Care Advisory Committee established under § 431.12 of this chapter or an advisory committee with similar membership.

§ 438.106 Liability for payment.

Each MCO and PHP must provide that its Medicaid enrollees are not held liable for any of the following:

(a) The MCO's or PHP's debts, in the event of the entity's insolvency.

(b) Covered services provided to the enrollee, for which—

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

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

(c) Payments for covered services furnished under a contract, referral, or other arrangement, to the extent that those payments are in excess of the amount that the enrollee would owe if the MCO or PHP provided the services directly.

§ 438.108 Cost sharing.

The contract must provide that any cost sharing imposed on Medicaid enrollees is in accordance with §§ 447.50 through 447.60 of this chapter.

§ 438.114 Emergency and post-stabilization services.

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

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

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

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

(b) *Information requirements.* To enrollees and potential enrollees upon request, and to enrollees during enrollment and at least annually thereafter, each State (or at State option, each MCO, PHP, and PCCM) must provide, in clear, accurate, and

standardized form, information that describes or explains at least the following:

(1) What constitutes emergency medical condition, emergency services, and post-stabilization services, with reference to the definitions in paragraph (a) of this section.

(2) The fact that prior authorization is not required for 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 MCO, PHP, and PCCM providers and hospitals furnish emergency services and post-stabilization services covered under the contract.

(5) The fact that, subject to the provisions of this section, the enrollee has a right to use any hospital or other setting for emergency care.

(6) The post-stabilization care services rules set forth at § 422.113(c) of this chapter.

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

(1) The MCO or PHP.

(2) The PCCM that has a risk contract that covers such services.

(3) The State, in the case of a PCCM that has a fee-for-service contract.

(d) *Coverage and payment: Emergency services.* (1) The entities identified in paragraph (c) of this section—

(i) Must cover and pay for emergency services regardless of whether the entity that furnishes the services has a contract with the MCO, PHP, or PCCM; and

(ii) May not deny payment for treatment obtained under either of the following circumstances:

(A) An enrollee had an emergency medical condition, including cases in which the absence of immediate medical attention would not have had the outcomes specified in paragraphs (b)(1)(A), (B), and (C) of the definition of emergency medical condition in § 422.113 of this chapter.

(B) A representative of the MCO, PHP, or PCCM instructs the enrollee to seek emergency services.

(2) A PCCM must—

(i) Allow enrollees to obtain emergency services outside the primary care case management system regardless of whether the case manager referred the enrollee to the provider that furnishes the services; and

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

(e) *Additional rules for emergency services.* (1) The entities specified in paragraph (c) of this section—

(i) May not limit what constitutes an emergency medical condition with reference to paragraph (a) of this section, on the basis of lists of diagnoses or symptoms; and

(ii) May not refuse to process any claim because it does not contain the primary care provider's authorization number.

(2) An enrollee who has an emergency medical condition may not be held liable for payment of subsequent screening and treatment needed to diagnose the specific condition or stabilize the patient.

(3) The attending emergency physician, or the provider actually treating the enrollee, is responsible for determining when the enrollee is sufficiently stabilized for transfer or discharge, and that determination is binding on the entities identified in paragraph (c) of this section as responsible for coverage and payment.

(f) *Coverage and payment: Post-stabilization services.* Post-stabilization care services are covered and paid for in accordance with provisions set forth at § 422.113(c) of this chapter. In applying those provisions, reference to ''M+C organization'' must be read as reference to the entities responsible for Medicaid payment, as specified in paragraph (c) of this section.

§ 438.116 Solvency standards.

(a) *Requirement for assurances.* (1) Each MCO and PHP that is not a Federally qualified HMO (as defined in section 1310 of the Public Health Service Act) must provide assurances satisfactory to the State showing that its provision against the risk of insolvency is adequate to ensure that its Medicaid enrollees will not be liable for the MCO's or PHP's debts if the entity becomes insolvent.

(2) Federally qualified HMOs, as defined in section 1310 of the Public Health Service Act, are exempt from this requirement.

(b) *Other requirements.*—(1) *General rule.* Except as provided in paragraph (b)(2) of this section, a MCO and a PHP must meet the solvency standards established by the State for private health maintenance organizations, or be licensed or certified by the State as a risk-bearing entity.

(2) *Exception.* Paragraph (b)(1) of this section does not apply to an MCO or PHP that meets any of the following conditions:

(i) Does not provide both inpatient hospital services and physician services.

(ii) Is a public entity.

(iii) Is (or is controlled by) one or more Federally qualified health centers and meets the solvency standards established by the State for those centers.

(iv) Has its solvency guaranteed by the State.

Subpart D—Quality Assessment and Performance Improvement

§ 438.200 Scope.

This subpart implements section 1932(c)(1) of the Act and sets forth specifications for quality assessment and performance improvement strategies that States must implement to ensure the delivery of quality health care by all MCOs and PHPs. It also establishes standards that States, MCOs and PHPs must meet.

§ 438.202 State responsibilities.

Each State contracting with an MCO or PHP must—

(a) Have a strategy for assessing and improving the quality of managed care services offered by all MCOs and PHPs:

(b) Document the strategy in writing.

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

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

(e) Conduct periodic reviews to evaluate the effectiveness of the strategy, and update the strategy as often as the State considers appropriate, but at least every 3 years.

(f) Submit to HCFA the following:

(1) A copy of the initial strategy, and a copy of the revised strategy, whenever significant changes are made.

(2) Regular reports on the implementation and effectiveness of the strategy, consistent with paragraph (e), at least every 3 years.

§ 438.204 Elements of State quality strategies.

At a minimum, State strategies must include the following—

(a) MCO and PHP 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 MCO and PHP contracts. These include, but are not limited to—

(1) Procedures that—

(i) Identify enrollees with special health-care needs; and

(ii) Assess the quality and appropriateness of care furnished to

enrollees with special health-care needs; and

(iii) Identify the race, ethnicity, and primary language spoken of each Medicaid enrollee. States must provide this information to the MCO and PHP for each Medicaid enrollee at the time of enrollment.

(2) Continuous monitoring and evaluation of MCO and PHP compliance with the standards.

(c) Performance measures and levels prescribed by HCFA consistent with section 1932(c)(1) of the Act.

(d) Arranging for annual, external independent reviews of the quality outcomes and timeliness of, and access to the services covered under each MCO and PHP contract.

(e) Appropriate use of intermediate sanctions that, at a minimum, meet the requirements of Subpart I of this part.

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

(g) Standards, at least as stringent as those in the following sections of this subpart, for access to care, structure and operations, and quality measurement and improvement.

Access Standards

§ 438.206 Availability of services.

(a) *Basic rule.* Each State must ensure that all covered services are available and accessible to enrollees.

(b) *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 an MCO, PHP, or PCCM contract.* If an MCO, PHP, or PCCM contract does not cover all of the services under the State plan, the State must make those services available from other sources and provide to enrollees information on where and how to obtain them, including how transportation is provided.

(d) *Delivery network.* The State must ensure that each MCO, and each PHP consistent with the scope of PHP's contracted services, meets the following requirements:

(1) Maintains and monitors a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to all services covered under the contract. In establishing and maintaining the network, each MCO and PHP must consider the following:

(i) The anticipated Medicaid enrollment, with particular attention to pregnant women, children, and persons with special health-care needs.

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

(iii) The numbers and types (in terms of training, experience, and specialization) of providers required to furnish the contracted Medicaid services.

(iv) The numbers of network providers who are not accepting new Medicaid patients.

(v) The geographic location of providers and Medicaid enrollees, considering distance, travel time, the means of transportation ordinarily used by Medicaid enrollees, and whether the location provides physical access for Medicaid enrollees with disabilities.

(2) Provides female enrollees with direct access to a women's health specialist within the network for covered care necessary to provide women's routine and preventive health care services. This is in addition to the enrollee's designated source of primary care if that source is not a women's health specialist.

(3) Provides for a second opinion from a qualified health care professional within the network, or arranges for the enrollee to obtain one outside the network, at no cost to the enrollee, if an additional qualified professional is not currently available within the network.

(4) When seeking an expansion of its service area, demonstrates that it has sufficient numbers and types (in terms of training, experience, and specialization) of providers to meet the anticipated additional volume and types of services the added Medicaid enrollee population may require.

(5) If the network is unable to provide necessary medical services, covered under the contract, to a particular enrollee, the MCO or PHP must adequately and timely cover these services out of network for the enrollee, for as long as the MCO or PHP is unable to provide them.

(6) Demonstrates that its providers are credentialed as required by § 438.214.

(7) Ensures that its providers do not discriminate against Medicaid enrollees.

(8) Requires out-of-network providers to coordinate with the MCO or PHP with respect to payment and ensures that cost to the enrollee is no greater than it would be if the services were furnished within the network.

(e) *Furnishing of services.* The State must ensure that each MCO and PHP complies with the requirements of this paragraph.

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

(i) Meet and require its providers to meet State standards for timely access to care and services, taking into account the urgency of need for services;

(ii) Ensure that its network's provider hours of operation are convenient for the enrollees, as determined by a State-established methodology, and at least comparable to Medicaid fee-for-service.

(iii) Make services available 24 hours a day, 7 days a week, when medically necessary.

(iv) Establish mechanisms to ensure compliance;

(v) Monitor continuously to determine compliance; and

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

(2) *Cultural considerations.* Each MCO and each PHP ensures that services are provided in a culturally competent manner to all enrollees, including those with limited English proficiency and diverse cultural and ethnic backgrounds.

§ 438.207 Assurances of adequate capacity and services.

(a) *Basic rule.* Each MCO and each PHP must give assurances to the State that it has the capacity to serve the expected enrollment in its service area in accordance with the State's standards for access to care under this subpart.

(b) *Nature of assurances.* Each MCO and each PHP must submit documentation to the State, in a format specified by the State and acceptable to HCFA, to demonstrate that it complies with the following requirements:

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

(2) Maintains a network of providers that is sufficient in number, mix, and geographic distribution to meet the needs of the anticipated number of enrollees in the service area.

(3) Meets the availability of services requirements in § 438.206.

(4) Has in place policies and practices to deal with situations in which there is—

(i) Unanticipated need for providers with particular types of experience; or

(ii) Unanticipated limitation of the availability of such providers.

(c) *Timing of documentation.* Each MCO and each PHP must submit the documentation described in paragraph (b) of this section at least once a year, and specifically—

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

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

(i) A significant change in the MCO's or PHP's services or benefits;

(ii) An expansion or reduction of the MCO's or PHP's geographic service area;

(iii) The enrollment of a new population in the MCO or PHP; and

(iv) A significant change in the MCO or PHP rates.

(d) *State review and submission to HCFA.* After the State reviews the documentation submitted by the MCO or PHP, the State must certify to HCFA that the MCO or PHP has complied with the State's requirements for availability of services, as set forth in § 438.206.

(e) *HCFA's right to inspect documentation.* The State must make available to HCFA, upon request, all documentation collected by the State from the MCO or PHP.

§ 438.208 Coordination and continuity of care.

(a) *Basic requirement.*—(1) *General rule.* Except as specified in paragraphs (a)(2) and (a)(3) of this section, the State must ensure that MCOs and PHPs comply with the requirements of this section.

(2) *PHP exception.* For PHPs, the State determines, based on the scope of the entity's services, and on the way the State has organized the delivery of managed care services, whether a particular PHP is required—

(i) To perform the initial and ongoing screenings and assessments specified in paragraphs (d) and (e) of this section; and

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

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

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

(b) *State responsibility to identify enrollees with special health care needs.* The State must implement mechanisms to identify to the MCO and PHP, upon enrollment, the following groups:

(1) Enrollees at risk of having special health care needs, including—

(i) Children and adults who are receiving SSI benefits;

(ii) Children in Title IV–E foster care;

(iii) Enrollees over the age of 65; and

(iv) Enrollees in relevant, State-established, risk-adjusted, higher-cost payment categories.

(v) Any other category of recipients identified by HCFA.

(2) Children under the age of 2.

(3) Other enrollees known by the State to be pregnant or to have special health care needs.

(c) *Requirements for MCOs and PHPs.* The State must ensure—

(1) That each MCO, and each PHP for which the State determines it is appropriate in accordance with paragraphs (a)(2) and (a)(3) of this section, meets the requirements of paragraphs (d), (e), and (h)(1) of this section; and

(2) That each MCO and each PHP meets the requirements of paragraphs (f), (g), and (h)(2) through (h)(6) of this section.

(d) *Initial screening and assessment.* Each MCO and each PHP must make a best effort attempt to meet the following standards:

(1) For enrollees identified under paragraph (b)(1) of this section,

(i) Performs enrollee screening within 30 days of receiving the identification; and

(ii) For any enrollee the screening identifies as being pregnant or having special health care needs, performs a comprehensive health assessment as expeditiously as the enrollee's health requires, but no later than 30 days from the date of identification.

(2) For enrollees identified under paragraphs (b)(2) and (b)(3) of this section, or who identify themselves as being pregnant or having special health care needs, performs a comprehensive health assessment as expeditiously as the enrollee's health requires, but no later than 30 days from the date of identification.

(3) For all other enrollees—

(i) Performs screening within 90 days from the date of enrollment; and

(ii) For any enrollee the screening identifies as being pregnant or having special health care needs, performs the comprehensive health assessment as expeditiously as the enrollee's health requires but no later than 30 days from the date of identification.

(e) *On-going screening and assessment.* Each MCO and each PHP must implement mechanisms to—

(1) Identify enrollees who develop special health care needs after they enroll in the MCO or PHP; and

(2) Perform comprehensive health assessments as expeditiously as the enrollee's health requires, but no later than 30 days from the date of identification.

(f) *Treatment plans.* For pregnant women and for enrollees determined to have special health care needs, each MCO and each PHP implements a treatment plan that—

(1) Is appropriate to the conditions and needs identified and assessed under paragraphs (d) and (e) of this section;

(2) Is for a specific period of time and is updated periodically;

(3) Specifies a standing referral or an adequate number of direct access visits to specialists;

(4) Ensures adequate coordination of care among providers;

(5) Is developed with enrollee participation; and

(6) Ensures periodic reassessment of each enrollee as his or her health condition requires.

(g) *Use of health care professionals.* Each MCO and each PHP uses appropriate health care professionals to—

(1) Perform any comprehensive health assessments required by this section; and

(2) Develop, implement, and update any treatment plans required by this section.

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

(1) Ensures that each enrollee has an ongoing source of primary care appropriate to his or her needs and a person or entity formally designated as primarily responsible for coordinating the health care services furnished to the enrollee.

(2) Coordinates the services the MCO or PHP furnishes to the enrollee with the services the enrollee receives from any other MCOs and PHPs;

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

(4) Ensures that in the process of coordinating care, each enrollee's privacy is protected consistent with the confidentiality requirements in § 438.224.

(5) Ensures that each provider maintains health records that meet professional standards and that there is appropriate and confidential sharing of information among providers.

(6) Has in effect procedures to address factors (such as a lack of transportation) that may hinder enrollee adherence to prescribed treatments or regimens.

(7) Ensures that its providers have the information necessary for effective and continuous patient care and quality improvement, consistent with the confidentiality and accuracy requirements of § 438.224 and the information system requirements of § 438.242.

§ 438.210 Coverage and authorization of services.

(a) *Coverage.* Each contract with an MCO, PHP, or PCCM must identify, define, and specify each service that the MCO, PHP, or PCCM is required to offer, and each contract with an MCO or PHP must meet the following requirements:

(1) Require that the MCO or PHP make available the services it is required to offer at least in the amount, duration, and scope that—

(i) Are specified in the State plan; and

(ii) Are sufficient to reasonably be expected to achieve the purpose for which the services are furnished.

(2) Provide that the MCO or PHP—

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

(ii) May place appropriate limits on a service—

(A) On the basis of criteria such as medical necessity; or

(B) For the purpose of utilization control, provided the services furnished can reasonably be expected to achieve their purpose, as required in paragraph (a)(1)(ii) of this section.

(3) Specify what constitutes ''medically necessary services'' in a manner that—

(i) Is no more restrictive than the State Medicaid program as indicated in State statutes and regulations, the State Plan, and other State policy and procedures; and

(ii) Addresses the extent to which the MCO or PHP is responsible for covering services related to the following:

(A) The prevention, diagnosis, and treatment of health impairments.

(B) The ability to achieve age-appropriate growth and development.

(C) The ability to attain, maintain, or regain functional capacity.

(4) Provide that the MCO or PHP furnishes the services in accordance with the specifications of paragraph (a)(3) of this section.

(b) *Processing of requests.* With respect to the processing of requests for initial and continuing authorizations of services, each contract must require—

(1) That the MCO or PHP and its subcontractors have in place, and follow, written policies and procedures that reflect current standards of medical practice;

(2) That the MCO or PHP—

(i) Not have information requirements that are unnecessary, or unduly burdensome for the provider or the enrollee;

(ii) Have in effect mechanisms to ensure consistent application of review criteria for authorization decisions; and

(iii) Consult with the requesting provider when appropriate.

(3) That any decision to deny a service authorization request or to authorize a service in an amount, duration, or scope that is less than requested, be made by a health care professional who has appropriate clinical expertise in treating the enrollees's condition or disease.

(c) *Notice of adverse action.* Each contract must provide for the MCO or PHP to notify the requesting provider, and give the enrollee written notice of any decision by the MCO or PHP to deny a service authorization request, or to authorize a service in an amount, duration, or scope that is less than requested. The notice must meet the requirements of § 438.404, except that the notice to the provider need not be in writing.

(d) *Timeframe for standard authorization decisions.* Each contract must provide for the MCO or PHP to make a standard authorization decision and provide notice—

(1) As expeditiously as the enrollee's health condition requires and within State-established timeframes that may not exceed 14 calendar days following receipt of the request for service, with a possible extension of up to 14 additional calendar days, if—

(i) The enrollee, or the provider, requests extension; or

(ii) The MCO or the PHP justifies (to the State agency upon request) a need for additional information and how the extension is in the enrollee's interest.

(e) *Timeframe for expedited authorization decisions.* (1) For cases in which a provider indicates, or the MCO or PHP determines, that following the standard timeframe could seriously jeopardize the enrollee's life or health or ability to attain, maintain, or regain maximum function, each contract must provide for the MCO or PHP to make an expedited authorization decision and provide notice as expeditiously as the enrollee's health condition requires and no later than 72 hours after receipt of the request for service.

(2) The MCO or PHP may extend the 72-hour time period by up to 14 calendar days if the enrollee requests extension.

(f) *Compensation for utilization management activities.* Each contract must provide that, consistent with § 438.6(g), and § 422.208 of this chapter, compensation to individuals or entities that conduct utilization management activities is not structured so as to provide incentives for the individual or entity to deny, limit, or discontinue medically necessary services to any enrollee.

Structure and Operation Standards

§ 438.214 Provider selection.

(a) *General rules.* The State must ensure that each contracted MCO and PHP implements written policies and procedures for selection and retention of providers and that those policies and procedures include, at a minimum, the requirements of this section.

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

(1) *Physicians and other licensed independent providers.* The process for physicians, including members of physician groups, and other licensed independent providers, includes—

(i) Initial credentialing when a physician or other provider enters the MCO or PHP network or a physician enters a physician group; and

(ii) Recredentialing within timeframes set by the State, which may be no less than the State requires for private MCOs.

(2) *Other providers.* The process for other providers must include an initial determination, and redetermination at specified intervals. The redetermination cycles must be the same as Federal or State credentialing cycles. The purpose is to ensure that, at a minimum, the provider—

(i) Is licensed (if required by the State); and

(ii) Has met any other applicable Federal or State requirements.

(3) *Exception.* The requirements of paragraphs (b)(1) and (b)(2) of this section do not apply to either of the following:

(i) Providers who are permitted to furnish services only under the direct supervision of a physician or other provider.

(ii) Hospital-based providers (such as emergency room physicians, anesthesiologists, or certified nurse anesthetists) who provide services only incident to hospital services. This exception does not apply if the provider contracts independently with the MCO or PHP or is promoted by the MCO or PHP as part of the provider network.

(4) *Initial credentialing.* Initial credentialing—

(i) Requires a written, dated and signed application that is updated in writing at recredentialing;

(ii) Requires that applications, updates, and supporting information submitted by the applicant include an attestation of the correctness and completeness of the information; and

(iii) Is based on primary source verification of licensure, disciplinary status, and a site visit as appropriate.

(5) *Recredentialing.* Recredentialing includes updating of information obtained during initial credentialing and an assessment of provider performance indicators obtained through the following:

(i) Quality Assessment and Performance Improvement Programs.

(ii) The utilization management system.

(iii) The grievance system.

(iv) Enrollee satisfaction surveys.

(v) Other MCO or PHP activities specified by the State.

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

(d) *Excluded providers.* MCOs or PHPs may not employ or contract with providers excluded from participation in Federal health care programs under either section 1128 or section 1128A of the Act.

(e) *State requirements.* Each MCO and PHP must comply with any additional requirements established by the State.

§ 438.218 Enrollee information.

The requirements that States must meet under § 438.10 constitute part of the State's quality strategy at § 438.204.

§ 438.224 Confidentiality and accuracy of enrollee records.

The State must ensure that (consistent with subpart F of part 431 of this chapter), for medical records and any other health and enrollment information that identifies a particular enrollee, each MCO and PHP establishes and implements procedures to do the following:

(a) Maintain the records and information in a timely and accurate manner.

(b) Abide by all Federal and State laws regarding confidentiality and disclosure.

(c) Specify—

(1) For what purposes the MCO or PHP uses the information; and

(2) To which entities outside the MCO or PHP, and for what purposes, it discloses the information.

(d) Except as provided in applicable Federal and State law, ensure that each enrollee may request and receive a copy of records and information pertaining to him or her and request that they be amended or corrected.

(e) Ensure that each enrollee may request and receive information on how the MCO or PHP uses and discloses information that identifies the enrollee.

§ 438.226 Enrollment and disenrollment.

The State must ensure that each MCO and PHP complies with the enrollment and disenrollment requirements and limitations set forth in § 438.56.

§ 438.228 Grievance systems.

(a) The State must ensure that each MCO and PHP has in effect a grievance system that meets the requirements of subpart F of this part.

(b) If the State delegates to the MCO or PHP responsibility for notice of action under subpart E of part 431 of this chapter, the State must conduct random reviews of each delegated MCO or PHP and its providers and subcontractors to ensure that they are notifying enrollees in a timely manner.

(c) The State must establish a process to review, upon request by the enrollee, any quality of care grievance that the MCO or the PHP does not resolve to the enrollee's satisfaction.

§ 438.230 Subcontractual relationships and delegation.

(a) *General rule.* The State must ensure that each MCO and PHP—

(1) Oversees and is accountable for any functions and responsibilities that it delegates to any subcontractor; and

(2) Meets the conditions of paragraph (b) of this section.

(b) *Specific conditions.* (1) Before any delegation, each MCO and PHP evaluates the prospective subcontractor's ability to perform the activities to be delegated.

(2) There is a written agreement that—

(i) Specifies the activities and report responsibilities delegated to the subcontractor; and

(ii) Provides for revoking delegation or imposing other sanctions if the subcontractor's performance is inadequate.

(3) The MCO or PHP monitors the subcontractor's performance on an ongoing basis and subjects it to formal review according to a periodic schedule established by the State, consistent with industry standards or State MCO laws and regulations.

(4) If any MCO or PHP identifies deficiencies or areas for improvement, the MCO and the subcontractor take corrective action.

(5) Consistent with §§ 438.604 and 438.606, each MCO and PHP requires from subcontractors certifications with respect to—

(i) Submissions that may be related to State payments; and

(ii) The performance of their duties under the contract.

Measurement and Improvement Standards

§ 438.236 Practice guidelines.

(a) *Basic rule.* The State must ensure that each MCO and PHP meets the requirements of this section.

(b) *Adoption of practice guidelines.* Each MCO and PHP adopts practice guidelines (for example, The Guidelines for the Use of Antiretroviral Agents in HIV–Infected Adults and Adolescents and the Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection) that meet the following requirements:

(1) Are based on valid and reliable clinical evidence or a consensus of health care professionals in the particular field;

(2) Consider the needs of the MCO's or PHP's enrollees;

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

(4) Are reviewed and updated periodically as appropriate.

(c) *Dissemination of guidelines.* Each MCO and PHP disseminates the guidelines to all affected providers and, upon request, to enrollees and potential enrollees.

(d) *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.

§ 438.240 Quality assessment and performance improvement program.

(a) *General rules.* (1) The State must require, through its contracts, that each MCO and PHP have 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 and PHPs.

(3) HCFA may specify standardized quality measures, and topics for performance improvement projects to be required by States in their contracts with MCOs and PHPs.

(b) *Basic elements of MCO and PHP quality assessment and performance improvement programs.* At a minimum, the State must require that each MCO and PHP comply with the following requirements:

(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.

(4) Have in effect mechanisms to assess the quality and appropriateness of care furnished to enrollees with special health care needs.

(c) *Minimum performance levels.* (1) Each MCO and PHP must meet the following requirements:

(i) Annually measure its performance, using standard measures required by the State, consistent with the requirements of § 438.204(c), and report its performance to the State.

(ii) Achieve all 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 MCOs and PHPs—

(A) Include any minimum performance measures and levels specified by HCFA;

(B) Consider data and trends for both the MCOs and PHPs and fee-for-service Medicaid in that State; and

(C) Establish the minimum performance levels prospectively, each time a contract is initiated or renewed.

(d) *Performance improvement projects.* (1) Performance improvement projects are MCO and PHP 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 Medicaid enrollee population to which the measurement specified in paragraph (d)(1)(i) of this section is relevant.

(3) The State must ensure that each MCO and PHP initiates each year one or more 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 MCOs and PHPs, the State must specify the appropriate distribution of projects.

(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) Grievances and appeals;

(ii) Access to, and availability of, services; and

(iii) Cultural competence.

(6) In addition to requiring each MCO and PHP to initiate its own performance improvement projects, the State may require that an MCO or PHP—

(i) Conduct particular performance improvement projects on a topic specified by the State; and

(ii) Participate annually in at least one Statewide performance improvement project.

(7) For each project, each MCO and PHP 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) Each MCO's and PHP's interventions must achieve improvement that is significant and sustained over time.

(10) Each MCO and PHP 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 each MCO's and PHP's quality assessment and performance improvement program. The review must include—

(i) The Each MCO's and PHP's performance on the standard measures on which it is required to report; and

(ii) The results of the each MCO's and PHP's performance improvement projects.

(2) The State may require that an MCO or PHP have in effect a process for its own evaluation of the impact and effectiveness of its quality assessment and performance improvement program.

§ 438.242 Health information systems.

(a) *General rule.* The State must ensure that each MCO and PHP 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, and disenrollments for other than loss of Medicaid eligibility.

(b) *Basic elements of a health information system.* The State must require, at a minimum, that each MCO and PHP 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 upon request to HCFA, as required in this subpart.

Subpart E [Reserved]

Subpart F—Grievance System

§ 438.400 Statutory basis and definitions.

(a) *Statutory basis.* This subpart is based on sections 1902(a)(3), 1902(a)(4), and 1932(b)(4)of the Act.

(1) Section 1902(a)(3) requires that a State plan provide an opportunity for a fair hearing to any person whose claim for assistance is denied or not acted upon promptly.

(2) Section 1902(a)(4) requires that the State plan provide for methods of administration that the Secretary finds necessary for the proper and efficient operation of the plan.

(3) Section 1932(b)(4) requires Medicaid managed care organizations to establish internal grievance procedures under which Medicaid enrollees, or providers acting on their behalf, may challenge the denial of coverage of, or payment for, medical assistance.

(b) *Definitions.* As used in this subpart, the following terms have the indicated meanings:

Action means—

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

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

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

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

(iv) For a resident of a rural area with only one MCO or PHP, the denial of a Medicaid enrollee's request to exercise his or her right to obtain services outside the network; or

(v) The failure to furnish or arrange for a service or provide payment for a service in a timely manner.

(vi) The failure, of an MCO or PHP, to resolve an appeal within the timeframes provided in § 408(i)(2).

(2) In the case of a State agency, the denial of a Medicaid enrollee's request for disenrollment. An appeal of this type is to the State Fair Hearing Office.

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

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

Grievance means an expression of dissatisfaction about any matter other than an action, as ''action'' is defined in this section. The term is also used to refer to the overall system that includes grievances and appeals handled at the MCO or PHP level and access to the State Fair Hearing process. (Possible subjects for grievances include, but are not limited to, the quality of care or services provided, and aspects of interpersonal relationships such as rudeness of a provider or employee, or failure to respect the enrollee's rights.)

Quality of care grievance means a grievance filed because the enrollee believes that any aspect of the care or treatment that he or she received failed to meet accepted standards of health care and caused or could have caused harm to the enrollee.

§ 438.402 General requirements.

(a) *The grievance system.* Each MCO and PHP must have a system that includes a grievance process, an appeal process, and access to the State's fair hearing system.

(b) *General requirements for the grievance system.* The MCO or PHP must—

(1) Base its grievance and appeal 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 policies and procedures before implementing them;

(3) Provide for its governing body to approve and be responsible for the effective operation of the system;

(4) Provide for its governing body to review and dispose of grievances and resolve appeals, or make written delegation of this responsibility to a grievance committee;

(5) Ensure that punitive action is neither threatened nor taken against a provider who requests an expedited resolution, or supports an enrollee's grievance or appeal;

(6) Accept grievances and appeals, and requests for expedited disposition or resolution or extension of timeframes from the enrollee, from his or her representative, or from the provider acting on the enrollee's behalf and with the enrollee's written consent.

(7) Provide to the enrollee and to his or her representative the notices and information required under this subpart; and

(8) At the enrollee's request, refer for State review any quality of care grievance resolution with which the enrollee is dissatisfied.

(9) Require providers to give notice in accordance with § 438.404(d).

(c) *Filing requirements.*—(1) *Authority to file.* (i) An enrollee may file a grievance and an MCO or PHP level appeal, and may request a State fair hearing.

(ii) A provider, acting on behalf of the enrollee and with the enrollee's written consent, may file an appeal. A provider may not file a grievance or request a State fair hearing.

(2) *Timing.* (i) For an action as defined in § 438.400 (b)(1)(v), the enrollee or the provider may file an appeal whenever the entity has delayed access to the service to the point where there is a substantial risk that further delay will adversely affect the enrollee's health condition.

(ii) For all other actions, the State specifies a reasonable timeframe that may be no less than 20 days and not to exceed 90 days from the date on the MCO's or PHP's notice of action.

Within that timeframe—

(A) The enrollee or the provider may file an appeal; and

(B) In a State that does not require exhaustion of MCO and PHP level appeals, the enrollee may request a State fair hearing.

(3) *Procedures.* (i) The enrollee may file a grievance either orally or in writing and, as determined by the State, either with the State or with the MCO or the PHP.

(ii) The enrollee or the provider may file an appeal either orally or in writing, and unless he or she requests expedited resolution, must follow an oral filing with a written, signed, appeal.

§ 438.404 Notice of action.

(a) *Language and format requirements.* The notice must be in writing and must meet the language and format requirements of § 438.10(b) and (c) of this chapter to ensure ease of understanding.

(b) *Content of notice.* The notice must explain the following:

(1) The action the MCO or PHP or its contractor has taken or intends to take.

(2) The reasons for the action.

(3) Any laws and rules that require or permit the action.

(4) The enrollee's or the provider's right to file an MCO or PHP appeal.

(5) The enrollee's right to request a State fair hearing.

(6) The enrollee's right to present evidence in person if he or she chooses.

(7) The procedures for exercising the rights specified in this paragraph.

(8) The circumstances under which expedited resolution is available and how to request it.

(9) The enrollees right to have benefits continue pending resolution of the appeal or issuance of a fair hearing decision, if the enrollee or the provider timely files the appeal or the enrollee timely requests a State fair hearing.

(10) The circumstances under which the enrollee may be required to pay the costs of any services furnished while the appeal is pending if the final outcome is an adverse decision.

(11) How the enrollee may request continuation of benefits.

(12) How to contact the MCO or PHP to receive assistance in filing an appeal or requesting a State fair hearing.

(13) How to obtain copies of enrollee records, including records other than medical records.

(14) That the enrollee has the right to represent himself or herself, to use legal counsel, or to use a relative, or friend or other individual as spokesperson.

(15) That filing an appeal or requesting a State fair hearing will not negatively affect or impact the way the MCO and the PHP and their providers, or the State agency, treat the enrollee.

(c) *Timing of notice.* Except as provided in paragraph (d) of this section, the MCO or PHP must mail the notice within the following timeframes:

(1) For termination, suspension, or reduction of previously authorized Medicaid-covered services, within the timeframes specified in §§ 431.211, 431.213, and 431.214 of this chapter.

(2) For denial of payment, at the time of any action affecting the claim.

(3) For standard service authorization decisions that deny or limit services, within the timeframe specified in § 438.210(d)

(4) If the MCO or PHP extends the timeframe in accordance with § 438.210(d), it must—

(i) Give the enrollee written notice of the reason for the decision to extend the

timeframe and inform the enrollee of the right to file a grievance if he or she disagrees with that decision; and

(ii) Issue and carry out its determination as expeditiously as the enrollee's health condition requires and no later than the date the extension expires.

(5) For service authorization decisions not reached within the timeframes specified in § 438.210(d) (which constitutes a denial and is thus an adverse action), on the date that the timeframes expire.

(6) For expedited service authorization decisions, within the timeframes specified in § 438.210(e).

(d) *Special rule for subcontractors and providers who are not employees.* (1) An MCO or PHP may permit its subcontractors and providers who are not employees to give enrollees notice that includes only the information specified in paragraphs (b)(4) through (b)(15) of this section.

(2) If the MCO or PHP elects the option provided in paragraph (d)(1) of this section, and receives an appeal on any action by the subcontractor or provider who is not an employee, the MCO or PHP must, in acknowledging the appeal, include the information required under paragraphs (b)(1) through (b)(3) of this section.

§ 438.406 Handling of grievances and appeals.

(a) *General requirements.* In handling grievances and appeals, each MCO and each PHP must meet the following requirements:

(1) Have an adequately staffed office that is designated as the central point for enrollee issues, including grievances and appeals.

(2) Establish an appeals process that meets the requirements of paragraph (b) of this section.

(3) Give enrollees any reasonable assistance in completing forms and taking other procedural steps. This includes providing interpreter services and toll-free numbers that have adequate TTY/TTD and interpreter capability.

(4) Ensure that the enrollee's communication is correctly classified as a ''grievance'' or an ''appeal'.

(5) Acknowledge receipt of each grievance and appeal.

(6) Ensure that each grievance and appeal—

(i) Is transmitted timely to staff who have authority to act upon it; and

(ii) Is investigated and disposed of or resolved in accordance with § 438.408.

(7) Ensure that the individuals who make decisions on grievances and appeals are individuals—

(i) Who were not involved in any previous level of review or decision-making; and

(ii) Who, if deciding any of the following, are health care professionals who have the appropriate clinical expertise in treating the enrollee's condition or disease.

(A) An appeal of a denial that is based on lack of medical necessity.

(B) A grievance regarding denial of expedited resolution of an appeal.

(C) A grievance or appeal that involves clinical issues.

(b) *Special requirements for appeals.* The process for appeals must consist of clearly explained steps that meet the following requirements:

(1) Include, for each step, timeframes that take account of the enrollee's health condition and provide for expedited resolution in accordance with § 438.410.

(2) Provide that oral inquiries about the opportunity to appeal are treated as appeals (to establish the earliest possible filing date for the appeal) and must be confirmed in writing, unless the enrollee or the provider requests expedited resolution.

(3) Ensure that the acknowledgment of an oral appeal specifies that, although the time allowed for the MCO or PHP to resolve the appeal has begun, unless the request is for expedited resolution, the MCO or PHP cannot complete the resolution until the enrollee or the provider submits the appeal in writing.

(4) Provide the enrollee a reasonable opportunity to present evidence, and allegations of fact or law, in person as well as in writing. (The MCO or PHP must inform the enrollee of the limited time available for this in the case of expedited resolution.)

(5) Provide the enrollee and his or her representative opportunity, before and during the appeals process, to examine the enrollee's case file, including medical records, and any other documents and records considered during the appeals process.

(6) Include, as parties to the appeal—

(i) The enrollee and his or her representative; or

(ii) The legal representative of a deceased enrollee's estate.

§ 438.408 Resolution and notification: Grievances and appeals.

(a) *Basic rule.* The MCO or PHP must dispose of each grievance and resolve each appeal, and provide notice, as expeditiously as the enrollee's health condition requires, within State-established timeframes that may not exceed the timeframes specified in this section.

(b) *Basis for decision.* The MCO or PHP must base the decision on the record of the case, including all relevant Federal and State statutes, program regulations and policies, and any evidence presented under § 438.406(b)(4), in connection with the filing of the appeal.

(c) *Specific timeframes.*—(1) *Standard disposition of grievances.* For standard disposition of a grievance and notice to the affected parties, the timeframe is established by the State but may not exceed 90 days from the day the MCO or PHP receives the grievance.

(2) *Expedited disposition of grievances.* For a grievance on a denial of a request to expedite resolution of an appeal, the timeframe is 72 hours after receipt of the grievance.

(3) *Standard resolution of appeals.* For standard resolution of an appeal and notice to the affected parties, the timeframe is 30 days after the MCO or the PHP receives the appeal. This timeframe may be extended under paragraph (d) of this section.

(4) *Expedited resolution of appeals.* For expedited resolution of an appeal, the timeframe for resolution and notice to the enrollee is 72 hours after the MCO or PHP receives the appeal. This timeframe may be extended under paragraph (d) of this section.

(d) *Extension of timeframes.*—(1) *Limits on extension.* (i) For a grievance on denial of a request to expedite resolution of an appeal, the timeframe may not be extended.

(ii) For expedited resolution of an appeal, the MCO or PHP may extend the 72-hour timeframe by up to 14 calendar days only if the enrollee requests extension.

(iii) For standard resolution of an appeal or for a quality of care grievance, the MCO or PHP may extend the 30-day timeframe for up to 14 calendar days if—

(A) The enrollee requests extension; or

(B) The MCO or PHP shows (to the satisfaction of the State agency, upon its request) that there is need for additional information and how the delay is in the enrollee's interest.

(2) *Requirements following extension.* If the MCO or PHP extends the timeframes, it must—

(i) For any extension not requested by the enrollee, give the enrollee written notice of the reason for the delay and of the enrollee's right to file a grievance if he or she disagrees with the decision to extend the timeframe; and

(ii) For any extension, dispose of the grievance or resolve the appeal no later than the date on which the extension expires.

(e) *Format of notice*—(1) *Grievances.* (i) For all written grievances and all

grievances that relate to quality of care, the MCO or PHP must provide a written notice of disposition.

(ii) For an oral grievance that does not relate to quality of care, the MCO may provide oral notice unless the enrollee requests that it be written.

(2) *Appeals.* (i) For all appeals, the MCO or PHP must provide written notice of disposition.

(ii) For notice of expedited resolution, the MCO or PHP must also provide oral notice.

(f) *Content of notice of MCO or PHP grievance disposition.* The written notice must explain the following:

(i) The disposition of the grievance.

(ii) The fact that, if dissatisfied with the disposition of a quality of care grievance, the enrollee has the right to seek further State review, and how to request it.

(g) *Content of notice of appeal resolution.* The written notice of the resolution must include the following:

(1) The title of the MCO or PHP contact for the appeal.

(2) The results of the resolution process and the date it was completed.

(3) A summary of the steps the MCO or the PHP has taken on the enrollee's behalf in resolving the issue.

(4) For appeals not resolved wholly in favor of the enrollees—

(i) The right to request a State Fair Hearing, and how to do so;

(ii) The right to request to receive benefits while the hearing is pending, and how to make the request; and

(iii) That the enrollee may be held liable for the cost of those benefits if the hearing decision upholds the MCO's or PHP's action.

(h) *Collaboration on State review of grievances.* The MCO or PHP must work with the State to dispose of the grievance if the State considers that the MCO or PHP response was insufficient.

(i) *Referral of adverse or delayed appeal decisions to the State Fair Hearing Office*—(1) *Basis for submission.* The MCO or PHP must submit to the State Fair Hearing Office the file and all supporting documentation—

(i) For any appeal that was subject to expedited resolution and for which the MCO or PHP—

(A) Reaches a decision that is wholly or partially adverse to the enrollee; or

(B) Fails to reach a decision within the timeframes specified in paragraph (i)(2) of this section.

(ii) For any appeal that was not expedited, at the request of the State.

(2) *Timeframes for decision*—(i) *Standard resolution.* For a standard resolution, the basic timeframe is 30 days from receipt of the appeal, and may be extended for an additional 14 calendar days if the enrollee requests extension or the MCO or PHP justifies (to the State agency upon request) a need for additional information and how the extension is in the enrollee's interest.

(ii) *Expedited resolution.* For an expedited resolution, the basic timeframe is 72 hours from receipt of the appeal and may be extended for up to 14 calendar days, but only if the enrollee requests extension.

(3) *Timeframes for submission.* The timeframes for submission to the State Fair Hearing Office are as follows:

(i) For a standard resolution: 72 hours after the MCO or PHP receives the State's request.

(ii) For an expedited resolution: 24 hours after the MCO or PHP reaches an adverse decision, or the basic or extended timeframe for decision expires.

(j) *Requirements for State fair hearings*—(1) *Availability.* The State must permit the enrollee to request a State fair hearing within a reasonable time period specified by the State, but not less than 20 or in excess of 90 days if—

(i) The State requires exhaustion of the MCO or PHP level appeal procedures, from the date of the MCO's or PHP's notice of resolution; and

(ii) The State does not require exhaustion of the MCO or PHP level appeal procedures and the enrollee appeals directly to the State for a fair hearing, from the date on the MCO's or PHP's notice of action.

(2) *Parties.* The parties to the State fair hearing include the MCO or PHP as well as the enrollee and his or her representative or the representative of a deceased enrollee's estate.

(3) *Timeframes for decision.* The State agency must take final administrative action as follows:

(i) Other than as specified in paragraph (j)(3)(ii) of this section, within a period of time not to exceed 90 days minus the number of days taken by the MCO or PHP to resolve the internal appeal. This timeframe begins on the date the State receives the beneficiaries' request for a State Fair Hearing.

(ii) For service authorization appeals that meet the criteria for expedited resolution as set forth in § 438.410, as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of a fair hearing request from the enrollee, or the file from the MCO or PHP.

§ 438.410 Expedited resolution of grievances and appeals.

(a) *General rule.* Each MCO and PHP must establish and maintain an expedited review process for grievances and appeals.

(b) *Requirements for grievances.* (1) The MCO or PHP must expedite disposition of grievances that pertain to denial of a request for expedited resolution of an appeal.

(2) The MCO or PHP may expedite disposition of other grievances, consistent with State guidelines.

(c) *Requirements for appeals.* Each MCO and PHP must meet the following requirements with respect to appeals:

(1) Establish a convenient and efficient means for an enrollee or a provider to request expedited resolution of an appeal;

(2) Provide expedited resolution of an appeal in response to an oral or written request if the MCO or PHP determines (with respect to a request from the enrollee) or the provider indicates (in making the request on the enrollee's behalf or supporting the enrollee's request) that taking the time for a standard resolution could seriously jeopardize the enrollee's life or health or ability to attain, maintain, or regain maximum function.

(3) Document all oral requests in writing; and

(4) Maintain the documentation in the case file.

(d) *Action following denial of a request for expedited resolution.* If the MCO or PHP denies a request for expedited resolution of an appeal, it must—

(1) Transfer the appeal to the timeframe for standard resolution, beginning the 30-day period as of the day it received the request for expedited resolution;

(2) Give the enrollee prompt oral notice of the denial, and follow up within two calendar days with a written notice that includes the following:

(i) Informs the enrollee of the right to—

(A) File a grievance if he or she is dissatisfied with the MCO's or PHP's decision not to expedite resolution of the appeal; or

(B) Resubmit the request with a provider's letter of support.

(ii) Explains that—

(A) If the enrollee files a grievance, the MCO or PHP will process the appeal using the 30-day timeframe for standard resolution; and

(B) If the enrollee resubmits the request with a provider's letter of support, the MCO or PHP will expedite resolution of the appeal.

(iii) Provides instructions about grievance procedures, including timeframes.

§ 438.414 Information about the grievance system.

(a) *To whom information must be furnished.* (1) Each MCO and PHP must provide the information specified in paragraph (b) of this section to enrollees and to all providers and subcontractors at the time they enter into a contract.

(2) Each MCO or PHP or, at State option, the State or its contracted representative must provide the information specified in paragraph (b) to all potential enrollees.

(b) *Required information.* The information that is provided under paragraph (a) of this section must explain the grievance system through a State-developed or State-approved description, in the format required under § 438.10(c), and must include the following:

(1) With respect to State fair hearing—

(i) The right to hearing;

(ii) The method for obtaining a hearing; and

(iii) The rules that govern representation at the hearing.

(2) The right to file grievances and appeals.

(3) The requirements and timeframes for filing a grievance or appeal.

(4) The availability of assistance in the filing process.

(5) The right to represent himself or herself or to be represented by legal counsel or a relative or friend or other spokesperson.

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

(7) The fact that filing a grievance or appeal or requesting a State fair hearing will not adversely affect or impact the way the MCO or the PHP and their providers or the State agency treat the enrollee.

(8) The fact that, when requested by the enrollee

(i) Benefits will continue if the enrollee files an appeal or a request for State fair hearing within the timeframes specified for filing; and

(ii) The enrollee may be required to pay the cost of services furnished while the appeal is pending, if the final decision is adverse to the enrollee.

(c) *Language, format, and timing requirements.* The information furnished under this section must meet the language and format requirements of § 438.10(b) and (c), and must be furnished to enrollees and potential enrollees at the times specified in § 438.10(e) through (h).

(d) *Aggregate information.* Upon request, the MCO or PHP must provide to enrollees, potential enrollees, and the general public, aggregate information based on the information required under § 438.416(d).

§ 438.416 Record keeping and reporting requirements.

Each MCO and PHP must comply with the following requirements, and in so doing must also comply with the confidentiality requirements of § 438.224.

(a) *Log.* Maintain a log of all grievances and appeals, showing the date of acknowledgment, the MCO's or PHP's decision, and the date of disposition or resolution.

(b) *Tracking.* Track each grievance and appeal until its final disposition or resolution, and classify them in terms of whether the disposition or resolution was standard or expedited.

(c) *Retention of records.* (1) Retain the record of each grievance and appeal, and its disposition or resolution in a central location, and accessible to the State, for at least 3 years.

(2) If any litigation, claim negotiation, audit, or other activity involving these records is initiated before the end of the 3-year period, retain the record until the later of the following:

(i) The date the activity is completed and any issues arising from it are resolved.

(ii) The end of the 3-year period.

(d) *Reporting.* As often as the State requests, but at least once a year, each MCO and PHP must analyze the records maintained under this paragraph and submit to the State a summary that includes the following information:

(1) The number and nature of all grievances and appeals.

(2) The timeframes within which they were acknowledged and disposed of or resolved.

(3) The nature of the decisions.

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

(a) *Terminology.* As used in this section, ''timely'' filing means filing on or before the later of the following:

(1) The expiration of the timeframe specified by the State (in accordance with § 438.404(c)(3)) and communicated in the notice of action.

(2) The intended effective date of the MCO's or PHP's proposed action.

(b) *Continuation of benefits.* The MCO or PHP must continue the enrollee's benefits if—

(1) The enrollee or the provider files the appeal timely;

(2) The appeal involves the termination, suspension, or reduction of a previously authorized course of treatment;

(3) The services were ordered by an authorized provider;

(4) The period covered by the authorization has not expired; and

(5) The enrollee requests extension of benefits.

(c) *Reinstatement of benefits.* The MCO or PHP must reinstate the enrollee's benefits under any of the circumstances specified in § 431.231 of this chapter.

(d) *Duration of continued or reinstated benefits.* If the MCO or PHP continues or reinstates the enrollee's benefits while the appeal is pending, the following rules apply:

(1) The MCO or PHP must continue the benefits until one of the following occurs:

(i) The enrollee withdraws the appeal.

(ii) The MCO or PHP resolves the appeal in the enrollee's favor.

(iii) The State Fair Hearing Office issues a hearing decision on a request received directly from the enrollee or referred by the MCO or PHP.

(2) If the MCO or PHP appeals the decision or the State fair hearing decision is favorable to the enrollee, the MCO or PHP must restore regular benefits.

(e) *Enrollee responsibility for services furnished while the appeal is pending.* If the final resolution of the appeal is adverse to the enrollee, that is, upholds the MCO's or PHP's action, the MCO or PHP may recover the cost of the services furnished to the enrollee while the appeal is pending, to the extent that they were furnished solely because of the requirements of this section, and in accordance with the policy set forth in § 431.230(b) of this chapter.

§ 438.424 Effectuation of reversed appeal resolutions.

(a) *Services not furnished while the appeal is pending.* If the MCO or PHP, or the State fair hearing officer reverses a decision to deny, limit, or delay services that were not furnished while the appeal was pending, the MCO or PHP must authorize or provide the disputed services promptly, and as expeditiously as the enrollee's health condition requires.

(b) *Services furnished while the appeal is pending.* If the MCO or PHP, or the State fair hearing officer reverses a decision to deny authorization of services, and the enrollee received the disputed services while the appeal was pending, the MCO or the PHP or the State must pay for those services, in accordance with State policy and regulations.

§ 438.426 Monitoring of the grievance system.

(a) *Basis for monitoring.* The records that the MCOs and PHPs are required to maintain and summarize under § 438.416 provide the basis for

monitoring by the MCO or PHP, and by the State.

(b) *Responsibility for corrective action.* If the summaries required under paragraph (d) of § 438.416 reveal a need for changing the system, the MCO or the PHP must conduct an in-depth review, and take corrective action.

Subpart G—[Reserved]

Subpart H—Certifications and Program Integrity Provisions

§ 438.600 Statutory basis.

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

(a) Section 1902(a)(4) requires that the State plan provide for methods of administration that the Secretary finds necessary for the proper and efficient operation of the plan.

(b) Section 1902(a)(19) requires that the State plan provide the safeguards necessary to ensure that eligibility is determined and services are provided in a manner consistent with simplicity of administration and the best interests of the recipients.

§ 438.602 Basic rule.

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

§ 438.604 Data that must be certified.

(a) *Data certifications.* When State payments to the MCO or PHP are based on data submitted by the MCO or PHP, the State must require certification of the data as provided in § 438.606. The data that must be certified includes, but is not limited to, enrollment information, encounter data, and other information required by the State and contained in contracts, proposals, and related documents.

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

(c) *Additional certifications.* Certification is required, as provided in § 438.606, for all documents specified by the State.

§ 438.606 Source, content, and timing of certification.

(a) *Source of certification.* With respect to the data specified in § 438.604, the MCO or PHP must require—

(1) That subcontractors certify the data they submit to the MCO or PHP; and

(2) That one of the following certify the data the MCO or PHP submits to the State:

(i) The MCO's or PHP's Chief Executive Officer.

(ii) The MCO's or PHP's Chief Financial Officer.

(iii) An individual who has delegated authority to sign for, and who reports directly to, the MCO's or PHP's Chief Executive Officer or Chief Financial Officer.

(b) *Content of certification.* The certification must attest, based on best knowledge, information, and belief, as follows:

(1) To the accuracy, completeness and truthfulness of data.

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

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

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

§ 438.608 Program integrity requirements.

(a) *General requirement.* The MCO or PHP must have administrative and management arrangements or procedures, including a mandatory compliance plan, that are designed to guard against fraud and abuse.

(b) *Specific requirements.* The arrangements or procedures must include the following:

(1) Written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable Federal and State standards.

(2) The designation of a compliance officer and a compliance committee that are accountable to senior management.

(3) Effective training and education for the compliance officer and the organization's employees.

(4) Effective lines of communication between the compliance officer and the organization's employees.

(5) Enforcement of standards through well-publicized disciplinary guidelines.

(6) Provision of internal monitoring and auditing.

(7) Provision for prompt response to detected offenses, and for development of corrective action initiatives relating to the MCO's or PHP's contract.

Subpart I—Sanctions

§ 438.700 Basis for imposition of sanctions.

(a) Each State that contracts with an MCO must, and each State that contracts with a PCCM may, establish intermediate sanctions, as specified in § 438.702, that it may impose if it makes any of the determinations specified in paragraphs (b) through (d) of this section. The State's determination may be based on findings from onsite survey, enrollee or other complaints, financial status, or any other source.

(b) An MCO acts or fails to act as follows:

(1) Fails substantially to provide medically necessary services that the MCO is required to provide, under law or under its contract with the State, to an enrollee covered under the contract.

(2) Imposes on enrollees premiums or charges that are in excess of the premiums or charges permitted under the Medicaid program.

(3) Acts to discriminate among enrollees on the basis of their health status or need for health care services. This includes termination of enrollment or refusal to reenroll a recipient, except as permitted under the Medicaid program, or any practice that would reasonably be expected to discourage enrollment by recipients whose medical condition or history indicates probable need for substantial future medical services.

(4) Misrepresents or falsifies information that it furnishes to HCFA or to the State.

(5) Misrepresents or falsifies information that it furnishes to an enrollee, potential enrollee, or health care provider.

(6) Fails to comply with the requirements for physician incentive plans, as set forth (for Medicare) in §§ 422.208 and 422.210 of this chapter.

(c) An MCO or a PCCM distributes directly, or indirectly through any agent or independent contractor, marketing materials that have not been approved by the State or that contain false or materially misleading information.

(d) An MCO violates any of the requirements in section 1903(m) of the Act and implementing regulations, or an MCO or a PCCM violates any of the requirements of section 1932 of the Act and implementing regulations. (For these violations, only the sanctions specified in § 438.702(a)(4) and (a)(5) may be imposed.)

§ 438.702 Types of intermediate sanctions.

(a) The types of intermediate sanctions that a State may impose under this subpart include the following:

(1) Civil money penalties in the amounts specified in § 438.704.

(2) Appointment of temporary management as provided in § 438.706. (The State may not impose this sanction on a PCCM.)

(3) Granting enrollees the right to terminate enrollment without cause. (The State must notify the affected enrollees of their right to disenroll.)

(4) Suspension of all new enrollment, including default enrollment, after the effective date of the sanction.

(5) Suspension of payment for recipients enrolled after the effective date of the sanction and until HCFA or the State is satisfied that the reason for imposition of the sanction no longer exists and is not likely to recur.

(b) State agencies retain authority to impose additional sanctions under State statutes or State regulations that address areas of noncompliance specified in § 438.700, as well as additional areas of noncompliance. Nothing in this subpart prevents State agencies from exercising that authority.

§ 438.704 Amounts of civil money penalties

(a) *General rule.* The limit on, or specific amount of, a civil money penalty the State may impose varies depending on the nature of the MCO's or PCCM's action or failure to act, as provided in this section.

(b) *Specific limits.* (1) The limit is $25,000 for each determination under the following paragraphs of § 438.700:

(i) Paragraph (b)(1) (Failure to provide services).

(ii) Paragraph (b)(5) (Misrepresentation or false statements to enrollees, potential enrollees, or health care providers).

(iii) Paragraph (b)(6) (failure to comply with physician incentive plan requirements).

(iv) Paragraph (c) (Marketing violations).

(2) The limit is $100,000 for each determination under paragraph (b)(3) (discrimination) or (b)(4) (Misrepresentation or false statements to HCFA or the State) of § 438.700.

(3) The limit is $15,000 for each recipient the State determines was not enrolled because of a discriminatory practice under paragraph (b)(3) of § 438.700. (This is subject to the overall limit of $100,000 under paragraph (b)(2) of this section).

(c) *Specific amount.* For premiums or charges in excess of the amounts permitted under the Medicaid program, the amount of the penalty is $25,000 or double the amount of the excess charges, whichever is greater. The State must deduct from the penalty the amount of overcharge and return it to the affected enrollees.

§ 438.706 Special rules for temporary management.

(a) *Optional imposition of sanction.* The State may impose temporary management if it finds (through onsite survey, enrollee complaints, financial audits, or any other means) that —

(1) There is continued egregious behavior by the MCO, including but not limited to behavior that is described in § 438.700, or that is contrary to any requirements of sections 1903(m) and 1932 of the Act;

(2) There is substantial risk to enrollees' health; or

(3) The sanction is necessary to ensure the health of the MCO's enrollees—

(i) While improvements are made to remedy violations under § 438.700; or

(ii) Until there is an orderly termination or reorganization of the MCO.

(b) *Required imposition of sanction.* (1) The State must impose temporary management (regardless of any other sanction that may be imposed) if it finds that an MCO has repeatedly failed to meet substantive requirements in section 1903(m) or 1932 of the Act, or this subpart. The State must also grant enrollees the right to terminate enrollment without cause, as described in § 438.702(a)(3).

(c) *Hearing.* The State may not delay imposition of temporary management to provide a hearing before imposing this sanction.

(d) *Duration of sanction.* The State may not terminate temporary management until it determines that the MCO can ensure that the sanctioned behavior will not recur.

§ 438.708 Termination of an MCO or PCCM contract.

A State has the authority to terminate an MCO or PCCM contract and enroll that entity's enrollees in other MCOs or PCCMs, or provide their Medicaid benefits through other options included in the State plan, if the State determines that the MCO or PCCM—

(a) Has failed to carry out the substantive terms of its contract; or

(b) Has failed to meet applicable requirements in sections 1932, 1903(m), and 1905(t) of the Act.

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

(a) *Notice of sanction.* Before imposing any of the alternative sanctions specified in this subpart, the State must give the affected entity timely written notice that explains—

(1) The basis and nature of the sanction; and

(2) Any other due process protections that the State elects to provide.

(b) *Pre-termination hearing.*—(1) *General rule.* Before terminating an MCO or PCCM contract under § 438.708, the State must provide the entity a pretermination hearing.

(2) *Procedures.* The State must—

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

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

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

§ 438.722 Disenrollment during termination hearing process.

After a State notifies an MCO or PCCM that it intends to terminate the contract, the State may—

(a) Give the entity's enrollees written notice of the State's intent to terminate the contract; and

(b) Allow enrollees to disenroll immediately without cause.

§ 438.724 Public notice of sanction.

(a) *Content of notice.* The State must publish a notice that describes the intermediate sanction imposed, explains the reasons for the sanction and specifies the amount of any civil money penalty.

(b) *Publication of notice.* The State must publish the notice—

(1) No later than 30 days after it imposes the sanction; and

(2) As a public announcement in—

(i) The newspaper of widest circulation in each city within the MCO's service area that has a population of 50,000 or more; or

(ii) The newspaper of widest circulation in the MCO's service area, if there is no city with a population of 50,000 or more in that area.

§ 438.726 State plan requirement.

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

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

(a) *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 acts or fails to act as specified in § 438.700(b)(1) through (b)(6).

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

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

(1) The State agency—

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

(ii) Allows the MCO 15 days from date of receipt of the notice to provide evidence that it has not acted or failed to act in the manner that is the basis for the recommended sanction;

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

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

(2) HCFA conveys the determination to the OIG for consideration of possible imposition of civil money penalties under section 1903(m)(5)(A) of the Act and part 1003 of this title. In accordance with the provisions of part 1003, the OIG may impose civil money penalties in addition to, or in place of, the sanctions that may be imposed under this section.

(c) *Informal reconsideration.* (1) If the MCO submits a timely response to the notice of sanction, the State agency—

(i) Conducts an informal reconsideration that includes review of the evidence by a State agency official who did not participate in the original recommendation; and

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

(2) The State agency decision under paragraph (c)(1) of this section, forwarded to HCFA, becomes HCFA's decision unless HCFA reverses or modifies the decision within 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.

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

(2) If the MCO seeks reconsideration, the following rules apply:

(i) Except as specified in paragraph (d)(2)(ii) of this section, the sanction is effective on the date specified in 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 or safety, HCFA may make the sanction effective earlier than the date of HCFA's reconsideration decision under paragraph (c) of this section.

(e) *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 substantial compliance with the physician incentive plan requirements set forth in §§ 422.208 and 422.210 of this chapter.

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

§ 438.806 Prior approval.

(a) *Comprehensive risk contracts.* FFP is available under a comprehensive risk contract only if—

(1) The Regional Office has confirmed that the contractor meets the definition of MCO or is one of the entities described in paragraphs (a)(2) through (a)(5) of § 438.6; and

(2) The contract meets all the requirements of section 1903(m)(2)(A) of the Act, the applicable requirements of section 1932 of the Act, and the implementing regulations in this part.

(b) *MCO contracts.* Prior approval by 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 participation in Federal health care programs under either section 1128 or section 1128A of the Act.

(ii) Any entity that would provide those services through an excluded individual or entity.

§ 438.810 Expenditures for enrollment broker services.

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

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

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

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

Enrollment services means choice counseling, or enrollment activities, or both.

(b) *Conditions that enrollment brokers must meet.* State expenditures for the use of enrollment brokers are considered necessary for the proper and efficient operation of the State plan and thus eligible for FFP only if the broker and its subcontractors meet the following conditions:

(1) *Independence.* The broker and its subcontractors are independent of any MCO, PHP, PCCM, or other health care provider in the State in which they provide enrollment services. A broker or subcontractor is not considered ''independent'' if it—

(i) Is an MCO, PHP, PCCM or other health care provider in the State

(ii) Is owned or controlled by an MCO, PHP, PCCM, or other health care provider in the State; or

(iii) Owns or controls an MCO, PHP, PCCM or other health care provider in the State.

(2) *Freedom from conflict of interest.* The broker and its subcontractor are free from conflict of interest. A broker or subcontractor is not considered free from conflict of interest if any person who is the owner, employee, or consultant of the broker or subcontractor or has any contract with them—

(i) Has any direct or indirect financial interest in any entity or health care provider that furnishes services in the State in which the broker or subcontractor provides enrollment services;

(ii) Has been excluded from participation under title XVIII or XIX of the Act;

(iii) Has been debarred by any Federal agency; or

(iv) Has been, or is now, subject to civil money penalties under the Act.

(c) *Prior approval.* 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.

§ 438.814 Limit on payments in excess of capitation rates.

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

PART 440—SERVICES: GENERAL PROVISIONS

1. The statutory citation for part 440 continues to read as follows:

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

2. In subpart A, a new § 440.168 is added, to read as follows:

§ 440.168 Primary care case management services.

(a) Primary care case management services means case management related services that—

(1) Include location, coordination, and monitoring of primary health care services; and

(2) Are provided under a contract between the State and either of the following:

(i) A PCCM who is a physician or may, at State option, be a physician assistant, nurse practitioner, or certified nurse-midwife.

(ii) A physician group practice, or an entity that employs or arranges with physicians to furnish the services.

(b) Primary care case management services may be offered by the State—

(1) As a voluntary option under the regular State plan program; or

(2) On a mandatory basis under section 1932 (a)(1) of the Act or under section 1915(b) or section 1115 waiver authority.

PART 447—PAYMENTS FOR SERVICES

1. The authority citation for part 447 continues to read as follows:

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

2. A new § 447.46 is added, to read as follows:

§ 447.46 Timely claims payment by MCOs.

(a) *Basis and scope.* This section implements section 1932(f) of the Act by specifying the rules and exceptions for prompt payment of claims by MCOs.

(b) *Definitions.* ''Claim'' and ''clean claim'' have the meaning given those terms in § 447.45.

(c) *Contract requirements.*—(1) *Basic rule.* A contract with an MCO must provide that the organization will meet the requirements of paragraphs (d)(2), (d)(3) of § 447.45, and abide by the specifications of paragraphs (d)(5) and (d)(6) of that section..

(2) *Exception.* The MCO and its providers may, by mutual agreement, establish an alternative payment schedule.

(3) Any alternative schedule must be stipulated in the contract.

§ 447.53 [Amended]

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

A. In paragraph (b) introductory text, the parenthetical phrase is removed.

B. Paragraph (b)(6) is removed.

4. A new paragraph (e) is added to read as follows:

(e) No provider may deny services, to an individual who is eligible for the services, on account of the individual's inability to pay the cost sharing.

§ 447.58 [Amended]

5. 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.

6. A new § 447.60 is added to subpart A to read as follows:

§ 447.60 Cost-sharing requirements for services furnished by MCOs.

Contracts with MCOs must provide that any cost-sharing charges the MCO imposes on Medicaid enrollees are in accordance with the requirements set forth in §§ 447.50 and 447.53 through 447.58 for cost-sharing charges imposed by the State agency.

§ 447.361 [Removed]

Section 447.361 is removed.

(Catalog of Federal Domestic Assistance Program No. 93778, Medical Assistance)

Dated: December 21, 2000.

Robert A. Berenson,

Acting Deputy Administrator, Health Care Financing Administration.

Dated: December 20, 2000.

Donna E. Shalala,

Secretary.

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