

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

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

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

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

disclosure and require State review of all health plan information.

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

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

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

#### c. Requirements and Prohibitions

Proposed § 438.104(b) provided that MCO, PHP, and PCCM contracts must specify the methods by which the entity assures the State agency that marketing plans and materials are accurate and do not mislead, confuse, or defraud beneficiaries or the State. The proposed rule also stated that MCO, PHP, and PCCM contracts must provide that the entity distribute materials to the entire service area—(1) does not distribute marketing materials without prior

approval; (2) complies with the information requirements in § 438.10; (3) does not seek to influence enrollment with the sale of other insurance; and (4) does not engage in cold-call marketing.

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

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

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

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

#### d. Service Area

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

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

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

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

*Comment:* Several commenters believed that the service area requirement in proposed § 438.104(b)(2)(ii) could impede an MCO's, PHP's, or PCCM's ability to reach targeted populations with unique needs or characteristics within service areas. Commenters provided examples such as mailings to certain zip codes informing members of activities at a hospital in their neighborhood and

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

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

sent only to those who are eligible or potentially eligible for Medicaid in a given service area.

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

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

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

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

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

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

*Response:* We agree with the commenters that it is important for

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

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

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

#### *Sale of Other Insurance*

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

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

Some commenters encouraged us to prohibit other types of bonuses or gifts as inducements to enroll. These commenters noted that in the past, gifts

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

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

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

#### *State Agency Review*

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

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

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

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

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

*Response:* The State may always add to the current MCAC composition requirements to include representatives of any affected groups or entities, such as MCOs, PHPs, or PCCMs. We encourage States to have an MCAC membership that is diverse and represents groups served by the State's program, for example, minorities and individuals with special needs. With respect to the final comment, we note

that § 431.12 requires that the State plan must "provide for a MCAC meeting the requirements of this section" and that the State plan is a public document. We would encourage States to ensure that the public is clearly and completely informed about the role and membership of the MCAC or any similar committee.

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

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

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

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

*Comment:* Many commenters contended that the use of a MCAC to review and approve specific pieces of marketing material was impractical, burdensome, unrealistic, and an example of micro-management. Many States' MCACs meet monthly, bi-monthly, or quarterly. Several commenters believe that it would be difficult, if not impossible, to provide the quick turnaround, in some cases ten days or less, necessary for approval of marketing materials. Some States require that marketing materials be

submitted sixty days prior to intended use and some commenters believed that adding another level of review would slow down the process. The regulation was also called, by one commenter "unnecessary and bureaucratic" and not in keeping with the guiding principles cited in the preamble.

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

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

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

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

suggested that the MCAC be held to confidentiality standards.

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

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

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

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

*Response:* The legislative history do not indicates that the Congress intended for the consultation to be of any specific

nature or have any specific outcome. Instead, it prescribe a Federal standard. We believe it is more appropriate to permit States to define the specific role of the committee.

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

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

#### 4. Liability for Payment (§ 438.106)

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

*Comment:* We received several comments in response to our request for public guidance on § 438.106(c) that refers to beneficiary liability for payments to a provider "in excess of the amount the enrollee would owe if the MCO provided the services directly". Most commenters agreed with our position that Medicaid managed care enrollees should not be responsible for more than nominal charges for cost sharing. One commenter sought clarification of when the situation described in § 438.106(c) would apply, and another suggested that the amount owed by the Medicaid beneficiary should be any cost sharing required by the contract. Another commenter

suggested that the provision may have been intended to address a recent trend in the managed care industry of establishing coverage options that allow enrollees to go out of network for services in exchange for higher premiums or co-pays (that is, "point-of-service" options), as there may have been concern that this type of coverage could be interpreted by MCOs as a non-Medicaid benefit for which they could charge.

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

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

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

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

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

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

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

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

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

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

*Response:* As stated above, we have revised § 438.106 to reflect that enrollees may not be held liable for "covered" services, which include family planning services. Section

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

##### 5. Cost Sharing (§ 438.108)

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

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

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

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

*Response:* The regulation clearly requires that any cost sharing imposed for services delivered either by an MCO or under fee-for-service be nominal. We agree with the commenters that cost sharing may act as a deterrent to obtaining care. Therefore, in § 447.53, we are adding a new paragraph (e) that states: "No provider may deny care or

services to an individual eligible for the care or services on account of the individual's inability to pay the cost sharing." This language closely tracks the statutory language in section 1916(e) of the Act. This provision applies to services furnished either by an MCO or under fee-for-service.

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

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

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

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

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

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

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

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

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

In addition, in § 438.56(d)(2)(iv), we specify that "good cause" for disenrollment by the enrollee includes poor quality care, lack of access to necessary specialty services covered under the contract, or other reasons satisfactory to the State agency. Under

this provision, the State could determine that a change in the MCO's cost-sharing policy constitutes "good cause" for disenrollment.

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

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

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

Allowing payment of a copayment up front in a hospital emergency room as the commenter suggested would raise the implication of non-compliance with the standard in § 447.53(b)(4). However,

enrollees should be aware that if they seek services in an emergency room when the standard in § 447.53(b)(4) is not met, they may be held liable for cost sharing.

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

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

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

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

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

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

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

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

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

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

physicians trained in mental illness to act as primary care providers for persons suffering from mental illness.

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

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

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

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

*Comment:* One commenter noted that neither States nor MCOs have developed a methodology to measure adequate capacity. The commenter states that while many States have required MCOs to submit a great deal of information with the intent to measure adequate capacity, that information for the most part has not been useful. Further, the commenter expressed concern that MCOs will be required to submit unnecessary data and information, thus wasting considerable

resources. This commenter suggested that the most expedient and effective way to measure adequacy and access is to ensure that enrollees know how to contact the managed care plan for information and how to file complaints and grievances. The commenter recommended that States be allowed to use their judgment on these issues under their existing certification processes.

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

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

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

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

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

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

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

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

only require that "assurances" be made to the Secretary.

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

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

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

such capacity, to expect documentation in support of the assurances it makes.

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

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

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

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

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

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

*Response:* Although section 1932(b)(5) of the Act refers expressly only to preventive and primary care services, it requires assurances of "capacity to serve the expected enrollment," presumably including those enrollees who need specialty services. While it specifies expressly that these assurances should "includ[e]" assurances with respect to preventive and primary care, this does not mean that assurances about other types of services are not necessary. Indeed, the very clause that references preventive and primary care (section 1932(b)(5)(A)) of the Act also references "an appropriate range of services," which we believe includes specialty services. Section 1932(b)(5)(B) of the Act refers to "a sufficient \* \* \* mix \* \* \* of providers of services," which again in

our view refers to having "sufficient" capacity for all types of providers, including specialists. We believe that section 1932(a)(5) of the Act, as we interpret it, provides authority for us to require assurances of specialty services. (We also have relied on our general authority under section 1902(a)(4)) of the Act.

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

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

Although we believe examples in the preamble discussion of proposed § 438.306 referenced by the commenter are appropriate for State consideration, we have not incorporated them in this

regulation. Given differences that may exist among States, it would be inappropriate to impose national ratio standards for access to specialty care.

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

*Comment:* We received one comment requesting that we define the term "mix" in proposed § 438.110(b)(2), which stated that the MCO must submit documentation to demonstrate that it "maintains a network of providers that is sufficient in number, mix, and geographic distribution to meet the needs of the anticipated number of enrollees in the service area." The commenter argued that the term "mix" is too vague. Further, as used in the context of the proposed regulation, the term could be interpreted to mean ethnic, language, and cultural diversity, or various types of specialties. The commenter recommended that we articulate this term to ensure that rights and protections are not restricted.

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

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

require an annual assessment of adequate capacity.

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

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

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

In response to commenters concerns, we have revised the provision in this final rule with comment period. We now require the MCO to submit documentation annually. The MCO is still required to submit the documentation at the time it enters into a contract and any time there has been a significant change in the MCO's

operation that would affect capacity and services. We also in § 438.207(c)(2) provide examples of what constitutes a significant change in the MCO's operations. Although States are free to include other changes, we believe, at a minimum, significant changes include— (1) a significant MCO service or benefit change; (2) an expansion or reduction of the MCO's geographic service area; (3) the enrollment of a new population in the MCO; and (4) a significant MCO rate change. We also specify that after the State reviews the documentation from the MCO, the State must certify to us that the MCO has complied with the State's requirements for availability of services, as set forth in § 438.206.

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

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

*Response:* In addition to reviewing managed care contracts, we regularly monitor the operation of Medicaid managed care programs throughout the country. We have a variety of different

monitoring tools, such as reviewing State reports and MCO or PHP documentation, interviewing representatives of the State, MCO or PHP, interviewing enrollees, reviewing provider agreements and contracts, and surveying participating providers.

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

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

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

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

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

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

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

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

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

As a general rule, § 438.206 requires the MCO to maintain and monitor a network of appropriate providers. We recognize, however, that geographic

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

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

*Response:* Section 1932(c)(2)(B) of the Act provides that States have the option of substituting private accreditation for the external quality review (EQR) required under section 1932(c)(2)(A) of the Act when EQR activities would duplicate an accreditation review. Section 1932(c)(2)(C) of the Act provides States the option to forgo EQR under section 1932(c)(2)(A) of the Act when the Medicaid MCO also has a Medicare+Choice contract in effect, and has complied with Medicaid EQR requirements for at least two years. The deeming provisions cited by the commenter only applies to the EQR requirements in section 1932(c)(2)(A) of the Act, and have no applicability to the requirement for assurances of adequate capacity in section 1932(b)(5) of the Act implemented in proposed § 438.110 and § 438.207 of this final rule with comment period. This final rule with comment period requires that assurances of adequate capacity be made at the time of contract approval and annually thereafter. We believe that it is essential that an adequate provider network be in place when beneficiaries are first enrolled in an MCO. The EQR activities are retrospective, that is, they take place after the fact and review for adherence to standards. While we

believe that the EQR review is important, it is not an appropriate substitute for an assurance of adequate capacity.

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

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

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

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

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

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

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

We interpreted the term "coverage" to mean that an MCO that pays for hospital services generally must pay for emergency services obtained by Medicaid enrollees. We interpreted coverage in the primary care case management context to mean that the PCCM must allow direct access to emergency services without prior authorization. We applied different meanings to the term "coverage" because while PCCMs are primarily individuals paid on a fee-for-service basis, they receive a State payment to manage an enrollee's care. We determined that while PCCMs, unlike MCOs, are not likely to be involved in a payment dispute involving emergency services, they could be involved in an authorization dispute over whether a self-referral to an emergency room is authorized without prior approval of the PCCM. Accordingly, proposed § 438.114(d)(2) provided that enrollees of PCCM are entitled to the same emergency services coverage without prior authorization as is available to MCO enrollees under section 1932(b)(2) of the Act.

Section 1932(b)(2)(B) of the Act defines emergency services as covered inpatient or outpatient services that are furnished by a provider qualified to furnish services under Medicaid that are needed to evaluate or stabilize an emergency medical condition. Emergency medical condition is defined in section 1932(b)(2)(C) of the Act as a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) that a prudent layperson, who possesses an average knowledge of health and medicine could reasonably expect the absence of immediate medical attention to result in placing the health of the individual (or with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy, serious impairment to bodily functions, or serious dysfunction of any bodily organ or part. While this standard encompasses clinical emergencies, it

also clearly requires MCOs to base coverage decisions for emergency services on the severity of the symptoms at the time of presentation and to cover examinations when the presenting symptoms are of sufficient severity to constitute an emergency medical condition in the judgment of a prudent layperson. The above definitions were set forth in proposed § 438.114(a). The identical definitions appear in the Medicare+Choice rules at § 422.113(b) and therefore, to avoid duplication, we incorporate those definitions by reference in this final rule with comment period.

*Comment:* One commenter stated that no protections now exist to require MCOs to cover ambulance services. The commenter cited proposed § 438.100(b), which states that Medicaid contracts with MCOs, PCCMs, or PHPs must either provide for all Medicaid services covered under the State plan or make arrangements to furnish those services. The commenter asserted that ambulance services should be covered in this regulation based on the authority in § 440.170(a), which states that transportation is a Medicaid covered service.

*Response:* Section 440.170(a) applies to non-emergency transportation, which is an optional Medicaid service that States may choose to provide or not to provide. Ambulance services are not included in the definition of "emergency services," as that definition refers to "inpatient or outpatient services." If a State covers ambulance services under its State plan, and these services are included in an MCO's contract, then the MCO must cover the ambulance services under the same terms they are covered under fee-for-service Medicaid. We recognize that the Medicare program has separate statutory authority to cover ambulance transportation when other transportation may jeopardize an enrollee's health, and that the Medicare+Choice statute thus obligates Medicare+Choice organizations to cover them. We do not, however, have that same statutory authority in the Medicaid program.

*Comment:* We received a number of comments on the rules governing post-stabilization care. Some commenters objected to requiring pre-approval from MCOs, PHPs, or PCCMs for post-stabilization services. Others opposed requiring an MCO, PHP, or PCCM with a risk contract that covers post-stabilization services to pay for those services without pre-approval if the MCO, PHP, or PCCM does not respond within one hour after receiving the provider's request or cannot be

contacted for approval. The commenters believe that the requirement is too burdensome and the time frame is too short for an MCO, PHP, or PCCM to make an informed decision. Others thought the time period was too long for emergency physicians who must keep track of patient condition and be responsible for the stability of the patient. Some commenters believed that our preamble definition of post-stabilization was inconsistent with the definition in the regulation. They noted that the proposed definition in the preamble better described "maintenance care," and that it should not be used in place of the regulation definition.

*Response:* We acknowledge that the definition of post-stabilization in the preamble differed from that in the proposed regulations text, and that the preamble definition was not consistent with the Medicare+Choice definition that we are required to apply to Medicaid under section 1932(b)(2)(A)(ii) of the Act. We regret any confusion that this may have caused.

Under the Medicare+Choice definition at § 422.113(c)(1), post-stabilization care services means "covered services, related to an emergency medical condition, that are provided after an enrollee is stabilized in order to maintain the stabilized condition, or \* \* \* to improve or resolve the enrollee's condition." The Medicare+Choice rules create a two-step process for post-stabilization care. The first step occurs during the one-hour time frame, while the hospital waits for a response from the MCO. The second step occurs after the first hour. When the MCO receives a call from the treating hospital requesting prior authorization or transfer, the MCO has one hour to make a decision on a course of treatment, and respond to the treating hospital. During that one hour, the MCO is responsible for services related to the emergency medical condition that are necessary to maintain stabilization. Any period of instability that rises to the level of an emergency medical condition that occurs during this time would be covered under provisions at § 422.113(b) related to emergency services.

The rule further establishes that if the MCO fails to respond within the one-hour time frame, or the MCO cannot be reached, the treating physician can proceed with post-stabilization services that are administered not only to ensure stability, but also to improve or resolve the patient's condition. If a nonphysician MCO representative and the treating physician cannot reach an agreement on a course of treatment, the MCO must allow the treating physician to speak with a plan physician and the

treating physician may proceed with care administered to improve or resolve the patient's condition until a plan physician is reached.

The MCO is financially responsible for post-stabilization services until the MCO and the treating physician execute a plan for safe transfer of responsibility. Safe transfer of responsibility should occur with the needs and the condition of the patient as the primary concern, so that the quality of care the patient receives is not compromised.

*Comment:* Many commenters recommended that we broaden the definition of emergency services to include coverage of "urgently needed" services. The commenters believe that expanding the definition would allow enrollees more leeway in seeking care in an emergency department for conditions that may benefit from earlier intervention. Some commenters stated that this policy would create a margin of safety for enrollees who may underestimate the severity of their illnesses and delay care if only the prudent layperson standard applies.

*Response:* The Congress has defined the obligations of an MCO to cover services received outside of an MCO's network. While MCO's are obligated to cover emergency services and post-stabilization services, there is no counterpart under the Medicaid statute for the obligation under section 1852(d)(C)(i) of the Medicare statute to cover "urgently needed services." This latter obligation generally applies only when an individual is out of the Medicare+Choice organization's service area, since it only permits services to be covered when they were not available through the organization's network. Since Congress in the BBA chose to obligate Medicare+Choice organizations to cover "urgently needed services, but chose not to do so in the same law in the case of Medicaid-contracting MCOs' we believe it would be inconsistent with Congressional intent to impose an obligation on MCOs to cover urgently needed services received out of area.

*Comment:* One commenter noted that some MCOs used a retrospective utilization review process to accept or deny an emergency claim based on a professional assessment of the nature of the emergency. The commenter believes that this violates the prudent layperson standard.

*Response:* Retrospective utilization review does not necessarily conflict with the prudent layperson standard as long as the MCO (or the State) reviews all documentation, takes into account the enrollee's presenting symptoms and applies the prudent layperson standard in making its determination. If the

retrospective review reveals that the enrollee acted in a manner consistent with the prudent layperson standard, the enrollee may not be held liable for any additional costs even if it turned out that the case did not present a clinical "emergency" (that is, even if it turned out that the reasonable belief of a "prudent layperson" was incorrect). Section 438.114(e)(2) of this final rule with comment period expressly states that an enrollee who has an emergency medical condition may not be held liable for payment of subsequent screening and treatment needed to diagnose the specific condition and stabilize the patient.

*Comment:* Many commenters were concerned that requiring MCOs, PHP, and PCCMs to provide a list of emergency settings and any other locations at which MCO, PHP, or PCCM physicians and hospitals provide emergency services covered under contract would imply that enrollees may not use any hospital or other proper setting for emergency care, but rather are limited to using participating hospitals. They suggested that we require that the list be accompanied by a clear statement of the enrollee's right to use any hospital or other setting for emergency care consistent with this section. One commenter requested that we prohibit MCOs from using lists of examples in their instructional materials of when it is inappropriate to use an emergency room because people with certain disabilities may require emergency treatment for some conditions that would not be emergencies for the general population.

*Response:* We agree with the first comment and have revised § 438.114(b) of this final rule with comment period to include as item (5) of the information that must be provided to enrollees and potential enrollees, the fact that, subject to the requirements of the section, the enrollee has the right to use any hospital or other setting for emergency care.

We believe that it is appropriate for MCOs, as well as States, to educate enrollees as to when they should or should not access emergency care. However, we have deleted the requirement that information provided to enrollees and potential enrollees include appropriate use of emergency services. States and MCOs can best determine how and when to provide this education to enrollees. Further, to monitor the appropriateness of the information provided, we encourage States to establish information requirements and review enrollee emergency information from MCOs before it is released.

*Comment:* Some commenters suggested that information regarding access to and availability of emergency and post-stabilization services should be available to potential enrollees upon request at any time, and this information should be posted prominently in emergency rooms and in providers' offices.

*Response:* We agree that potential enrollees should receive information regarding emergency care access. We have revised the introductory text of § 438.114(b) to require that the information be furnished to potential enrollees upon request. We encourage States, MCOs, PHPs, and PCCMs to disseminate information on access to enrollees as broadly as possible. We do not agree that we should require that this information be posted in emergency rooms as this is more appropriately provided by the State or the MCO, PHP, or PCCM.

*Comment:* Some commenters suggested that the MCO, PHP, or PCCM or State should be required to provide the enrollee with information regarding the education and board certification and recertification status of the health care professionals staffing the emergency departments in the enrollees' geographical region. They noted that under proposed § 438.10(f)(2)(ii), this information is provided only upon request. The commenters explained that in emergencies, the enrollee will not have time to choose which emergency department to use and that unless the enrollees have the information on the education and board certification and recertification status ahead of time, they will not be able to use these markers of quality in an emergency situation.

*Response:* Under section § 438.10, enrollees may request information from MCOs, PHPs, and PCCMs regarding education and board certification status of its participating health care professionals and hospitals. If enrollees are particularly concerned about these issues, they may request the information immediately upon enrollment so that they have it available before they need emergency services.

*Comment:* Some commenters believed that the regulations should prohibit MCOs from developing lists of "symptoms" and diagnoses for coverage of emergency services under the "prudent layperson" standard. In these commenters' view, the development of such lists is an attempt to establish plan-specific "prudent layperson" standards in the commenters' view, and could have the effect of vitiating legislative intent. They believe that lists should be expressly prohibited, and that the prudent layperson standard requires

review on a case-by-case basis that considers not only the patient's complaint, but also age and medical history. The commenters suggest revising the regulation to prevent the use of lists under the prudent layperson definition. If such lists are permitted, these commenters believe that MCOs should be required to conduct broad scale enrollee education regarding the list of symptoms for coverage of emergency services. One commenter suggested that we add the following language to § 438.114: "What constitutes an emergency medical condition with reference to the definitions in paragraph (a) of this section cannot be limited by lists of diagnoses or symptoms, or by retrospective audits based on such restrictive emergency lists, including refusal by the MCO, PHP, or PCCM, to process any claim which does not contain the primary care provider's authorization number." Another commenter also stated that some MCOs require the primary care provider's authorization number to appear on filed claims in order to receive reimbursement, and that this conflicts with the prudent layperson standard.

*Response:* We believe that the use of authorization codes in the payment approval process may be an effective and efficient way for a State, MCO, or PHP to avoid the need to apply the prudent layperson standard on a case-by-case basis, in that it can be assumed that the primary care physician has already done so. However, the absence of such an authorization cannot be used to deny an emergency room claim. Denials must be based on a case-by-case review applying the "prudent layperson" standard. We agree with the commenter's suggestion that this final rule with comment period should state what constitutes an emergency may not be limited "on the basis of diagnoses or symptoms," and have included a provision in § 438.114(e)(1)(i) of this final rule with comment period. We also agree that the regulations should expressly state that coverage of emergency room services cannot be denied based on the fact that it does not contain the primary care provider's authorization number. This suggestion is reflected in section 438.114(e)(1)(ii) of this final rule with comment period. With respect to the question of "retrospective" audits, we have addressed this above, and believe that this is addressed in the regulations in § 438.114(d)(1)(ii)(A) that makes it clear that coverage cannot be denied because the symptoms turned out not to be a "real" emergency in the sense that health was really at risk in the sense a

prudent layperson might reasonably believe it would be. This should not be construed as mandating States, MCOs, or PHPs to pay a claim if the hospital or other provider has not submitted the pertinent documentation within either reasonable, or where applicable, legal time frames.

*Comment:* One commenter believed that the provisions of proposed § 438.114(f) that requires the attending physician to determine when an enrollee is stable, is an important safeguard to ensure that the person most knowledgeable about the enrollee's current condition will make this determination. Others disagreed, stating that allowing the attending physician to be the sole person to determine when an enrollee is stabilized enough for transfer may undercut the MCO's ability to manage inpatient services and has potential for abuse. These commenters recommended allowing the attending physician's decision to come under retrospective review.

*Response:* Once an emergency medical condition is acknowledged, the emergency physician is in the best position to decide when stabilization is achieved. As noted above, section 1932(b)(1)(2)(A)(ii) of the Act requires that MCOs and PCCMs follow the "post-stabilization" guidelines established for the Medicare+Choice program under section 1852(d)(2) of the Act. The Medicare+Choice regulations state that the emergency physician decides when a patient is stable, and that this decision is binding on Medicare+Choice organizations. Because Medicare+Choice post-stabilization rules govern Medicaid, we would have no discretion to adopt a different rule for Medicaid even if we agreed with the commenter.

*Comment:* Commenters expressed concern that MCOs will argue that in some cases, coverage of screening is not covered under the definition of emergency services in proposed § 438.114, even in cases in which a screening is required under the Emergency Medical Treatment and Labor Act (EMTALA). These commenters contended that MCOs frequently refuse coverage, relying on their own definitions of reimbursable emergency services, when these definitions are more narrow than what the hospital is required to cover under EMTALA requirements. This policy places physicians and hospitals in the position of being legally obligated to render treatment for which they will not be paid. Some commenters recommend adding in the emergency services definition that "evaluate or stabilize," includes those services required under

EMTALA. One commenter recommended adding "within the meaning of 42 U.S.C. 1395dd" at the end of the emergency services definition at proposed § 438.114(a)(2), and adding preamble language that states that the MCO must "pay for the cost of emergency services obtained by Medicaid enrollees." However, one commenter stated that under such a definition, an emergency condition exists if certain acute symptoms are manifested even though the underlying condition may not be an emergency. The commenter asserted that EMTALA requirements are expansive, and would result in more emergency room services being approved for payment. This commenter believed additional benefits to Medicaid beneficiaries are appropriate, but that unless additional funding is provided, expanding emergency services effectively creates an unfunded mandate for additional services for which an MCO will have to pay.

*Response:* The definition of emergency services includes the evaluation necessary to stabilize a patient with an emergency medical condition. We believe that all screening (beyond the initial routine procedures for example, checking blood pressure and, temperature) used to determine whether an emergency medical condition actually exists involve medical screens and tests that would have to be covered. We do not agree that MCOs should be required to cover any screening required under EMTALA. The Congress only required MCOs to cover services if the "prudent layperson" standard is satisfied. Under EMTALA, a hospital would have certain screening obligations even in a case in which the prudent layperson standard clearly was not met, but an individual nonetheless presented himself for treatment at an emergency room. Because the Congress limited an MCO's obligation to situations in which the "emergency medical condition" definition containing the prudent layperson standard is met, we would have no authority to require MCOs to pay for services when this definition is not met, even if EMTALA would require the hospital to incur costs. Under this regulation, MCOs may not refuse coverage by relying on their own definition of reimbursable emergency services if the prudent layperson standard is met, regardless of EMTALA.

We are not addressing the issue of additional funding for emergency services in this regulation. We note, however, that under § 438.6(c) all capitation rates paid under risk contracts must be actuarially sound and

appropriate for the services to be furnished under the contract.

*Comment:* Some commenters were concerned that States will attempt to obtain a waiver of the emergency services provisions in the BBA under section 1915(b) of the Act or section 1115 of the Act, and require prior authorization for emergency services. They recommend not allowing the emergency services section to be waived through section 1915(b) of the Act or section 1115 of the Act.

*Response:* We view access to emergency services using the prudent layperson standard as an important enrollee protection and we do not foresee a circumstance under which we would exercise our authority under section 1115 of the Act to permit an MCO to engage in prior authorization. We note that section 1915(b) of the Act only permits waivers of section 1902 provisions, and would not provide authority to permit prior authorization even if we were inclined to do so.

*Comment:* Some commenters recommended that we establish a central contact point at HCFA's central and regional offices where individuals and entities could direct inquiries regarding State and MCO or PCCM activity with respect to emergency services, establish a process for obtaining a timely remedy for these concerns, and clearly set out penalties that States or HCFA can impose for violations of the regulations and statute.

*Response:* The appropriate HCFA regional office should be contacted regarding any concerns about application of the emergency services provision of the regulation. In turn, our regional office will contact the central office should they need policy guidance. This is the regular procedure within HCFA and we believe it appropriate to follow it for these issues as well as all others. We note, with respect to penalties, that a failure to comply with the requirements in § 438.114 would constitute a failure to comply with section 1932(b)(2) of the Act, and would be sanctionable under § 438.700(d) of this final rule with comment period.

*Comment:* One commenter recommended stating in § 438.114 that copayments not permitted under fee-for-service may not be imposed for emergency services under managed care.

*Response:* Restrictions on copays in managed care are by statute, the same as for fee-for-service. This issue is addressed in the comments on § 438.108, which incorporates the fee-for-service limits on cost-sharing in § 447.50 through § 447.58.

*Comment:* One commenter believed that the provision of information that describes or explains what constitutes an emergency should be the responsibility of the State and should not be left to the MCO. The commenter recommended allowing States to provide information on what constitutes an emergency service. Others stated that the provision at § 438.114(b) requires States, MCOs, and PHPs to provide information annually, especially on post-stabilization because it is burdensome, unnecessary, and potentially confusing to enrollees. Others suggested removing the annual requirement or making information available upon request of the enrollee.

*Response:* We have revised § 438.114(b) to require that the information must be furnished by the State or at State option, by the MCO, PHP, or PCCM. We believe that States should be permitted to delegate this dissemination responsibility to MCOs, PHPs, or PCCMs. We do not believe that it is too burdensome to require this information, including post-stabilization requirements to be furnished on an annual basis and therefore, we have retained this requirement. We note that under the Medicare+Choice program, we also require that information regarding emergency services be provided annually.

*Comment:* One commenter believed that HCFA should include in the regulatory text, rather than just the preamble, a statement that MCOs must pay for the cost of emergency services obtained by Medicaid enrollees. Some commenters felt that the language in proposed § 438.114(e)(1)(i) was confusing, and did not make clear that MCOs must pay for treatment at facilities outside its network. They suggested replacing paragraph (i) with "(i) An enrollee had an emergency medical condition as defined at § 438.114(a)." However, some commenters disagreed, stating that the language clearly articulates the requirement to cover and pay for emergency services that meet the prudent layperson standard."

*Response:* While we have not changed the policy, we have clarified the requirements in this section by revising paragraph (d) to state that the specified entities must cover and pay for emergency services regardless of whether the entity that furnishes the service has a contract with the MCO, PHP, or PCCM. In addition, we specify that the entities may not deny payment for treatment obtained when either—(1) an enrollee had an emergency medical condition, including cases in which the absence of immediate medical attention

would not have had the outcomes specified in the definition of emergency medical condition, or (2) a representative of the MCO, PHP, or PCCM instructs the enrollee to seek emergency services. This paragraph also outlines the coverage and payment rules that apply to PCCMs not responsible for payment.

*Comment:* One commenter believed that paragraph (b)(6) concerning preauthorization was confusing. The commenter noted that "prior authorization," "pre-authorization," and "pre-approved" are used synonymously throughout the regulation and that we should choose one word to be consistent. They recommend revising (b)(6) to read, "\* \* \* but payment is required if the MCO does not provide prior authorization within an hour \* \* \*" and choose one word for prior authorization throughout.

*Response:* We agree with the commenter and have adopted the term "prior authorization" throughout the regulation. In addition, we have revised § 438.114(b) to add to the list of required information the post stabilization rules set forth at § 422.113(c) of the Medicare regulations. Proposed paragraph (c) (coverage and payment for post-stabilization services) has been replaced by a paragraph (f) that provides for coverage and payment "in accordance with § 422.113(c) of this chapter."

*Comment:* Some commenters urged that the regulation make clear that the attending physician determines the point at which prior authorization must be sought for post-stabilization services. One of the commenters recommended changing "attending physician" to "emergency physician" to clarify who is actually physically present caring for the patient.

*Response:* We agree with the commenters' point, and in this final rule with comment period at § 438.114(e)(3), we use the term "attending emergency physician" to describe who determines that the patient's condition is stable.

*Comment:* One commenter suggested replacing "MCE physicians" in proposed § 438.114(b)(4) with "MCO, PHP, or PCCM providers" to accurately reflect the full range of qualified health professionals.

*Response:* We agree with the commenter and have revised paragraph (b)(4) as suggested (as noted above, we have also replaced references to "MCEs" with references to all entities subject to the rule, in this case, MCOs, PHPs, and PCCMs). In addition, we are changing "practitioner" in proposed § 438.114(f) to "provider" in § 438.114(e)(3) of this final rule with comment period. However, we want to make clear that an

emergency physician must provide oversight to those providers who are not physicians.

*Comment:* Some commenters suggested striking the phrase “with an average knowledge of health and medicine” from the definition of emergency services at § 438.114(a). The commenters believe the phrase is ambiguous and likely to invite legal challenge because what is average in one community or culture may be different in another.

*Response:* The language referenced by the commenters is in the statute and therefore we have retained it.

*Comment:* Some commenters question the meaning of proposed § 438.114(c)(4), specifying the circumstances under which the State must pay for post-stabilization services not covered under an MCE (that is, MCO or PCCM) risk contract. The commenters recommend stating, “if post-stabilization services are not covered by an MCO, PHP, or PCCM risk contract, the State must pay for all medically necessary services.”

*Response:* We agree with the commenters that the language in proposed § 438.114(c)(4) was confusing. We have replaced this section with a reference to the post-stabilization requirements in § 422.113(b) of the Medicare+Choice regulations. We note that if the hospital contacts the MCO, PHP, or PCCM for prior approval, and the MCO, PHP, or PCCM determines that it is not at risk for that specific service because it is not obligated to cover the service under its contract, then it should refer the hospital to the appropriate payer. For example, if a hospital contacts an MCO for prior approval for mental health services after the enrollee has been stabilized and the MCO contract does not include mental health services, then the MCO should refer the hospital to either the State or the appropriate PHP.

*Comment:* Many commenters believed that the prudent layperson standard is not easily adapted to non-medical conditions such as behavioral health which is not generally evaluated based on impairment of bodily function or dysfunction of a bodily organ or part. The commenters felt that individuals with mental health problems should have the same protections as others who may experience a medical emergency. Other commenters stated that the concept of “danger to others” inherent in many definitions of emergent behavioral health conditions is absent and arguably is not easily assessed by a person untrained in the assessment of behavioral health risks. They suggested separately defining urgent conditions as mental health crises that require

immediate treatment to avoid hospitalization, and suggested establishing authorization criteria similar to post-stabilization criteria in the proposed rule. One commenter believed that both the “danger to others” and “prudent layperson” standards could be used simultaneously without violating the regulations. Other commenters suggested that the emergency medical condition definition encompasses mental illness as well as physical illness because it states “\* \* \* could reasonably expect the absence of immediate medical attention to result in placing the health of the individual in serious jeopardy \* \* \*”

*Response:* We agree that the emergency medical condition definition using the prudent layperson standard pertains to mental health as well as physical health. We note that this is also the case with EMTALA. We believe that the reference to “placing the health of the individual in serious jeopardy” is sufficient to cover mental health emergencies.

#### 8. Solvency Standards (§ 438.116)

Section 4706 of the BBA added new solvency standards to section 1903(m)(1) of the Act, requiring that an MCO’s provision against the risk of insolvency meet the requirements of a new section 1903(m)(1)(C)(i) of the Act unless exceptions in section 1903(m)(1)(C)(ii) of the Act apply. Under section 1903(m)(1)(C)(i) of the Act, the organization must meet “solvency standards established by the State for private health maintenance organizations” or be “licensed or certified by the State as a risk-bearing entity.” The exceptions to this new requirement in section 1903(m)(1)(C)(ii) of the Act apply if the MCO—(1) is not responsible for inpatient services; (2) is a public entity; (3) has its solvency guaranteed by the State; or (4) is controlled by FQHCs and meets standards the State applies to FQHCs. Section 4710(b)(4) of the BBA provided that the new solvency standards applied to contracts entered into or renewed on or after October 1, 1998. Proposed § 438.116 essentially reflected these statutory provisions. In addition to the specific comments addressed below, we received many comments indicating general support for the implementation of the new solvency exceptions.

*Comment:* One commenter expressed concern that proposed § 438.116(c)(5), which would exempt MCOs with contracts entered into on or before October 1998, will lead to the lack of beneficiary protection in the event of insolvency in these plans. The commenter questioned whether this

exemption applies to contracts in effect in 1998 as well.

*Response:* The BBA specified contracts entered into or renewed on or after October 1, 1998, as the effective date of the new solvency requirements. At this time, all contracts are subject to the new requirements. In this final rule with comment period, we have removed paragraphs (c)(5) and (c)(6).

*Comment:* One commenter asked if all MCOs, PHPs, and PCCMs must be licensed or certified as risk-bearing entities, and if carve-out services provided by PHPs would be considered “public entities,” and be exempt from the solvency standards.

*Response:* This section does not require that all MCOs, PHPs, and PCCMs be licensed or certified as risk bearing entities. First, the solvency requirements in this section are only applicable to MCOs and PHPs, not to PCCMs. While § 438.116(b)(1) provides that subject to certain exceptions, an MCO or PHP must meet the solvency standards established by the State for private HMOs, or be licensed or certified by the State as a risk-bearing entity. The commenter is correct that this requirement does not apply to MCOs that are public entities. With respect to carve-out services provided by a PHP, if the PHP is a public entity, it does not have to meet the private HMO solvency standards or be licensed or certified by the State as a risk bearing entity. However, the PHP would still have to make assurances satisfactory to the State that it has adequate provision against the risk of insolvency.

*Comment:* One commenter questioned whether in a subcontracting situation, the subcontractor would be subject to the solvency standards. The commenter noted that it is important for all entities serving Medicaid beneficiaries be solvent.

*Response:* We agree that it is important for all entities serving Medicaid enrollees to be solvent. We believe that the responsibilities of subcontractors and MCOs with respect to their subcontractors are adequately addressed in other sections. We note that § 438.6(l) provides that all subcontracts must fulfill the requirements of this part that are appropriate to the service or activity delegated under the subcontract. In addition, § 438.230 requires that the State ensure that each MCO oversees and is accountable for any functions and responsibilities that it delegates to any subcontractor. It also requires that each MCO monitors the subcontractor’s performance on an ongoing basis and subjects the subcontractor to formal review “according to a periodic

schedule established by the State, consistent with industry standards or State MCO laws and regulations.”

*Comment:* One commenter noted that under the Medicare+Choice regulations, MCOs are permitted to apply for a Federal waiver (preemption) from State solvency requirements if such requirements are more stringent than the Federal PSO requirements. The commenter suggested that in light of the availability of waivers in Medicare, Medicaid regulations should recognize that some PSOs are not going to meet State solvency requirements, and permit their participation in Medicaid managed care without meeting the State requirements.

*Response:* We do not have the statutory authority to exempt PSOs from the Medicaid solvency requirements in section 1903(m)(1) of the Act. The waiver authority in the BBA for PSOs that wish to enter into Medicare+Choice contracts BBA applies only to the Medicare program.

*Comment:* One commenter does not believe that Federally Qualified HMOs should be exempt from solvency requirements.

*Response:* Federally Qualified HMOs from solvency requirements are subject to detailed solvency requirements under title XIII of the Public Health Service Act and part 417 of this chapter. The commenter is correct, section 1903(m)(1)(A) of the Act provides that “an organization that is a qualified health maintenance organization as defined in section 1310(d) of the Public Health Service Act is deemed to meet the solvency requirements in section 1903(m)(1)(A)(i) and (ii) of the Act.” Since this exemption is set forth in the statute, we do not have the authority to change it. This comment has prompted us to recognize that we did not provide for this exemption in proposed, § 438.116, therefore, we have revised this final rule with comment period.

*Comment:* Several commenters asserted that the basic rule of this section was confusing with respect to the solvency requirements an MCO must meet.

*Response:* In response to this comment, we have revised § 438.116 to separate the “basic rule” from the “other requirements” that must be met as required under section 1903(m)(1)(C).

*Comment:* One commenter believed that proposed § 438.116(c)(2) which provides that the State solvency requirements in paragraph (b) do not apply if the MCO is a public entity, would mean that a county consortium would not need to meet the State’s financial solvency requirements. The

commenter asked if these Federal regulations preempt the State statute.

*Response:* Section § 438.116(b)(2) in this final rule with comment period (§ 438.116(c)(2) in the proposed rule) does not exempt public entities from all solvency requirements under Federal regulation. Section § 438.116(b)(1) specifies that unless an exception in paragraph (b)(2) applies, an MCO must meet the solvency standards established by the State for private HMOs or be licensed or certified as a risk bearing entity by the State. While paragraph (b)(2) exempts public entities from this requirement, under § 438.116(a), these entities must still make assurances satisfactory to the State showing that they have adequate provision against the risk of insolvency. States retain the flexibility to determine what assurances must be provided.

*Comment:* Several commenters supported the provision that exempts public entities from solvency standards imposed on private HMOs.

*Response:* While we acknowledge the support of this comment, we would like to reiterate that public entities are not exempt from all solvency standards. Public entities must still provide assurances satisfactory to the State showing that they have adequate provision against the risk of insolvency in accordance with § 438.116(a).

*Comment:* One commenter recommended that Federal requirements for capitalization should apply to all managed care organizations. In addition, the commenter suggested Federal and State governments should pre-approve all contracts with managed care organizations whose enrollees are primarily Medicaid insured, and require both Federal and State governments to guarantee provider payments if organizations become insolvent.

*Response:* We do not have statutory authority to establish Federal requirements for capitalization to guarantee payments to providers, or to require States to do so. However, under § 438.6 (Contract requirements), our Regional Office will review and approve all MCO and PHP contracts, and under § 438.806(b), prior approval by us is required for all MCO contracts with a value in excess of \$1,000,000. While there is no Federal requirement that States guarantee provider payments, if, under § 438.116(b)(2)(iv), an MCO has its solvency guaranteed by the State, the State would be liable for all of the MCO’s debts, including provider payments, if the MCO became insolvent.

*Comment:* One commenter noted that proposed § 438.116(c) provided that public entities are not required to meet the standards a State imposes on its

private HMOs. The commenter questioned how this policy would affect a State that imposes the same or similar requirements on both private and public HMOs. In addition, the commenter asked if this provision applies to tribal governments.

*Response:* Even though public entities are not required to meet the solvency standards established by the State for private HMOs, public entities are still required to make adequate assurances satisfactory to the State that they have adequate provision against the risk of insolvency. States still have the flexibility to determine what assurances they consider adequate. Therefore, a State may require that public entities meet requirements that are the same or similar to those it imposes on private HMOs. With respect to tribal governments, if the MCO operates outside of the reservation, State solvency standards apply. But a State does not have jurisdiction to impose solvency standards on an on-reservation tribal MCO as a general operating condition.

*Comment:* One commenter expressed concern that we intend to accept State solvency standards rather than imposing Federal solvency standards.

*Response:* We do not have statutory authority to require a Federal solvency standard because the BBA specifically provides for State flexibility in this area.

#### **D. Quality Assessment and Performance Improvement (Proposed Subpart E Recodified as Subpart D)**

##### *Background*

Section 4705 of the BBA created section 1932(c) of the Act, paragraph (1) which requires State agencies that contract with Medicaid MCOs under section 1903(m) of the Act to develop and implement quality assessment and improvement strategies. Proposed subpart E (recodified as subpart D in this final rule with comment period) implemented section 1932(c)(1) of the Act, and set forth specifications for the quality assessment and performance improvement strategies that States must implement to ensure the delivery of quality health care through contracts with MCOs and (where applicable) PHPs.

Proposed § 438.302 established standards for State contracts with MCOs and PHPs, and required that each State must have a strategy for continually monitoring and evaluating MCO and PHP compliance with those standards. Proposed § 438.304 set forth minimum elements required in each State’s quality improvement strategy. Proposed § 438.306 set forth standards for

availability of services addressing: (1) Beneficiary choice of entities; (2) services not covered by the MCO or PHP; (3) the MCO or PHP delivery network including: assurance of adequate capacity and services; the right to access to a women's health care specialist; credentialing requirements; 24 hour, seven day per week access; and convenient hours of operation; (4) coordination of care including screening and assessment; (5) procedures designed to identify and treat pregnancy and complex and serious medical conditions, and (6) a cultural competency requirement.

Proposed subpart E also contained rules regarding coverage and authorization decisions (proposed § 438.310), provider selection (proposed § 438.314), enrollee information (proposed § 438.318), enrollee rights (proposed § 438.320), confidentiality and accuracy of enrollee records (proposed § 438.324), and enrollment and disenrollment requirements (proposed § 438.326).

Additionally, proposed § 438.328 required an effective grievance system that meets the requirements of subpart F of this part; and proposed § 438.330 provided for oversight and accountability by the MCO or PHP of functions and responsibilities delegated to subcontractors.

Proposed § 438.340 required that MCOs and PHPs have an ongoing quality assessment and performance improvement program for the services it furnishes to enrollees; that the performance improvement programs achieve any minimum performance levels required by the State; and that the MCO or PHP achieves significant and sustained improvement in significant aspects of clinical care and non-clinical care areas that can be expected to have a favorable effect on health outcomes and enrollee satisfaction. The State also would be required under proposed § 438.336 to ensure that each MCO and PHP uses practice guidelines meeting specified criteria and under proposed § 438.342 to maintain a health information system that collects, analyzes, integrates, and reports data on the achievement of the objectives of this subpart.

#### 1. Scope (Proposed § 438.300)

Proposed § 438.300 set forth the scope of subpart E.

*Comment:* Several commenters found the provisions in subpart E on Quality Assessment and Performance Improvement to be overly prescriptive. One commenter believed that the lack of flexibility would prevent States from accommodating new approaches and

standards in a rapidly changing marketplace. One commenter contended that the provisions do not make allowances for resource limitations of States, while another suggested that the provisions of this part are unnecessary because of our review and approves MCO contracts.

*Response:* We understand the concern that this rule establishes substantial new requirements for States, MCOs, and PHPs. However, we believe that these provisions are important beneficiary protections, and reflect the intent of the Congress in enacting the quality and beneficiary protections of the BBA. As required by a directive from President Clinton, we also sought to incorporate the provisions of the Consumers Bill of Rights wherever permissible under our legal authority. When drafting the proposed rule, we spoke to States as well as representatives of beneficiaries to inform ourselves as to their views. We then tried to strike an appropriate balance that would reflect the Congressional intent, but also maintain flexibility for States, where possible, and avoid unreasonable burden and costs on MCOs and PHPs. Public comment on the proposed rule provided us an additional opportunity to hear the opinions of stakeholders. In this final rule with comment period we make many of the changes suggested by commenters.

*Comment:* Several commenters believed that these regulations would discourage or prevent State innovation in designing managed care programs, especially as States would fear the loss of Federal financial participation.

*Response:* We hope that these regulations will not have the effect of discouraging State innovation in managed care, because we recognize the important contributions made by States who have led the way in the past. We will continue to encourage and support State innovation in the future. However, we believe that a formal approach to quality assessment and improvement is an essential component of all successful health care delivery programs, including managed care programs, and that it is appropriate to incorporate such formal quality approaches into Medicaid managed care programs. We note that the approaches to quality assessment and improvement that are contained in this regulation are consistent with quality measurement and improvement activities currently in use throughout the health care industry

*Comment:* Several commenters contended that the quality provisions of subpart E are so burdensome to MCOs that this will discourage their participation in Medicaid managed care.

*Response:* We are concerned that some MCOs have decided to leave the Medicaid market and we have seriously considered the burden these regulations carry as we developed this final rule with comment period. While we have made some changes in recognition of this burden, we must balance this concern with beneficiary concerns raised by numerous commenters. This is especially important because the Medicaid population includes many individuals with special health care needs.

*Comment:* One commenter stated support for the comprehensive quality assessment framework of the proposed rule.

*Response:* We believe that the statute intends that State quality strategies be sufficiently broad to ensure a high quality of care for Medicaid managed care enrollees. This is the reason why we proposed a comprehensive strategy, and are retaining it in the final rule with comment period.

*Comment:* Several commenters discussed the provision of the BBA that requires us to conduct a study of the protections (if any) that may be needed when enrolling individuals with special health care needs into managed care. The commenters believed that we should have begun the study promptly following enactment of the BBA so that the results of the study could be reflected in the final rule with comment period.

*Response:* The research, analysis, and writing of this BBA-mandated study was underway during the public comment period for the proposed rule. As a result, in analyzing and responding to the comments, we were able to consider the comments in light of the findings and evidence resulting from this study. While we believe that the proposed rule addressed the needs of all Medicaid enrollees, including those with special health care needs, we have made revisions to the proposed rule in response to comments that have been informed by the findings in the BBA special needs study.

*Comment:* Numerous commenters raised questions about the relationship of the requirements of subpart E to our standards and guidelines for Medicaid and Medicare managed care organizations contained in our Quality Improvement System for Managed Care (QISMC) document. Several commenters interpreted the regulation to incorporate QISMC requirements. One commenter contended it was unrealistic to expect a small State to implement QISMC without allowing for incremental implementation over an extended period of time. Another

commenter suggested that the regulation should require the use of QISMIC, and that QISMIC should be modified and strengthened by incorporating ideas contained in our document titled "Key Approaches to the Use of Managed Care Systems for Persons with Special Health Care Needs." Another commenter asserted that not requiring States to use QISMIC for Medicaid, when we are using it for Medicare, discriminates against Medicaid beneficiaries. Another commenter asked how future improvements to QISMIC will be incorporated into the regulations. Another commenter asked how we will review State strategies when States choose not to use QISMIC. One commenter felt that QISMIC was inadequate to improve the health care provided to vulnerable populations.

*Response:* All these comments reflect some confusion about the relationship of this BBA regulation to QISMIC. The quality provisions of the BBA regulation and QISMIC are similar, but not identical.

In 1996, before the BBA was enacted, we began an initiative that aimed, in part, to—

- Develop a coordinated Medicare and Medicaid quality oversight system that would reduce duplicate or conflicting quality requirements for Medicaid and Medicare managed care and send a uniform message on quality to managed care organizations and beneficiaries; and
- Make the most effective use of existing quality measurement and improvement tools, while allowing sufficient flexibility to incorporate new developments in the rapidly advancing state of quality measurement.

This initiative was QISMIC. The most prominent products of the QISMIC initiative were standards and guidelines for Medicaid and Medicare-contracting MCOs. For Medicaid, these standards updated and replaced earlier standards sent by us to States as part of the Quality Assurance Reform Initiative (QARI). The QARI standards were provided to States as technical assistance tools for their discretionary use although most States with MCO contracts used them, in part or in whole. QISMIC was intended to replicate the success of QARI, in part by disseminating revised standards that reflected advances in private sector accreditation standards, as well as advances in quality measurement and improvement in both the public and private sectors.

After the BBA was passed in 1997, our development of the regulations to implement the quality assessment and improvement provisions of the law was informed by our prior work in

developing QISMIC. From the QISMIC work, we identified those fundamental activities that formed the essence of quality measurement and improvement. These activities and standards were revised as necessary to reflect a level of detail appropriate for regulations and included in our proposed rule. For this reason, many of the regulations implementing the BBA quality provisions reflect QISMIC standards. However, while QISMIC was developed as a set of standards that address MCOs and PHPs, the legal requirements set forth in this final rule with comment period address States as well as MCOs and PHPs.

QISMIC has been offered to States as a tool to use to the extent the State wishes, as long as the State complies with the requirements in this final rule with comment period. While full compliance with QISMIC would help satisfy the quality requirements in subpart D that were based in part on QISMIC standards, a State may meet the minimum standards in the regulation without requiring the use of QISMIC. If a State requires MCOs and PHPs to follow QISMIC, this will promote compliance with the regulatory requirements that overlap the QISMIC standards. However, compliance with QISMIC is not sufficient to meet all the provisions of the regulation because this regulation includes a much broader range of topics than is covered by QISMIC. For the foregoing reasons, we will not use QISMIC to monitor States, but rather monitor against the regulatory requirements.

*Comment:* Several commenters questioned the relationship of Medicaid quality provisions and those used by private accrediting organizations for the commercial managed care market. Two commenters suggested that private sector standards be used for Medicaid, either at State direction or through deeming. Another commenter recommended against use of private sector standards because he believes that they are geared to a generally healthy population while the Medicaid population includes populations with special health care needs.

*Response:* The Medicare+Choice statute, at section 1852(e)(4) of the Act, provides authority for Medicare+Choice organizations that are reviewed by private accreditation bodies to have a broad range of Medicare+Choice requirements "deemed" satisfied based on such private accreditation (if the private accreditation body applies standards at least as stringent as Medicare's). This authority includes the authority to "deem" compliance with QISMIC standards, which is mandatory

for Medicare+Choice organizations. There is no comparable broad deeming authority provided for MCOs or PHPs under the Medicaid statute. The only Medicaid authority for "deeming" by private accreditation bodies relates to the deeming of external review requirements under section 1932(c)(2)(A) of the Act. This rulemaking does not address these requirements, or provisions for the deeming of these requirements in section 1932(c)(2)(B) and (C) of the Act. These are being addressed in a separate rulemaking, in which a notice of proposed rulemaking was published on December 1, 1999, 64 FR 67223.

*Comment:* Several commenters questioned the applicability (or non-applicability) of subpart E to entities other than MCOs. One commenter agreed with applying the provisions of this subpart to PHPs. Another commenter suggested that we extend these requirements to all MCEs, including PCCMs. Another commenter suggested that the provisions of subpart E not be applied to capitated PCCMs. Lastly, another commenter suggested that PHPs be excluded from external quality review, because the commenter believed that this imposes an undue burden on States for contracts that are limited in scope.

*Response:* In section 1932 of the Act, the Congress included provisions that apply to all MCEs (that is, to MCOs and PCCMs), provisions that apply only to MCOs, and provisions that apply only to PCCMs. Since the Congress thus addressed PCCMs in section 1932 of the Act, we believe that where it applied a requirement only to MCOs, this reflects a clear and expressed intent that the requirement not apply to PCCMs. We therefore are not applying the regulations implementing section 1932(c)(1) of the Act to PCCMs. With respect to PHPs, as we have noted above, the Congress was silent, in section 1932 of the Act and its legislative history, concerning what requirements should be applied to these entities. At the time the Congress acted, we had longstanding regulations in place applying selected section 1903(m) of the Act requirements to PHPs. We believe that given that PHPs are paid on a risk basis, the concerns that caused the Congress to impose the quality requirements in section 1932(c) of the Act on MCOs apply with equal force to PHPs, and that the extension of these requirements to PHPs under our authority in section 1902(a)(4) of the Act is appropriate. With respect to the comment on risk-based PCCMs, they are not subject to these requirements by virtue of their status as PCCMs, since as

we have just noted, we are not imposing these requirements on PCCMs. Rather, as a risk contractor, they also meet the definition of PHP, and are subject to these requirements by virtue of their status as PHPs. Only PCCMs that fall in both categories would be subject to the requirements in subpart D.

*Comment:* Several commenters questioned the relationship of the quality provisions to waiver approval requirements. One contended that the relationship is unclear and duplicative. Another questioned if waivers of any of the quality provisions will be approved in light of the proposed rule's preamble language which states that waivers will only be granted if the quality requirements in this regulation are met or exceeded.

*Response:* We believe that the BBA quality requirements that are addressed in this subpart should apply to managed care provided through MCOs and PHPs regardless of the authority used to establish these programs. Quality is equally important whether the managed care program is established through a waiver granted under section 1115 or 1915(b) of the Act or as a State plan amendment under section 1932(a) of the Act. Therefore, generally, States will be required to follow these provisions as a condition for approval of a waiver. However, the Secretary has the discretion to waive these requirements if quality is addressed in the waiver program in a manner that equals or exceeds the quality requirements contained in this subpart. We believe that to do less would deny beneficiaries important protections and be counter to Congressional intent.

*Comment:* One commenter believed that the most important quality standard for persons with disabilities is that these individuals be served in the least restrictive setting, and that the standard for outcomes should include the achievement of the highest level of functioning for each individual.

*Response:* We agree that it is important to serve persons with disabilities in the setting that they desire. We further agree that achievement of the highest level of functioning is a desirable outcome for this population. This is consistent with the provisions of the proposed regulation. However, we are not specifying in the regulation particular performance measures for any of the populations served by the Medicaid program. The strength of each particular performance measure is dependant upon the specifications for calculating the measure. Performance measure specifications typically change over time as information systems, coding,

survey instruments and other methods of data collection change over time. For this reason, we do not believe it is appropriate to establish specific performance measures in regulation.

*Comment:* One commenter noted that the proposed rule only addresses requirements that States and MCOs must meet, and suggested that these requirements will be effective in improving the quality of health care only if they are acted upon by external sources.

*Response:* Subpart D of this final rule with comment period interprets and implements section 1932(c)(1) of the Act and sets forth required quality standards. We agree that these new provisions must be executed well to have the desired impact of improving the health care provided to Medicaid beneficiaries. In this regard, States play a key role. They establish the provisions of MCO and PHP contracts and are primarily responsible for ensuring that the regulatory requirements are effectively implemented by MCOs and PHPs. We are responsible for overseeing the States' adherence to these rules. To this end we have revised, and will be further revising (based on this final rule with comment period), protocols that HCFA Regional Offices use to monitor State compliance with statutory and regulatory requirements.

*Comment:* Several commenters questioned the consistency between Medicaid and Medicare quality requirements. One suggested that the Medicaid requirements should be the same as those for Medicare. The other commenter suggested that the Medicaid subpart be reworked because it is not appropriate to apply the Medicare standards to Medicaid due to differences in the populations covered by each program.

*Response:* As stated in the introduction, the proposed Medicaid rule is consistent with the Medicare+Choice regulations wherever we believe it is appropriate. We believe that quality provisions should be consistent for all of our programs unless the statutory requirements differ, or program or population differences necessitate different standards. In creating this consistency, we carefully considered the needs of both Medicaid and Medicare beneficiaries and, where possible, proposed quality provisions that meet the needs of both. We believe that this approach best meets the needs of our beneficiaries (many of whom are eligible for both programs), and reduces burden on MCOs that contract with both programs. In subpart D, the regulatory requirements are consistent with those that apply to Medicare+Choice

organizations. As noted above, however, under Medicare, Medicare+Choice organizations are all required to comply with QISMC, while States have the option of using all or part of QISMC in the case of Medicaid-contracting MCOs and PHPs.

*Comment:* Several commenters suggested that particular quality measures be incorporated into the regulation. One commenter wanted to ensure use of quality standards for patients with end stage renal disease, including a specific standard identified by the commenter. Another commenter suggested that all States measure quality against objectives contained in "Healthy People 2000 and 2010," publications of the Department of Health and Human Services that outline a comprehensive health promotion and disease prevention agenda for the nation. Another commenter suggested that we establish, for children and adults with disabilities, a distinct set of quality standards (that is, performance levels) to ensure that these persons obtain the quality health care and health-related services necessary for them to lead full lives.

*Response:* We do not believe that particular quality measures should be specified in the regulation. Performance measures and quality standards change over time and it is important that the most current and useful measures can be quickly adopted. However, in response to these comments we have added a provision at § 438.204(c) that requires States to use performance measures and levels prescribed by us, as part of their State quality strategy. We also have provided in § 438.240(c)(2)(ii)(A) of the final rule with comment period that States must require their contracting MCOs and PHPs to meet these specific performance levels. This allows us to establish performance measures and levels for subsets of the Medicaid population, such as persons with end stage renal disease or other disabilities. We plan to use performance measures and levels that are widely accepted, standardized, and have undergone validity and reliability testing. At the present time, we are not aware of large numbers of such measures specific to persons with disabilities such as end stage renal disease that would meet these requirements. However, we expect measures to be developed over time that will meet these criteria. In the meantime, in response to the comment concerning the disabled population, we have added a new § 438.240(b)(4) to require States to have procedures to identify enrollees with special health care needs and to assess the quality and

appropriateness of care provided to these individuals. Also in response to this comment, we have in § 438.204(e)(2) required that the number of MCO and PHP enrollees with special health care needs be reported to us. The identification of these individuals and the assessment of their care and services is an essential step in assuring high-quality health care for them. We note that we also provide, in § 438.240(c)(1), for States to specify performance measures for their MCOs and PHPs to support quality improvement.

*Comment:* Several commenters suggested that we establish quality performance levels for States and MCOs.

*Response:* We agree with these commenters, and in response to these comments, and as noted above, we have added a new § 438.204(c) that requires that State quality strategies include our-prescribed performance measures and levels that States must require their MCOs and PHPs to meet. We believe that by requiring States to require their MCOs and PHPs to meet a specified level of performance on specific measures, we are carrying out its responsibility to ensure quality in the Medicaid program. We intend to use widely-recognized measures and establish levels through a public process, or based on statutory requirements. We have retained the States' authority to set minimum performance levels for MCOs and PHPs.

*Comment:* Several commenters suggested that States and MCOs be required to have vision and mission statements.

*Response:* We do not agree that it is essential for each State and MCO to have a vision and mission statement to support its quality strategy, nor do we believe it would be appropriate for us to mandate such a statement. While this approach can be an effective management tool, we believe that States should have the discretion to decide whether to adopt this approach, as long as they meet the elements for a comprehensive quality strategy set forth in this final rule with comment period.

*Comment:* Several commenters suggested that State quality strategies be required to address all statutory and regulatory requirements, not only those addressed in subpart E.

*Response:* We believe that the scope of this subpart is sufficiently broad to include the wide range of areas related to quality. We note that none of the commenters provided any specific examples of additional areas that they believe would be appropriate for inclusion. Therefore, we are not broadening the scope of the State

quality strategy beyond the areas covered in the proposed rule.

## 2. State Responsibilities (Proposed § 438.302)

Proposed § 438.302 set forth the State's responsibilities in implementing its quality strategy. Specifically, § 438.302 required that each State: (1) have a strategy for assessing and improving the quality of services provided by an MCO and PHP; (2) ensure compliance with standards established by the State agency; and (3) conduct regular, periodic reviews to evaluate the effectiveness of its strategy, as often as the State agency determines appropriate, but at least every 3 years.

*Comment:* We received a large number of comments suggesting that the regulation require States to involve stakeholders in the development of their quality strategies, as is recommended in the preamble to the proposed rule. One commenter suggested that the Medical Care Advisory Committee perform this function. Another commenter suggested that the proposed State quality strategy should be published and comments from the public should be considered before the plan is made final.

*Response:* As stated in the preamble of the proposed rule, we expect that State agencies will consider the input of stakeholders when developing performance goals that are clear, fair, and achievable. We also believe that it is reasonable and appropriate for States to consider the ideas of stakeholders and other members of the public in the design of their quality strategies. Therefore, in response to this comment, and earlier comments on § 438.110 discussed in section II. C. above, in § 438.202(c) of the final rule with comment period we require States to provide for input of beneficiaries and other stakeholders regarding their quality strategies, and specifically, to make the strategies available to the public before adopting them. We do not specify what process States must use to obtain public input, because we wish to allow States flexibility to structure this process as they find appropriate. For several years, States with section 1115 demonstration projects have been required to have a process for public input. States with 1115 demonstrations may want to use this process for receiving comments on their quality strategy or choose another process.

*Comment:* Several commenters suggested that we add more specificity to the requirement for a State quality strategy. Most of the commenters suggested that the regulation should require that the strategy be put in writing. Two commenters suggested that

standards be established to measure the success of the strategy. One commenter suggested that we incorporate in the regulation the language contained in the preamble that the strategies should be "well considered," "well coordinated," and "overarching." Another commenter suggested that the regulation require State strategies to address all statutory and regulatory standards, identify each component of the strategy, address how the components are coordinated, ensure adequate monitoring and oversight, and be effective.

*Response:* We agree that the State quality strategies should be in writing, and in response to this comment, we are including this requirement in the final rule with comment period, in § 438.202(b). We believe that this new requirement, along with the requirement at § 438.202(c) that States consider the input of stakeholders in the design of their strategies, the requirement at § 438.202(e) that States conduct periodic reviews of the effectiveness of their strategy, and the requirement in § 438.204(g) that the State strategy include standards at least as stringent as those set forth in subpart D, provide the best mechanisms to ensure that the strategies will (1) be well considered, well coordinated, and overarching; (2) identify each component of the strategy and how components are coordinated; and (3) be effective. Therefore, we have not added the specific requirements suggested by the commenter to the regulation.

*Comment:* Several commenters considered the proposed maximum three year period between State reviews of the effectiveness of their quality strategies to be too long. The commenters instead suggested an annual review of MCO or PHP compliance with contract requirements. One commenter believed that the three year time period was inconsistent with QISMC requirements, and certification and licensing procedures. Another commenter expressed support of the three year time frame.

*Response:* The commenters who objected to the three year maximum period between reviews of the State quality strategy appear to have misunderstood the intent of § 438.202(e). Section 438.202(e) does not apply to State review of MCO and PHP compliance with contracts, but to review of the effectiveness of the State's quality strategy. State monitoring and review of MCOs and PHPs is addressed, in the context of the State's quality strategy, in § 438.204(b)(2), which requires States to continuously monitor and evaluate MCO and PHP compliance with the standards specified in the

subpart. The evaluation of the State's quality strategy under § 438.202(e) is intended to be a broad review of the interrelationship of all the elements that the State is required to include in its quality strategy to determine the effectiveness of this strategy as a whole. We believe it is particularly important for States to step back and review the "big picture" at least every three years because the field of quality review and measurement is rapidly evolving, making it important for States to reassess their approach at regular intervals. Requiring periodic review on a more frequent basis may not provide the State with sufficient time to effectively implement its strategy. For this reason, we are retaining the provision requiring review at least every three years.

*Comment:* Several commenters suggested that the final regulation require that beneficiaries be provided information about the State quality assurance program and MCO and PHP quality. In particular, the commenters wanted enrollees and potential enrollees to receive information on quality indicators, quality improvement topics, external review results, compliance audits, summarized complaint and grievance data, and disenrollment counts.

*Response:* We agree that beneficiaries, upon request, should have access to information concerning the State quality strategy and MCO and PHP performance. In § 438.202(b) and (c) of the final rule with comment period with comment period we require that the States' quality strategies be in writing and that stakeholders have an opportunity to make suggestions and comment on the strategy. We believe that this requirement will also serve the purpose of ensuring that beneficiaries can obtain information on that strategy. Section 438.10 of the regulation specifies what information must be furnished to enrollees and potential enrollees by the State, the MCO or PHP, and the enrollment broker. For MCOs, PHPs, and as appropriate PCCMs that enroll beneficiaries under a State plan program under section 1932(a) of the Act, this includes quality and performance indicators that can be used to compare plans. In addition, the proposed rule implementing the external quality review (EQR) requirements in section 1932(c)(2) of the Act, published in the **Federal Register** on December 1, 1999 (64 FR 67223), identifies EQR results that it proposes must be made available to enrollees. We believe that these requirements will ensure that enrollees and potential enrollees have access to information

that will enable them to compare the performance of MCOs and to make an informed choice.

*Comment:* One commenter suggested that we add a new paragraph to proposed § 438.302 that would require that State strategies address all covered services, including midwifery services.

*Response:* We do not believe it is appropriate to specify that all covered services be included, since all covered services may not be included under an MCO or PHP contract. We also believe that the existing regulations already cover all services that are covered under the contract, as § 438.202(a) refers to "managed care services offered" by MCOs and PHPs. This would include any services they offer. Under § 438.206(c) of the final rule with comment period, the State is responsible for making available to the enrollee any Medicaid service not covered under the MCO or PHP contract, and these thus would not be included in an MCO or PHP quality strategy.

*Comment:* One commenter believed that furnishing quality oral health services requires planning and treatment decisions that are made by the dentist and the patient together.

*Response:* We agree with the commenter, and believe that the final rule with comment period addresses this issue. Paragraphs (b)(5) and (b)(6) of § 438.100 (previously designated as § 438.320(b)(4) and (5) in the proposed rule) specify the right of enrollees to receive information on available treatment options, and to participate in decisions regarding their health care.

*Comment:* One commenter asked what criteria we will use to review and evaluate State quality strategies.

*Response:* Since the requirement that States develop and follow State strategies is new, we have no experience with reviewing and evaluating these strategies. In response to the commenter's concern, however, we have added a new paragraph (f) to § 438.202 requiring States to submit to us a copy of their initial strategies and all significant revisions thereafter. We also in paragraph (f)(2) specify that States must regularly report to us on the implementation and effectiveness of their strategies.

### 3. Elements of State Quality Strategy (Proposed § 438.304)

Proposed § 438.304 set forth the minimum elements of a State quality strategy, including contract provisions that incorporate the standards specified in this subpart. Specifically, quality strategies would include procedures for assessing the quality and

appropriateness of care and services provided, including but not limited to: (1) contract provisions that incorporate the standards specified in this subpart; (2) procedures for assessing the quality and appropriateness of care and services, including, but not limited to continuous monitoring and evaluation of MCO and PHP compliance with the standards; (3) annual, external independent reviews of quality outcomes, and timeliness of, and access to services covered under each MCO and PHP contract; (4) appropriate use of intermediate sanctions that at a minimum, meet the requirements in subpart I; (5) an information system sufficient to support initial and ongoing operation and review of the State's quality strategy; and (6) standards, at least as stringent as those required under proposed §§ 438.306 through 438.342, for access to care, structure and operations, and quality measurement and improvement. In developing a strategy, we communicated our expectations that each State will work with beneficiaries and their advocates, quality experts, managed care organizations, and other stakeholders to develop performance goals that are clear, fair, and achievable.

*Comment:* As proposed, § 438.304 required States to "continuously monitor" MCO and PHP compliance with the quality standards. Many commenters urged that we revise this requirement. Several commenters suggested that the regulation require an annual audit of each MCO for compliance with the standards; that the requirement include monitoring of grievances and logs of calls to beneficiary "hotlines"; and that a medical records review be required of catastrophic events, random records, and persons with disabilities. Other commenters suggested replacing the continuous monitoring requirement with a more flexible standard related to the MCO's or PHP's contract cycle or to the need for monitoring based on the plan's performance.

*Response:* We continue to believe that States should be required to continuously monitor and evaluate MCO and PHP compliance with quality standards. States may choose, as part of their quality strategies, to conduct a comprehensive audit of MCOs and/or PHPs on an annual or other basis, but this should not relieve them of the ongoing responsibility to ensure that MCOs and PHPs are meeting the standards at all times. States are in the best position to decide how best to accomplish this activity and may vary their requirements according to their knowledge of particular MCOs and

PHPs. We believe the requirement in § 438.416(d) requiring MCOs and PHPs to submit to the State summaries of their handling of grievances and appeals is sufficient to address the comments regarding monitoring of grievances. However, we have not required MCOs and PHPs to have a "hotline", therefore, including a monitoring requirement for hotlines would not be appropriate. With respect to medical records, we do not believe that we should specify what records States should review or the frequency with which they should perform review. Rather, we believe that this should be left to States to determine as part of their overall quality strategies. With respect to persons with disabilities, we have added new requirements for monitoring. New § 438.204(b)(1) requires States, as a part of their quality strategies to have procedures to identify, and assess the quality and appropriateness of care furnished to, enrollees with special health care needs.

*Comment:* One commenter suggested that, as part of the State quality strategy, States should be required to evaluate the effectiveness of services provided to beneficiaries with limited English proficiency. Another commenter suggested that States should collect and analyze data on cultural competency. This commenter further suggested that States conduct demonstration projects related to cultural competency to better understand this new and critical area of quality assessment.

*Response:* We agree that in order for States' MCOs and PHPs to effectively address cultural competency, they all must have basic information on the cultural characteristics of their Medicaid enrollees. We therefore have revised § 438.204(b)(1) of the final rule with comment period to require States, as a part of their quality strategies, to include procedures to identify the race, the ethnicity, and primary language spoken of each MCO and PHP enrollee and to provide this information to each MCO and PHP at the time of each Medicaid beneficiary's enrollment in the MCO or PHP. Further, § 438.306(e)(4) of the proposed rule has been modified as § 438.206(e)(2) of the final rule with comment period to require the State to ensure that each MCO and PHP provides services in a culturally competent manner to all enrollees, including those with limited English proficiency and diverse cultural and ethnic backgrounds. This means that, as part of its quality strategy, the State must monitor and evaluate the effectiveness of these provisions. We would welcome State demonstrations or other strategies to develop effective

means of evaluating cultural competency in the provision of services.

*Comment:* Several commenters recommended that we add a State quality strategy element requiring the State to have an information system capable of managing the data that MCOs are required to report under proposed § 438.342. Another commenter stated that the regulation should require compatibility between the MCO's and the State's information systems.

*Response:* Section 438.204(g) of the final rule with comment period includes, as an element of the State quality strategy, that the State provide for "structure and operations" standards (among other standards) at least as stringent as those of this subpart. Because the health information systems requirement is included in the subpart, it is unnecessary to add this as an element of the State quality strategy. Likewise, the information systems requirements in § 438.242 are sufficient. While this section does not specify that MCO and PHP systems must be compatible with those of the State, we believe that it is in the State's best interest to require this. If a State chooses not to impose this requirement on an MCO or PHP, the State remains responsible for obtaining from the MCO or PHP the information specified in § 438.242 and incorporating into its information system. Some States may choose this option for MCOs or PHPs that need time to acquire a compatible system or to modify an existing system to make it compatible.

*Comment:* Numerous commenters requested information concerning the EQR element of the State quality strategy. Several commenters felt that requiring States to review quality outcomes, timeliness, and access to care under the EQR would be expensive and excessive; and that therefore, review of all three of these areas should not be required annually. One commenter suggested that States should be allowed to conduct an in-house review. Another commenter believed that well performing MCOs and PHPs should not be required to undergo an annual review. One commenter wanted additional information about how EQR fits into the State quality strategy and QISMC. Another commenter suggested that we should establish criteria for EQR organizations. One commenter suggested that we publish interim standards for EQR that would allow States to access the 75 percent matching rate established by the BBA.

*Response:* As noted above, on December 1, 1999, we published in the **Federal Register** a proposed rule to implement the BBA provision that

requires an annual, external independent review of the quality outcomes and timeliness of, and access to, services covered under each MCO contract. 64 FR 67223. This proposed regulation includes information that will address the comments made concerning § 438.304(c) of the proposed rule. The statute requires that we contract with an independent quality review organization to develop protocols to be used in the reviews. That work is now underway. Until that work is completed, we cannot publish standards to permit States to access the 75 percent matching rate provided by the BBA. We note, however, that States may currently receive a 75 percent Federal match under section 1903(a)(3)(c) of the Act for EQR activities conducted by Peer Review Organizations (PROs) and entities that meet the requirements for contracting as a PRO.

*Comment:* One commenter suggested that we add the word "items" before "services" in § 438.304(c) of the proposed rule, as it is included in the statute. The commenter also suggested that we include a list of examples of such items, such as durable medical equipment, assistive devices, certain birth control items, and prescriptions.

*Response:* Ordinarily, we do not use the term "items" in our regulations because the term "services," as used in the regulations, includes covered "items" as well. While only the Medicare regulations expressly specify that "services" includes "items" (42 CFR 400.202), section 1905(a) of the Act uses the term "care and services" to encompass all services or items for which Medicaid payment may be made. References in the regulations to "services" therefore, include covered "items" as well. Because of this, we are not adding the word "items" before "services" in § 438.204(d) (§ 438.304(c) in the proposed rule).

*Comment:* One commenter expressed the need to clarify that appeals on coverage and claims are handled through the State fair hearing process, and not through complaints to the EQR.

*Response:* The commenter is correct that appeals on coverage and claims decisions by enrollees are properly addressed through the internal appeals process of the MCO and PHP and the State fair hearings process. The proposed EQR regulation makes clear that handling enrollee appeals is not an EQR function.

#### 4. Availability of Services (Proposed § 438.306)

Section 1932(c)(1)(A)(i) of the Act, as added by section 4704 of the BBA,

requires each State that contracts with MCOs under section 1903(m) of the Act to develop and implement standards for access to care under its quality assessment and improvement strategy. Section 438.306 of the proposed rule established standards for access to care. Paragraph (a) required that States ensure that all covered services are available and accessible to enrollees. Paragraph (b) specified that if a State agency limits freedom of choice, the State agency must comply with the requirements of proposed § 438.52, which specify the choices that the State agency must make available. Paragraph (c) specified that if an MCO or PHP contract did not cover all services under the State plan, the State agency must arrange for those services to be made available from other sources, and instruct all enrollees on where and how to obtain them, including how transportation is provided. In § 438.306(d) we proposed new requirements for the delivery networks of MCOs and PHPs to ensure that all covered services under a contract are available and accessible to enrollees. These requirements would be imposed on State agencies, which in turn would enforce these requirements on MCOs and PHPs. Specifically, paragraph (d)(1) proposed that the State agency require all MCOs and PHPs to maintain and monitor a network of appropriate providers that is supported by written arrangements and is sufficient to provide adequate access to covered services. In this context, adequate access generally means that all contracted services, other than out-of-area emergency care services, are available within the MCO's or PHP's network. In establishing and maintaining such a network, the proposed rule required that MCOs and PHPs consider (1) anticipated enrollment, with particular attention to pregnant women and children; (2) the expected utilization of services, considering enrollee characteristics and health care needs; (3) the numbers and types of providers required to furnish contract services; (4) the number of network providers who are not accepting new patients; (5) the geographic location of providers and enrollees, considering distance, travel time, the means of transportation ordinarily used by enrollees, and whether the location provides physical access for enrollees with disabilities.

In § 438.306(d)(2) we proposed that the State be required to ensure that MCOs and PHPs allow women direct access to a woman's health specialist for women's routine and preventive services, and in paragraph (d)(3) we

proposed that MCOs and PHPs seeking an expansion of their service area demonstrate that they have sufficient numbers and types of providers to meet the anticipated additional volume and types of services the additional enrollee population may require. Proposed § 438.306(d) also required that: (1) the State agency ensure that each MCO and PHP demonstrate that its providers are credentialed as described in proposed § 438.314, (2) when medically appropriate, each MCO and PHP make services available 24 hours a day, 7 days a week, (3) as part of the State quality strategy, the State must ensure that each MCO and PHP requires its providers to meet the State-established standards for timely access to care and member services, taking into account the urgency of need for services; and (4) that each MCO and PHP establish mechanisms to ensure compliance and monitor continuously for compliance, and take corrective action in cases of non-compliance.

In § 438.306(e) we proposed that each MCO and PHP be required to provide each enrollee with an initial health assessment within 90 days of the effective date of enrollment, and that pregnant women and individuals with complex and serious medical conditions receive this baseline health risk assessment within a shorter period of time. We further proposed that each MCO and PHP have in place State-approved procedures to identify and furnish care to pregnant women and individuals with complex and serious medical conditions; and that appropriate medical procedures be implemented to address and monitor their care, including specifying an adequate number of direct access visits to specialists as required by the treatment plan.

Finally, proposed § 438.306(e)(4) required that the State ensure that each MCO and PHP provide services in a culturally competent manner, including satisfying the language requirements in § 438.10(b).

*Comment:* We received several comments in support of the proposed rule, but a few commenters suggested that we revise it to include more specific wording. For instance, one commenter recommended that we expand the rule to make clear that access includes receiving services in a timely manner. Another commenter suggested that we change the language to ensure that all covered services are available to each enrollee as medically necessary. Another commenter suggested that the regulation be revised to reflect that both services and "items" were available and accessible to

enrollees. This commenter was concerned that the proposed language did not address access to medical equipment, drugs, and other supplies covered by a State Medicaid plan.

*Response:* Paragraph (a) was intended to convey the broad general intent of the subsequent provisions. Subsequent provisions of the final rule provide more detailed specifications for what access standards must include, including timely access to care and medical necessity. As noted in a previous response, we have not added the word "items" to explicitly address access to "items and services" covered by an MCO or PHP contract because the term "services," as used in the regulations, includes covered "items" as well. While only the Medicare regulations expressly specify that "services" includes "items" (42 CFR 400.202), section 1905(a) of the Act uses the term "care and services" to encompass all services or items for which Medicaid payment may be made. References in the regulations to "services" therefore, include covered "items" as well.

*Comment:* We received numerous comments in response to proposed § 438.306(c), which requires a State—

- To arrange for State plan services not covered under an MCO or PHP contract to be made available from other sources; and
- To instruct enrollees on where and how to obtain these services, including how transportation is provided.

Most of the commenters supported the inclusion of this provision, indicating that distribution of information on out-of-plan services has been unsatisfactory in the past. However, a few commenters requested clarification of this provision and wondered whether States could delegate this responsibility to MCOs. In contrast, one commenter disagreed that MCOs should have the responsibility to advise enrollees on where and how to obtain services not provided by the MCO.

*Response:* We recognize that States have discretion to contract with MCOs or PHPs to provide a specific set of services that may not include all services covered under a Medicaid State plan. Our intention in proposing this provision was to ensure that enrollees in managed care have access to services covered under a State plan but not provided by an MCO or PHP. We believe that the duty to inform enrollees on how to obtain those services rests primarily with the State. However, we agree that a State may delegate this responsibility to an MCO or PHP as part of its contract.

*Comment:* One commenter believed that we have gone beyond our authority

in proposing § 438.306(c). The commenter suggested that our use of the words "arrange for services to be made available from other sources" expands the State's responsibility to a greater degree under managed care than under a fee-for-service arrangement. In light of such concerns, the commenter recommended that the clause be deleted, and argued that States should only be responsible for guaranteeing payment for State plan services not covered under an MCO contract.

*Response:* States continue to have the same responsibility they have always had to ensure that covered benefits are available to eligible beneficiaries in accordance with a Medicaid State plan. In proposing § 438.306(c), it was never our intent to imply that States act as case managers in "arranging for services to be available from other sources." Therefore, we agree that some change to the proposed rule is necessary to clarify the State's responsibility. In the final rule with comment period, § 438.206(c) requires that, if the MCO or PHP does not cover all of the services under the State's plan, the State must make available those services from other sources and provide enrollees with information on where and how to obtain them, including how transportation is provided.

*Comment:* We received several comments on proposed § 438.306(c) with regard to the provision of transportation. One commenter noted that transportation has been an issue in certain counties within its State. Another commenter noted that transportation is particularly important for adolescents. Several commenters made specific recommendations. For example, one commenter recommended that we clarify how transportation is reasonably provided, and require that it be subject to the availability of public transportation in the region. Other commenters recommended that we make the transportation requirement a separate provision.

*Response:* Under § 431.53 of our regulations, a State Medicaid agency is required to specify in its State plan that the agency will (1) ensure all necessary transportation for recipients to and from providers, and (2) describe the methods that the agency will use to meet this requirement. Proposed § 438.306(c) was intended to ensure that, under managed care, enrollees still receive necessary transportation services consistent with what is described in the Medicaid State plan. We do not believe any changes are necessary to further require access to transportation services under managed care.

*Comment:* Several commenters requested that § 438.306(c) specifically refer to services excluded from a contract because of religious beliefs. In addition, commenters requested that we address the knowledge and expertise of providers with respect to the scope of services provided by the MCO.

*Response:* We believe that the information requirements in §§ 438.10(e)(2)(xii) and 438.102 specifically address the commenters' concerns. Section 438.10(e)(2)(xii) requires that, either the State or the MCE, as appropriate, must furnish enrollees and potential enrollees with information on how to obtain services covered under a State plan. This encompasses information on services not covered under an MCO or PHP contract because of moral or religious objections and information on the education, licensure, and board certification of providers. Section 438.102(c) requires that MCOs or PHPs that elect on moral or religious grounds under § 438.102(b)(3) not to provide, reimburse, or provide coverage of a counseling or referral service that they would otherwise be required to under § 438.102(b)(1), must furnish information about the services it does not cover to the State and to potential enrollees and enrollees at certain times.

*Comment:* We received several comments suggesting that proposed § 438.306(d)(1), which set forth requirements for establishing, maintaining, and monitoring a network of appropriate providers, imposed an undue administrative burden on States. Commenters objected to the general requirement for the State to ensure that MCOs maintain and monitor a network of appropriate providers "that is supported by written agreements and is sufficient to provide adequate access to all services covered under the contract." One commenter believed that documentation referenced in the general requirement was rarely available to the Medicaid agency, much less to MCOs. The commenter viewed the requirement as impractical, and believed that there was potential for large implementation problems. Another commenter suggested that, although it is the duty of the State to monitor MCO contracts, it would be a huge administrative burden to verify that a written agreement exists with each provider.

*Response:* We do not agree that this requirement is impractical or imposes an undue burden on States. This provision is consistent with § 438.230, which requires written agreements that specify the delegated activities and reporting responsibilities of a subcontractor. We believe that, without

written agreements, MCOs and PHPs cannot assure their enrollees sufficient access to network providers. Therefore, States must obtain assurances from and monitor MCOs and PHPs, as appropriate, to verify that such agreements exist.

*Comment:* Numerous commenters suggested that we revise proposed § 438.306(d)(1) to add a requirement that States and MCOs make available, as part of their network, providers experienced in serving individuals with certain conditions, and providers with specialty training. For example, commenters suggested that we require MCOs to contract with providers experienced in serving individuals with HIV/AIDS, children with special health care needs, individuals with chronic diseases, and individuals with physical and developmental disabilities. One commenter recommended that the final regulation establish minimum standards for a provider's experience in serving persons with chronic diseases and disabilities in managed care plans. Minimum standards suggested by commenters include: (1) current caseload of persons with certain chronic diseases or disabilities, (2) provider training in treating persons with certain diseases or disabilities, (3) extent or duration of experience serving persons with certain chronic diseases or disabilities, and (4) measures of successful outcomes in treating persons with chronic diseases or disabilities.

*Response:* We agree that States should ensure that MCOs make available, as part of their network or through other arrangements, access to providers experienced in treating conditions such as HIV/AIDS and access to specialty providers for certain chronic conditions. Therefore, in response to this comment, in § 438.206(d)(1)(iii), we have added "training and experience" to the list of attributes MCOs and PHPs must consider when establishing their provider networks. We also have added, in § 438.206(d)(1)(i) "persons with special health care needs" as a category of enrollees to whom States, MCOs and PHPs should pay particular attention in meeting this requirement.

We do not believe it is appropriate to further specify in regulation the types of specialists that must be included in an MCO's or PHP's provider network, nor do we believe it appropriate to define what constitutes an experienced provider for certain types of conditions. Because the evidence base regarding how to precisely define all types of "experienced providers" is still limited, we believe that States are in a better position to impose specific requirements on MCOs and PHPs,

consistent with their standards for access to care and the population enrolled in managed care. However, also in response to the concerns raised in this comment, we have added a requirement at § 438.206(d)(5) that if the network is unable to provide necessary medical services, covered under the contract, to a particular enrollee, the MCO or PHP must adequately and timely cover these services out of network for the enrollee, for as long as the MCO or PHP is unable to provide them. We intend that the inability to provide medically necessary services would extend to a situation in which the enrollee needs related and covered services (for example, a Cesarean section and a tubal ligation) to be performed at the same time; not all related and covered services are available within the network; and the enrollee's primary care provider or another provider determines that receiving the services separately would subject the enrollee to unnecessary risk. We further specify at § 438.206(d)(8) that the State must ensure that use of out-of-network-providers incurs no greater cost to the enrollee beyond what he or she would have paid had the services been received from a network provider.

We emphasize that § 438.206 is integrally linked to § 438.207, which requires MCOs and PHPs to give the State assurances of adequate capacity and services to serve the MCO's and PHP's expected Medicaid enrollment, including access to specialty services. In meeting the requirements of the final rule with comment period, each MCO and PHP will have to submit assurances of its capacity to States, and States will have to submit certification to us, annually and at any time there has been a significant change in the MCO's and PHP's network that would affect adequate capacity and services. We reserve the right to inspect documentation submitted by MCOs and PHPs to the State. With these requirements, we believe that appropriate checks are in place to ensure that States are monitoring MCOs and PHPs against the State's standards for access to care.

*Comment:* We received several comments suggesting that proposed § 438.306(d)(1)(i) should specifically consider other populations with special health care needs in addition to pregnant women and children. Commenters recommended that we revise § 438.306(d)(1)(i) to also consider people with disabilities, adults with special health needs, persons with mental illness, persons with substance abuse problems, persons with

developmental disabilities, and persons with functional disabilities or complex problems involving multiple medical and social needs such as HIV/AIDS and homelessness.

*Response:* We agree and have revised this provision. As noted above, § 438.206(d)(1)(i) of the final rule with comment period requires that each MCO and PHP, in establishing its provider network, take into consideration "persons with special health care needs," as well as pregnant women and children. Also, in response to this comment, § 438.208(b) of the final rule with comment period requires that States implement "mechanisms to identify to the MCO or PHP, upon enrollment" categories of enrollees at risk of having special health care needs, children under age 2, and other enrollees known to be pregnant or have special health care needs.

"Persons with special health care needs" is the terminology used by the Congress at section 4705(c)(2) of the BBA that called for the Secretary to conduct a study of the safeguards needed when such individuals are enrolled in Medicaid managed care. In undertaking this study, we conceptualized individuals with special health care needs as persons who either (1) have functional disabilities (e.g., difficulty bathing, dressing, eating, communicating, or problems with mobility) or (2) live with health or social conditions that place them at risk of developing functional disabilities (for example: mental retardation; serious chronic illnesses such as HIV, schizophrenia, or degenerative neurological disorders; disabilities resulting from many years of chronic illness such as arthritis, emphysema, or diabetes; and certain environmental risk factors such as homelessness or family problems that lead to the need for placement in foster care). From this conceptual framework, our study identified six groups of individuals with special health care needs:

- (1) children with special health care needs;
- (2) children in foster care;
- (3) individuals with serious and persistent mental illness/substance abuse;
- (4) individuals who are homeless;
- (5) older adults (individuals 65 years of age and older) with disabilities; and
- (6) adults under 65 who are disabled or who have a chronic condition, whether physical or mental.

As noted above, under new § 438.208(b)(1), States are required to identify enrollees in these categories to their MCO or PHP.

Subsequent to the passage of the BBA, we also began to explore the concept of

"persons with complex and serious medical conditions." This category of persons was referenced in the proposed rule because they are a group of individuals addressed in the Consumer Bill of Rights and Responsibilities (CBRR). On August 31, 1999, the Institute of Medicine (IOM) submitted a report to us entitled "Definition of Serious and Complex Medical Conditions." This study was requested in order to provide guidance to Medicare M+C organizations (who do not have a BBA mandate with respect to "persons with special health care needs"). While the IOM recommended that the establishment of an administrative definition for serious and complex medical conditions would be premature at this time, it also described a "serious and complex condition" as: \* \* \* one that is persistent and substantially disabling or life threatening that requires treatments and services across a variety of domains of care to ensure the best possible outcomes for each unique patient or member."

In examining the similarities and differences between the concepts of "special health care needs" and "serious and complex medical conditions" as articulated in our work for its Report to the Congress and the IOM, respectively, it is clear that individuals with, "persistent and substantially disabling \* \* \* [conditions] that require treatments and services across a variety of domains of care to ensure the best possible outcomes for each unique patient or member," are included in our conceptual framework of "persons with special health care needs." The only component of the IOM description of persons with serious and complex medical conditions that is not readily apparent as included in our conceptual description of persons with special health care needs are those health conditions that are "life threatening." However, we believe that persons with life threatening conditions can reasonably be considered to have a special health care need. Therefore, the provisions of this final rule with comment period require States to ensure that each MCO and PHP establish and maintain a network of providers that considers the MCO's or PHP's anticipated enrollment, with particular attention to pregnant women, children, and persons with special health care needs. We have also, throughout this final rule with comment period, deleted the language, "individuals with serious and complex health care needs" where used in the proposed rule, and replaced

it with "persons with special health care needs."

*Comment:* We received numerous comments that generally supported the requirement in proposed § 438.306(d)(1)(iii) that MCOs consider the numbers and types of providers needed to furnish contracted services. Many commenters recommended that, instead of providing examples in the preamble, we establish in regulation specific enrollee-to-provider ratio standards. While several commenters suggested that we incorporate the examples from the preamble into the regulation itself, other commenters suggested that we apply other enrollee-to-primary care provider ratios ranging from 1200:1 to 2500:1. Some providers believed that primary care assignments should be discontinued when a patient load reaches 3,000. Several believed that enrollee-to-provider ratios should encompass all patients treated by a provider, and not just Medicaid patients. Finally, some commenters also believed that specific ratios for specialists should be established in regulation, such as ratios for pediatric specialists and providers serving persons with HIV/AIDS.

*Response:* We do not believe it is appropriate to set national standards that specify maximum enrollee-to-provider ratios. We believe that the inclusion of such ratios in regulations would be too prescriptive, and would not be appropriate for all Medicaid managed care programs across the country. The variation in the comments we received attests to this. Because of such variation, we believe that States are in a better position to establish specific standards to ensure that an adequate number of providers is maintained within MCO and PHP networks.

*Comment:* Some commenters requested that we establish specific standards in the final rule with comment period outlining the types of providers that must be included in an MCO's network. One commenter specifically recommended that the term "provider" be defined when establishing standards for the various disciplines and specialty areas of practice. Other commenters recommended that an MCO be required to include in its network specified types of providers such as nurse-midwives, obstetricians and gynecologists, pediatric specialists, and providers with demonstrated competence in serving enrollees with mental illness, substance abuse problems, developmental disabilities, functional disabilities, and complex problems involving multiple

medical and social needs such as homelessness and HIV/AIDS.

*Response:* We do not believe it appropriate to impose national standards requiring specific numbers and types of providers. States have implemented varying and often unique programs that cover a variety of benefits. Some of these programs serve a broad spectrum of Medicaid enrollees; while others serve a narrower group. One set of standards may not be appropriate in every circumstance. However, we have required at § 438.206(d) that each State must ensure that each MCO and PHP maintain and monitor a network of providers that is sufficient to provide adequate access to all services covered under the contract, and that in constructing this network, each MCO and PHP must consider (among other requirements): (1) the anticipated enrollment, with particular attention to pregnant women, children and persons with special health care needs, and (2) the numbers and types (in terms of training and experience) of providers required to furnish the contracted services.

*Comment:* We received a number of comments suggesting that we establish in the final rule with comment period a national geographic access standard. Section 438.306(d)(1)(v) of the proposed rule required MCOs and PHPs, when establishing and maintaining their provider networks, to take into account the geographic location of providers and enrollees, considering distance, travel time, the means of transportation ordinarily used by enrollees, and whether the location provided physical access for enrollees with disabilities. Commenters offered a variety of recommendations to supplement this provision. Some commenters suggested that geographic standards be based on travel time and not distance, and others urged that we liberalize geographic access standards to take into account allowable public transportation time. Several commenters recommended that we require a general time of 30 minutes from an enrollee's residence, and others recommended an exception for frontier areas. Further, other commenters suggested varying standards, such as 30 miles or 30 minutes for rural areas, 20 miles or 30 minutes for urban areas, and 45 minutes for specialty care; whereas other commenters suggested a 30 minute or 30 mile standard, with a 60 minute or 60 mile standard for rural areas.

*Response:* We do not believe it is appropriate to set national geographic access standards in these regulations. We recognize that there are unique circumstances which exist in each State

for which a national standard could be inappropriate. This is reflected in the comments received and in the preamble to the proposed rule in which we noted that a provider network should be structured so that an enrollee residing in the service area does not have to travel an unreasonable distance to obtain a covered service, beyond what is customary under a Medicaid fee-for-service arrangement. The preamble to the proposed rule also acknowledged that many Medicaid enrollees may use public transportation. We stated that "in areas where Medicaid managed care enrollees rely heavily on public transportation, the State should ensure that providers are accessible through these means within the same time frames as enrollees who have their own means of transportation." Because of this, we believe that States are in a better position to establish access standards, including geographic access standards, as part of their States' quality assessment and improvement strategy. Our availability of services requirements under § 438.206 of the final rule with comment period allow States sufficient flexibility to develop access standards that are appropriate for their own circumstances, and ensure that States take into consideration important factors such as distance, travel time, and the means of transportation normally used by enrollees.

*Comment:* We received several comments requesting that we be more specific with respect to our requirement that MCOs and PHPs take into account a location's physical accessibility for enrollees with disabilities. While the commenters generally supported inclusion of this provision, they also believed that we should be more specific in our final rule with comment period. Several commenters believed that we should require States, at a minimum, to ensure that sites are physically accessible and comply with the Americans with Disabilities Act. One commenter suggested that States and MCOs ensure access not only to locations, but also to all aspects of medical treatment. Other commenters stressed that in addition to physical access, it is just as important for populations with special health care needs, such as persons with mental retardation, to have access to knowledgeable and trained staff, to receive understandable information, to be able to communicate with a provider if he or she is hearing impaired, and to have longer appointment times. They recommended that we reflect these adaptations in the final rule with comment period.

*Response:* We believe that several of the requirements in this final rule with comment period address many of the commenters' concerns. We specifically refer commenters to the following:

- Sections 438.206(d)(1)(i) and (d)(1)(ii) require each MCO and PHP, when establishing their provider networks, to take into consideration their anticipated enrollment, with particular attention to persons with special health care needs, and their expected utilization of services, considering the enrollees' characteristics and health care needs.
- Section 438.206(d)(1)(iii) requires each MCO and PHP to also consider the numbers and types (in terms of training and experience) of providers needed.
- Section 438.206(d)(1)(v) requires MCOs and PHPs to consider distance, travel time, means of transportation ordinarily used by enrollees, and whether the location provides physical access for enrollees with disabilities.
- Section 438.100 requires the State to ensure that MCOs, PHPs, and PCCMs, comply with applicable Federal and State laws that pertain to enrollee rights. The Americans with Disabilities Act is explicitly mentioned as one of these Federal laws. Section 438.100 also requires States to ensure that enrollees receive information on available treatment options and alternatives, presented in a manner appropriate to the enrollees' conditions and ability to understand.
- Section 438.102(b)(2)(ii) requires that steps be taken to ensure that enrollees with disabilities have effective communication with all health system participants in making decisions with respect to treatment options.

All these requirements were designed to ensure that States address issues such as physical access and composition of provider networks. We have not required in this final rule with comment period that populations with special health care needs always have longer appointment times because it is not yet possible to precisely define all individuals with special health care needs, and because all such individuals may not always require longer appointment times.

*Comment:* We received several comments on proposed § 438.306(d)(2), which requires that female enrollees have direct access to women's health specialists within the network for women's routine and preventive services, notwithstanding that the MCO maintains a primary care provider for each enrollee.

Overall, many commenters supported inclusion of this provision. However, a few commenters requested clarification

of regulatory terms. For example, several commenters expressed concern over what they viewed as the ambiguity of the term "women's health specialist." They requested that we expand the definition of that term in the final regulation to include specific provider types, such as nurse-midwives or obstetricians/gynecologists. Others felt that this provision could be construed to include non-licensed practitioners or laypersons.

*Response:* We do not define "women's health specialist" in this final rule with comment period, because different types of health professionals may, through education and/or clinical experiences, be appropriately thought of by a contracting MCO or PHP or enrollee as a "women's health specialist." However, we intend for the term to refer to licensed health professionals with specific clinical education and training in women's health care, including obstetricians, gynecologists, nurse midwives, and nurse practitioners, consistent with State licensing requirements.

*Comment:* Several commenters felt that the term "routine and preventive services" in proposed § 438.306(d)(2) should be excluded from this provision, while other commenters felt that we should define the term further. One commenter felt that we should define the term based on existing professional guidelines. Others requested that we define the term to include specific services, such as prenatal care, labor and delivery services, breast exams, mammography, and pap smears.

*Response:* We agree that some clarification is needed. In § 438.206(d)(2) of the final rule with comment period, an MCO or, as appropriate, a PHP is required to provide female enrollees with direct access to a woman's health specialist within the network for covered care necessary to provide women routine and preventive health care services. This would include initial and follow-up visits for services unique to women such as prenatal care, mammograms, pap smears, and for services to treat genito-urinary conditions such as vaginal and urinary tract infections and sexually transmitted diseases.

*Comment:* Several commenters requested that we expand proposed § 438.306(d)(2) to clarify whether the requirement applies to both adult females and to minor adolescent females. Other commenters suggested that we add language that would allow direct access to a women's health specialist for pregnant enrollees of any age, but otherwise would set a limit for

access to a women's health specialist to age 15 or older.

*Response:* We used the term "female enrollees" to include minor females. Thus, we believe that if there is a medical need to see a women's health specialist, there should be no impediment based on the age of the enrolled female.

*Comment:* One commenter believed that proposed § 438.306(d)(2) would conflict with recent insurance legislation in the State which allows MCOs to require a women's health specialist to have a referral arrangement with, but not actual referrals from, an enrollee's primary care physician. Another commenter stated that it is unclear whether a female enrollee would be able to choose any women's health specialist within the network.

*Response:* We believe that, within MCO and PHP networks, female enrollees must have direct access to a women's health specialist for covered care necessary to provide women's routine and preventative health care services. We believe that this means that each woman should have access to any women's health specialist within the network, unless some network providers are not accepting new enrollees or there are other network restrictions based on the enrollee's choice of primary care provider. (For example, a woman may choose a primary care provider that is part of a subnetwork of providers within an MCO. As long as the woman was informed of the consequences of choosing a primary care provider that is a part of a subnetwork, at the time of her enrollment, she can be restricted to using only those specialists, including women's health specialists that are part of the subnetwork—although provisions for using out-of-network providers would still apply.) This provision was proposed consistent with statutory authority requiring States to develop standards for access to care "in a manner that ensures continuity of care and adequate primary care and specialized services capacity" (section 1932(c)(1)(A)(i) of the Act). Moreover, this provision is consistent with the beneficiary rights in the CBRR.

*Comment:* We received several comments recommending that proposed § 438.306(d)(2) be applied to all managed care entities, including PCCMs, HIOs, and PHPs. Commenters also suggested that we should apply this provision to individuals in managed care plans with 6-month eligibility.

*Response:* Section 438.206(d)(2) is based on authority in section 1932(c)(1)(A)(i) of the Act. As noted above, with respect to the quality assurance requirements implementing

section 1932(c)(1) of the Act generally, the Congress chose to apply this provision only to MCOs, while other provisions in the same section were made applicable to both MCOs and PCCMs (*i.e.*, to "MCEs"). The Congress thus expressed a clear intent that these requirements not apply to PCCMs. With respect to HIOs, if they are required to meet the definition of MCO and comply with section 1903(m) of the Act requirements, these requirements would apply to them. If, however, they have a specific statutory exemption from section 1903(m) of the Act, again, the Congress has spoken directly to the question of whether these requirements should apply, and determined that they should not. We therefore believe it would be inconsistent with clearly expressed Congressional intent to subject PCCMs or section 1903(m) of the Act-exempted HIOs to requirements based on the authority in section 1932(c)(1) of the Act. Also as noted above, however, in the case of PHPs, the Congress was silent as to what standards should apply, and based on our authority under section 1902(a)(4) of the Act, we have applied the requirements in subpart D (including the woman's health requirement in § 438.306(d)(2)) to PHPs, as appropriate. We do not believe that we need to explicitly reference individuals with six-month eligibility because the provision applies to all women regardless of their length of eligibility or enrollment.

*Comment:* One commenter suggested that § 438.306(d)(2) should not apply to behavioral health organizations, since women's health specialists do not exist in such settings.

*Response:* We agree with the commenter that this requirement may not apply to PHPs that deliver a limited set of services under a capitated arrangement. PHPs of this type typically include organizations contracted to provide mental health or substance abuse services and organizations that provide dental services. Section 438.8(a) of the final rule with comment period specifies that the quality assessment and performance improvement requirements apply to PHPs "to the extent that they are applicable to the services furnished by the PHP." In the example of a behavioral health organization, access to a women's health specialist for covered care necessary to provide women's routine and preventive health care services would not be applicable.

*Comment:* Several commenters believed that § 438.306(d)(2), pertaining to women's direct access to a women's health specialist, as proposed, would impede continuity of care. They recommended that this provision be

eliminated. Another commenter recommended that we delete the phrase "notwithstanding that the MCO maintains a primary care provider for each enrollee."

*Response:* As we have stated, we believe that female enrollees must have direct access to a women's health specialist within an MCO's and PHP's network as applicable and PHP's network as applicable. This provision was proposed in order to provide access in a manner that ensures adequate specialized services as required under section 1932(c)(1)(A)(i) of the Act and in order to implement the CORR. To make this purpose and the provision more clear, we have replaced the words "notwithstanding that the MCO maintains a primary care provider for each enrollee" with the sentence, "This [direct access to a women's health specialist] is in addition to the enrollee's designated source of primary care, if that source is not a women's health specialist." This change of wording also emphasizes that a female enrollee's right to directly access a women's health specialist cannot be satisfied, under Medicaid, by simply offering the opportunity to choose a women's health care specialist as a primary care case manager. We believe that in the case of the Medicaid population, direct access for these services is critical, and that the opportunity to choose a primary care case manager who provides these services is not sufficient, since a woman may not wish to see a woman's health specialist for general care.

*Comment:* We received one comment referencing § 438.306(d)(2) which suggested that OB/GYNs be able to serve as primary care physicians. The commenter expressed concern that women may not receive information about when they are entitled to self-refer to OB/GYNs. The commenter recommended that such information be required.

*Response:* Our intent in the proposed rule was not to require States and MCOs or PHPs to allow (or preclude States and MCOs or PHPs from allowing) OB/GYNs, or other specialists, to serve as primary care providers. The final rule with comment period, as amended, provides flexibility for States to determine the appropriate specifications to impose on MCOs and PHPs regarding the types of primary care providers, depending on the nature of the managed care program in the State and the enrollee population being served. Moreover, the information requirements at § 438.10, as amended, are written to ensure that enrollees receive adequate information on procedures for obtaining

all benefits, including information on the right of female enrollees to directly access a women's health specialist within the MCO or PHP network for covered care necessary to provide women's routine and preventive health care services.

*Comment:* We received a comment on the grievances and appeals provisions urging that enrollees faced with an adverse decision have the right to a second opinion, and that this right be mentioned in the adverse action notice. The commenter felt that enrollees should have the right to out-of-network, unbiased, second opinions, and this right should be specified in the regulations.

*Response:* We agree that enrollees should have access to an unbiased second opinion. We believe that this right extends beyond an adverse action notice to any instance in which the enrollee requests a second opinion. Therefore, we have added requirements in the regulation, both in Enrollee rights (§ 438.100) and in the Availability of services provisions (§ 438.206(d)(3)), with regard to second opinions. Contrary to the commenter's suggestion, we believe that an enrollee can receive an unbiased opinion from another qualified health professional in the network. Accordingly, we have specified that the MCO or PHP must provide for an enrollee to have access to a second opinion from a qualified provider *within the network* or arrange for the enrollee to obtain a second opinion outside of the network if an additional qualified health care professional is not currently available within the network.

*Comment:* We received many comments on proposed § 438.306(d)(5), which required the State to ensure that, when medically appropriate, the MCO or PHP makes services available 24 hours a day, 7 days a week. The proposed regulations stated that this provision applies, at a minimum, to emergency services and post-stabilization services, and to non-emergency services that are required immediately because of unforeseen illness. A majority of the comments requested further clarification of terms and standards. Specifically, several commenters requested that the term "unforeseen illness" be clarified or deleted. Many commenters argued that the term is too restrictive, invites legal controversy over its interpretation, and is contrary to managed care's emphasis on prevention, early detection, and treatment. Other commenters urged that we adopt and apply specific standards for urgent care of 24 to 48 hours depending on the day of the week an

unforeseen illness occurs. One commenter specifically recommended that we add an additional standard of 24 hour, 7 day "crisis services" for beneficiaries with mental illness. Another commenter felt that MCOs should have a mechanism to conduct triage and assessment, but should not have to make available non-emergency, non-urgent care 24 hours a day, 7 days a week. Finally, one commenter stated that the availability of services under this provision should be based on medical necessity and not medical "appropriateness."

*Response:* Our intent in proposing § 438.306(d)(5) was to ensure that individuals who require home health services or other types of non-hospital based services receive care, when medically necessary, during non-business hours. After further review and consideration of comments received, we have revised the policy so that the final rule with comment period requires MCOs and PHPs to ensure that services are available 24 hours a day, 7 days a week, when medically necessary (§ 438.206(e)(1)(iii)). We believe this change ensures access to care without using potentially ambiguous terms such as "unforeseen illness" and "medically appropriate." We further believe that this requirement is consistent with our overall intent as reflected in other provisions in the final rule with comment period, including § 438.114, Emergency and post-stabilization services, and § 438.210, Coverage and authorization of services.

*Comment:* Several commenters felt that proposed § 438.306(d)(5) was too prescriptive and costly. One commenter believed that the provision was likely to increase the number of providers who refuse to see Medicaid patients, and suggested that normal physician practice standards should be acceptable for all populations. Other commenters recommended that the provision be deleted.

*Response:* As we have indicated above, we believe this provision is important to ensure that enrollees have access to medically necessary care during traditional, non-business hours.

*Comment:* We received numerous comments on proposed § 438.306(d)(6), which required MCOs and PHPs to ensure that its providers' hours of operation are convenient to enrollees, and do not discriminate against Medicaid enrollees. One commenter supported the provision, but suggested that we reference populations with special health care needs. Other commenters believed that the term "convenient" in the proposed regulation was too ambiguous and subjective, and

that this term required further clarification. One commenter specifically argued that we were imposing a new requirement in Medicaid managed care that we have not imposed in Medicaid fee-for-service. Finally, other commenters suggested that this particular provision, if included in the final rule with comment period, would have widespread implications for the program. They argued that we have exceeded our statutory authority in proposing this provision.

*Response:* Upon further consideration, and based on comments received, we agree that the term "convenient" needs clarification. As a result, we have moved this requirement to § 438.206(e), because we believe that it more appropriately falls under the "provision of services" paragraph. Under paragraph (e)(1)(ii), the MCO or PHP must ensure that its providers' hours of operation are convenient for the enrollees, as determined by a State-established methodology, and that they are at least comparable to Medicaid fee-for-service.

We believe that the State should establish standards for what is convenient for enrollees in terms of provider hours of operation. Those standards should be at least comparable to Medicaid fee-for-service. Thus, an enrollee who was able to schedule weekend or evening appointments under the Medicaid fee-for-service program should have access to appointments during those hours under Medicaid managed care.

We continue to believe that the State and MCO or PHP must ensure that providers do not discriminate against Medicaid enrollees. Thus, we retain this requirement in § 438.206(d)(7).

*Comment:* One commenter suggested that we apply proposed § 438.306(d)(6) to MCEs, and not just MCOs.

*Response:* We proposed § 438.306(d)(6) under the authority of section 1932(c)(1)(A)(i) of the Act. As discussed above in connection with proposed § 438.306(d)(2), the Congress expressed a clear intent that requirements under section 1932(c)(1) of the Act apply to MCOs, but not PCCMs. When the Congress wanted to apply requirements to PCCMs as well as MCOs, it did so by referencing "MCEs," which includes MCOs and PCCMs. We thus believe it would be inconsistent with clearly stated Congressional intent to apply requirements under section 1932(c)(1) of the Act to PCCMs.

*Comment:* We received numerous comments on proposed § 438.306(e)(1)(i), which required MCOs and their providers to meet State-

established standards for access to care and member services, taking into account the urgency of the need for services. Several commenters recommended that we incorporate into the final regulation the suggested standards outlined in the preamble to the proposed rule. The commenters' rationale for incorporating the suggested standards in the final rule with comment period is that the standards reflect existing managed care contracts and there appears to be no reason for State flexibility regarding maximum wait times for care. The same commenters argued that the BBA gives us the authority to establish minimum standards for quality assessment and improvement strategies. Several other commenters noted the importance of establishing standards for in-office waiting times, especially for mental health services.

Commenters offered a number of recommendations that included standards in addition to, or as alternatives to, those presented in the preamble to the proposed rule. Moreover, the recommendations referenced both in-office waiting times and appointment scheduling times. Specifically, the additional standards included referral appointments to specialists within 30 days for routine care, 72 hours for urgent care, and 24 hours for emergency appointments. Other additional standards included routine, prenatal visits within 2 weeks for the first trimester, 1 week for the second trimester, and 3 days for the third trimester. Recommended alternative standards included in-office waiting times of no longer than 45 minutes or 1 hour, and appointment times for routine appointments ranging from 2 weeks to 30 days.

*Response:* Section 1932(c)(1)(A)(i) of the Act provides that "the State shall develop \* \* \* a quality assessment and improvement strategy," that shall include "[s]tandards for access to care." Under the authority of section 1932(c)(1)(A)(i) of the Act, we have proposed regulations to ensure that States take into consideration certain requirements when developing their standards for access to care. One of these requirements (contained in § 438.306(e)(1)(i) of the proposed rule) is that MCOs and PHPs and their providers meet State-established standards for access to care.

We disagree with commenters who suggest that national standards should be established in the final regulation. First, as just noted, the statute calls for "the State" to "develop" such standards, not us. This suggests that the Congress contemplated that standards

be State-specific. Secondly, patterns of care delivery typically vary across the country. Because of this, a single national standard may not be appropriate in all localities. Therefore, we only included suggested standards in the preamble to the proposed rule as examples for States to consider. The various additional and alternative suggestions offered by commenters may also be appropriate for States to consider. However, we will not mandate any of them in this final rule with comment period.

*Comment:* Several commenters suggested that proposed § 438.306(e)(1)(i) was too burdensome, and not consistent with the common practice of wait times for appointments of six to eight weeks. Further, commenters suggested that if more stringent standards are imposed for Medicaid managed care enrollees than commercial enrollees, providers may avoid serving Medicaid members.

*Response:* We do not agree with commenters who suggest that we are imposing more stringent standards for Medicaid enrollees than commercial enrollees. In this final rule with comment period, we require MCOs and PHPs to meet State-established standards. Further, we require that provider hours of operation be at least comparable to fee-for-service. We included examples in the preamble of the proposed rule for State consideration only. These examples were not mandatory requirements. In fact, we specifically indicated that States should evaluate a number of factors, including common waiting times for comparable services in the community. We believe that this statement reflects our intent that, in designing standards for timely access to care, States consider existing practice patterns.

*Comment:* We received one comment that we should revise proposed § 438.306(e)(1)(i) to add the word "subcontractors" after providers, to ensure that subcontractors are required to meet State-established standards for timely access to care and member services.

*Response:* We do not believe that such a change is necessary for the final rule with comment period. Section 438.230 of the final rule with comment period establishes requirements for subcontractual relationships and delegation. It ensures that each MCO and PHP oversees and is held accountable for any functions and responsibilities that it delegates to a subcontractor. In addition, § 438.6(l) requires that all subcontracts meet the contracting requirements that are

appropriate to the service or activity delegated under that subcontract. We believe that these provisions are adequate to ensure that subcontractors are held to the same access standards imposed on MCOs and PHPs by the State.

*Comment:* Several commenters took issue with the examples contained in the preamble for proposed § 438.306(e)(1)(i), which requires States to establish mechanisms to ensure MCO compliance with standards for timely access to care. Several commenters expressed concern that documenting in-office waiting times would be administratively burdensome, would lead to increased costs, and may reduce the willingness of HMOs to participate in Medicaid. One commenter believed that satisfaction surveys would be sufficient to indicate if a problem exists, which can then be explored with audits of individual providers. Another commenter suggested that our preamble discussion on compliance include methods for gaining consumer feedback in addition to mail and telephone surveys.

*Response:* In the preamble to the proposed rule, we offered a number of mechanisms that States, MCOs and PHPs could use to monitor compliance with timeliness standards, including the use of surveys, analysis of complaints and grievances, provider self-reports, random audits, and test calls. While we cautioned States on the use of general surveys of its enrolled population, we did not discount the use of surveys all together. For example, the Agency for Healthcare Research and Quality's (AHRQ's) Consumer Assessment of Health Plans Study (CAHPS) survey tools are reliable and valid survey instruments that can be used to assess many aspects of health care, including access to quality and timeliness of care. We believe that States should consider all appropriate mechanisms for measuring MCO and PHP performance against State standards, and rely on those mechanisms which are most effective.

*5. Proposed § 438.306(e)(2) (Initial Assessment) and (e)(3) (Pregnancy and Complex and Serious Medical Conditions)*

Paragraph (e)(2) of proposed § 438.306 required States to ensure that MCOs and PHPs provide initial assessments of each enrollee within 90 days, and within a shorter period of time for pregnant women and enrollees with complex and serious medical conditions. Paragraph (e)(3) of proposed § 438.306 set forth specific requirements for dealing with the two groups and for

their treatment plans. We received a great many comments on these proposed provisions which, in the final rule with comment period, are redesignated under § 438.208, and incorporate several additional groups and time frames.

*Comment:* Many commenters requested clarification on what constitutes an initial assessment as proposed. Several commenters questioned whether a telephone call or questionnaire might suffice. Other commenters suggested that initial assessment should be face-to-face, and should cover both health and social issues. Several commenters suggested that, particularly for enrollees with complex or serious medical conditions, and populations such as the homeless, pregnant women, newborns, and children, assessments should be conducted face-to-face. One commenter specifically recommended that we define initial assessments to include the following services: a comprehensive health and developmental history, a comprehensive unclothed physical exam, laboratory tests including blood level assessments appropriate for age and risk factors, and health education.

*Response:* We agree that the term "initial assessment" is misleading. While our original intent was that this term be analogous to the term "screening," we are persuaded by comments that certain individuals require a more thorough and timely assessment by an MCO or PHP provider after enrollment. Accordingly, in § 438.208(d) and (e) we are now requiring that the MCO or PHP make a best effort to identify, screen, and comprehensively assess pregnant women, children under the age of 2 years old, and enrollees with special health care needs.

In order to assist MCOs and PHPs in conducting the types of assessments suggested by the commenters, in section 438.208(b) we are requiring States to identify to MCOs and PHPs populations "at risk" of having special health care needs, children under age 2, and other enrollees known by the State to be pregnant or to have special health care needs. The "at risk" populations include: (1) Children and adults receiving SSI benefits; (2) children in title IV-E foster care; (3) enrollees over age 65; (4) enrollees in relevant, State-established, risk-adjusted, higher-cost payment categories; and (5) any other groups of enrollees identified by us (§ 438.208(b)(1)).

Also in order to address the commenters' concerns about ensuring appropriate assessments, in § 438.208(e) of the final rule with comment period,

we require the MCO or PHP to implement mechanisms to ensure the ongoing screening of its enrolled population to identify and comprehensively assess persons who become pregnant or who develop special health needs following enrollment in the MCO or PHP.

We believe that a State and MCO or PHP should have the flexibility to choose the form and substance of the initial screen or screens. Initial screens may take the form of a phone call, mailed questionnaire, home visit or physical examination; however, it must be sufficient to identify individuals with special health care needs. Further, the initial screen should also attempt to collect information on any languages or TTY requirements, and needs for accessible medical facilities and/or transportation services. The comprehensive health assessment, on the other hand, should include a physical examination by an MCO or PHP provider. In fulfilling the screening and assessment requirements, the MCO or PHP must ensure that its providers have the information required for effective and continuous patient care and quality improvement.

*Comment:* We received many comments with respect to time frames. Commenters varied in their opinions. Several commenters believed that 90 days was too long to wait for an initial assessment (now referred to as "screening" in the final rule with comment period), particularly for enrollees with serious and complex medical conditions. Many other commenters expressed concern over whether an MCO or PHP could perform an initial assessment (screening) on each enrollee within 90 days. These commenters noted the difficulty in contacting an enrollee and ensuring the cooperation of an enrollee in seeing a physician in order to have an assessment (screening) completed. They felt that initial assessments (screening) within 90 days was unrealistic and longer time frames were needed. One commenter suggested that the issue of timing can better be addressed in the contract between the State and the MCO or PHP. The commenter believed that the 90 day requirement should not be a Federal mandate.

Many recommendations were offered. One commenter suggested that a health assessment (screen) need only take place once a year, with an initial assessment (screening) occurring within 180 days if (1) the member has not used the emergency room within the last 90 days, (2) the member is in good health, and (3) the member has reported to the MCO or PHP that it has had a health

assessment. Other commenters recommended a shorter time frame of 30 days, and recommended special time standards for specific populations, such as requiring an initial assessment (screening) within 15 to 30 days from enrollment for newborns and young children and within 72 hours for enrollees with HIV. Other commenters suggested more general standards of no more than 60 days to complete initial assessments (screening), to 180 days for adults and 90 days for children. One commenter recommended that MCOs or PHPs only be required to make a good faith effort to contact each new member at least two times to schedule an appointment with his or her primary care provider. Other commenters recommended that we revise the final rule with comment period to require MCOs and PHPs to meet a variation of the following language: (1) Make a good faith effort to conduct an assessment (screening), (2) make available within 90 days of enrollment an initial assessment (screening), (3) inform enrollees of the need for an initial assessment (screening), or (4) make a substantial attempt to provide initial assessments (screenings). One commenter suggested that an assessment for a child under the age of 21 should meet the requirements of the EPSDT guidelines set forth in §§ 441.50 through 441.62.

*Response:* We agree with many of the comments received. Specifically, we agree with the comment that an MCO or PHP should only be required to make an "effort" to perform a screening or assessment. We agree that, through no fault of its own, an MCO or PHP may not be able to achieve full compliance with the proposed initial assessment (screening) requirement. We therefore have revised the requirement to provide, in § 438.208(d) of the final rule with comment period that MCOs and PHPs must make a "best effort" to perform the screening and assessment required in this section. A "best effort" means that the MCO or PHP should follow-up on unsuccessful attempts to contact an enrollee. With this change, we wish to make clear that the MCO or PHP is not relieved of the obligation to screen all enrollees. Rather, we only wish to acknowledge that an MCO or PHP may not be able to achieve 100 percent compliance with the screening and assessment requirements. We also recognize that some enrollees may be unable to cooperate with the MCO's or PHP's efforts to screen and assess them. In these cases, MCOs and PHPs should document the attempt to screen and (as applicable) assess individual enrollees.

We also agree with the commenters who believed that a 90 day time frame

was too long, and specifically with the suggestion of a 30 day time frame in connection with enrollees with special needs. Because of this, we have revised the rule to include different time frames for screening the especially vulnerable groups of pregnant women and persons who either have been identified as having special health care needs, or have been identified by the State under § 438.208(b) as being in categories at risk for having special health care needs. Although we have not identified children under 2 years of age as enrollees "at risk," we recognize the importance of timely screening and assessment of young children and have added them to the groups requiring quicker screening. Specifically, under § 438.208(d), we require MCOs (and PHPs as determined by the State in accord with § 438.208(a)(2)) to make a "best effort" to screen and comprehensively assess pregnant women, children under 2 years of age, and persons determined to have special health care needs in accordance with the following timeframes:

(1) For enrollees identified by the State as at risk of having special care needs, screening within 30 days of receiving the State's identification, and for those the screening identifies as being pregnant or having special health care needs, comprehensive health assessment as expeditiously as the enrollee's health requires but no later than 30 days from the date of identification through screening.

(2) For enrollees identified by the State as being children under age 2, and for other enrollees who are identified by the State or who identify themselves as being pregnant or having special health care needs, comprehensive health assessment as expeditiously as the enrollee's health requires, but no later than 30 days after the date of identification.

(3) For all other enrollees, screening within 90 days of enrollment and for those the screening identifies as being pregnant or having special health care needs, comprehensive health assessment as expeditiously as the enrollee's health requires, but no later than 30 days after the date of identification.

We believe that these standards are reasonable to ensure that persons requiring special medical attention from MCOs and PHPs receive services as expeditiously as possible. Because we agree with the commenters recommending these shorter time frames that such time frames are necessary to help ensure the health of vulnerable beneficiaries, we are not accepting the comments that suggested

longer time frames, or abandoning this requirement altogether.

*Comment:* Several commenters suggested that an initial assessment (now referred to as "screening" in the final rule with comment period) not be required for enrollees who are continuing patients of the MCO or provider, or when a prior assessment (screening) is available to the MCO.

*Response:* We recognize that in some situations it would be duplicative and unnecessary to require screening of an enrollee. For instance, we would not expect an MCO to screen enrollees for whom current health care information is available, such as enrollees already under the care of providers with the MCO's network, or who maintain the same primary care provider when enrolling in a different MCO. In such a case, the screening required under this rule could be considered to have been performed. To ensure compliance with the revised requirements for enrollee screening, MCOs and PHPs should document in the enrollee's health record why screening is not necessary.

*Comment:* We received a few comments that the proposed initial assessment (screening) requirements should not apply to PHPs, such as managed behavioral health organizations. The commenters recommended that this provision apply only to managed care organizations that provide primary and preventive care services.

*Response:* As previously indicated, § 438.8 makes the subpart D rules applicable to PHPs to the extent that they are applicable to the services furnished by the PHP. Some PHPs provide services to the most vulnerable Medicaid enrollees, many of whom are diagnosed with chronic conditions or who are determined to have long-term care needs. Thus, timely screening and assessment of these individuals by PHPs, in relationship to the scope of services provided by the PHP, is necessary to ensure that those requiring special attention receive necessary medical care.

We acknowledge, however, that a State might design a managed care initiative that involves PHPs for which an initial screening by the PHP might be duplicative. For example, a State may utilize a separate "carve-out" program for mental health services in which an enrollee may require referral by the MCO contracted to provide physical health services. In such a case, a State might design its managed care initiative to have the MCO screen for both physical and mental health. The MCO could screen the enrolled population to identify enrollees who likely require

mental health services, and could share the results of the screen with the PHP. The PHP, in turn, would conduct a comprehensive health assessment through appropriate health care professionals. States must determine the most effective and efficient strategy for assuring that all Medicaid MCO and PHP enrollees are screened.

While the State is responsible for ensuring that a screening is carried out on all Medicaid managed care enrollees by some combination of the enrollee's MCO and PHP, in response to this comment, we are under § 438.208(a)(2) of this final rule with comment period providing the State with the flexibility to decide how this responsibility will be carried out, and whether PHPs will be required to perform screenings and assessments in cases in which an enrollee is enrolled in both an MCO and a PHP or more than one PHP.

Our decision in response to the comment to permit State flexibility with respect to PHP screening raises issues of coordination between MCOs and PHPs and responsibilities for screening, assessment and treatment planning for Medicaid enrollees who also receive Medicare and are enrolled in a Medicare+Choice plan. The commenter presumably was concerned about possible duplication of efforts in urging that only the single entity furnishing primary care perform screenings. We believe that this concern about duplication can be addressed, while still providing for PHP screening where appropriate, by requiring in a new § 438.208(h)(3), that each MCO or PHP share the results of its screening or assessment of an enrollee (or both, if the MCO or PHP performs both) with other entities serving the enrollee, so that those entities need not duplicate the MCO's or PHP's screening or assessment (or both). To address the issue of Medicaid enrollees also receiving Medicare and enrolled in a Medicare+Choice plan, we have added a new provision at § 438.208(a)(3) requiring the State to determine the extent to which each MCO is to perform initial screening, assessment and treatment planning for such enrollees, consistent with the services the State requires the MCO to provide.

*Comment:* We received a number of comments on proposed § 438.306(e)(3)(iii) which required the MCO to develop treatment plans that are appropriate for the conditions identified, specify an adequate number of direct access visits to specialists, and are updated periodically by the physician responsible for the overall coordination of the enrollee's health care. Some commenters suggested that

MCOs and physicians need to be given the flexibility to evaluate each enrollee's circumstance. Other commenters urged that the regulations require that enrollees participate in treatment planning. Several commenters believed that enrollees with complex and serious medical conditions should be permitted direct access to specialists, even if they are out-of-network providers. Other commenters suggested that this provision be deleted because it can be interpreted to permit unlimited access to specialists. One commenter expressed the view that direct access to specialists is a benefit that has just begun to evolve in commercial plans, and accordingly should not be applied until MCOs and PHPs can further manage a direct access system.

*Response:* We disagree with commenters who suggest that this provision permits unlimited access to specialists. It was never our intent to guarantee unlimited access. Proposed § 438.306(e)(3)(iii) was drafted to ensure that enrollees with complex and serious medical conditions (now referred to as enrollees with special health care needs) be permitted a sufficient number of direct access visits to specialists as required by the treatment plan. Our overall intent in the final rule with comment period remains the same. We continue to believe that enrollees with special health care needs who are undergoing an approved course of treatment should be able to access specialists within the MCO's or PHP's network without having to obtain numerous authorizations from their primary care providers, and that this is necessary in order to meet the "access to care" standard in section 1932(c)(1)(A)(i) that services be available "in a manner that ensures \* \* \* adequate \* \* \* specialized services capacity." In recognition of varying MCO and PHP practices, the final rule with comment period, requires the treatment plan to specify either an adequate number of direct access visits to specialists or a standing referral to specialists. However, we continue to require that the treatment plan be time-specific, and updated periodically to determine whether continued access to a specialist for a course of treatment is necessary. To avoid confusion, in this final rule with comment period, we also have added a specific requirement that we believe was implicit in the proposed rule. Section 438.206(f)(6) now expressly requires that the treatment plan ensure periodic reassessment for each enrollee as his or her health requires. In addition, in response to the comments

on the need for enrollee participation and that treatment planning consider the needs and preferences of the enrollee, at § 438.206(f)(5) we added a requirement that treatment plans be developed with enrollee participation.

*Comment:* We received a number of comments urging that we revise proposed § 438.306(e)(3) to further address and consider populations with special health care needs. Many commenters wanted us to further clarify and define the term “complex and serious medical conditions.” Specifically, one commenter recommended that we revise the wording of proposed § 438.306(e)(3)(ii) to state: “Timely identifies individuals with complex and serious medical conditions or mental disabilities, assesses those conditions, and identifies appropriate health care services for monitoring, treatment, or rehabilitation.” Another commenter recommended that the regulation include a list of conditions that mandate the actions spelled out in proposed § 438.306(e)(3)(ii) and (iii). Although the commenter recognized that it would be impractical to include an exhaustive list, he argued that there are some chronic conditions that should be listed, particularly where continuing attention and monitoring are vital. Some of the populations that commenters recommended include persons with mental disabilities, cancer patients, persons with end stage renal disease, persons awaiting organ transplants, persons with HIV/AIDS, children with special health care needs, and persons with cerebral palsy or other conditions related to the presence of a developmental disability. In contrast to identifying an exhaustive list of conditions, one commenter suggested that we develop a definition for complex and serious medical conditions based on patient requirements for higher levels of resources. This commenter argued that such a definition would require MCOs that enroll persons whose needs exceed normal actuarial physical and mental utilization estimates for a working age population to demonstrate higher capacity both in their networks and with respect to their access standards.

*Response:* We agree that clarification is needed and, as previously discussed, have revised this provision to require that MCOs and—where applicable—PHPs, screen and comprehensively assess “enrollees with special health care needs,” which, as noted above, is how we now refer to individuals with complex and serious medical conditions. As we discussed previously, “persons with special health care

needs” is the terminology used by the Congress at section 4705(c)(2) of the BBA. We have conceptualized this term to include:

- (1) children with special health care needs;
- (2) children in foster care;
- (3) individuals with serious and persistent mental illness/substance abuse;
- (4) individuals who are homeless;
- (5) older adults (individuals 65 years of age and older) with disabilities; and
- (6) adults under 65 who are disabled or who have a chronic condition, whether physical or mental.

We note that this listing of individuals with special health care needs is not an operational definition of persons with special health care needs and that health services research is still in the process of developing conceptual models, screening tools and approaches to identifying individuals with special health care needs.

*Comment:* We received a number of comments suggesting that under proposed § 438.306(e)(2) and (3), we should require continuing coverage of on-going treatment, even if it is out-of-network, until the time of an initial assessment when a primary care physician, in consultation with a specialist, establishes a new care plan. Commenters believed that unless an MCO is given prior information, it will not know if an enrollee is pregnant or has a complex medical condition to provide an assessment prior to 90 days. Other commenters noted that the disruption of services can be particularly harmful for enrollees with complex and serious medical conditions. To facilitate the initial assessment, one commenter recommended that we require the State Medicaid agency to provide the MCO with information on age, eligibility category, and whether a child is in foster care or is in an out-of-home placement.

*Response:* We believe that most States already have mechanisms in place to transition enrollees with ongoing health care needs to managed care. However, we acknowledge the commenters’ concerns that our proposed regulation did not address the potential disruption of services, even for a short period of time, between enrollment and the time of assessment by the new primary care physician/specialist in the receiving MCO or PHP. To address this concern, as discussed in section II. B. above, we have added a new paragraph (b) to proposed § 438.62 to require a State to have a mechanism to ensure continued access to services when an enrollee with ongoing health care needs is

transitioned from fee-for-service to an MCO, PHP or PCCM; from one MCO, PHP or PCCM to another; or from an MCO, PHP or PCCM to fee-for-service. We believe this provision, plus the requirements in § 438.208 for (1) State identification of enrollees with special needs or at risk for special needs, and (2) MCO and PHP screening and assessments, respond to commenters’ concerns that MCOs have the means to identify, in an expedient fashion, enrollees who require immediate attention, and provide needed services to such enrollees.

*Comment:* One commenter objected to the fact that proposed § 438.306(e)(3) required an MCO to implement and update a treatment plan. Specifically, the commenter suggested that requiring an MCO to implement a treatment plan for specific enrollees is not appropriate for such an administrative entity, as such plans should be developed and implemented only by a patient’s physician or other health care professional.

*Response:* We agree with the commenter. Section 438.208(g) of the final rule with comment period, requires MCOs and PHPs to use appropriate health care professionals to perform comprehensive health assessments and to develop and implement treatment plans.

*Comment:* A commenter suggested that proposed § 438.306(e)(3) be revised to require the MCO to timely provide effective EPSDT screens and mandated EPSDT services.

*Response:* EPSDT screenings are required in current regulations. We believe it would be duplicative to restate those requirements in this final rule with comment period.

*Comment:* One commenter believed that proposed § 438.306(e)(3)(iii)(C) is unclear, and recommends that the final rule with comment period be changed to read “a treatment plan that specifies an adequate number of direct access visits to specialists as appropriate to the enrollee’s condition.” Further, the commenter suggests that we add the phrase “or, when required by the condition, the names of specialists to whom the enrollee shall have direct access for the duration of the treatment plan.”

*Response:* We agree that the proposed language was unclear. We have revised the cited provision, which is now redesignated as § 438.208(f), to require MCOs and PHPs to implement a treatment plan that: (1) is appropriate to the enrollee’s conditions and needs identified by screening and assessment, and (2) specifies either a standing referral or an adequate number of direct

access visits to specialists. We expect that the treatment plan will specify the specialist(s) to whom the enrollee has direct access, but do not believe it necessary to require in regulations text that the treatment plan must specify the actual names of specialist to whom the enrollee shall have direct access for the duration of the treatment plan.

*Comment:* Several commenters expressed concern with proposed § 438.306(e)(3)(iii)(D). Commenters suggested that requiring physicians themselves to update a treatment plan is unrealistic and administratively burdensome. One commenter recommended that the final rule with comment period, be revised to permit the updating of a treatment plan by a specialist instead of a primary care provider.

*Response:* We agree on the need to allow for situations in which a specialist or other health care professional within an MCO or PHP assumes the responsibility for updating an enrollee's treatment plan. While we believe that a treatment plan should be developed in coordination with an enrollee's primary care provider, we recognize that MCOs or PHPs may permit professionals other than the enrollee's primary care provider to update the enrollee's treatment plan. Accordingly, in the final rule with comment period, § 438.208(g) requires MCOs and PHPs to use "appropriate health care professionals" to develop, implement, and update any required treatment plan.

*Comment:* We received a number of comments on proposed § 438.306(e)(4), which required that MCOs and PHPs ensure services are provided in a culturally competent manner, including at least meeting the language requirements of § 438.10. Overall, the majority of commenters supported this provision, but many suggested that we clarify the provision in the final rule with comment period. Several commenters requested that we define cultural competency and strengthen the regulation to require that MCOs include in their networks providers that have an understanding of enrollees' customs and traditions.

Commenters offered many recommendations. One commenter suggested specific language: "the MCO ensures that services are provided in a culturally competent manner to all enrollees, by providers with appropriate knowledge and skills to treat enrollees who are members of linguistic or ethnic minorities, and adults and children with special health care needs, including recipients with mental illness, substance abuse problems, developmental disabilities, functional

disabilities, or complex problems involving multiple medical and social needs (for example, HIV/AIDS and homelessness)." Several other commenters recommended that we add requirements such as: (1) full attention by the MCO to racial and ethnic minorities, (2) interpreter services, including braille and sign language, (3) an appropriate number of caregivers properly trained in cultural competency, and (4) provider awareness of medical risk related to racial, ethnic, and socioeconomic factors. Finally, other commenters recommended that we: (1) mandate California's standards for cultural competency, (2) limit providers who are culturally aware to 5 percent or 200 in number to combat recruitment or other training burdens, (3) revise the rule to require that MCOs identify enrollees who belong to ethnic minority groups that may have special barriers in accessing care, and make continued efforts to improve accessibility, or (4) mandate that the National Committee for Quality Assurance (NCQA) require MCOs to collect ethnicity data to ensure quality so that appropriate educational, screening, and treatment programs can be developed.

*Response:* We do not believe it is appropriate to add all of the specificity suggested by the commenters, however we do agree that further strengthening and clarification is needed. As a result, we have added a provision at § 438.204 that requires States, as an element of their State quality strategies, to identify and provide MCOs and PHPs with information, on, the race, ethnicity, and primary language spoken by each Medicaid beneficiary at the time of their enrollment in an MCO or PHP. We will provide technical assistance to States on implementing these requirements. Our final rule with comment period also has been revised at § 438.206(e)(2) to require MCOs and PHPs to ensure that services are provided in a culturally competent manner to all enrollees, including those with limited English proficiency, and diverse cultural and ethnic backgrounds.

While we decline to add a definition of cultural competency in regulation text because the state of the art with respect to standards for cultural competency is still evolving. States should undertake efforts to further define cultural competency in their contracts and in standards for access to care under their quality assessment and performance improvement strategies. We offer the following statement as one that States may consider using in any definition of cultural competency: "Cultural competency in health care is

a set of attitudes, skills, behaviors, and policies that enable organizations and individuals to work effectively in cross-cultural situations. It reflects an understanding of the importance of acquiring and using knowledge of the unique health-related beliefs, attitudes, practices, and communication patterns of beneficiaries and their families to improve services, enhance beneficiary understanding of programs, increase community participation, and eliminate disparities in health status among diverse population groups."

*Comment:* Several commenters believed that we needed to further clarify proposed § 438.306(e)(4) to ensure appropriate linguistic access. One commenter recommended that the comment period be strengthened to require, at a minimum, that MCOs and PHPs have a means of communicating during medical and administrative encounters.

*Response:* We agree that some clarification in the final rule with comment period is needed. As noted above, we have provided in § 438.206(e)(2) that MCOs and PHPs must provide services in a culturally competent manner to all enrollees, including those with limited English proficiency, and diverse cultural and ethnic backgrounds. Further, as noted above in section II.A., we require in § 438.10(b) that States and MCOs, PCCMs and PHPs make interpreter services available to meet the needs of all enrollees. We believe that § 438.10(b) is sufficient to ensure that enrollees have means of communication during medical and administrative encounters.

##### 5. Continuity and Coordination of Care (Proposed § 438.308)

Proposed § 438.308 set forth a series of requirements to ensure that a State require MCOs and PHPs to maintain continuity and coordination of care for its enrollees. Proposed § 438.308(a) required that MCOs and PHPs have in place written policies that provide each enrollee with an ongoing source of primary care appropriate to the enrollee's needs, as well as, formally designating a practitioner who is responsible for coordinating the enrollee's overall health care.

In proposed § 438.308(b), MCOs and PHPs were required to ensure coordination of services, both internally and with services available from the community.

Proposed § 438.308(c) required MCOs and PHPs and their providers to have the information necessary for effective and continuous patient care and quality improvement, including procedures to ensure that each provider maintains

health records that meet requirements established by the MCO or PHP, taking into account professional standards, and there is appropriate and confidential exchange of information among providers.

Proposed § 438.308(d) required procedures to ensure that providers inform enrollees of specific health conditions that require follow-up, and if appropriate, provide training in self care, and deal with factors that hinder enrollee compliance with prescribed treatment or regimens.

*Comment:* We received a number of comments urging that proposed § 438.308 address the continuation of an enrollee's ongoing treatment when transitioning to managed care. (Similar comments, discussed above, were also received on proposed § 438.306(e)). Although many commenters commended us for addressing the issue of continuity and coordination of care once a beneficiary has been enrolled in managed care, many also expressed concern that the proposed regulation did not highlight the need for identification and continuation of an enrollee's treatment when transitioning from fee-for-service into managed care or from one managed care organization to another. Several commenters stated that the interruption of treatment for only a short period of time could have serious and possibly irreversible consequences on a individual's health. Other commenters suggested that ongoing treatment without interruption was especially critical for persons suffering from mental illness, substance abuse, and chronic conditions such as HIV/AIDS.

A number of recommendations were offered. Some commenters recommended that we require continued coverage of ongoing treatment until a new care plan is established as a result of an initial assessment in the receiving MCO. Other commenters suggested that we define continuing treatment to include equipment, medical supplies, and prosthetic and orthotic appliances. Several commenters also recommended specific regulatory language that would permit an enrollee to continue to be covered for a course of treatment for a specified transition period. These commenters suggested that State agencies or the MCO or both be required to notify enrollees of the right to have treatment continued. In addition, the forwarding MCO should be required to share all medical files on a transferring enrollee with the receiving MCO.

*Response:* As noted above in this section, and as discussed more fully in section II. B., in response to the large

number of comments on this issue, we have added to § 438.62 a new paragraph (b) that requires States to have a mechanism to ensure continued access to services when an enrollee with ongoing health care needs is transitioned from fee-for-service into a MCO, PHP or PCCM; from one MCO, PHP or PCCM to another MCO, PHP, or PCCM; or from an MCO, PHP, or PCCM to fee-for-service. We further have specified minimum requirements that the State transition mechanisms must address, and have identified specific population categories that State transition mechanism must cover.

*Comment:* Several commenters believed that proposed § 438.308 did not adequately address the issue of prior existing relationships. Commenters voiced concerns about the impact on enrollees when existing relationships have to be discontinued as a result of mandatory managed care programs, or as a result of providers leaving the network. These commenters specifically referenced populations with special health care needs and pregnant women as particular populations who would suffer an adverse impact. Some commenters recommended that pregnant women have the option to continue care with their OB/GYN until completion of post-partum care and others recommended that women who have already initiated prenatal care be exempted from the mandatory enrollment requirement. Other commenters focused their recommendations on other populations with special health care needs, with some recommending that we require MCOs to contract with providers currently serving Medicaid beneficiaries, and others requesting that we exempt populations with special health care needs from managed care entirely, particularly children with special health care needs.

*Response:* In section 1932(a)(2) of the Act, the Congress specifically exempted certain categories of children with special needs and Medicare eligible beneficiaries from mandatory enrollment under section 1932(a)(1) of the Act. Given the level of specificity in the statute, we believe that it would be inconsistent with Congressional intent to exempt additional categories of beneficiaries. With respect to the suggestion that MCOs be required to cover out-of-network services, once again the Congress has specified in detail those circumstances (e.g., post-stabilization services), for which an MCO is required to pay for out-of-network services or those circumstances (e.g., family planning services) for which an MCO cannot limit an enrollee

to its network of providers. We do not believe that we would have authority to require MCOs to cover non-emergency services furnished by a provider with whom the MCO has no relationship. However, we understand the commenters' concerns that an existing relationship may be disrupted as a result of a beneficiary enrolling in managed care, and as discussed in the previous comment response, we believe we have addressed this problem in § 438.62(b). We wish to make clear that the requirements in § 438.62(b) are not intended to preempt State laws that require continuation of care outside the network.

*Comment:* We received numerous comments on proposed §§ 438.308(a)(1) and (a)(2). Several commenters argued that certain individuals with disabilities and other chronic conditions may require a specialist or other qualified and experienced practitioner as their primary care provider. Some commenters recommended that the final regulation explicitly provide for the designation of a specialist as the primary care provider in certain instances, such as for persons with complex and serious medical conditions. One commenter suggested that an MCO be required to refer chronic renal disease patients to a nephrologist for primary care services before a patient develops end stage renal disease. Another commenter suggested that we add language to allow residents, under supervision, to serve in the role of "continuing physician." Finally, one commenter recommended that primary care systems not be allowed as care managers for complex behavioral needs.

*Response:* We agree that there may be instances where a specialist would be an appropriate choice for a primary care provider, particularly for individuals with special health care needs. However, we decline to impose that degree of specificity in regulation because: (1) the existing evidence base regarding better health outcomes for individuals whose primary care provider is a specialist is limited; and (2) it is not possible at present to specify in this regulation all the decision rules to direct when a given individual must have a specialist as a primary care provider. We believe that States, MCOs, and PHPs have sufficient flexibility under the final rule with comment period to permit specialists or other experienced providers to serve as primary care providers, as appropriate.

We also do not believe that it is appropriate to revise this final rule with comment period, to prohibit primary care systems from acting as care managers for persons with complex

behavioral needs. Again, States have the flexibility to decide the appropriate specifications to impose on MCOs and PHPs regarding the types of primary care providers, depending on the nature of the managed care program in the State and the population being served.

*Comment:* One commenter recommended that we revise proposed §§ 438.308(a)(1) and (a)(2) to allow an MCO or enrollee to designate a medical group or provider entity, instead of an individual, for primary care and overall coordination.

*Response:* We agree that the MCO should have the flexibility to include medical groups and other provider entities as sources of primary care and overall coordination. Our intent in drafting the proposed rule was to ensure that enrollees have an ongoing source of primary care and a designated person or entity responsible for coordinating their health care. Section 438.208(h) in the final rule with comment period, now requires the State to ensure that each MCO and each PHP: (1) provide each enrollee with an ongoing source of primary care appropriate to his or her needs; and (2) have a mechanism to identify the person or entity formally designated as primarily responsible for coordinating the enrollee's health care. While we thus have added flexibility to designate a medical group or entity as the primary care source, we urge MCOs and PHPs to make every effort to promote a relationship between an enrollee and a single primary care provider.

*Comment:* Several commenters requested that we clarify whether we are proposing a "case-manager" or "point-of-entry" care coordination model in proposed § 438.308(a). One of these commenters stated that under either model, the entity must be intimately familiar with the varied needs of the enrollee, and stressed that appropriate safeguards must be in place to ensure effective coordination among care providers. One commenter specifically recommended that we modify the proposed rule to indicate that, based on the initial assessment under proposed § 438.306(e)(2), the type of care coordination for each enrollee be determined by an analysis of individual need.

*Response:* Our intent was not to propose a "case-manager," "point-of-entry," or any other particular model of care coordination. Rather, our intent was to ensure that MCOs and PHPs, regardless of the model of care coordination, make every effort to promote a relationship between the enrollee and the primary care provider source. We recognize that some MCOs

and PHPs might have systems of care coordination under which a person or entity, other than the enrollee's primary care provider, coordinates services. We believe that our revised language in § 438.208(h) better reflects our intent.

With respect to the specific comment that the type of care coordination for each enrollee be determined by an analysis of individual need, we believe that the comprehensive assessment, treatment plan, and coordination program requirements in § 438.208 sufficiently address this issue.

*Comment:* A commenter found proposed § 438.308(a)(1) unclear, and thought that it could be interpreted to mean that an MCO must provide each enrollee with a primary care provider, and allow self-referral to a specialist on an as-needed basis. This commenter recommended that we delete this provision because, as the commenter interpreted it, it was unworkable in a managed care environment.

*Response:* We have clarified our final rule with comment period so that each MCO and each PHP must provide an enrollee with an ongoing source of primary care appropriate to his or her needs, and have a mechanism to identify the person or entity who is formally designated as primarily responsible for coordinating the enrollee's health care. We believe that this language is clear and cannot be interpreted to allow self-referral to a specialist.

*Comment:* We received several comments supporting the proposed provision in § 438.308(b), which requires an MCO to ensure coordination of services internally and with services available from community organizations and other social programs. Many of these commenters requested that we expand the coordination of services list. In contrast, several other commenters stated that they felt that the proposed regulation was unclear and questioned whether it was practical for an MCO to serve as a gatekeeper for non-medical services. Some commenters questioned our authority in proposing this provision, with a few stating that this provision was a major expansion of State and MCO responsibility. Several of these commenters indicated that this provision would be difficult for States to monitor, and recommended either that we clarify the regulatory language or delete the provision entirely. In addition, one commenter referenced the cost-effectiveness test under 1915(b) of the Act waiver programs, noting that such a test is based on a comparison to historic fee-for-service costs that does not include costs associated with

coordinating services with other social programs.

*Response:* We agree that the extent to which an MCO can coordinate all health and health-related services that are needed by an individual enrollee is variable, and that effective approaches to care coordination has not been well addressed to date by health services research. MCO responsibility for care coordination can range from: (1) coordination of all Medicaid services included in the contract between the MCO and the State; (2) coordination of all Medicaid services regardless of whether they are included in the MCO's contract with the State; and (3) coordination of all health, social, educational, and other services needed to maintain optimal health of an enrollee. Determining the appropriate level of responsibility for the MCO for care coordination is complex. The ability of the MCO to coordinate care is determined, in part, by the authority the MCO has to coordinate care provided by entities not a part of the MCO and by the MCO's available resources. Further, social or community organizations external to the MCO may not desire the MCO to coordinate care out of concern that care will be "medicalized" or that the authority of other agencies for care coordination will be weakened.

Since these are complex issues, we encourage all State Medicaid agencies to work with beneficiaries, MCOs and PHPs and other stakeholders in their State to determine the appropriate responsibilities of MCOs and PHPs in the State for care coordination. We accordingly have, in response to the above comments, deleted the requirement in proposed § 438.308(a)(2) that MCOs and PHPs coordinate services available from community organizations and social programs. We note, however, that an MCO or PHP may still have responsibilities for coordination that exist under fee-for-service Medicaid. Under § 431.615, State Medicaid agencies are required to establish, as part of their State plan, "arrangements" with State health and vocational rehabilitation agencies and Title V grantees. These arrangements must include coordinating plans for health services provided or arranged for recipients. In addition, similar arrangements are required under § 431.620, between a State Medicaid agency and State mental health authority or mental institutions. Section 431.635 also outlines requirements for the coordination of Medicaid with Special Supplemental Food Programs for Women, Infants, and Children (WIC). While these requirements are imposed on States, we believe that States may

delegate some of these coordination responsibilities to MCOs and PHPs. To the extent that these responsibilities are delegated, MCOs and PHPs must ensure coordination of health-related services with community and other social groups. This is now a State option, however.

In response to comments, § 438.208(h) of the final rule with comment period, thus requires that: "Each MCO and PHP must implement a coordination program that: (1) Meets the requirements specified by the State; (2) Ensures that each enrollee has an ongoing source of primary care appropriate to his or her needs and a person or entity formally designated as primarily responsible for coordinating the health care services furnished to the enrollee; (3) Coordinates the services it furnishes to enrollees with the services the enrollee receives from any other MCOs and PHPs; (4) Ensures that the results of its screen or assessment of an enrollee (or both, if the MCO or PHP performs both) are shared with other entities serving the enrollee, so that those entities need not duplicate the MCO's or PHP's screening or assessment or both; (5) Ensures that in the process of coordinating care, each enrollee's privacy is protected consistent with the confidentiality requirements in § 438.224; (6) Ensures that each provider maintains health records that meet professional standards and that there is appropriate and confidential sharing of information among providers; (7) Has in effect procedures to address factors (such as a lack of transportation) that may hinder enrollee adherence to prescribed treatments or regimens; and (8) Ensures that its providers have the information necessary for effective and continuous patient care and quality improvement, consistent with the confidentiality and accuracy requirements of § 438.224 and the information requirements of § 438.242. We are further requiring in § 438.10(d)(2)(i)(C) that the scope of MCO and PHP coordination be disclosed to potential enrollees by adding "MCO and PHP responsibilities for coordination of enrollee care" as an additional type of information that must be provided to potential enrollees.

*Comment:* Several commenters suggested that proposed § 438.308(b) would not achieve continuity and coordination of services if an MCO contract does not cover all medically necessary services included in a State plan. These commenters believed that an MCO should take responsibility for coordinating all Medicaid services that are not part of its contract. One commenter requested that we clarify

whether a State may determine that a State entity, local organization, or community organization is more appropriate to fulfill the coordination role. As an alternative, the commenter recommends that we revise the final rule with comment period to state, "With the permission of the enrollee, or when consistent with the State's confidentiality laws, the MCO must provide that its providers release information concerning the enrollee's medical treatment to community organizations and other social programs when so requested by such organizations or programs."

*Response:* Consistent with our response to the prior comment, and with our revisions to this section, we do not believe that § 438.208(h) prevents a State Medicaid agency from delegating the responsibility for coordinating health-related services to entities other than the MCO or PHP, such as other State and local organizations. Under the final rule at with comment period, § 438.208(h), States have the discretion to contract with MCOs and PHPs to provide a specific set of services that may not include all services covered under a Medicaid State plan. In a situation where the State has assumed a coordination function or delegated it to an entity other than the MCO or PHP, the MCO or PHP must still coordinate care and services to the extent and manner specified by the State and ensure that in the process of coordinating care, each enrollee's privacy is protected consistent with the confidentiality requirements in § 438.224.

*Comment:* We received several comments on proposed § 438.308(c)(2), which would require an appropriate and confidential exchange of information among providers. One commenter indicated that he or she was pleased to see the importance of confidentiality stressed. However, several comments suggested that proposed § 438.308(c)(2) lacked specificity about what information should and should not be shared between primary care and behavioral health providers. Several of these commenters recommended that enrollees be provided informed consent before information is shared. One commenter specifically noted that existing confidentiality requirements, especially those related to substance abuse treatment, severely limit the practitioner's ability to exchange treatment information. Another commenter stated that it is difficult to know what proposed § 438.308(c)(2) means without a definition of the term "confidential." This commenter recommended that we reference

applicable State law in the final rule with comment period.

*Response:* Our intent in drafting this provision was to ensure that MCOs and PHPs and their providers have the information necessary for effective and continuous patient care and quality improvement. In proposed § 438.308(c), we referenced the need for providers to maintain health records consistent with the requirements established by MCOs and PHPs, taking into account professional standards. In proposed § 438.308(c)(2), we also referenced the need for confidential exchange of information among providers. Both of these requirements were included in an effort to reinforce the confidentiality requirements in proposed § 438.324. We did not intend that the proposed rule be interpreted to require informed consent or to supersede relevant State law governing the exchange of information between providers.

We decided to revise the requirement to provide further clarification and to avoid confusion over the interface of this provision with § 438.224. Accordingly, § 438.208(h)(7) of the final rule with comment period, specifies that each MCO and PHP must ensure that its providers have the information necessary for effective and continuous patient care and quality improvement "consistent with the confidentiality and accuracy requirements of § 438.224 and the information requirements of § 438.242". In addition, at § 438.208(h)(4), we require that MCOs and PHPs have coordination programs that ensure that each enrollee's privacy is protected consistent with the requirements of § 438.224. Based on these revisions, we believe that there is no need to define the term "confidential."

*Comment:* We received several comments in support of proposed § 438.308(d), which would require MCOs and PHPs to have procedures in place to ensure that providers: (1) Inform enrollees of specific conditions that require follow-up and, if appropriate, provide training in self-care, and (2) deal with factors that hinder enrollee compliance with prescribed treatments or regimens. One commenter noted that the proposed rule recognizes the value of disease management programs. Another commenter supported the rule but felt that we should further clarify it to ensure that MCOs take responsibility to educate patients as to when they may go to emergency rooms. Another commenter asked that we recognize that there are limits on self-care requirements due to the nature of an enrollee's disability.

Other commenters objected to the proposed rule. One commenter opined that self-care cannot be legislated. This commenter believed that by making this a compliance issue, we were exceeding her authority. Another commenter felt that this provision was not practical and would lead to increased administrative costs.

*Response:* We continue to believe in the value of providing information and training on conditions that may improve with self-care, and encourage MCOs to provide for this. However, we are persuaded by commenters that some of the conceptual language on “specific health conditions that require follow-up” and “if appropriate, provide training in self-care” are unclear and subjective. We note that potentially all health conditions that require a visit to a health care practitioner require some degree of “follow-up.” Accordingly, in § 438.208(h)(6) of the final rule with comment period, we only require that MCOs and PHPs have in effect procedures to “address factors (such as lack of transportation) that hinder enrollee adherence to prescribed treatment regimens.”

With regard to the comment that MCOs and PHPs should have the responsibility to educate beneficiaries on the proper use of the emergency room, we encourage MCOs and PHPs to undertake this type of education. However, any training effort must be consistent with the emergency services requirements in § 438.114.

#### 6. Coverage and Authorization of Services (Proposed § 438.310)

Proposed § 438.310 set forth requirements to ensure that each contract with an MCO or PHP identify all services offered under the contract and follow written policies and procedures for processing requests for services in a manner that ensures access to these services. Further, the proposed requirements would ensure that utilization management activities are not structured in a manner that is detrimental to enrollees. These standards implement section 1932(b)(1) of the Act, and to the extent appropriate and applicable, are consistent with Medicare+Choice regulations at § 422.112.

In paragraph § 438.310(a) we proposed that the State ensure through its contracts with MCOs and PHPs that each MCO or PHP identifies, defines, and specifies the amount, duration, and scope of all Medicaid benefits that the MCO or PHP must furnish. Furthermore, the contract must specify what constitutes medically necessary services to the extent they are described in the

State plan, and provide that the MCO or PHP furnishes the services in accordance with that provision. We believe these requirements are essential, as it is a concern that an MCO's or PHP's authorization procedures, if unduly burdensome, can prevent an enrollee from having access to, or receiving services to which they are entitled under the State plan. In addition to serving as a protection for enrollees, these requirements support the provider's needs and desires to know what is required for authorization determinations.

In § 438.310(b) we proposed to require that, in processing requests for initial or continuing authorization of services, the MCO or PHP and its subcontractors: (1) follow written policies and procedures that reflect current standards of medical practice; (2) specify the information required for authorization decisions; (3) have in effect mechanisms to ensure consistent application of review criteria; (4) consult with the requesting provider when appropriate; and (5) observe time frames specified in paragraph (d) of proposed § 438.310.

In paragraph (c), we proposed that MCO and PHP contracts be required to provide that written notice be provided, within the time frames in paragraph (d), of decisions to “deny, limit, reduce, delay, or terminate” services, including specific reasons for the decision, along with information on the enrollees right to file a grievance or request a State Fair Hearing.

In paragraph (d), we proposed that contracts be required to specify that services will be provided as expeditiously as the enrollee's health condition requires, and within State-established time frames not to exceed 14 days in ordinary cases, and 72 hours if a further delay could “seriously jeopardize the enrollee's life or health or ability to regain maximum function.

In paragraph (e) we required that each MCO and PHP contract must provide that, consistent with § 438.6(g) and § 422.208, compensation to individuals or entities that conduct utilization management activities is not to provide incentives to deny, limit or discontinue medically necessary services.

*Comment:* Numerous commenters expressed the view that proposed § 438.310(a)(1) would be difficult to implement. These commenters felt that while a general description of categories of core benefits and service limitations seemed reasonable, the requirement to include the amount, duration, and scope of each service in the contract was not reasonable, and would make the contract too extensive to manage; create unintended exclusions; not allow for

consideration of patient specific needs; and require frequent contract amendments to keep current. They also urged that States have the flexibility to determine the level of detail to include in contracts, and believed that the requirements in proposed § 438.310 went beyond legislative intent. Commenters recommended that the contract identify, define, and specify each service that must be offered, but that the amount, duration, and scope be defined in a State Plan or other document. In contrast to the commenters who were opposed to the provision, several commenters supported the proposed provision, stating that it was essential that contracts make clear the services that an MCO must offer to ensure that the enrollee receives the services that they are entitled to under the State Plan. Commenters who supported the provision did not distinguish between the requirement to identify the services and the requirement to include the amount, duration, and scope of each service.

*Response:* The intent behind this provision was to ensure that enrollees receive the services that they are entitled to receive under the State plan, regardless of the MCO or PHP that they elect, with the recognition that some MCOs and PHPs may not directly provide some services, in which case the State must arrange for these services. While we acknowledge the difficulties that were raised concerning implementing this provision as proposed, we also agree with commenters who stated that it was essential that the contract make clear the services an MCO or PHP is to offer. Any limitations in amount, duration and scope are important features of benefit coverage. Failure to address them in a contract creates the potential for confusion between the State and MCO or PHP and thereby the possibility that an enrollee may not have timely access to service to which he or she is entitled. Because of these concerns, the final rule with comment period at § 438.210 still requires that the amount, duration, and scope of services be specified, now on the basis of what is contained in the State Plan. It further requires that the amount, duration, and scope be such as can reasonably be expected to achieve the purposes for which the services are furnished. However, we also note that if an MCO or PHP does not cover a particular service, the State must make arrangements to ensure that enrollees are able to receive all services covered under the State plan.

*Comment:* One commenter believed that proposed § 438.310(a)(1) gives the impression that States and MCOs may negotiate away existing Federal requirements governing coverage determinations in the Medicaid program. Specifically, the commenter pointed out that existing regulations for fee-for-service at § 440.230 require that services be provided in sufficient amount, duration, and scope “to reasonably achieve its purpose.” It further prohibits States from arbitrarily denying or reducing the amount, duration, or scope of such services solely on the basis of diagnosis, type of illness, or condition. Although State agencies may place limits on a service, limitations must be based on appropriate criteria such as “medical necessity” or on utilization control procedures. The commenter was concerned that § 438.310(a)(1) could be read to undermine these requirements by implying discretion to define amount, duration, and scope in contracts in a manner negotiated between the State and MCO or PHP.

*Response:* We agree with the commenter that the provisions at § 440.230 should also apply to a managed care arrangement, and we accordingly have included them in § 438.210 of the final rule with comment period in response to this comment. In addition, we have clarified that services limited for the purpose of utilization control must still be provided in sufficient amount, duration, and scope to reasonably achieve the purpose for which they are furnished.

*Comment:* One commenter suggested that benefits and services referenced in § 438.310(a)(1) include all Federally mandated benefits and services, including nurse-midwifery services.

*Response:* Federal law allows States to “carve-out” specific Medicaid services from contracts with MCOs and PHPs, and offer them on a fee-for-service basis or through a separate managed care contractor. For this reason, proposed § 438.310(a)(1) was not intended to govern what services are to be included in or covered by an MCO or PHP contract, but to require that, for those services that are included in or covered by the contract, that the contract identify, define and specify those services. Therefore, we are not requiring in the final rule with comment period that each MCO and PHP contract include all Federally mandated benefits and services, including nurse-midwifery services.

*Comment:* Many commenters suggested the regulation mandate a definition of medical necessity for States to use in their managed care

contracts, or more specific guidance regarding the definition. Commenters presented a range of reasons for including a standard definition, including the need for consumers and providers to understand the scope and limits of health care benefits, ensuring enrollees are not denied services to which they are entitled, avoiding disputes between States and MCOs or PHPs and providers, eliminating State variances in the definition, curbing future lawsuits, and improving the incentive for managed care plans to compete based on innovative quality improvements, rather than restrictive authorizations.

Several different definitions were suggested by different commenters. Some of the recommendations suggested that the definition reflect maintenance of functioning, prevention of deterioration, optimum participation in community living, consideration of the differences between children and adults (especially age-appropriate services and the developmental, rather than rehabilitative, nature of some services for children), and should specifically address mental health needs.

Other commenters found the provision regarding medical necessity too prescriptive and believed that medical issues should not be resolved through a regulation or contracting process.

*Response:* We disagree that the provision is too prescriptive. States have existing medical necessity specifications in Medicaid fee-for-service programs and individuals enrolled in managed care are entitled to the same services as all other Medicaid eligible persons in the State. Clear specifications of medical necessity in the contract are critical in determining what a State is paying MCOs and PHPs to provide and, in some cases, what the State is providing outside the managed care setting for all parties in the program. The application of State specifications in individual situations allows for medical judgement.

However, we also do not agree that a definition of medical necessity should be included in the regulations. There currently exists no widely-accepted national definition, and at present States currently are allowed under § 440.230(d) to “place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures,” and have great flexibility in defining that criteria. Therefore, we do not believe it is appropriate to promulgate a national definition at this time. However, we believe that more specific guidance regarding State contract specifications is needed. In particular we believe that

medical necessity criteria used by Medicaid MCOs and PHPs should not be more restrictive than the State Medicaid medical necessity criteria used in the State’s Medicaid program overall, and that this be evident to all parties, thus decreasing the potential for disputes.

Therefore, we have revised the regulation to require that the specifications of medical necessity in the contract must be no more restrictive than any such specifications in the State Medicaid fee-for-service program, described in State statute, regulations, State plan, or other policy or procedures. This addition of “State statute, regulations or other policy or procedures” provides greater specificity than the sole reference to “State plan.” found in the proposed rule. We further agree that the contract should be clear about what the State’s specifications are with respect to medical necessity criteria. Therefore, we have added provisions requiring that the contract address the extent to which the MCO or PHP is responsible for covering medically necessary services to: (1) prevent, diagnose, and treat health impairments; (2) enable the enrollee to achieve age-appropriate growth and development; and (3) attain, maintain or regain functional capacity. While we are not mandating that services must be covered to meet these goals, the contract must clearly address the extent of each MCO’s and PHP’s responsibility to provide such services. This provision will promote greater consistency of medical necessity specifications across MCOs and PHPs within a State. We believe that services to meet mental health needs are understood to be under the purview of these specifications without specific mention.

We believe this revised regulatory provision, in conjunction with other provisions in this regulation, will meet commenters’ concerns regarding beneficiary understanding as well. Section 438.10 requires that information regarding the kinds of benefits, and amount, duration and scope of benefits available under the contract must be provided to enrollees or potential enrollees upon request. This provision should improve the understanding of beneficiaries so they are not denied services to which they are entitled. This section also requires the provision of information regarding grievance, appeal and fair hearing procedures to assure that beneficiaries understand their ability to dispute decisions made by MCOs and PHPs.

We anticipate that greater specificity in MCO and PHP contracts will reduce the potential for MCOs and PHPs to

develop specifications of medical necessity inconsistent with those developed by the State Medicaid agency. However, it must be noted that medical necessity relates to determinations regarding specific care given to a specific patient with specific medical condition under certain circumstances and is thus more focused on individual situations. Some potential for dispute is inherent in such decisions.

*Comment:* Many commenters indicated that the regulation should recognize the special status of Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) provisions, and provide specific reference to them under the medical necessity provision.

*Response:* This regulation does not affect any of the pre-existing EPSDT regulations. Further, some EPSDT services may be provided by the State outside of the managed care contract. We believe it is redundant and unnecessary to repeat all existing requirements in this regulation, which focuses on managed care programs. For this reason, we have not included any specific reference to EPSDT in the provisions on medical necessity.

*Comment:* Some commenters found that the proposed regulation gave the impression that the States and MCOs may negotiate away the Federal legal requirements governing coverage determinations in the Medicaid program. Comments suggested that the regulations ensure that States include in managed care contracts a definition of medical necessity consistent with Federal law.

*Response:* The provision addressing medical necessity in no way affects any other Federal requirements governing coverage determination in the Medicaid program. All parties must adhere to all other Federal statutes and regulations. However, we believe it would be redundant to repeat all such requirements in this regulation.

*Comment:* Commenters urged that we review and approve definitions of medical necessity before approving managed care contracts.

*Response:* Section 438.6 of this final rule with comment period requires us to review and approve MCO and PHP contracts. As part of that review, we will assure that regulatory requirements at § 438.210 pertaining to MCO and PHP contract provisions on medical necessity are met. While these provisions are not a definition of medical necessity, they will promote greater shared understanding by MCOs, and PHPs and beneficiaries about how medical necessity is determined.

*Comment:* One commenter asserted that ongoing monitoring by us is essential to ensure that States or MCOs do not define medical necessity so narrowly that they deprive beneficiaries of services to which they are entitled under Medicaid.

*Response:* We agree that ongoing monitoring of managed care programs is important. We utilize a variety of mechanisms to monitor State contracts and State Medicaid managed care initiatives. These mechanisms include: data reviews, State and MCO on-site reviews, and input from beneficiaries, advocates and providers. Furthermore, other provisions in this regulation, such as § 438.204(d) (which requires external reviews of the timeliness of and access to services covered under each MCO and PHP contract), provide significant additional information to assist us and States in monitoring.

*Comment:* One commenter believed that each State operating a Medicaid managed health care plan that includes children should be required to consult with the State agency that is responsible for overseeing the delivery of early childhood intervention services (under Paragraph B and C of Individuals with Disabilities Education Act) to ensure that the plan includes adequate provisions for coordination of health and early intervention services to such youngsters.

*Response:* We strongly support coordination between appropriate State agencies. In § 438.202, we require States to provide for the input of recipients and other stakeholders in the development of the State strategy for quality assessment and performance improvement. We consider other State agencies such as State Mental Health and Substance Abuse agencies, Title V Maternal and Child Health agencies, and IDEA agencies as stakeholders who should have input into the development of the strategy.

*Comment:* We received comments urging that there be no gaps in Medicaid services. A major problem, in the view of these commenters, is that States often are unaware of their responsibility to fill gaps left in the case of services not provided through an MCO or PHP.

*Response:* We agree that all needed Medicaid covered services must be furnished. In the final rule with comment period—

Section 438.210 requires that the contract identify, define, and specify services that the MCO or PHP is required to offer; and

Section 438.206 specifies if an MCO or PHP contract does not cover all of the services in the State plan, the State must make those services available from other

sources and give enrollees information on how and where to obtain them, including how transportation is provided.

In determining whether services should be provided in individual cases, fair hearing officers are bound by their interpretation of the State's overall Medicaid program coverage criteria, and must apply these criteria rather than specific coverage criteria in the contract if the hearing officer determines that the contract criteria are inconsistent with State criteria. The State retains overall responsibility for covering all services in accordance with the Medicaid State plan and implementing policies and procedures, regardless of whether some or all of these services may have been contracted to an MCO or PHP.

*Comment:* Commenters expressed divergent views on the basis for medical necessity determinations, including preferences for evidence-based standards, professional standards, generally accepted standards of medicine, or deference to the recommendation by the treating professional. Some voiced concern that the evidence-based standard for determining which services are medically necessary would limit obligations to services deemed effective based on quantitative or scientific studies. Quantitative evidence of efficacy does not always exist with respect to persons with developmental disabilities or other special populations who have not been involved in studies. On the other hand, some commenters felt the professional standard of review was inappropriate because of disputes among professionals.

*Response:* Because of the variable evidence base for the efficacy of the multitude of therapeutic interventions possible for any population, and the lack of consensus regarding the best approach to medical necessity determinations (as evidenced by the comments received) we do not mandate a single approach for determining medical necessity. States have great flexibility in establishing this standard, which is applicable in both fee-for-service and managed care.

*Comment:* Commenters indicated that MCO subcontracts should be required to include the same "medical necessity" definition, as well as EPSDT requirements and access standards, and the clear description of benefits that are contained in contracts between the State and MCOs.

*Response:* MCOs and PHPs are responsible for assuring that services are provided in accordance with their contract with the State, regardless of any subcontracts in place. MCOs and PHPs

may delegate activities, but not responsibility, for contract provisions. Section 438.230(a)(1) requires the State to ensure that each MCO or PHP oversees and is accountable for functions delegated to subcontractors. States must monitor this process on an ongoing basis and insure the development of corrective action plans, where necessary.

*Comment:* A commenter believed that all coverage decisions made by the MCO should be consistent with current standards of medical practice.

*Response:* Section 438.210(b)(1) of the final rule with comment period, requires that the MCO or PHP and its subcontractors follow written policies and procedures that reflect current standards of medical practice in processing requests for initial and continuing authorization of services.

*Comment:* A commenter was concerned that proposed § 438.310(b)(1) could be interpreted to require a written authorization for every authorization decision. The commenter felt that while this may be possible for many courses of treatment, it was not universally possible.

*Response:* Section 438.210(b)(1) of the final rule with comment period requires MCOs and PHPs to follow written policies and procedures that reflect current standards of medical practice. The provision applies to the authorization process in general, not each determination. The intent is to ensure that actual determinations are consistent and made in accordance with policies and procedures that reflect current standards of medical practice.

*Comment:* Some commenters noted that a stated intent of the service request processing requirements in proposed § 438.310(b) was to ensure that the authorization process was not unduly burdensome for providers. These commenters believed that this objective would be better achieved by a more general requirement that the MCO's process be reasonable, rather than by asking States and MCOs to establish specific requirements in their contracts. They felt the requirements were too detailed for a contract, and that the level of specificity was not called for under the BBA. Commenters were most opposed to the requirement that each contract specify the information required for authorization decisions. In contrast, one commenter believed that there should be more specificity than we proposed, especially in the area of routine authorization decisions.

*Response:* The reason for proposed § 438.310(b) was that there is concern that the authorization process itself could be one of the reasons enrollees do

not receive services to which they are entitled under the State plan. We want to ensure that the authorization procedure itself does not prevent enrollees from receiving services that they are entitled to receive under the State plan, and that the MCO's or PHP's information requirements do not place undue burden on the provider or the enrollee. To make explicit our intent that the authorization process not be unduly burdensome for providers or enrollees, in response to the above comments, we have expressly stated this in § 438.210(b)(2)(i) of this final rule with comment period.

*Comment:* One commenter believed that the requirement for consistent application of review criteria should be eliminated because in this commenter's view it would require health plans to establish another complicated audit process. The commenter felt that the inconsistencies that this provision addresses would be picked up by existing audit procedures.

*Response:* We believe that consistent application of review criteria is essential in assuring beneficiaries' access to care. Therefore, at § 438.210(b)(2) we retain the requirement that MCOs and PHPs have mechanisms in effect to ensure consistent application of review criteria for authorization decisions. Whether a mechanism is acceptable, as well as how a mechanism is defined, is not dictated in the regulations, but left up to the discretion of the State and the MCO or PHP.

*Comment:* One commenter felt that it was important to establish a structure that would assure that MCOs' authorization procedures are evaluated on a periodic basis, with the input of practice managers.

*Response:* Since the requirements of § 438.210 are part of MCO and PHP contract requirements for access to care, States are responsible for ensuring compliance with service authorization requirements as part of their overall quality strategy, as set forth in § 438.202 (State Responsibilities) and § 438.204 (Elements of State Quality Strategies). MCOs and PHPs are also required by § 438.240 to have an ongoing quality assessment and performance improvement program that has in effect mechanisms to detect both underutilization and overutilization of services. In light of the above requirements, we do not believe it is additionally necessary to require in this rule that authorization procedures separately be evaluated on a periodic basis with the input of practice managers.

*Comment:* One commenter recommended that the regulation

require that initial coverage decisions that alter the request of the provider in any way be made, and certified, by a licensed medical doctor. The commenter also urged that initial coverage decisions mirror the requirement in the grievance process (proposed § 438.406(d)) that the review of a denial based on medical necessity be conducted by a "provider with appropriate expertise in the field of medicine that encompasses the enrollee's condition or disease."

*Response:* We agree, in part, with these comments. While we agree that individuals who make initial coverage decisions should be health professionals who have appropriate clinical expertise, we note that relevant expertise may be possessed by health care professionals who are not always physicians. Dentists, psychologists and certified addiction therapists are examples of health professional who are not physicians, but who may have appropriate clinical expertise. Therefore, in response to the above comments, we have provided in § 438.210(b)(3) of the final rule with comment, that any decision to deny or limit a service must be made by a health care professional who has appropriate clinical expertise in treating the enrollee's condition or disease.

*Comment:* Commenters contended that the requirement in proposed § 438.310(c) that a written notice be sent to the provider for all authorization decisions not fully approved as requested is not current practice for commercial MCO contracts.

*Response:* We believe that the provider should be notified of all MCO and PHP service authorization decisions that are not fully approved as requested. In § 438.210(c) of the final rule with comment period, we have removed the requirement that this notice be in writing to ease the burden on MCOs and PHPs.

*Comment:* Numerous commenters had difficulty distinguishing between the requirements at §§ 438.310(c) and (d) pertaining to a notice of adverse action and the time frames for such action, and those in § 438.404 requiring an MCO to give notice of intended action when an MCO intends to deny, limit, reduce, delay or terminate a service or deny payment for a service. There were other comments on these provisions.

*Response:* We agree that, in the proposed rule, the distinction between proposed §§ 438.310(c) and (d) and proposed § 438.404 was not clear. In the final rule with comment period, § 438.210(c) requires only that the notice of adverse action meet the requirements of § 438.404, and paragraphs (d) and (e) set forth only the

time frames for standard and for expedited authorization decisions, respectively. For further clarity, we note that the distinction between proposed § 438.310 and § 438.404 is drawn at the point the authorization decision is made. If the decision is authorized outright, there is no link to § 438.404; however, if the decision is made to deny or limit a service, notice must be given in accordance with § 438.404, as these decisions are subject to the grievance and appeal process.

*Comment:* Some commenters were opposed to proposed § 438.310(d) which specified the time frames for providing services. They did not believe it was reasonable to expect services to be provided within the specified time frames. Several commenters suggested that the time frames be consistent for both the Medicaid and the Medicare programs, since providers participate in both programs.

*Response:* There was an unintended ambiguity in proposed § 438.310(d). The time frames were intended to apply to authorization of services, not furnishing of services. The final rule with comment period, at § 438.210(d) and (e), makes clear that the time frames are applicable to standard and expedited authorizations. The time frames are necessary to ensure that the appeal time frames can be met when an authorization is not approved. In general, the time frames are consistent with those in Medicare.

*Comment:* In addition to comments interpreting the time frames in proposed § 438.310(d) to apply to the furnishing, rather than the authorization of services, there were comments that understood § 438.310(d) to apply to authorizations, but found 14 calendar days insufficient for a routine authorization if all of the supporting documentation was not present. The commenters recommended that the 14 days should begin after all of the supporting information is received.

*Response:* The time frame in proposed § 438.310(d) and § 438.210(d) of this final rule with comment period, allows for an extension of up to an additional 14 days if the enrollee or the provider requests extension, or the MCO or PHP justifies to the State agency that additional information is needed and that the extension is in the enrollee's interest.

*Comment:* Numerous commenters questioned whether enrollees were adequately protected by the provision in § 438.310(d)(2) requiring authorization to be made no later than 3 working days after receipt of the request for service (with a possible extension of up to 14 additional calendar days) if the ordinary

14 day time frame could seriously jeopardize the enrollees' life or health or ability to regain maximum function. The commenters felt that each case is unique, and that in some cases, immediate authorization is necessary, and in others, 24 hours, etc. A standing minimum of 3 working days, with an extension of 14 days possible, was not acceptable to these commenters. One commenter believed that 14 days was excessive for an ordinary authorization that could be completed in a much shorter time.

*Response:* We recognize that there may be situations in which 72 hours, or the additional 14 days, would be detrimental to the enrollee's health. Under § 438.210(e) of the final rule with comment period, the time frame for an expedited authorization decision is "as expeditiously as the enrollee's health condition requires" and in the case of a decision that denies or limits services, early enough to permit the MCO or PHP to process an appeal within 72 hours after receipt of the request for service. The time frames are provided as minimum requirements, but we expect States, MCOs and PHPs to consider the enrollee's health concern as the foremost deciding factor.

*Comment:* A commenter suggested that we revise § 438.310(d) to allow the provider, rather than just the enrollee, to request extensions in service authorization time frames. As justification, the commenter said that the time required for the provider to arrange for the enrollee to request an extension may force an MCO to deny services that would otherwise be approved, if the provider had time to submit additional documentation.

*Response:* We agree with the commenter, and in the final rule with comment period, have provided that the provider, acting on behalf of the enrollee, as well as the enrollee may request extension for a standard authorization decision, but only the enrollee may request extension for an expedited decision.

*Comment:* A commenter indicated that in § 438.310(d), as well as others in the subsection, the reference to "physician" should be deleted and "attending provider" should be inserted. The rationale for this recommendation was that the language should more accurately reflect the full range of qualified health professionals.

*Response:* We agree and have replaced the term "physician" with "provider."

*Comment:* Two commenters offered their support for the requirement in proposed § 438.310(e) that compensation to utilization review

entities not be structured so as to provide incentives to deny, limit, or discontinue medically necessary services.

*Response:* We have retained this provision as § 438.210(f) of this final rule with comment period.

*Comment:* Several commenters encouraged us to avoid duplication in the regulation.

*Response:* We agree, and have attempted to avoid unnecessary duplication in this final rule with comment period. For example, we have eliminated duplication of information requirements that in the NPRM appeared both in proposed § 438.10 and proposed § 438.318.

#### 7. Establishment of Provider Networks (Proposed § 438.314)

Proposed § 438.314 placed requirements on State Medicaid agencies to ensure that contracted MCOs and PHPs have written policies and procedures for the selection and retention of providers. This proposed section required States to ensure that such policies include requirements for initial provider credentialing and recredentialing in accordance with time frames set by the State, but not less frequently than what the State requires for private HMOs.

*Comment:* Many commenters believed that proposed § 438.314 was too prescriptive. Some commenters interpreted the proposed rule as extending credentialing requirements to providers who perform services under the supervision of physicians, and argued that these requirements generally should only apply to physicians. These commenters expressed the view that requiring credentialing of a broader range of providers adds no value. There were a number of recommended credentialing approaches ranging from adoption of the NCQA credentialing criteria, the American Medical Association's credentialing process, and Medicare policy.

*Response:* We reexamined the proposed rule in light of these comments and in response to these comments, have made several clarifications to the final rule with comment period. We believe these changes will address most of the commenters' overriding concerns about ambiguity as to who will be subject to credentialing requirements. The final rule with comment period at § 438.214(b) now includes provisions on credentialing that were intended, but not explicit in the proposed rule. Specifically, in § 438.214(b) we now clarify which providers are subject to credentialing and recredentialing

requirements, distinguishing in § 438.214(b)(1) requirements that must be met by physicians and other licensed, independent providers from requirements in § 438.214(b)(2) that must be met by other providers. Exceptions to these requirements are described in § 438.214(b)(3). These exceptions apply to providers who are permitted to furnish services only under the direct supervision of a physician or other provider, and for hospital-based health care professionals (such as emergency room physicians, anesthesiologists, and certified registered nurse anesthetists) who provide services only incidental to hospital services. The latter exception does not apply if the provider contracts independently with the MCO or PHP or is promoted by the MCO or PHP as part of the provider network.

We did not adopt the NCQA standards as suggested by commenters. While our requirements are not identical to the NCQA standards, they have much in common. For example, the exceptions to credentialing outlined above are the same as the exceptions under the NCQA standards. The AMA credentialing process no longer exists.

*Comment:* One commenter recommended that board certification be dropped as a credentialing criterion.

*Response:* No change was required in response to this comment, since board certification was not a requirement in the proposed rule, and is not in this final rule with comment period.

*Comment:* One commenter believed that credentialing criteria should be appropriate to the nature of the services provided.

*Response:* We believe the credentialing criteria are sufficiently flexible to recognize the characteristics of each MCO and PHP, and the providers within its network.

*Comment:* One commenter believed that provider selection should be based on objective quality standards.

*Response:* We believe that the final rule with comment period, as structured, provides for objective quality standards.

*Comment:* One commenter recommended that we require "economic profiling" to be adjusted to reflect varying practice characteristics.

*Response:* We cannot respond to this comment because we do not understand what the commenter means by "economic profiling," or what its relationship is to credentialing. The intent of this rule was to ensure that MCOs and PHPs implement a formal selection process and, at a minimum, that the process address provider qualifications, provider discrimination,

the exclusion of certain providers and additional requirements States may want to impose.

*Comment:* One commenter recommended that there be written policies and procedures for selection and retention of physicians.

*Response:* We agree, and in response to this comment, the final rule with comment period at § 438.214(a) now specifies that States must ensure that MCOs' and PHPs' selection and retention policies and procedures must be in writing.

*Comment:* One commenter recommended that the final rule with comment period, prohibit MCOs from removing providers from their networks without good cause.

*Response:* While States would be permitted under § 438.214(e) to adopt such a rule if they believe it would be appropriate based on conditions in the State, we do not believe that such a requirement should be imposed nationally in this final rule with comment period. This is because we believe that it may be reasonable, in some cases, for an MCO or PHP to remove providers from its network without cause. For example, there may be a need for an MCO to reduce the size of its provider network if its enrollment declines, and its payments to providers are based on a certain volume. In addition, evaluating the quality of care of providers may be facilitated by having fewer providers serve greater numbers of enrollees. We wish to note that under § 438.12(a)(1), if an MCO or PHP declines to include a provider in its network, it must give the provider written notice of the reason for this decision.

*Comment:* A number of commenters believed that there was a need to specifically assure that there be no discrimination against providers who traditionally serve more vulnerable populations, such as those who serve limited English proficient populations, high risk populations, and those requiring high-cost treatments. One commenter suggested that such providers be given priority in network selection and referrals. The same commenter believed that MCO gatekeepers frequently do not have professional credentials, and therefore should not control access to care.

*Response:* It is not clear why the commenters believe there is a need for assurance that there be no discrimination against providers who traditionally serve vulnerable populations, since proposed § 438.314(b)(3) expressly provided that selection and retention criteria could not "discriminate against \* \* \* those

who serve high risk populations." This provision has been retained in the final rule with comment period at § 438.214(c). We believe the commenters' concerns are also addressed in a number of other sections. For example, as discussed above, § 438.10(b) requires that information be available in languages spoken in the service area, and that interpreters be available to meet the needs of all enrollees, and § 438.206(e)(2) requires that MCOs and PHPs provide services in a culturally competent manner. Both of these provisions would encourage the use of providers who "serve limited English proficient populations."

Under § 438.206(d), in establishing a provider network, MCOs and PHPs are required to consider persons with special health care needs and include the numbers and types of providers "in terms of training and experience" required to serve the population. Again, this favors the use of providers with experience with vulnerable populations. Finally, under § 438.50(f)(2), in the case of a default enrollment process under a mandatory program under section 1932(a)(1) of the Act, an attempt must be made to preserve existing provider-beneficiary relationships, and relationships with providers that have traditionally served the Medicaid populations. Again, this favors giving priority to providers serving the vulnerable populations cited by the commenter.

With respect to the concern that gatekeepers do not have necessary professional credentials, § 438.210(b)(3) requires that any denials of an authorization for services be made by "a health care professional who has appropriate clinical expertise in treating the enrollee's condition or disease." We believe that all of the foregoing provisions adequately address the commenter's concerns.

*Comment:* Several commenters were unclear on the meaning of "high-risk populations" as used in proposed § 438.314(b)(3), and sought clearer standards under this provision. Commenters suggested specific examples of high risk patients, including adults and children with special health care needs, such as those with mental illness, substance abuse problems, developmental disabilities, functional disabilities, or complex problems involving multiple medical and social needs like HIV/AIDS, and the homeless. Other commenters felt that the provision governing providers who serve "high-risk" populations should be dropped from the rule as too vague to implement, and questioned the wisdom of employing such standards, which

they believed would lead to unresolvable disputes.

*Response:* We disagree with the commenters who believe that we should delete the requirement in proposed § 438.314(b)(3), because we believe that many Medicaid beneficiaries are best served by providers who are experienced in caring for individuals with the health or social conditions that make an enrollee “high risk;” (for example, poverty, homelessness, disrupted family situations). We agree that the specific examples of high risk populations cited by the commenters are examples of high risk populations. We do not believe, however, that we should include regulations text specifically citing such categories, since this may be seen as limiting the scope of this provision. We instead believe that States should be free to interpret “high risk populations” based on their knowledge of the high risk populations in their State.

*Comment:* One commenter discussed the very valuable role nonprofit social service agencies play in the care delivery system for Medicaid beneficiaries, and expressed the view that these provider agencies would gain more credibility if they were accredited by the Medicaid program. There are now standards for such agencies that are recognized by many States. The commenter recommended that such agencies be accredited, and that they have the option of accreditation from the Council of Accreditation (COA), a body more representative of the social service model, as well as by a medical accrediting body such as the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) or a JCAHO-type accrediting body.

*Response:* We do not believe it would be appropriate at this time to provide for accreditation of these agencies because (1) accreditation standards and procedures for such entities are in their formative stage, and (2) to the extent these agencies provide specific Medicaid State plan services, they would already be subject to any accreditation requirements applicable to the service in question. We note, however, that there is no Federal prohibition preventing States from adopting such quality standards if they choose.

*Comment:* One commenter took exception to the requirement at proposed § 438.314(b)(1) that provider selection criterion would be based in part on eligibility for payment under Medicaid. The commenter believed that there would be times when an MCO may wish to provide services through a provider in good standing who is not an

eligible provider type under fee-for-service.

*Response:* We have clarified the final rule with comment period at § 438.214(d) to better reflect our intent to preclude only providers who have been barred from participation in the Medicaid program (for example, providers convicted of fraud). We did not intend to preclude States from allowing MCOs or PHPs to provide services through providers in good standing who do not participate in the traditional part of the Medicaid program (for example, alternative providers or providers who have not otherwise chosen to participate in the Medicaid fee-for-service program).

*Comment:* A commenter recommended that MCOs not be permitted to have separate panels of providers for Medicaid and for their other lines of business.

*Response:* Our experience has demonstrated that such a requirement is not practical. We have considered imposing such a requirement in the past, and have determined that it would not be in the best interests of Medicaid beneficiaries to do so. Some of the most successful managed care programs have employed providers with particular experience in treating the Medicaid population. Permitting these providers to exclusively serve Medicaid beneficiaries allows more Medicaid beneficiaries to access these experienced providers. It is also the case that some managed care organizations include physicians in their networks who would not agree to accept Medicaid patients. In such a case, if these MCOs or PHPs were not permitted to limit Medicaid patients to a subset of physicians who agree to treat Medicaid beneficiaries, they would not be available as a Medicaid option. We therefore are not including this requirement.

#### *8. Enrollee Rights (Proposed § 438.320) (Redesignated as § 438.100)*

As part of these standards, in proposed § 438.320(a), we required that each contract with an MCO or PHP have written policies with respect to enrollee rights, and the MCO or PHP ensure compliance with Federal and State laws affecting the rights of enrollees, and ensure that its staff and affiliate providers take these rights into account when furnishing services. Under proposed § 438.320(b), States must ensure that each enrollee has a right to: Receive information regarding their health care; have access to health care; be treated with respect and consideration for enrollee dignity and privacy; participate in decision making

regarding his or her health care; receive information on available treatment options or alternative courses of care, and have access to his or her medical records. Proposed § 438.310(c) required that States ensure compliance with various civil rights laws.

*Comment:* Several commenters felt that the rights in proposed § 438.320 should be extended to individuals enrolled in PCCMs, as well as those in MCOs and PHPs.

*Response:* As discussed above, to the extent requirements in proposed subpart E are grounded in section 1932(c)(1) of the Act, we determined that it would be inconsistent with the Congressional intent to apply them to PCCMs, since the Congress made a conscious decision not to do so even when other provisions in section 1932 of the Act did so apply. We believe that the rights in § 438.100(a)(2), (b)(1), (b)(4), (b)(5), (b)(6), (b)(8), (c), and (d), however, are supported by our authority under section 1902(a)(4) of the Act to specify methods necessary for proper and efficient administration, and the requirement in 1902(a)(19) of the Act that States provide “safeguards as may be necessary to assure that \* \* \* care and services will be provided \* \* \* in the best interests of the recipients.” Therefore, in response to this comment, we are revising § 438.100(a)(2), (b)(1), (b)(4), (b)(5), (b)(6), (b)(8), (c), and (d) to make these paragraphs and subparagraphs applicable to PCCMs.

*Comment:* Several commenters suggested that without proper enforcement, the “rights” that were contained in proposed § 438.320 were just “paper rights.”

*Response:* We agree that to be effective, enrollees’ rights must be enforced, and believe that the final regulation with comment period include provision for enforcement. First, under subpart F, discussed in section II. E. below, enrollees have the right to file a grievance with their MCO or PHP if they believe any of their rights have been violated. In addition, (1) § 438.66 mandates that States actively monitor MCOs’ and PHPs’ operations, (2) § 438.202(d) requires that States ensure compliance by MCOs and PHPs with the quality standards established by the State, and (3) § 438.204(b)(2) requires that State quality strategies include continuous monitoring and evaluation of MCO and PHP compliance with standards. We believe that these provisions do provide for enforcement of enrollee rights.

*Comment:* Several commenters were concerned that the enrollee rights outlined in proposed § 438.320 contained too much subjective language

that could be construed in any way that an MCO chooses.

*Response:* We believe that the provisions for Enrollee Rights now set forth in § 438.100 are specific enough to ensure specified rights for enrollees of MCOs, PHPs, and PCCMs, while still affording States the flexibility to determine how to guarantee that these rights are upheld.

*Comment:* Several commenters found the rights outlined in proposed § 438.320 too sparse, and believed that they did not fully implement the recommendations in the Consumer Bill of Rights and Responsibilities (CBRR).

*Response:* Proposed § 438.320 was intended to articulate a broad set of fundamental enrollee rights, and was not intended to encompass all aspects of the CBRR, which are reflected in detail in numerous provisions throughout virtually every subpart in part 438. For example, important enrollee rights are reflected in the information requirements in § 438.10 in subpart A, the continuity of care requirements in § 438.62 in subpart B, the rights related to provider enrollee-communication and emergency services in §§ 438.102 and 438.114 in subpart C, the right to access to a woman's health care specialist in § 438.206(d)(2) in subpart D, and the grievance and appeal rights throughout subpart F. See our discussion of these and other provisions for further discussion of how this final rule with comment period implements the CBRR.

*Comment:* One commenter objected to the provision in § 438.320(c) requiring that MCOs and PHPs must "comply with any other Federal and State laws that pertain to enrollee rights," because the commenter believed it was not appropriate for the Federal government to regulate compliance with State laws.

*Response:* The language in the proposed rule was intended to acknowledge that there are a number of States with their own requirements pertaining to enrollee rights. We do not believe that it is inappropriate to require that the State ensure that the MCOs, PHPs and PCCMs also comply with these regulations. However, we are not expecting States to take over the enforcement of State and Federal laws that are not within their jurisdiction. In order to more narrowly define the Federal and State laws that are being referenced, we have added the term "applicable" to the final regulation.

*Comment:* One commenter suggested that in addition to providing services in accordance with proposed §§ 438.306 through 438.310, proposed § 438.320(b)(2) should also include the right to "receive all services provided under the State plan."

*Response:* The requirement that a beneficiary receive all services provided under the State plan is set forth in § 438.206(c), which is incorporated in § 438.100(b)(2), so that this right is included in § 438.100.

*Comment:* One commenter requested that we explicitly state that enrollees have a right to a second opinion.

*Response:* We agree, and in response to this comment, have added a reference at § 438.100(b)(3) to the right to a second opinion provided for under § 438.206(d)(3).

*Comment:* Several commenters offered their support for proposed § 438.320(b)(3) which required that enrollees be treated with respect and due consideration for their dignity and privacy. It was the commenter's belief that populations with special needs have not always been treated in this manner. However, one commenter, while supporting the provision, felt that the standard was not appropriate for a Federal regulation, and would be difficult for States to measure or enforce.

*Response:* We believe that there are ways to monitor compliance with this provision retrospectively through such means as enrollee surveys, site visits, hot lines, and grievance procedures. In addition, including respect, dignity and privacy as explicit enrollee rights attempts to address this issue proactively. As commenters indicated, we believe this is a fundamental and important enrollee right and, as such, should be included in the regulation.

*Comment:* Several commenters suggested that we revise the language in proposed § 438.320(b)(4) to state that the information must be presented in a language appropriate to the consumer's condition and ability to understand.

*Response:* Section 438.100 provides that enrollees receive information in accordance with § 438.10, which requires that all information furnished to enrollees and potential enrollees meet specified language and format requirements. We believe these provisions address the commenter's concern. We therefore do not believe that a revision to the language at § 438.100 is necessary.

*Comment:* While offering support for the provision that requires information to be provided to enrollees, some commenters suggested that we revise the proposed regulation to require "full and complete" information on "all" available treatment options and "alternatives," including alternatives as to the "site of care." These commenters felt that these revisions are essential in ensuring that enrollees receive

information on family planning services that are not covered by the MCO.

*Response:* We consider the commenters' suggestions already addressed in the regulations. For example, § 438.102(b)(1)(ii) and (iii) give enrollees a right to all "information the enrollee needs in order to decide among all relevant treatment options." and "the risks, benefits and consequences of treatment or non-treatment." With respect to information on family planning services, § 438.10(e)(2)(vi) expressly requires that information be provided on how enrollees may obtain family planning services from out-of-network providers. In the case of services not covered through the MCO or PHP, under § 438.10(e)(2)(xii), information must be provided on how and where the enrollee must obtain the benefits. In the case of benefits not covered on moral or religious grounds, information must be provided on how or where to obtain information about the service.

*Comment:* Several commenters offered their support for proposed § 438.320(b)(5), requiring that enrollees be permitted to participate in decisions on their health care, but requested that this provision be revised to clarify that enrollees not only have the right to participate in decisions, but that they also had the right to refuse treatment. Additionally, commenters wanted this provision to explicitly state that enrollees had the right to participate in "all" treatment decisions and to make "informed decisions."

*Response:* We agree with the commenters that it may not be clear that the right to participate in decisions also includes the right to refuse care, although this was our original intent. Consequently, we have revised § 438.100 (b)(6) to expressly include the right to refuse treatment. However, we believe that the suggested changes to include the qualifiers "all" and "informed" are not necessary, as these concepts are already contained in the provision as written.

*Comment:* A number of commenters believed that enrollee "access" to records was not sufficient, and that they also needed to be able to receive "copies" of their medical records, and all relevant documents, at no cost. They also requested that we revise proposed § 438.320(b)(6) to include the right to correct inaccuracies, and to append the record if there was a disagreement.

*Response:* We agree with the commenters that enrollees should also have the right to receive copies of medical records, and have addressed the commenters concerns in § 438.224 (Confidentiality and accuracy of

enrollee records), discussed in section II. D. 8. below. In response to this comment, we have provided in § 438.100(b)(7) for the right to receive a copy of records, and request that they be amended or corrected, and have referenced § 438.224. We have not, however, required that enrollees be able to receive a copy of his or her medical record at no cost, because we believe that providers may incur some costs in responding to numerous requests to photocopy medical records and related documents.

*Comment:* Some commenters suggested that we provide additional detail on the specific relevant sections of the laws cited in proposed § 438.320(c) and citations for the regulations implementing these provisions.

*Response:* In response to this comment, we have included additional detail, including citations to implementing regulations in some cases, in § 438.100(d) of the final rule with comment period.

*Comment:* A commenter recommended that the text of proposed § 438.320(c), and not just the preamble, make clear the point that State Medicaid Agencies are not expected to take over the enforcement of State and Federal laws not within their jurisdiction.

*Response:* We believe that it is clear from the preamble to the proposed rule and to this final rule with comment period, that we are not expecting States to take over the enforcement activities that are not within their jurisdiction. However, as noted above, in order to more narrowly define the Federal and State laws that are being referenced, we have added "applicable" to the regulation.

*Comment:* A number of commenters believed that enrollees should be free to exercise their rights without fear from reprisal from the MCO or PHP in which they are enrolled, including the right to refuse services, without the loss of other desired services or disenrollment.

*Response:* We agree with commenters, and in response to this comment have added language at § 438.100(c) to ensure that an enrollee's free exercise of his or her rights does not adversely affect the way the MCO, PHP, PCCM, their providers, or the State agency treats the enrollee.

*Comment:* Commenters requested that we include explicit statements of additional enrollee rights, including the right to: (1) Fully participate in the development of their plan of care and treatment decisions; (2) participate in research or experimentation only with informed, voluntary, written consent; (3) be free from physical, verbal, sexual,

or psychological abuse, exploitation, coercion, or neglect; and (4) be treated in a humane environment that affords reasonable protection from harm and ensures privacy.

*Response:* Section 438.100(b)(6) provides enrollees with the right to participate in decisions regarding their health care, which we believe would include plans of care, treatment decisions, or participation in any research or experimentation. With respect to the right to be free from abuse, exploitation, or neglect, or to be treated in a humane environment that affords protection from harm and ensures privacy, we believe that these rights are inherent in the right under § 438.100(b)(4) to be treated with respect and dignity and the confidentiality rights in § 438.224, discussed in section II.D.9. below. Further, we have revised proposed § 438.306(e)(3)(iii)(now § 438.208(f)(5) to require that treatment plans, developed for individuals who are pregnant or who have special health care needs, are to be developed "with enrollee participation".

*Comment:* Commenters suggested that we add as a right that beneficiaries have the right to be free from seclusion, physical or chemical restraints, used by staff as a means of coercion, discipline, convenience or retaliation.

*Response:* We agree that this is a fundamental right, and in response to this comment, have added it to the requirements of § 438.100 in the final rule with comment period.

*Comment:* Commenters proposed the inclusion in proposed § 438.320 of a number of additional rights in the following areas: information standards, complaint and grievance procedures, quality assurance, service authorization, choice, disenrollment, emergency services, access and capacity, and benefits and coverage.

*Response:* As discussed previously, § 438.100 was intended to put forth a basic and general fundamental set of rights. More detailed and specific enrollee rights are articulated in greater detail in other sections of the regulation. The suggested changes in the areas of information standards, complaint and grievance procedures, quality assurance, service authorization, choice, disenrollment, emergency services, access and capacity, and benefits and coverage are more fully detailed in the corresponding provisions of the regulations which are dedicated to these respective topic areas. Therefore, the specific suggestions offered by the commenters were considered in the context of these other provisions. For example, the comment that the enrollee has the right to receive timely and

adequate advance written notice of any decision to deny, delay, reduce, suspend, or terminate medical services is addressed in §§ 438.210(c) and 438.404.

#### 9. Confidentiality (Proposed § 438.324)

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

In proposed § 438.324, consistent with the regulations at part 431 subpart F, we proposed that the State ensure, through its contracts with MCOs and PHPs, that each MCO and PHP (1) maintain records and information (in oral, written, or electronic format) in a timely and accurate manner, (2) safeguard the privacy of any information that identifies a particular enrollee by ensuring that original records are released only in accordance with Federal or State law, or court orders or subpoenas; copies of records and information are released only to authorized individuals; and unauthorized individuals do not gain access to, or alter, patient records, (3) protect the confidentiality and privacy of minors, subject to applicable State and Federal laws, (4) ensure that enrollees have timely access to records and information that pertain to them, and (5) abide by all Federal and State laws regarding confidentiality and disclosure of mental health records, medical records, other health information, and any information about an enrollee. The requirements we proposed in this section are consistent with the right to confidentiality of health information supported by the CBRR.

We received numerous comments in response to this section requesting that we include specific guidelines and address substantive issues in more detail. Prior to addressing these comments, we must first clarify our original intent in proposing this section. We included this section in order to ensure that MCOs and PHPs would be held responsible for safeguarding the confidentiality of enrollee information. We did not intend to impose specific guidelines for the use and disclosure of enrollee information. We recognized that there are many different State and Federal laws that specifically address confidentiality and it was not our intent to interfere with these laws. Several States have enacted strong privacy

protections that will continue to apply to MCOs and PHPs participating in the Medicaid program. In addition, the Secretary is currently developing a final regulation that will address confidentiality of health information at the Federal level in accordance with section 264 of the Health Insurance Portability and Accountability Act (HIPAA) (Public Law 104–191). In order to remain consistent with existing laws and regulations, as well as the forthcoming HIPAA regulation, we only included general requirements in this section.

*Comment:* We received two comments on proposed § 438.324(b)(1), which provided that original medical records must be released only in accordance with Federal or State law, or court orders or subpoenas. One commenter recommended that we revise the regulation to require that both the original and copies of patient medical records be released to Medicaid fraud control units and other law enforcement agencies. Another commenter suggested that this provision conflicts with requirements in § 431.306(f). That section requires that when a court issues a subpoena for a case record, the Medicaid agency must inform the court of the applicable statutory provisions, policies, and regulations restricting the disclosure of information. The commenter believed that in light of this existing requirement, the release of information should not be required through the use of subpoena power alone.

*Response:* The requirement proposed in § 438.324(b)(1) was intended to highlight the importance of ensuring the integrity and availability of original medical records. If an MCO or PHP receives a request for an enrollee's information, we would expect that the MCO or PHP would typically only release a copy of that information. However, as the commenters note, the proposed language could create confusion regarding the requirements for this subset of identifiable health information, and how it differs from the protections afforded to other such information. It was our intent that originals should only be released in accordance with applicable laws. Therefore, in order to more accurately reflect this intent, in § 438.224(c) of the final rule with comment period, we have deleted the specific reference to court orders and subpoenas, and eliminated the provision singling out original records from other health information. We rely on the State, the MCO, and the PHP to make appropriate decisions regarding disclosure of copies versus originals, based on the specific

circumstances of each disclosure. Procedures to be followed in response to a subpoena are addressed by the requirement (in the parenthetical in the first line of § 438.224) that MCOs and PHPs must follow subpart F of part 431.

*Comment:* We received several comments in response to proposed § 438.324(b)(2), which requires that copies of records and information from MCOs be released only to authorized individuals. Several commenters believed that we did not define the term “authorized individual” or “authorized representative” in the proposed rule, and that it was thus unclear who may receive medical records from an MCO or PHP. Other commenters found that this provision did not include necessary language addressing inappropriate disclosures of information within an MCO or PHP. Specific recommendations made by commenters were that the definition of “authorized individual” include family members, guardians, and legally authorized representatives.

*Response:* We recognize that the use of the term “authorized” in this section has generated some confusion. It was our expectation that the MCO or PHP would establish and follow procedures to specify who would be “authorized” to receive confidential enrollee information, and that these procedures would reflect applicable Federal and State law. We recognize that the term could be interpreted in other ways. Therefore, in § 438.224(b) and (c) of the final rule with comment period, we have revised the language to make more explicit our intent as to what would constitute an authorized disclosure, and in doing so, we removed the term “authorized individual.”

*Comment:* Several commenters requested that the proposed rule be strengthened with regard to limiting the flow of identifiable data. Some commenters suggested that we require MCOs and PHPs to use non-identifiable data whenever identifiable data is not needed to complete a task. Some commenters stressed that the final rule with comment period should also include additional safeguards to protect a beneficiary's sensitive health information, so that the disclosure of identifiable data can be used only for activities which MCOs or PHPs and providers need for legitimate purposes. One commenter recommended that an MCO or PHP should be required to define when identifiable data is necessary for a particular activity. In addition, several commenters recommended that we include technical standards in the regulations to address electronic and paper records. Finally, other commenters suggested we include

incentives in the regulation for MCOs and PHPs to use non-identifiable data, and include a requirement for MCOs and PHPs to justify the use of identifiable data needed for an activity.

*Response:* These comments describe many standard procedures that should be in place for protection of health information and ones which MCOs and PHPs will likely put in place to comply with the requirements of this section. However, consistent with the above discussion of our purpose in writing this section of the rule, our intent was not to create specific technical mechanisms (including standards regarding the use of identifiable and non-identifiable data) that MCOs and PHPs must have to safeguard data. As discussed previously, we proposed this section because we believe that MCOs and PHPs should have safeguards in place (including, as appropriate, the ones suggested by the commenters) to ensure that patient-identifying information is used for legitimate purposes. To underscore our intent not to create new technical standards, we have deleted sections of the proposed rule (§ 438.224(d) and (e)) that we believe are already covered by the requirements at Subpart F of part 431 and which may have inadvertently lead readers to believe that we were attempting to create new standards.

Therefore, we have not revised this section to include technical standards for securing electronic and paper records, or to impose specific requirements on MCOs and PHPs as to when they must use non-identifiable data. However, in response to the broad concern expressed by commenters about the different ways patient-identifying information might be used or disclosed to others, we have added a new requirement at § 438.224(e) that requires the State to ensure that each MCO and PHP establish and implement procedures to ensure that enrollees receive, upon request, information pertaining to how MCOs and PHPs use and disclose identifiable information.

*Comment:* We received several comments in support of proposed § 438.324(c), which requires MCOs and PHPs to have procedures to protect the confidentiality and privacy of minors, subject to applicable Federal and State law. Several commenters indicated that a major obstacle to minors obtaining needed health care is due to concerns about the lack of confidentiality. They suggested that we maintain the proposed regulation and preamble, which they believe is clear in that it refers to services and treatment which minors can obtain without parental consent and what information can be

released to a parent upon request. They also suggested that family planning, mental health, and substance abuse services be addressed by the MCO's or PHP's procedures.

In contrast, several commenters contended that all information about a minor should be released to parents barring a court order stating otherwise. One commenter focused on the developmentally disabled population, and believed that copies of medical records, treatment options, and confidential information relevant to the receipt of medical services must be communicated to a family member or guardian prior to proceeding with the proposed treatment. Other commenters suggested that the final regulation stress confidentiality of family planning services for adults as well as minors.

*Response:* Section 438.324, as a whole, was intended to ensure that MCOs and PHPs have procedures to protect the confidentiality of all enrollees. We proposed a specific provision addressing the confidentiality of minors in recognition of the large number of enrollees under age 18. It was not our intent to interfere with Federal and State laws that address the confidentiality of minors. Therefore, in the final rule with comment period, we have removed the reference to minors because we intend the term "enrollee" to encompass all enrollees.

*Comment:* Several commenters recommended that we revise proposed § 438.324(d) to clarify that, in addition to enrollees, authorized representatives of enrollees must have timely access to records and information. One commenter recommended that we revise this provision to require MCOs to provide enrollees with access to their records within 24 hours (excluding weekends and holidays); and to obtain photocopies. Another commenter pointed out that under their State law, the Medicaid agency is not required to provide timely access to records if the beneficiary is currently under civil or criminal investigation. Another commenter questioned this provision, and suggested that under patient/doctor confidentiality, the patient holds the privilege of confidentiality, not the provider. Further, the commenter contended that patients are the owners of their medical records and always have had the opportunity to review and correct errors. The commenter wondered what role an MCO or PHP should play in enforcing patient rights. Several commenters also suggested that enrollees be able to receive copies of their records. Commenters also recommended that enrollees be able to

request amendments or corrections to their records.

*Response:* We proposed § 438.324(d) to ensure that MCOs and PHPs have orderly procedures to enable an enrollee to access his or her medical records in a timely manner. It was not our intent to interfere with Federal or State laws governing access to medical records or other information. While we have not included specific time lines, exceptions, and rules in this provision, we have, in § 438.224 of the final rule with comment period, clarified the language to more clearly reflect our intent. We have replaced the general term "access" with more specific language in § 438.224(f) that requires the State to ensure that each MCO and PHP has procedures to ensure that the enrollee can request and receive a copy of his or her records and information and that the enrollee may request amendments or corrections.

*Comment:* Several commenters questioned proposed § 438.324(e), which required MCOs and PHPs to abide by all Federal and State laws regarding confidentiality and disclosure of mental health records, medical records, other health information, and any information about an enrollee. One commenter believed that it was redundant for the Federal government to regulate compliance with State law. Another commenter contended that Federal requirements should preempt State and local confidentiality laws. This commenter suggested that requiring multi-state Medicaid MCOs to adopt different State confidentiality procedures in each State was unduly burdensome, and serves no legitimate purpose. This commenter recommended that confidentiality requirements be uniform and pre-empt State and local confidentiality laws.

*Response:* It was not our intent to preempt or supersede other Federal or State laws governing confidentiality. Rather, we intended to create a baseline of protections for Medicaid managed care enrollees that is consistent with other applicable laws. We continue to believe that it is important to highlight other applicable laws and to require that States ensure that MCOs and PHPs have procedures that comply with these laws; and therefore, we have retained this requirement. With respect to the commenter urging that Federal requirements be established that would pre-empt State law, we believe that this would be inconsistent with the structure of the Medicaid program, which is a State-run program under which States are granted discretion to establish their own approach. While a national MCO or PHP may have to follow different rules in different States under the Medicaid

program, this would be equally true for their commercial lines of business in different States.

*Comment:* We received several comments supporting proposed § 438.324(e). Several commenters appreciated that we made a distinction between medical records, and the sharing of necessary information between physical health providers and mental health and substance abuse providers. While some commenters recommended that the language be maintained, other commenters recommended that we clarify the regulation to require compliance with Federal rules concerning confidentiality of substance abuse treatment and to emphasize the primacy of 42 CFR Part 2, Confidentiality of Alcohol and Drug Abuse Records.

*Response:* Under this provision, MCOs and PHPs must abide by all Federal and State laws regarding the confidentiality of health information, including laws pertaining to the confidentiality of substance abuse treatments. We have clarified our final rule with comment period to require that the State must ensure that, for medical records and any other health and enrollment information that identifies a particular enrollee, the MCO or PHP establishes and implements procedures to abide by all Federal and State laws regarding confidentiality and disclosure. We believe that this provision, as stated, includes existing laws that govern confidentiality and disclosure of medical records, mental health records, substance abuse records, and any other identifiable information.

*Comment:* A commenter expressed concern that § 438.324 does not address how confidentiality policies will affect the use of patient information in research. The commenter stressed that studies of disease, epidemiology, therapy, and health services depend on access to patient records, including records for Medicaid managed care enrollees. The commenter recommended that we address the issue of research in the final rule with comment period so that medical records are available through a process that meets confidentiality concerns but is not unduly burdensome.

*Response:* The use and disclosure of health information for research is an extremely complicated issue. We do not believe that this regulation is the appropriate vehicle to specify when such uses and disclosures are appropriate and what specific safeguards must be in place to protect that information. We do require the State to ensure that MCOs and PHPs safeguard the confidentiality of any