



# Federal Register

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**Friday,  
January 19, 2001**

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**Part VIII**

## **Department of Health and Human Services**

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**Health Care Financing Administration**

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**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-A170

### 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 through 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:**  
Subparts A and B—Bruce Johnson: (410) 786-0615  
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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 adjusters.

*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 adjusters, 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 adjusters (both health status and demographic risk adjusters) 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 contracts. 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 § 438.6(j)(2) ("sufficiently near . . . to reach . . . within a reasonable time") and "sufficient" in proposed § 438.6(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 continue 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 MCO'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 enrollees 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 these 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 underserved 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 versus 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 be 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 subspecialty 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 (re-designated 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 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 beneficiary’s 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