

plans. And another commenter said that it is not usual practice for States to track providers' hours of operation if they do not treat Medicaid patients. One commenter said that the requirement should be that services are available and accessible to the same extent that they are for FFS beneficiaries or the general public. Another commenter supported the provision as written.

Response: In the final rule we have retained the provision related to hours of operation as proposed. The purpose of this requirement is to make certain that Medicaid enrollees have the same access to providers as do enrollees of other payers. We believe that the provision is appropriate and is enforceable by MCOs, PIHPs, and PAHPs through their contracts with providers. Access can be monitored by the State or the MCO, PIHP, or PAHP by reviewing patient appointments or by monitoring enrollee grievances. The commenter who stated that States do not track providers' hours of operation if they do not treat Medicaid patients misunderstood the provision. It applies only to providers in Medicaid managed care networks. For those providers who serve only Medicaid patients, we set the hours of operation for FFS Medicaid patients as the standard that must also be applied to managed care enrollees.

Comment: One commenter suggested that proposed § 438.204(b)(3) should not require States to "continuously" monitor hours of operation, as this represents an increased burden on States. Rather the regulation should require that States monitor for this requirement "regularly".

Response: We agree that the use of the term "continuously" may be confusing and that "regularly" better conveys our intent. We have revised § 438.204(b)(3) of the regulation to reflect this change.

Comment: Many commenters said that the requirement that MCOs participate in States' efforts to promote the delivery of care in a culturally competent manner is not sufficient. They believe that systems of care must be designed to be respectful of and responsive to cultural and linguistic needs in order to provide equal access to quality health care. Failure to provide information about treatment options in a culturally sensitive way could affect patient compliance, lead to declines in the patient's health, and escalate costs.

Response: We agree that health care needs to be delivered in a culturally competent manner for it to be most effective. However, in the final regulation we have retained the provision of the proposed rule, that MCOs, PIHPs, and PAHPs participate in State efforts to promote the delivery of

care in a culturally competent manner, because we believe that it is through this requirement that MCOs, PIHPs, and PAHPs, will gain the knowledge and experience to provide culturally competent care.

Comment: Several commenters supported the approach taken in the NPRM regarding cultural competency and believe that the State is in the best position to lead initiatives on cultural competency. This allows States to advance initiatives crossing FFS and managed care.

Response: We agree with the commenters and have retained this provision in the final rule.

Comment: Many commenters said that MCOs, all PHPs, and PCCMs should be required to provide services in a culturally competent manner because, as recipients of Federal funds, they are all required to do this.

Response: This regulation requires MCOs, PIHPs, and PAHPs to participate in State efforts to promote cultural competency in order to comply with the requirements of section 1932 of the Act. It does not address requirements of other statutes that might also apply.

Comment: One commenter objected to the Medicaid rule having what he viewed as weaker requirements relating to cultural competency than the Medicare+Choice rule. He noted that in the preamble to that rule CMS stated that the M+C provisions are consistent with title VI of the Civil Rights Act, recommendations from the President's Race Initiative, and the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry.

Response: Medicaid is a State/Federal program and States retain responsibility for much of the program and operational policy of their programs. We believe that States can best decide how to advance cultural competency in their managed care programs. We are working with the Medicare program to develop tools for managed care organizations to use to improve the delivery of culturally competent health care. When these tools are available, we will share them with States so that they can use them at their option.

Comment: One commenter suggested that the new standards developed by the Office of Minority Health (National Standards on Culturally and Linguistically Appropriate Services) be referenced as a more detailed document that clarifies the regulatory provision.

Response: We agree that these guidelines are a valuable tool and we encourage States to review them and consider their use.

Comment: Many commenters suggested the addition of a provision to prohibit discrimination by providers toward Medicaid enrollees. One commenter noted that the President's Commission on Consumer Protection and Quality in the Health Care Industry opposed discrimination on the basis of source of payment.

Response: We have decided not to include a provision in the regulation to prohibit providers from discriminating against Medicaid enrollees. We do not believe that this provision is needed in this regulation. States remain responsible for ensuring Medicaid enrollees adequate access to providers and are in the best position to choose the mechanisms they believe will be effective to ensure this result. We also have a provision in the regulation that requires that network providers offer Medicaid enrollees the same hours of operation offered to commercial enrollees. We believe that this requirement will help ensure equal access for Medicaid enrollees to providers.

Comment: Many commenters recommended inclusion of a provision to require States that limit freedom of choice to comply with the requirements of § 438.52.

Response: The requirements related to freedom of choice at § 438.52 apply in accordance with the provisions of that section. It is unnecessary to reiterate or cross reference those requirements in this section.

5. Assurances of Adequate Capacity and Services (Proposed § 438.207)

Under the authority of section 1932(b)(5) of the Act, proposed § 438.207(a) required that the MCO and PIHP provide the State with adequate assurances that the MCO or PIHP has the capacity to serve the expected enrollment in the service area. Proposed § 438.207(b) required that documentation submitted to the State must be in a format set by the State and acceptable to CMS and must demonstrate that the MCO or PIHP offers an appropriate range of services, including preventative services, primary care services, and specialty services. The MCO and PIHP was also required to document that it maintains a network of providers sufficient in number, mix, and geographic distribution.

Section § 438.207(c) specified when documentation must be provided including (1) at the time the MCO or PIHP enters into a contract with the State, and (2) whenever there has been a significant change in the MCO's or PIHP's operations that would affect adequate capacity and services such as

changes in services provided, benefits, geographic service areas, payments, or enrollment of a new population.

Comment: One commenter recommended that this section apply to dental plans.

Response: We agree that it is important for PAHPs, including dental plans, as well as MCOs and PIHPs to have adequate provider networks and to provide the State with assurances as to the adequacy of their networks. Therefore, in the final rule, we extend the provisions of this section to PAHPs. We note that the provider network for PIHPs and PAHPs need only include provider types necessary to provide the services included in their contracts.

Comment: One commenter stated that MCOs and PIHPs need to contract with the appropriate number and mix of pediatric-trained specialists and tertiary care centers for children in order to ensure that they have adequate capacity to serve their expected enrollment. If a plan fails to contract with an adequate number of these providers, the plan should be required to provide these services out of network at no additional cost.

Response: As we stated earlier in this preamble, we have chosen not to specify types of specialists or other providers that health plans must contract with in order to meet the requirements of the regulation. Rather, in § 438.206(b)(1), we retain the general requirement that provider networks must be adequate to provide adequate access to all services covered under the contract. In § 438.206(b)(4), we provide that necessary medical services not available within the network, must be covered by the MCO, PIHP, or PAHP out of network.

Comment: One commenter suggested that this provision be revised to require the State to ensure, through its contracts, that MCOs provide a full range of psychiatric services and have a sufficient number of psychiatrists participating in the plan.

Response: As stated above, in the final rule we are not specifying specific provider types needed by MCOs, PIHPs, and PAHPs, but rather providing a general requirement that the networks be sufficient to provide adequate access to covered services to all enrollees.

Comment: One commenter disagreed with CMS' decision to interpret "adequate assurances" to require extensive documentation suggested in the preamble. The commenter believes that extensive and detailed data are of little use in determining the adequacy of the provider network and that network deficiencies are often found when an enrollee changes

primary care physicians, calls enrollee services, or files a grievance.

Response: We continue to believe that it is necessary and appropriate for the regulation to require that each MCO, PIHP, and PAHP document that it has adequate provider capacity to provide necessary medical services. The heading for section 1932(b)(5) of the Act is "Demonstration of Adequate Capacity and Services." We believe that the MCO, PIHP or PAHP cannot demonstrate that it has the capacity to serve its expected enrollment without providing documentation. In addition, we require that the State have documentation to support its certification to the Secretary under § 438.207(d). This documentation is required prospectively to avoid problems that may otherwise not be detected until an enrollee complains or takes other steps to address a situation caused by the lack of an adequate provider network.

Comment: Many commenters objected to the omission of a provision to require MCOs and PIHPs to have in place policies and procedures to respond to situations in which there is an unanticipated need for providers with particular types of expertise or an unanticipated limitation on the availability of such providers. The commenters believe that such a provision is necessary to meet the statutory requirement for a quality strategy that includes access standards to ensure that covered services are available within reasonable timeframes and in a manner that ensures continuity of care and adequate primary care and specialty care. Another commenter supported the omission of such a provision.

Response: We have not included a provision in the final rule to require MCOs, PIHPs, and PAHPs to have policies and procedures in place to respond to situations in which there is an unanticipated need for providers or a limitation on the availability of needed providers. We again rely on the requirement in § 438.206(b)(1) and § 438.206(b)(4) that MCOs, PIHPs, and PAHPs must have adequate provider networks or, if the MCO, PIHP, or PAHP is unable to provide them, must adequately and timely provide these services out of network.

6. Coordination and Continuity of Care (Proposed § 438.208)

Proposed § 438.208 contained provisions specifying how the care of Medicaid beneficiaries enrolled in MCOs and PIHPs is to be provided in order to promote coordination and continuity of care, especially with

respect to individuals with special health care needs. In proposed paragraph (a) we allowed for two exceptions to some of these coordination and continuity of care provisions. In the first instance, provisions pertaining to some screening, assessment and primary care requirements would apply to PIHPs as the state determines appropriate, based on the scope of the PIHP's contracted services and the way the state has organized the delivery of managed care services. In the second instance, for Medicaid-contracting MCOs that serve certain Medicaid enrollees also enrolled in Medicare+Choice plans and receiving Medicare benefits, the State similarly determines, based on the services it requires the MCO to furnish to dually eligible enrollees, the extent to which the MCO must meet certain screening, assessment, referral, treatment planning, primary care and care coordination requirements. In proposed paragraph (b) we put forth requirements for the state Medicaid agency to identify certain enrollees with special health care needs and to further identify these enrollees to its enrollment broker, if applicable, and contracting MCOs and PIHPs. In proposed paragraph (c) we specified requirements for the screening and assessment of individuals with special health care needs. In proposed paragraph (d) we specified requirements for referrals and treatment plans for MCO and PIHP enrollees determined to have ongoing special conditions that require a course of treatment or regular care monitoring. These requirements addressed access to specialists and the development of treatment plans. In proposed paragraph (e) we specified requirements pertaining to MCO and PIHP care coordination programs, including requirements that these programs: provide each enrollee with an ongoing source of primary care, coordinate each enrollee's health care services, appropriately share with other MCOs and PIHPs the results of any screenings or assessments in order to prevent unnecessary burden on the enrollee, and protect enrollee privacy and confidentiality.

One commenter heartily endorsed § 438.208 of the proposed rule and urged CMS to preserve it in the final rule and monitor for compliance with it. However, many other commenters recommended that this section of the regulation include more specific or stronger requirements for States and managed care entities, particularly with respect to the care of individuals with special health care needs. Most commenters offered specific

recommendations for changing this section of the regulation. We agree with these comments and have revised § 438.208 as discussed below, in response to these comments.

Identification of "At Risk" Individuals

Comment: Many commenters recommended that we require States to identify individuals "at risk" of having special health care needs. Many of these commenters identified these individuals as: children and adults who receive SSI benefits; children in foster care; enrollees over the age of 65; enrollees in relevant, state-established, risk-adjusted, higher-cost payment categories; and any other category of recipients identified by CMS. A few commenters recommended that we allow States to use additional State-identified categories of people who are "at risk" for having special health care needs. One commenter stated that children under age 2 and pregnant women should be identified as being "at risk" of having special health care needs. Another commenter stated that children enrolled in a State's Title V program for children with special health care needs should be included in a regulatory definition of persons "at risk" of having special health care needs.

Response: The proposed rule at § 438.208(b) required States to identify individuals "with" (as opposed to individuals "at risk of having") special health care needs. For several reasons, we believe it is appropriate to retain this distinction in this final rule, and not additionally require States to identify individuals "at risk of having" special health care needs. First, States already well appreciate the increased risk that certain populations (for example, children and adults who receive SSI benefits; children in foster care; enrollees over the age of 65; and enrollees in relevant, state-established, risk-adjusted, higher-cost payment categories) have for needing special services or high levels of service. States can also readily identify these individuals. We do not believe that regulations are necessary to call States' attention to these individuals or that States need encouragement or assistance in identifying these individuals. To additionally require States to create a new administrative mechanism in order to categorize as "at-risk" those individuals who are already well-known to State Medicaid agencies and can be easily identified, would dilute the attention paid to individuals who actually have special health care needs. Instead, in § 438.208(c) of this final regulation we require States to focus their attention more closely on

identifying individuals who actually have special health care needs. Second, the concept of "at risk" of having special health care needs (beyond the categorical groups discussed above) is widely recognized as difficult to put into operation. Well-known researchers in this field have explicitly declined to address the concept of "at risk" when developing screening tools to identify children and adults with special health care needs. Because the science in this area is still elementary, we believe it is premature to ask States to implement this concept at this time. Finally, we note that commenters did not agree among themselves on which populations should be included in a category of "at risk of having" special health care needs. For these reasons, in this final rule we do not require States to identify individuals "at risk" of having special health care needs.

Definition of Individuals With Special Health Care Needs

Comment: Many commenters recommended that proposed § 438.208(b) should specify certain groups of individuals as "having" special health care needs. Many of the recommended groups were identical to the groups identified by other commenters as individuals who should be considered "at risk" of having special health care needs. Specifically, the following groups were recommended by many commenters: children and adults who are receiving SSI benefits; children in foster care; enrollees over the age of 65; enrollees in relevant, state-established, risk-adjusted, higher-cost payment categories; and any other category of recipients identified by CMS. Many commenters also identified children under age 2 and other enrollees known by the State to be pregnant or having other special health care needs as categories of persons requiring special attention and about whom the State should notify the MCO/PIHP of their having a special health care need.

Other commenters stated that proposed § 438.208(b) should specify a threshold or minimum definition of persons with special health care needs. One commenter stated that the definition should be as follows, "Individuals with special health care needs include adults and children who daily face physical, mental, or environmental challenges that place at risk their health and ability to fully function in society (for example, individuals with mental retardation or serious chronic illnesses, pregnant women, children under the age of 7, children in foster care or out-of-home placement, and individuals over age

65)." Other commenters stated that children with special health care needs should be defined consistent with the Department's Maternal and Child Health Bureau's definition which reads, "Children with special health care needs are those who have or are at elevated risk for chronic physical, developmental, behavioral, or emotional conditions and who also require health and related services of a type or amount not usually required by children."

In contrast, several commenters expressed support for allowing States to define which populations need to be identified and how to identify them. One commenter asked us to confirm that the proposed rule would allow States the flexibility to define "individuals with special health care needs." Another commenter stated that the requirement for States to identify enrollees with special health care needs and identify these enrollees to its enrollment broker (if applicable) and MCOs should be eliminated. The commenter stated that this requirement is neither feasible nor practical because (1) the State does not have a mechanism to identify persons with special health care needs—other than individuals who receive SSI; (2) enrollees may not choose to reveal information about their health, which should be held between the enrollee and his or her provider, and possibly the health plans; and (3) the appropriate mechanism for identifying a person with a special health care need is through an assessment which is required elsewhere in the regulation.

Response: In our report to the Congress, Safeguards for Individuals with Special Health Care Needs Enrolled in Medicaid Managed Care, dated November 6, 2000, we identified, "the presence or increased risk of disability," as a shared characteristic of populations with special health care needs. We identified 6 populations as examples of groups that had an increased prevalence or risk of disability: (1) Children with special health care needs; (2) children in foster care; (3) individuals with serious and persistent mental illness and/or substance abuse; (4) individuals who are homeless; (5) older adults with disabilities; and (6) non-elderly adults who are disabled or chronically ill with physical or mental disabilities. However, this same report, while calling these groups to the attention of States, recognized the difficulty that States face in identifying not just population groups that have an increased prevalence or risk of disability, but in identifying *individuals* who actually have a special health care need. Because of this, we entered into a contract with

the Foundation for Accountability (FACCT) to produce a reference manual for State Medicaid agencies and other interested parties. The manual will present and discuss reliable and valid approaches to identifying individuals who have special health care needs. In addition, we asked FACCT to develop a new screening tool that can be used to help identify adults with special health care needs. This adult screener has now been developed and tested. It, along with other valid and reliable approaches to identifying adults and children with special health care needs, will be included in the reference manual for States. Because this research conducted for us by FACCT has documented that there are different ways (with varying degrees of sensitivity, specificity, and resource implications) to identify individuals with special health care needs, we do not believe it appropriate to require one approach, and thereby one definition. Rather, we encourage States to review these different approaches, in conjunction with beneficiaries and stakeholders, as a part of their State quality strategy developed under § 438.204, and select the approach or approaches to identifying individuals with special health care needs that best complements the design of the State's Medicaid program and managed care initiatives.

Comment: Many commenters recommended that States also be required to identify enrollees with special health care needs to PAHPs and PCCMs.

Response: We agree with the commenters and we have revised § 438.208(c) to include PAHPs. However, we have not applied these provisions to PCCMs because, as noted elsewhere in this preamble, the statutory provisions of the BBA, which authorized these quality requirements, apply only to prepaid, capitated forms of managed care.

Screening and Assessment

Comment: Many commenters expressed confusion over the use of the words "screening" and "assessment" in § 438.208(c) of the proposed rule. One commenter erroneously stated that the provisions for screening and assessment of special needs individuals were not contained in the proposed regulation. Many commenters stated that the proposed rule did not differentiate between the words, "screening" and "assessment." One commenter urged us to specify that an initial screen must be sufficient to identify individuals with special health care needs and facilities that can meet those needs, and that a health assessment must be

comprehensive and include a physical examination.

Response: We agree that the proposed rule provisions at §§ 438.208(b) and (c) respectively calling for "State responsibility to identify certain enrollees with special health care needs," and "Screening and assessment" are confusing, in part because of some redundancy. The proposed rule intended to convey that identification of individuals with special health care needs should be accomplished through some form of screening. Therefore, we have revised § 438.208(c) and replaced the word "screening" with the words, "mechanisms to identify." This change is supported by information from several experts in screening who reminded us that screening tools by their very nature are not perfect, and that subsequent follow-up through a more intensive assessment is needed in order to better determine if an individual's special health care needs actually require a course of therapy or monitoring. We also made other changes to the organization of this section in order to better distinguish the identification activity from the assessment function.

However, we did not, as requested by one commenter, specify that an initial screen (identification mechanism) must be sufficient to identify facilities that can meet an individual's special needs. We believe that determining appropriate facilities, when care in a facility is needed, should not be based on the results of a screen or identification mechanism, but upon an assessment and ongoing communication between the patient and his or her health care provider(s). We further did not explicitly state in § 438.208(c)(2) that the enrollee's health assessment must be comprehensive because we believe that "comprehensive" is subject to varying interpretations, and therefore is not readily able to be reliably monitored or consistently enforced by CMS. Further, the provisions in § 438.208(c)(2) already require assessments to "identify any ongoing special conditions of the enrollee that require a course of treatment or regular care monitoring" and that the assessment mechanisms must use appropriate health care professionals. We also have not required that the assessment include a physical examination, because we believe that for some individuals, a course of treatment or regular care monitoring might be determined to be unnecessary without a physical examination. We therefore defer to States to set further standards for assessment, noting that these standards for identification and

assessment are included as part of a State's quality strategies under § 438.204. Therefore, any State standards for assessment will be developed with the input of Medicaid beneficiaries and other stakeholders. We believe that any greater specificity in requirements pertaining to assessments should be developed as a part of this process.

Comment: One commenter stated that proposed § 438.208(c) failed to quantify what will be substantial burden associated with the requirements for screening and assessment.

Response: It would be very difficult to more accurately quantify the overall impact and burden of this provision of the regulation because of the variation in State programs and how States will choose to implement these provisions. In § 438.208(c) of the final rule we have retained State flexibility in identification, assessment, treatment planning for individuals with special health care needs, and with respect to how provisions will be applied to MCOs, PIHPs, and PAHPs that serve dually eligible enrollees. Because of our desire to allow States to have this flexibility, and the variations in practice that currently exist within the managed care industry, it is not possible to more accurately quantify the burden of these provisions.

Comment: One commenter stated that it could not comply with the requirement stated in the preamble to proposed § 438.208 that in instances when an MCO is not able to meet requirements for screening or assessment for an individual enrollee, because, for example, it is not possible to contact the enrollee or the enrollee refused to respond to the MCO, that the MCO ensure that the reason why the enrollee could not be screened or assessed be documented in the enrollee's medical record. The commenter stated that it does not own its contracted providers and does not have the ability to enforce the requirement.

Response: We disagree with the commenter. We believe that MCOs can include this as a requirement in their written agreements with participating providers. However, the commenter is incorrect in indicating that we have required this in the preamble. Rather, the preamble states that an MCO or PIHP "should" take steps to ensure that this information is documented.

Identification

Comment: One commenter asked us to clarify CMS's goal with respect to individuals with special health care needs given the commenter's

observation that these individuals will have great variability in the coverage and care they will receive between States. One commenter stated that § 438.208(b) of the proposed rules did not emphasize clearly the importance of identifying all persons with special health care needs. A few commenters expressed concern that the proposed rule did not contain provisions that would require the State to have a strategy to identify enrollees with special health care needs. One commenter stated that the regulation does not contain requirements that MCOs have procedures in place to identify individual enrollees with serious and multiple medical conditions, "whether they be physical-health, mental health, or substance-abuse related in nature." The commenter maintained that CMS must include these provisions. A few commenters stated their support for a requirement that MCOs must screen all enrollees to detect special health care needs. A few commenters also stated that each MCO and PHP should be required to implement a mechanism to identify enrollees who develop special health care needs after they enroll in the MCO or PIHP. One commenter asked if CMS would be monitoring States with respect to the requirement in § 438.208(b) pertaining to State's responsibility to identify certain enrollees with special health care needs, and if so, if the monitoring will use a tool that has been developed for CMS by FACCT.

Response: We have revised § 438.208(c)(1) and (c)(2) to clarify our goals with respect to individuals with special health care needs and emphasize the importance of identifying the individuals. We did not, as one commenter directed, require MCOs to have procedures in place to identify individual enrollees with serious and multiple medical conditions, "whether they be physical-health, mental health, or substance-abuse related in nature," because we believe that the State should be the one to consider the issues as it develops its mechanism to identify individuals with special health care needs, as part of its quality strategy, and with the input of Medicaid recipients and other stakeholders. In our revisions, we also did not require each MCO and PIHP to implement a mechanism to identify enrollees who develop special health care needs after they enroll in the MCO or PIHP. We believe that the extent to which this should occur should be considered by the States in the context of the States' overall strategy and mechanism for identifying

individuals with special health care needs. Finally, we affirm that CMS will be monitoring States with respect to the requirement to identify enrollees with special health care needs. However, we note that the tool that has been developed for CMS by FACCT is a screening tool, not a monitoring tool. Additionally, it is one of several screening tools that will be shared with States for their discretionary use. Therefore, the FACCT tool is not likely to be used by CMS for monitoring activities.

Assessment

Comment: One commenter stated that the proposed rule does not contain provisions that MCOs assess the condition of individual enrollees with serious and multiple medical conditions. The commenter maintained that CMS must include these provisions. Another commenter stated that the regulation should specify groups of beneficiaries for whom special health assessments should be required so that there will not be significant variation in access and quality of care among the various state Medicaid programs. In contrast, other commenters expressed support for the provisions of the regulation pertaining to assessment of people with special health care needs and for allowing states and plans to develop timelines and procedures that meet the needs of their enrolled population. Still other commenters further expressed support for allowing States to determine how to assess individuals with special health care needs.

Response: The final regulation contains requirements that MCOs (and also PIHPs and PAHPs at the discretion of the State) assess individual enrollees with special health care needs. We believe that individuals with "serious and multiple medical conditions" are included in the concept of special health care needs, and intend that States' mechanisms to identify individuals with special health care needs will identify individuals with serious and multiple medical conditions. However, in § 438.208(c)(1) we allow States the discretion of determining how to identify individuals with special health care needs, and therefore how to implement this concept. Consistent with this position, we do not believe that we should specify groups of beneficiaries for whom special health assessments should be required.

Initial Assessments

Comment: One commenter expressed concern that the proposed regulation

does not require MCOs or PHPs to conduct initial assessments of all new Medicaid enrollees, noting that Medicare+Choice plans are required to conduct the assessments.

Response: We used the term "initial assessment" in a Medicaid proposed rule published on September 29, 1998 (63 FR 52022) to implement these same statutory provisions. Since that time, we have received numerous and ongoing comments that the purpose and scope of an "initial" assessment has not been well understood. The words "initial assessment" do not appear in widespread use in the private sector or in health services research or policy studies. We have attempted to address this problem in subsequent versions of the regulation, and in § 438.208(c)(1) and (c)(2) of this final regulation, by dropping the terminology "initial assessment" and separating out what we believe are the two essential activities; that is, identifying individuals who have special health care needs, and assessing their needs. We do not believe it necessary to further specify the need for primary care providers operating under the auspices of an MCO, PIHP, or PAHP to assess the health of their patients, because we believe this to be a well-established component of primary health care.

Timeframes

Comment: One commenter stated that the regulation must ensure that people with identifiable risks for having special health care needs receive an expedited review of their health care needs. Many commenters stated that the final rules should include a health assessment soon after enrollment to identify pregnant women's health care needs and course of treatment. Many other commenters stated that the regulation should specify timeframes for managed care entities to screen and assess individuals with special health care needs, individuals "at risk" of special health care needs, and other enrollees. Many of these commenters recommended a variety of specific timeframes as follows. MCOs and PHPs should be required to: (1) Screen enrollees identified as "at risk" by the State within 30 days of the enrollees being so identified; (2) screen all other enrollees within 90 days of enrollment to determine whether the enrollee is pregnant or has a special health care need; (3) for any screened enrollee identified as being pregnant or having special health care needs, provide a comprehensive health assessment as expeditiously as the enrollee's health condition requires, but no later than 30 days from the date of the identification;

(4) for enrollees identified by the State as being pregnant, or who have self-identified as being pregnant or having special health care needs, provide a comprehensive health assessment within 30 days without needing an initial screen. Other commenters stated that screening should be performed on enrollees identified by the State as having special health care needs within 30 days after having been so identified by the State. One commenter stated that the regulation should require initial assessment of each pregnant woman by her MCO as soon as possible, but always within 30 days of enrollment. The commenter also stated that standards for individuals with complex and serious medical conditions should be similarly revised. Another commenter recommended that each MCO and PHP be required to make a best effort to screen the following individuals within 30 days of their being identified: Children and adults who receive SSI, children in Title IV-E foster care, enrollees over the age of 65, and enrollees in relevant, state-established, risk-adjusted, higher cost payment categories, and other categories identified by CMS. This commenter also recommended that each MCO and PHP be required to make a best effort to assess individuals who are pregnant or who have a special health care need within 30 days of their being identified. Another commenter recommend that disabled children and adults, foster children, enrollees over the age of 65, pregnant enrollees and infants and toddlers be screened by their MCOs within 30 days; other MCO enrollees should be screened within 90 days. Several other commenters, however, did not recommend a specific timeline. One commenter stated that timelines should be specified in advance by the State and approved in advance by CMS.

In contrast, one commenter stated that proposed § 438.208(c) and (d) that pertain to assessment and treatment of people with special health care needs are realistic and allow States and plans to develop timelines and procedures that meet the needs of their enrolled population. Another commenter expressed support for allowing States the authority to determine workable timeframes for their individual programs.

Response: We have carefully reviewed all the suggestions, and we do not believe it best for the Federal government, rather than the States, to establish timeframes specifying when all managed care entities are to screen and assess individuals with special health care needs, individuals "at risk" of special health care needs, and other

enrollees. We believe that it would be more appropriate and effective for screening and assessment timelines to be established by the State agency, in consultation with beneficiaries and other stakeholders, taking into consideration access and availability standards set by the State, the definitions and mechanisms chosen by the State agency to identify individuals with special health care needs, the character of the state's managed care marketplace, and State and/or local standards in both the public and private marketplace. With respect to the comment that timelines should be specified in advance by the State and approved in advance by CMS, we note that because we believe that any necessary timelines should be established by the State based on State considerations, CMS would not likely have more relevant information than the State, on existing access and availability standards set by the State, definitions and mechanisms chosen by the State agency to identify individuals with special health care needs, the character of the State's managed care marketplace, and State and/or local standards in both the public and private marketplace. We therefore decline to require prior Federal approval of State timelines.

Treatment Plan

Comment: Many commenters supported our proposed § 438.208(d) that pertains to a treatment plan for enrollees with special health care needs, but disagreed with the provision in § 438.208(d)(2) that states that the decision is left to the discretion of the enrollee's MCO/PHP of whether or not an individual with special health care needs would receive a treatment plan. Many commenters further stated that the regulation should indicate the individuals for whom health plans must develop and implement treatment plans, including individuals with special health care needs and pregnant women, particularly those pregnant women at high risk such as those with gestational diabetes or with a history of miscarriages.

Many commenters also suggested a number of additional provisions be added to the requirements for a treatment plan; specifically, that treatment plans: (1) Be appropriate to the enrollee's identified and assessed conditions and needs; (2) be for a specific period of time and updated periodically; (3) specify a standing referral or an adequate number of direct access visits to specialists; (4) ensure adequate coordination of care among providers; (5) be developed with enrollee participation and (6) ensure

periodic reassessment of each enrollee as his or her health condition requires. A few commenters stated that the treatment plan should be required to be appropriate to the standard of care for the enrollee's condition and identified needs. Other commenters noted that the Medicare+Choice regulations require a treatment plan for all enrollees with serious medical conditions. One commenter stated that the regulation should add a new provision requiring that, "the MCO or PHP must continue the existing treatment plan of an enrollee until an initial assessment of that enrollee occurs." The commenter stated that this provision would address the adverse effects that individuals can experience when there is an interruption in the ongoing clinical treatment of their illness or health condition. One commenter recommended the inclusion of requirements that treatment plans include direct access to specialists as required by the treatment plan and that the treatment plan be updated periodically by the physician responsible for the overall coordination of the enrollee's health.

In contrast, a few other commenters supported the provisions of the regulation pertaining to assessment and treatment of people with special health care needs, stating that the provisions are realistic and reasonable and allow states and plans to develop timelines and procedures that meet the needs of their enrolled population. One commenter stated that the enrollee, provider, and MCO clinical staff should determine the provisions that need to be included in a member's treatment plan. One commenter expressed support for allowing states to determine the extent to which MCOs must put in place mechanisms to allow enrollees to participate in the development of the treatment plan. One commenter recommended that an additional exemption be created in paragraph (a) with respect to the requirement that there be consultation with the primary care provider in the development of the treatment plans. The commenter noted that in his or her State, fee-for-service primary care providers are not a part of the specialty managed care network, and are not responsible for coordinating their primary care with mental health professionals. The commenter recommended that a new exception be added as section 438.208-(a)(2) (iii) "to consult with the enrollee's primary care provider in the development of a treatment plan as specified in paragraph (d)(2) of this section."

Response: We have revised § 438.208(c)(2) of this regulation, that

left the decision of whether or not an individual with special health care needs receives a treatment plan up to the discretion of the enrollee's MCO, PIHP, or PAHP. We agree with many of the commenters that this decision should not be left up to the MCO, PIHP, or PAHP and have revised the regulation to give States the authority to determine the extent to which treatment plans would be required. States will be required to address this as a component of their quality strategy and to develop these standards with input from Medicaid recipients and other stakeholders.

For a variety of reasons, we disagree with commenters that we should add certain other requirements for treatment plans; that is that treatment plans be required to: (1) Be appropriate to the enrollee's identified and assessed conditions and needs; (2) be for a specific period of time and updated periodically; (3) ensure periodic reassessment of each enrollee as his or her health condition requires; and (4) be required to be appropriate to the standard of care for the enrollee's condition and identified needs. We found a number of these requirements to be vague and therefore difficult to monitor and enforce, and not providing significant benefit to beneficiaries; for example, "be for a specific period of time and updated periodically," "appropriate to * * * conditions and needs" and "appropriate to the standard of care for the enrollee's condition and identified needs." In addition, we note that two of these proposed additions to treatment plan requirements are more strongly addressed elsewhere in this section. The recommended requirement that the treatment plan specify a standing referral or an adequate number of direct access visits to specialists is addressed in paragraph (c)(4), Direct Access to Specialists, which states that, "For enrollees determined through assessment to need a course of treatment or regular care monitoring, each MCO, PIHP, and PAHP must have a mechanism in place to allow enrollees to directly access a specialist (for example, through a standing referral or an approved number of visits) as appropriate for the enrollee's condition and identified needs." The recommended requirement that the treatment plan ensure adequate coordination of care among providers is addressed in paragraph (b), *Primary care and coordination of health care services for all MCO, PIHP, and PAHP enrollees*. We also did not add a requirement that, "The MCO or PHP must continue the existing treatment plan of an enrollee

until an initial assessment of that enrollee occurs." We believe that the situation, which the commenter has identified, is addressed by the provisions at § 438.208(b) pertaining to primary care and coordination of health care services.

Direct Access to Specialists

Comment: One commenter stated that proposed § 438.208(d) that pertains to direct access to specialists should be clarified that direct access to a specialist should be a determination made in concert with the primary care physician, health plan, patient, and specialist based on each patient's specific circumstances, not made through a screening instrument that identifies an individual as having special health care needs. Another commenter expressed support for the regulatory provisions allowing States to determine MCOs mechanisms through which Medicaid enrollees with special health care needs will have direct access to specialists.

Response: We agree that a decision about access to specialists should not be based on the results of screening. In § 438.208(c)(4) of the final rule, we clarify that access to specialists should be made as a result of a more detailed assessment using (consistent with § 438.208(c)(2)) "appropriate health care professionals." We believe appropriate health care professionals include the enrollee's primary care provider, but not necessarily the MCO or a specialist. Participation of the enrollee in this decision is guaranteed under the provisions in § 438.100 (b)(2)(iv) pertaining to the enrollee's right to participate in decisions regarding his or her health care.

Exemptions

Comment: One commenter expressed support for the exemption allowing State Medicaid agencies to determine to what extent any MCO that serves enrollees who are also enrolled in a M+C plan and receive Medicare benefits must meet the screening and assessment, referral and treatment plan, and primary care and coordination requirements of proposed § 438.208(c), (d), and (e)(1) (now § 438.208(b) and (c)). The commenter recommended that dual eligible enrollees receive one screening and assessment that satisfies requirements for Medicare+Choice.

Response: We appreciate and agree with the commenter's support for the provision in § 438.208(b) and (c) that allow State Medicaid agencies to determine to what extent any MCO that serves enrollees who are also enrolled in a M+C plan and receive Medicare benefits must meet requirements

pertaining to coordination, identification, assessment, and treatment planning. We agree that it is desirable for dual eligible enrollees to receive one screening and assessment that satisfies requirements for both Medicaid and Medicare+Choice, but we are not imposing this requirement at this time, in recognition of the operational and policy issues that first must be addressed in order to accomplish this and because it may not be feasible in all instances.

Patient Confidentiality and Sharing of Information

Comment: One commenter expressed concern about the provision of proposed § 438.208(e)(3) which would require MCOs and PIHPs to share with other MCOs and PIHPs serving an enrollee, the results of its screening and assessments so that those activities need not be duplicated. The commenter understood of the intent of the provision but expressed concern over possible effects on patient confidentiality. The commenter offered no specific recommendation to address these competing concerns. Another commenter noted that the requirements might present concerns about patient confidentiality if MCOs are not able to obtain enrollee consent for the sharing of information. One commenter supported the proposed regulation's provision in § 438.208(e)(4) pertaining to the protection of enrollee privacy.

Response: We also share commenters' concerns about protecting the privacy of patient information. For this reason, we have retained the provision, now at § 438.208(b)(4), that states that, "* * * in the process of coordinating care, each enrollee's privacy is protected in accordance with the privacy requirements in 45 CFR parts 160 and 164, subparts A and E, to the extent that they are applicable.

Primary Care and Coordination Program

Comment: One commenter noted that the proposed regulations in § 438.208(e) allowed primary care coordination to be conducted by "a person or entity." The commenter stated that it is inappropriate to allow MCOs or PHPs to delegate management of an enrollee's health care to an unlicensed or non-credentialed person or entity. The commenter recommended that primary care coordination be performed by a health care professional, as that term is defined in proposed § 438.102. One commenter recommended that CMS should describe in the regulation necessary coordination efforts and include specific references and examples.

Response: We have retained the wording, “a person or entity” in this final rule to acknowledge that sometimes care coordination might be performed by an organization, such as a Federally Qualified Health Center (FQHC), as opposed to an individual. We have not described in the regulation necessary coordination efforts and specific references and examples because we believe that there are more appropriate vehicles than this regulation for disseminating best practices, reference materials and examples of care coordination.

Monitoring

Comment: One commenter recommended that CMS: (1) Closely monitor State agency and managed care entity procedures to identify any problems or disruptions in the continued treatment of patients with mental illness, including a substance abuse disorder; (2) provide direction to the State or State agency to facilitate effective solutions; and (3) use CMS resources to assure that continuity and coordination is maintained.

Response: We will closely monitor State agencies and their managed care initiatives to identify any problems or disruptions in the services or treatment of all Medicaid enrollees, including enrollees with special health care needs such as mental illness and/or substance abuse. When deficiencies are found, we typically direct the State agency to undertake solutions and use our resources to assure that the solutions are effective.

Factors That Hinder Access

Comment: Many commenters recommended an addition to MCO/PIHP coordination provisions at proposed § 438.208(e) to require plans to have in effect procedures to address factors, such as lack of transportation, that may hinder enrollee access to health care treatments or regimens.

Response: We do not agree with this recommendation. We know that many States and MCOs, PIHPs, and PAHPs in the absence of federal regulations, have in effect procedures to address factors, such as lack of transportation, that may hinder enrollee access to health care treatments or regimens. However, we believe that the extent to which these procedures should be the responsibility of the MCO, PIHP, or PAHP in contrast to the State agency or other agent of the State, is a decision best made by the State agency.

Maintenance of Health Records

Comment: Many commenters recommended that a provision be added

to require each MCO and PHP to ensure that its providers have the information necessary for effective and continuous patient care and quality improvement, consistent with certain confidentiality and accuracy requirements. Many commenters also recommended that each MCO and PHP be required to ensure that each provider maintains health records that meet professional standards and that there is appropriate and confidential sharing of information among providers.

Response: We believe that both of these issues are already addressed in other sections of the regulation. Section 438.242, *Health Information Systems*, requires the MCO and PIHP to maintain a health information system that “collects, analyzes, integrates, and reports data and can achieve the objectives of this subpart” and “ensures that data received from providers is accurate and complete.” We believe that this requirement is a stronger and more effective standard than a requirement that each provider maintain health records that meet professional standards. In addition, § 438.224, *Confidentiality*, requires each MCO and PIHP to establish and implement procedures in accordance with confidentiality requirements in 45 CFR parts 160 and 164. We believe these provisions more strongly address confidential sharing of information among providers.

7. Coverage and Authorization of Services (Proposed § 438.210)

Proposed § 438.210 set forth requirements to ensure that each contract with an MCO or PIHP identifies all services offered under the contract, and that the MCO or PIHP establishes and follows written policies and procedures for processing requests for services in a manner that ensures appropriate beneficiary 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 sections 1932(b)(1) and (b)(4) of the Act.

In § 438.210(a) we proposed that the State, in its contracts with MCOs and PIHPs, identify, define, and specify the amount, duration, and scope of all Medicaid benefits that the MCO or PIHP 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 PIHP furnish the services in accordance with that provision. We believe that it is important for enrollees and providers to

know that the contract includes specific information on all services available under the contract and how the State applies its medical necessity criteria. We also required that the contract be clear on coverage of services related to (1) the prevention, diagnosis, and treatment of health impairments; (2) the ability to achieve age appropriate growth; and (3) the ability to attain, maintain, or regain functional capacity.

In § 438.210(b) we required that MCOs and PIHPs, and their subcontractors, have in place and follow written policies and procedures for initial and continuing authorization of services. We also required that MCOs and PIHPs consistently apply review criteria when authorizing services; consult with the requesting provider, when appropriate; and that decisions to deny requests for authorizations, or authorize a service in an amount, duration, or scope that is less than was requested, must be made by a health care professional who has the appropriate clinical expertise in treating the enrollee’s condition or disease.

In paragraph (c), we proposed that MCO and PIHP contracts provide that written notice of decisions to deny a service authorization request or to authorize the request in an amount, duration, or scope that is less than what was requested be provided to the enrollee and the provider. The notice to the enrollee must be in writing.

In paragraph (d), we proposed timeframes for decisions to authorize services. For standard authorization decisions, the notice must be provided as expeditiously as the enrollee’s health condition requires and within State-established timeframes that do not exceed 14 calendar days following the request for service. A 14 calendar-day extension would apply at the enrollee’s or provider’s request or if the MCO or PIHP justifies a need for additional information and how the extension is in the enrollee’s interest. We believe that an extension would be in the enrollee’s interest when more information is needed for the MCO or PIHP to authorize the service and failure to extend the timeframe would result in a denial of the authorization.

For expedited authorization decisions, we proposed that the MCO or PIHP have a maximum of 3 working days after receipt of the request to make a decision. This period could be extended for 14 days under the same circumstances as apply for standard decisions.

In proposed § 438.210(e), we required that each MCO and PIHP contract must provide, consistent with § 438.6(g) and § 438.210(a)(2), that compensation to

individuals and entities that conduct utilization management activities not be structured so as to provide incentives to deny, limit, or discontinue medically necessary services to enrollees.

Comment: One commenter expressed the opinion that § 438.210 should apply to dental plans.

Response: We agree with the commenter. We decided to extend the provisions of § 438.210 to include PAHPs as well as MCOs and PIHPs because we believe that enrollees of PAHPs need the protections provided under this section. This includes dental plans as well as other PAHPs. We note that the services included in the plans are limited to those provided for under the contract and that the provisions are not always applicable to certain PAHPs, for example, transportation PAHPs.

Comment: Several commenters recommended a Federal definition of medical necessity be included in the regulation that includes access to rehabilitative services. One commenter said that rehabilitative services are important for children and adults with severe mental impairments.

Response: We do not agree that the regulation should include a Federal definition of medical necessity. There currently exists no widely accepted national definition and at present States 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 those criteria. Therefore, we do not believe it is appropriate to promulgate a national definition. However, we believe it is necessary to provide some specific guidance regarding what State contracts must include. In particular, we believe that whatever a State’s fee-for-service Medicaid program uses as medical necessity criteria should not be further restricted by Medicaid MCOs, PIHPs, and PAHPs. Making this clear to all parties should decrease the potential for dispute. If the State’s fee-for-service medical necessity criteria address whether a service is needed “to attain, maintain or regain functional capacity,” the regulation requires the contract with the MCO, PIHP, or PAHP to address this as well. We believe this would address the extent to which rehabilitative services are considered medically necessary. While we are not mandating that specific services must be covered to meet these goals, the contract must clearly address the extent of each MCO’s, PIHP’s, and PAHP’s responsibility to provide such services.

Comment: One commenter asked that the words “enrollee’s ability to attain,

maintain, or regain maximum function * * * could be jeopardized” should be deleted from the definition of medical necessity, as this definition is so broad that it could be applied to nearly all medical necessity determinations.

Response: These words are not part of a definition of medical necessity. Rather, they make clear that State policies related to medical necessity under fee-for-service address any of the items listed in § 438.210(a)(4)(ii), then the State’s contract with an MCO, PIHP or PAHP must also address these items. We believe this greater clarity will decrease the potential for disputes, among beneficiaries, the State and MCOs, PIHPs, and PAHPs.

Comment: One commenter expressed concern that the proposed rule allows MCOs and PIHPs to limit services on the basis of the medical necessity definition and utilization controls. This commenter noted that the EPSDT provision of the Medicaid statute ensures children the full range of needed health care services and recommended specific language in the regulation to ensure this end.

Response: Under § 440.230(d) States already have the authority to “place limits on a service based on such criteria as medical necessity or on utilization control procedures” and have great flexibility in defining those criteria. This provision also applies to services provided through the EPSDT program.

This managed care regulation does not affect any of the pre-existing EPSDT regulations. Furthermore, some States may choose to provide EPSDT services 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.

Comment: One commenter expressed concern that an MCO should not be “placed in the middle of a decision” by a provider to deny a service based on “field experience and clinical documentation”. The commenter said that their State has consumer safeguards in place, both in the coverage and authorization process and grievance and appeal process, to protect enrollees.

Response: Section 1932(b)(4) of the Act requires that MCOs have internal grievance procedures for enrollees. Therefore, we must provide for such a process in the regulation and the MCO or PIHP must approve or disapprove a provider’s decision.

Comment: Several commenters asked that the notice of action and right to appeal be removed in the case of a physician who denies a request for service, as this is not a realistic

requirement and would trigger service continuation requirements. The commenter stated that there is no practical way for an MCO to know that a physician counseled against a medical service. Also, the requirement is unduly burdensome, particularly as it relates to modified requests for service authorizations that are agreed to by the requesting provider. One commenter said that this requirement is inconsistent with industry and Medicaid practice.

Response: We acknowledge that it is difficult for an MCO or PIHP to know when a physician counseled against a service and that it would be burdensome to require physicians to provide notice of denial to enrollees or to inform the MCO or PIHP that a requested service was not provided. To address this issue, in the final rule, at § 438.404(b)(1), we have revised the regulation to specify that the enrollee has the right to appeal a denial by the MCO or PIHP. The physician’s decision to provide a service does not trigger an appeal right. This will require the enrollee who wishes to receive a service that the physician will not provide to contact the MCO or PIHP to request approval of the service. A denial of the service at that point by the MCO or PIHP will constitute an action that may be appealed by the enrollee. In response to the comment related to service continuation, we note that services must be continued only if they have been approved in advance by the MCO or PIHP, or by a provider acting on behalf of the MCO or PIHP.

Comment: One commenter asked for clarification that § 438.210 applies to provider requests for authorization and not when a beneficiary requests a service that the provider does not find to be medically necessary.

Response: As explained in the previous response, we specify in the final rule that the appeal right is triggered when an action is taken by the MCO or PIHP to deny a requested service or authorize it in an amount, duration, or scope that is less than was requested by the enrollee.

Comment: One commenter asked if the regulation intends to require that a “clinical peer” within the MCO be used to deny a service authorization. If so, the commenter stated that this would impose an additional requirement beyond what is required in State law (which permits any licensed physician to deny an authorization). This would require a significant change in operation for MCOs in that State.

Response: We do not use the term “clinical peer” to describe the qualifications of the health care

professional who must make a service authorization decision. Rather we say that the health care professional must have "appropriate clinical expertise in treating the enrollee's condition or disease". We believe that this criterion provides States latitude to specify what clinical experience will be required for individuals making authorization decisions. We also do not specify that the health care professional must be employed by the MCO or PIHP. This permits MCOs and PIHPs to contract for the services of health care professionals if they choose and the State approves.

Comment: One commenter believes that the standard set by the regulation, that prior authorization decisions be made by a health care professional who has appropriate clinical expertise, is unclear and may lead to unnecessary litigation. The commenter also noted that this standard is not imposed in FFS, nor is this expertise required at a State fair hearing.

Response: We believe that it is important that individuals who make authorization decisions for MCOs and PIHPs have appropriate medical knowledge and clinical experience when making these decisions. This supports the credibility of decisions and may be a factor in the enrollee's decision to appeal. In FFS and State fair hearings the situation is different, but in both cases, professional clinical judgments are available. In FFS, the beneficiary has an option to seek out another provider should a physician not agree to provide requested services. For State fair hearings, beneficiaries may present medical evidence in support of their claims.

Comment: One commenter suggested changing "treating" to "assessing" or "evaluating" in regard to the health care professional who must deny or limit a service authorization request. This would allow clinicians some latitude to determine if their level of expertise is appropriate for the review. The State in which the commenter resides holds licensed physician professionals accountable for consulting with appropriate specialists for each decision to deny care.

Response: We continue to believe that the requirement should be that health care professionals have clinical experience in treating the condition or disease under review. As noted above, we believe that the requirement provides some latitude for States to determine what experience is appropriate. We do not think it appropriate for a health care professional without clinical treatment experience to make judgments regarding treatment.

Comment: One commenter said that the lack of a definition of "appropriate" in § 438.210(b)(3) is problematic. This relates to health care professionals with the expertise to deny a service authorization request.

Response: We believe that the word "appropriate" conveys a responsibility to the State to specify further criteria to meet the intent of this provision. We do not believe that Federal regulations should provide greater detail as we are not able to address all medical situations or local conditions. We believe this responsibility should rest with the States.

Comment: One commenter suggested that the health care professional denying a request for services should be required to see the patient.

Response: We do not agree that a health care professional denying a request should be required to see the patient. We include a requirement under § 438.210(b)(2)(ii) that the MCO or PIHP policies and procedures include consultation with the requesting provider, when appropriate. We believe that this requirement will ensure that the MCO or PIHP has the information needed to make an informed decision.

Comment: One commenter suggested that we add "or who has considered advice from a health care professional with clinical expertise in treating the enrollee's condition or disease" at the end of § 438.210(b)(3).

Response: We do not agree that it is sufficient for the decision maker to rely on information gained through consultation with a clinical expert. We believe that the decision maker must be capable of rendering a decision based on his or her own expertise. Therefore, we have not revised the regulation as requested by the commenter.

Comment: Several commenters asked how we define "standard decisions," as no definition is provided in the regulation.

Response: A standard decision is one that does not meet the criteria for an expedited decision. These criteria are specified in § 438.210(d)(2) and again at § 438.410(a).

Comment: Many commenters urged that expedited authorizations be required to be made within 72 hours rather than in 3 working days. A 72-hour standard would ensure that decisions are made in a timeframe consistent with the urgent medical needs of the case. This would also apply to Medicaid enrollees the same protections that apply to other private and public health programs and are consistent with the provision of the patient's bill of rights.

Response: In § 438.210(d)(2), we have retained the maximum timeframe for expedited decisions at 3 working days because this provides a State flexibility to set a timeframe that it believes appropriate while protecting beneficiaries by stipulating a maximum timeframe. The regulation also requires that the decision be made "as expeditiously as the enrollee's health care condition requires." This provides beneficiaries further protection when a quicker decision is necessary because the timeframes set by the State would seriously jeopardize the enrollee's life or health.

Comment: Many commenters disagreed with the provision that would allow MCOs and PIHPs to extend the timeframe for expedited authorization decisions by 14 days when the extension is in the interest of the enrollee. The commenters believe that this provision undermines the strength of the shorter timeframe for expedited decisions and lessens the likelihood that the expedited timeframe will be met in practice. They also note that the provision is inconsistent with the Employee Retirement Income Security Act (ERISA) rules governing employer-sponsored groups and the patients' rights legislation supported by the Administration.

Response: We retain the provision that allows the MCO or PIHP to extend the decision period by up to 14 days when the extension is in the best interest of the enrollee. We believe this protects the enrollee in situations in which sufficient information is not available to authorize a service at the end of the 3-day period. Without this provision, the enrollee would be denied the service and would need to appeal the denial to pursue the request. With this provision, the MCO or PIHP can continue to pursue the outstanding information and, ultimately, approve the request, if appropriate.

Comment: One commenter suggested that the timeframe for authorization should begin when all information necessary to make a decision is received by the MCO and not when the enrollee's request is first denied.

Response: We have not accepted this comment because this would require a separate decision that all information needed to make a decision has been received. The authorization decision is generally made when information sufficient to make a decision is reviewed by the deciding health care professional. We believe that it is an important protection for the enrollee that the timeframe begin when the request for service is denied. It also provides an incentive for the MCO or

PIHP to promptly gather information needed for a decision.

Comment: One commenter said that the 14-day extension should not apply when MCOs and PIHPs make late requests for additional information.

Response: It would be difficult to assess when a request for information is late, as the deciding health care professional may find a need for additional information when reviewing the information associated with the request. Therefore, we do not believe that this is an appropriate standard to use.

Comment: One commenter asked that the regulation not provide a national timeframe for authorization decisions. Rather, States should be required to set standards based on community norms.

Response: We note that the timeframe provided in the regulation is a maximum timeframe; States may set shorter timeframes if they choose. We continue to believe that it is appropriate to set a maximum national timeframe as an important protection to Medicaid managed care enrollees.

Comment: Several commenters asked for a provision to prohibit requests for authorizations from having unnecessary or unduly burdensome information requirements for enrollees or providers. The commenters believe that such a provision is necessary to prohibit MCOs and PIHPs from increasing the "hassle factor" on physicians as a means of cutting costs.

Response: It is not possible or reasonable to regulate against unnecessary or burdensome information requirements. States have other tools to ensure that MCOs and PIHPs with which they contract are not deliberately making it difficult for enrollees to access services. These include monitoring grievances and appeals by enrollees; requirements for adequate provider networks, as providers are unlikely to contract with MCOs or PIHPs that make it difficult for them to provide services; and other monitoring by the State.

Comment: Many commenters asked that the regulation include a provision to require that MCO and PIHP policies and procedures for decisions on coverage and authorization of services reflect current standards of medical practice. One commenter believes that omission of such a provision suggests that providers would be permitted to have policies and procedures that do not reflect current medical practice standards.

Response: We believe that such a provision is unnecessary as the requirement related to medical necessity will ensure that coverage and authorization decisions reflect current

standards of medical practice. The omission of this as a requirement in no way implies that States or CMS sanction or permit practitioners to have policies and procedures contrary to current standards of medical practice. On the contrary, the provision on practice guidelines at § 438.236 requires that MCOs, PIHPs, and PAHPs (where appropriate) adopt and disseminate practice guidelines to their contracting providers to ensure that enrollees' care is consistent with the latest and most effective clinical practices.

8. Provider Selection (Proposed § 438.214)

Proposed § 438.214 required State Medicaid agencies to ensure that contracted MCOs and PIHPs have written policies and procedures for the selection and retention of providers and a documented process for the initial credentialing and recredentialing of providers. It also required that MCOs and PIHPs not discriminate against providers who serve high-risk populations or specialize in conditions that require costly treatment. Finally, it prohibited MCOs and PIHPs from contracting with providers excluded from participation in Medicare and State health care programs.

Comment: One commenter asked that language be added under § 438.214(b) to say "state-licensed providers" and add "of primary care, including at a minimum, physicians, psychologists, physician assistants, midwives, and nurse practitioners".

Response: The definition of provider, at § 400.203, as amended by this regulation, requires that the individual or entity be legally authorized by the State to deliver health care services. Therefore, it is not necessary to say "state-licensed providers." In addition, it is not necessary to specifically list types of providers, as the definition of provider is broad enough to encompass these types of individuals or entities.

Comment: Many commenters recommended that we apply the Medicare+Choice credentialing rules to Medicaid MCOs, PIHPs, and PAHPs.

Response: We have decided not to apply the Medicare+Choice credentialing rules. Since each State Medicaid managed care program is unique, we do not believe that it would be appropriate to create detailed national standards. The regulation was written to promote State flexibility to manage their programs. However, we agree that there should be a uniform State standard for credentialing and recredentialing and have revised § 438.214(b) to require the State to set this standard policy. These policies and

procedures must, at a minimum, include a documented process for credentialing and recredentialing, not discriminate against providers that serve high-risk populations or specialize in conditions that require costly treatment, and may not employ or contract with providers excluded from participation in Federal health care programs. We also revised § 438.214 to apply it to PAHPs, based on general comments requesting that all the provision of subpart D apply to PAHPs.

Comment: One commenter expressed approval of not including specific requirements in the regulation but asked that CMS require States to use a process consistent with the credentialing guidelines of the National Committee on Quality Assurance (NCQA).

Response: We have decided not to require States to use a process consistent with NCQA's credentialing guidelines. It is up to each State to decide if they want to use these guidelines. Our regulation only requires MCOs, PIHPs, and PAHPs to implement written policies for the selection and retention of providers. However, we do require that each State set a uniform credentialing policy for all of its MCOs, PIHPs, and PAHPs.

Comment: One commenter seeks clarification that MCOs not be required to credential non-physician providers of licensed health facilities under contract to the plan if the facility itself credentials its providers.

Response: We do not address this level of specificity in the final rule. This provision speaks to the credentialing of providers and does not make a distinction between non-physician and physician providers or who does the credentialing. At a minimum, each MCO, PIHP, and PAHP must follow a documented process for credentialing and recredentialing providers who have signed contracts or participation agreements with the MCO, PIHP, or PAHP. Further, a provider in Medicaid managed care is defined as any individual or entity who is engaged in the delivery of health care services and is legally authorized to do so by the State in which he or she delivers the services.

Comment: One commenter stated that in the absence of a credentialing regulation, in many States, providers would set their own standards.

Response: This final rule does not allow individual providers to establish their own credentialing standards. Section 438.214(b) requires States to set uniform credentialing policies and each MCO, PIHP, and PAHP must follow this policy for credentialing providers.

Comment: One commenter expressed the opinion that a lack of specific credentialing requirements is an open door for States to lower standards for doctors who see Medicaid beneficiaries.

Response: We do not believe that States will establish lower standards for doctors who serve Medicaid beneficiaries. We allow States the flexibility to determine the credentialing policy that best fits their State's needs. The providers being credentialed must be legally authorized to deliver services in the State. Further, States must ensure that each MCO, PIHP, and PAHP maintains a network of providers that is appropriate to meet the needs of its enrolled population.

9. Enrollee Information (Proposed § 438.218)

This section provided that the information requirements under § 438.10 are part of a State's quality strategy. We received no comments on this section and have retained it as in the proposed rule.

10. Confidentiality (Proposed § 438.224)

This section of the proposed rule required that States must ensure that MCOs and PIHPs meet the privacy requirements of subpart F of part 431 of this chapter and 45 CFR parts 160 and 164.

Comment: Many commenters suggested that we strengthen the regulation to make clear that monitoring and oversight do not end with inclusion of contract language. The commenters suggested the addition of the following language "The State must ensure, through its contracts and by monitoring compliance with those contracts, that etc."

Response: We agree that monitoring and oversight require more than the inclusion of contract language. However, we provide for monitoring and oversight within the regulation. Under § 438.204(b)(3), the State quality strategy must include procedures to regularly monitor and evaluate MCO and PIHP compliance with the contract standards.

Comment: One commenter asked if State confidentiality laws that are stricter than Federal privacy laws will continue to apply.

Response: The Federal privacy laws do not pre-empt State confidentiality laws, to the extent that State laws are stricter.

Comment: One commenter noted that the privacy regulation cross referenced in this rule does not take effect until April 14, 2003. Assuming this regulation takes effect prior to that date, the commenter asked whether the

privacy rules take effect earlier for Medicaid managed care MCOs and PIHPs.

Response: The privacy rule became effective on April 14, 2001. Most health plans and providers that are covered by the new rule must comply with the new requirements by April 14, 2003. Enforcement of the privacy rule will not occur until April, 2003. This final rule does not alter these dates, nor does it impose privacy requirements in addition to those of the privacy final rule that became effective on April 14, 2001 (65 FR 82462).

Comment: Several commenters requested that the regulation make clear that the confidentiality provisions extend to minors who seek health services through Medicaid.

Response: Section 438.224, as a whole, was intended to ensure that MCOs and PIHPs have procedures to protect the confidentiality of all enrollees. We intend the term "enrollee" to encompass all enrollees, regardless of age. Further, the privacy rule provides all individuals with certain rights with respect to their personal health information, including the right to obtain access to, and request amendment of, health information about themselves. The privacy rule also has specific requirements regarding a minor and the minor's personal representative and their control over the minor's health care information (See 45 CFR 164.502(g)).

11. Enrollment and Disenrollment (Proposed § 438.226)

This section of the proposed rule provided that each MCO and PIHP contact must comply with the enrollment and disenrollment requirements and limitations set forth in § 438.56. We received no comments on this section and have retained it as proposed.

12. Grievance Systems (Proposed § 438.228)

Proposed § 438.228(a) required that the State ensure through its contracts with MCOs and PIHPs that they have grievance systems that met the requirements of subpart F. Paragraph (b) required States that delegate to the MCO or PIHP responsibility for notifying enrollees of an adverse action to conduct random reviews of the MCO, PIHP, and their providers to ensure that notices are provided in a timely manner.

Comment: Many commenters urged that the provisions of subpart F on grievances and appeals be applied to PAHPs. They believe that enrollees of these plans should have equal rights to grieve and appeal and that States should

have access to data on grievances and appeals to monitor PAHPs for quality. Another commenter said that enrollees of PAHPs should have access to grievances and appeals because managed care, by its nature, includes conflicts of interest between the plans and their enrollees.

Response: We do not agree that the grievance system required under Federal regulation should apply to PAHPs. The services provided by PAHPs are generally of a much more limited scope than those provided by MCOs and PIHPs. We note that States may extend the grievance system requirements to PAHPs, or may require another grievance and appeals process.

Comment: Many commenters suggested that the State should be required to review quality of care grievances at the request of the enrollee. Without a provision for quality of care grievances no external record exists of MCOs and PIHPs that consistently fail to adhere to basic quality standards. Another commenter stated his opposition to inclusion of a category of grievance for quality of care.

Response: The final regulation does not include a category of grievance for those related to quality of care. Rather, grievances related to quality of care fall into the general grievance category. We agree that data on grievances and appeals provide States with important information about the quality of care delivered by MCOs and PIHPs. For this reason, in § 438.416, we require that States must require MCOs and PIHPs to maintain records of grievances and appeals and review that information as part of the State quality strategy. While we do not require that States review quality of care grievances, we believe that States are responsive to issues raised by enrollees related to quality and will generally review these grievances when requested.

13. Subcontractual Relationships and Delegation (Proposed § 438.230)

Proposed § 438.230(a) set forth requirements specifying that an MCO or PIHP that contracts with the State retains full accountability for any activities under its contract that it delegates to a subcontractor. Paragraph (b) required that before an MCO or PIHP delegates responsibility to a subcontractor it must (1) evaluate the prospective contractor's ability to perform the functions to be delegated, and (2) have a written agreement that specifies the activities and report responsibilities of the subcontractor and provides for revoking the delegation or imposing sanctions if the subcontractor's performance is

inadequate. Paragraph (c) required that the MCO or PIHP monitor the performance of the subcontractor and conduct periodic formal reviews on a schedule established by the State.

We received no comments on this section and we have retained § 438.230 as proposed.

14. Practice Guidelines (Proposed § 438.236)

Proposed § 438.236 required that States ensure that each MCO and PIHP adopt practice guidelines that (1) are based on valid and reliable clinical evidence or a consensus of health care professionals in the particular field, (2) consider the needs of the MCO's or PIHP's enrollees, (3) are adopted in consultation with contracting health care professionals, and (4) are reviewed and updated periodically as appropriate. We also proposed that MCOs and PIHPs disseminate the guidelines to all affected providers and, upon request, to enrollees and potential enrollees. Finally, we specified that decisions with respect to utilization management, enrollee education, coverage of services, and other areas to which the guidelines apply must be consistent with the guidelines.

Comment: One commenter said that § 438.236 should apply to dental plans.

Response: We agree with the commenter. This section should apply to PAHPs, including dental plans, as well as to MCOs and PIHPs, and we have revised § 438.236 accordingly. We note that the scope of services in the PAHP contract will determine the areas in which practice guidelines are appropriate. For example, dental guidelines would only be appropriate for plans that are responsible for providing dental services. Likewise, a clinical practice guideline is incompatible with transportation services, making this section inapplicable to transportation PAHPs.

Comment: One commenter recommended that the regulation require MCOs and PIHPs to use practice guidelines developed and/or endorsed by the American Academy of Pediatrics.

Response: We are not specifying what guidelines MCOs and PIHPs must adopt but rather are establishing criteria to be used by MCOs and PIHPs in adopting guidelines.

Comment: Several commenters objected to the requirement that MCOs and PIHPs adopt practice guidelines. One commenter said that guideline adoption should not be required because nationally accepted standards are not available for all clinical areas, for example, for rehabilitative mental health services. Another commenter

objected to this provision because he believes that to require use of clinical practice guidelines substitutes the judgment of CMS, the States, and MCOs and PIHPs for the judgment of health care professionals. Other commenters supported the provision but suggested that reference be made to HIV/AIDS guidelines or that the provision also require the use of clinical review criteria that are directed specifically to meeting the needs of at-risk populations.

Response: We continue to believe that States should require MCOs, PIHPs, and PAHPs (where appropriate) to adopt clinical practice guidelines in order to ensure the highest quality of care to enrollees. We are aware that clinical practice guidelines are not available for all areas of clinical practice. However, we believe that it is important to promote the use of guidelines based on clinical evidence. Guidelines are being developed by a variety of organizations in a variety of areas and will increasingly become available for use. This is why we have set criteria for MCOs, PIHPs, and PAHPs to use when adopting guidelines rather than specifying particular guidelines to be used. We do not agree that requiring the use of practice guidelines substitutes the judgement of CMS, States, or health plans for the judgement of health care professionals. Rather, guidelines assist health care professionals to apply the best evidenced-based practice to clinical care. Guidelines are developed to assist the health care professional, not to dictate a specific course of action. We require that MCOs, PIHPs, and PAHPs consult with their contracting health care professionals when adopting practice guidelines to ensure that the health care professionals have input into these decisions.

Comment: One commenter stated that the regulation should require MCOs to consult with organizations that develop practice guidelines.

Response: We do not agree that it is necessary or practical to require MCOs, PIHPs, and PAHPs to consult with organizations that develop practice guidelines. What we believe is important is that the guidelines are valid and reliable, are relevant to the enrollee population, are adopted in consultation with the contracting health care providers, and are reviewed and updated periodically to ensure that they continue to reflect the most recent evidence. Therefore, these are the criteria we specify in the regulation for MCOs, PIHPs, and PAHPs to use when adopting practice guidelines.

15. Quality Assessment and Performance Improvement Program (Proposed § 438.240)

This section sets forth the State's responsibility to ensure that each MCO and PIHP with which it contracts have in place a quality assessment and performance improvement program for the services it furnishes to Medicaid enrollees. In the NPRM we proposed that States must require that each MCO and PIHP include the following basic elements in its quality assessment and performance improvement program: (1) Conduct performance improvement projects, (2) have in effect mechanisms to detect both underutilization and overutilization of services, and (3) have in effect mechanisms to assess the quality and appropriateness of care furnished to enrollees with special health care needs.

In our proposed rule we specified that CMS, in consultation with States, and other stakeholders, may specify standardized quality measures and topics for performance improvement projects to be required by States in their contracts with MCOs and PIHPs. We proposed that MCOs and PIHPs measure performance using standardized measures annually, and implement performance improvement projects that address clinical and non-clinical areas. We also proposed that States review, at least annually, the impact and effectiveness of their quality assessment and performance improvement programs.

Comment: Several commenters supported the quality assessment and performance improvement provisions.

Response: We retain the provisions in § 438.240 in the final rule with certain revisions, discussed below.

Comment: One commenter supported the provision that CMS will consult with States and other stakeholders if we decide to exercise our authority to specify quality measures or topics for performance improvement projects that we would require States to include in their contracts with MCOs.

Response: We believe it is important to include all stakeholders in any discussions that would lead to specifying performance measures or topics for performance improvement projects that we would require States to include in their contracts with MCOs and PIHPs.

Comment: Several commenters were concerned that measures identified and developed by CMS, in consultation with States and other stakeholders, would be measures that are not routinely collected nor applicable to the unique circumstances of States and MCOs/

PIHPs and that the standardized performance measures would impose additional burden. The commenters suggested this requirement be removed. One commenter agreed that some standardization of performance measures is appropriate but believes the specifications for the measures should be determined by the MCO or PIHP.

Response: We hope that by including all stakeholders in discussions about performance measures that we will reach agreement about measures that are important to a wide range of stakeholders and to CMS. We recognize that each State and MCO and PIHP will have unique program circumstances and that the national measures chosen will not meet all these needs. However, the requirement to use standard measures does not preclude States, MCOs, and PIHPs from also using performance measures that they find useful. We believe we should have the ability to specify standard measures and topics for performance improvement projects to provide comparability across States for some measures and to establish national priority areas for performance improvement projects. Therefore, we retain this provision in the final rule.

Comment: Several commenters requested that we permit exceptions or deviations from the standard measures required by us.

Response: As we stated in the preamble to the proposed rule, we believe we should have the ability to specify standard measures and that we will be working in consultation with States and other stakeholders to agree upon standard measures. Policy regarding the implementation of the measures, including whether any exceptions should apply, will also be determined in consultation with stakeholders.

Comment: Several commenters disagreed with our proposal to allow CMS to specify topics for performance improvement projects. One commenter stated that States are in the best position to identify State health priorities and how to allocate their resources and suggested that this provision be removed. Several commenters encouraged us to defer to States in determining the number and type of studies to be performed. One commenter agreed that the identification of standard performance improvement project topics is appropriate but believes that the intervention and measurement specifications should be left up to the MCOs/PIHPs.

Response: As stated in the preamble of the August 2001 proposed rule, we believe that as the art of quality

improvement and measurement advances, we should have the ability to specify standard measures and topics for performance improvement projects. We retain this provision in the final rule. As in the proposed rule, in the final rule, we do not specify the number or types of quality improvement projects nor do we specify improvement interventions that MCOs and PIHPs must implement.

Comment: Several commenters expressed concern that requiring performance improvement projects to achieve demonstrable and sustained improvement is not always feasible. Commenters said that this requirement could have a negative impact on quality improvement activities because it may impact the willingness of MCOs and PIHPs to take on difficult projects. One commenter suggested that the language in this section be changed to reflect that these projects have the goal of achieving demonstrable and sustained improvement as opposed to requiring the projects to achieve this improvement. Another commenter suggested deeming MCOs/PIHPs as having satisfied the quality assurance requirements found in this subpart if the MCO or PIHP is accredited by a private accreditation organization.

Response: We agree with the commenters that achieving demonstrable improvement is not always feasible. We have revised § 438.240(b)(1) to require that performance improvement projects be designed to achieve significant improvement sustained over time. This language is consistent with Medicare requirements that define demonstrable improvement as "significant improvement sustained over time." We plan to address deeming of MCO and PIHP quality initiatives in the EQR final rule.

Comment: One commenter suggested that we allow States discretion to require demonstrable improvement or not.

Response: As indicated in the response to the previous comment, we are no longer requiring that performance improvement projects achieve demonstrable improvement. We are requiring that these projects be designed to achieve significant improvement sustained over time. States will have the discretion to define what is to be considered significant improvement.

Comment: Many commenters argued that MCOs and PIHPs should be required to meet minimum performance levels established by the States as part of their quality assessment and performance improvement program. The commenters recommended that this

requirement be added under § 438.240(b). One commenter supported that we did not propose to require MCOs and PIHPs to meet minimum performance standards. The commenter argued that it is difficult to identify reasonable performance levels when taking into consideration the variation of local conditions, beneficiaries, and unique program characteristics. This commenter recommended that the provision for standard quality measures be modified to allow States to recommend modification to the standards on a regional or State basis.

Response: We do not agree that we should require States to establish minimum performance levels that MCOs and PIHPs must meet as an element of the quality assessment and improvement program. States have the option to establish such levels, whether they are State standards or regional standards. We agree that performance measures should be included as an element of the quality assessment and performance improvement program. This was our original intent. We have changed § 438.240(b)(2) to add calculation of performance measures as a basic element of quality assessment and performance improvement programs.

Comment: One commenter suggested that States require that the information obtained from assessments of underutilization and overutilization and of the quality and appropriateness of care to enrollees with special health care needs be reported by age, race, and ethnicity of Medicaid enrollees.

Response: We do not agree that this regulation should specify that information obtained on underutilization and overutilization of services or the quality and appropriateness of care furnished to enrollees with special health care needs should be reported according to age, race, and ethnicity. We believe that each State should specify how the information should be reported based upon individual State needs.

Comment: One commenter agreed with the requirement that MCOs and PIHPs annually measure performance using standard measures required by the State and report this information to the State. The commenter believes that this provision maintains MCO and PIHP accountability while providing critical flexibility in the manner in which the requirements are carried out.

Response: We agree with the commenter and we have retained the provision in § 438.240(c) of the final rule. We also take this opportunity to clarify that the State performance measures described in § 438.240(c) must

reflect any national performance measures that may be prescribed by the Secretary, consistent with § 438.204(c) and § 438.240(a)(2).

We also have taken the opportunity to recognize an additional approach to producing performance measures that maintains MCO and PIHP accountability while providing flexibility in the manner in which provisions at § 438.240(c) pertaining to performance measurement are met. Specifically, we have been reminded of a practice used by a growing number of States in which State agencies calculate measures of the performance of their MCOs or PIHPs using encounter and claims data transmitted by the MCO or PIHP to the State. We believe this is an acceptable practice that can reduce burden on MCOs and PIHPs, especially when MCOs or PIHPs are already transmitting encounter data to the State. Therefore, we have revised § 438.240(c) to indicate that there are three acceptable ways for States to obtain performance measures for each MCO and PIHP: (1) The MCO or PIHP could calculate the measures according to the States' specifications; (2) the State could calculate the measures using encounter or similar data submitted to the State by the MCO or PIHP; and (3) a State could obtain performance measures using a combination of these two approaches. We authorize States to determine the best approach or approaches to be used in its State, recognizing that a State may decide to use different approaches for individual MCOs or PIHPs.

Comment: Several commenters agreed with the limited detail included in this regulation related to performance improvement projects. The commenters argued that the regulation sufficiently describes Federal standards while allowing States and MCOs and PIHPs the flexibility to develop processes that work best to fit their programs. One commenter requested that we work with MCOs and PIHPs and other stakeholders to develop guidance related to the final regulation that will further explain our expectations for implementing performance improvement projects (for example, challenges inherent in efforts to positively affect quality of care and outcomes given eligibility status, changes of enrollees, small populations, etc.).

Response: We retain § 438.240(d) in our final rule. We have developed guidance for States on implementing performance improvement projects. As part of the development of the EQR regulation, we were statutorily mandated to contract with a national accreditation organization to develop protocols to be used in EQR. We

awarded a contract to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to develop these protocols. The JCAHO, as part of this effort, convened an expert panel composed of State agencies, MCOs, experts on quality improvement activities, and other stakeholders to provide us feedback on the development of the protocols. Two protocols address performance improvement projects. One protocol provides guidance on how to conduct performance improvement projects and one provides guidance on how to validate performance improvement projects. These protocols can be found on our web site at <http://www.hcfa.gov/medicaid/mceqrhmp.htm>.

Comment: Several commenters asked us to clarify under § 438.240(d)(2) what is meant by the "new information on quality of care every year" that we are requiring be reported by the MCO or PIHP on each project upon request by the State.

Response: The MCO or PIHP should provide to the State new information from performance improvement projects underway or information on projects that had been initiated since the previous annual report. For example, a project recently initiated by the MCO or PIHP may only be able to describe the topic selected and methodology to be used at the time of the first report. In year two, the intervention may have been implemented, but there may not yet be data to report. In year three, base line data may be collected, and in year four, there may be a repeat measurement. As projects progress, different information will be available to report.

Comment: Many commenters argued that our final rule should include more specific requirements related to performance improvement projects that include more specificity such as (1) that the MCOs/PIHPs include objective, clearly and unambiguously defined measures based on current clinical knowledge or health services research (2) that the measures measure outcomes such as change in health status, functional status, enrollees satisfaction, or proxies of these outcomes, and (3) that over time, MCOs/PIHPs vary projects to focus on a full spectrum of services rather than repeatedly monitoring areas that are easy to measure and improve. One commenter was concerned that the lack of specificity in the NPRM will result in MCOs and PIHPs developing quality measures that may be irrelevant to patient care and projects that may not protect patients. Another commenter was concerned that the lack of

specificity relieves States and MCOs from developing and monitoring performance measures for specific conditions such as mental illness and other severe disabilities.

Response: We do not agree that this regulation should provide more detail on performance improvement projects or on the indicators used to measure performance. We believe the final regulation creates a balance between an appropriate amount of detail needed to ensure that States implement interventions to improve quality, while at the same time, provides States with the flexibility to determine the measures and levels they want to require of their contracting MCOs and PIHPs. We believe that States and MCOs and PIHPs will use performance measures and performance improvement projects that reflect important areas. These activities are costly and time-consuming and we believe that States and MCOs/PIHPs will target the investments in financial and staffing resources required for these activities to topics that will benefit from program improvement.

Section 438.240 requires, as a basic element of a quality assessment and performance improvement program, that MCOs and PIHPs have in effect mechanisms to assess the quality and appropriateness of care furnished to enrollees with special health care needs. This includes beneficiaries with conditions such as mental illness and other severe disabilities.

Comment: Many commenters argued that MCOs and PIHPs should be required to conduct performance improvement projects on topics specified by the State and that MCOs and PIHPs should be required to participate in at least one statewide project. The commenters recommended that we incorporate these requirements in our final rule.

Response: We do not agree that this rule should require that States have their MCOs and PIHPs participate in statewide projects. We reserve the right to set performance improvement project topics in the future as specified in § 438.240(a)(2). A State, at its discretion, however, may choose to specify topics for MCOs or PIHPs improvement projects or to mandate participation in statewide projects.

Comment: One commenter encouraged us to recognize the long-term nature of quality initiatives, that improvement in quality is incremental. The commenter was concerned that the short-term commitment to initiatives that is usually the perspective of States does not provide a paradigm for studying and understanding what works in managed care. The commenter argued

that quality initiatives should not change capriciously from year to year.

Response: We agree with the commenter and acknowledge that quality improvement initiatives need a sufficient amount of time to be implemented and for findings to be determined. We do not prescribe the duration in which performance improvement projects must be completed. We only require that a project be completed in a reasonable time period and that information be provided on the project's progress annually.

Comment: Several commenters asked for clarification on how the program review by States will be coordinated with the EQR regulations. Several commenters suggested that we coordinate these efforts to avoid duplication of efforts. For example, one commenter suggested that we permit MCOs and PIHPs that are certified by an accreditation agency or who are reviewed by another State agency to be exempt from Medicaid reviews and EQR. One commenter suggested that we provide a cross reference to the EQR regulation and that we provide States sufficient discretion to define and modify their external review activities. Another commenter suggested that we amend the regulation to allow a State to use the EQR to meet the program review by the State requirements under § 438.240(e).

Response: States at their option may use EQR findings to meet the program review requirements under § 438.240(e)(1). The final EQR rule addresses the circumstances under which an MCO or PIHP may be exempt from quality initiatives and what types of quality initiatives we consider to be EQR activities. We are not providing a cross reference to the EQR provisions or amending this rule to stipulate that EQR can be used to meet this requirement. We are providing States with the flexibility to decide if they want to use EQR or some other activity to meet these requirements.

Comment: One commenter agreed with the requirement that States review the MCO's and PIHP's performance on standard measures on which MCOs and PIHPs are required to report.

Response: In the final rule, we retain § 438.240(e)(1) as proposed.

16. Health Information Systems (Proposed § 438.242)

Section 1932(c)(1)(iii) of the Act requires States that contract with MCOs to develop a quality assessment and improvement strategy that includes procedures for monitoring and evaluating the quality and

appropriateness of care and services to enrollees. It also provides that MCOs provide quality assurance data to the State using the data and information set specified by the Secretary for the Medicare+Choice program or other data specified by the Secretary in consultation with States. Section 438.242 proposed that States require that MCOs and PIHPs have health information systems sufficient to provide data to States and CMS.

Paragraph (a) required that States must ensure that MCOs and PIHPs maintain data systems that collect, analyze, integrate, and report data to achieve the objectives of subpart D. It required that the system must provide information on utilization, grievances, and disenrollments (other than those that result from ineligibility for Medicaid). Paragraph (b) provided that the State must require MCOs and PIHPs to collect data on enrollee and provider characteristics and on services furnished to enrollees, and to ensure the accuracy and completeness of data received from providers by (1) verifying its accuracy and completeness; (2) screening the data for completeness, logic, and consistency; and (3) collecting service information in standard formats to the extent feasible and appropriate.

Paragraph(c) required MCOs and PIHPs to make all data available, as required in this subpart, to the State and, on request, to CMS.

Comment: One commenter urged CMS to establish national data collection standards for collection of encounter data, EPSDT information, and network information by States, using standards established under the Health Insurance Portability and Accountability Act (HIPAA) where possible.

Response: We do not agree that CMS should establish national data collection standards as part of this regulation. Under HIPAA, the Secretary is establishing standards for the electronic transfer of health data, including encounter data. The HIPAA regulations also specify the entities to which the standards apply. Medicaid MCOs and PIHPs, as well as State Medicaid agencies, will need to comply with the HIPAA regulations to the extent they apply.

Comment: One commenter noted that MCO and PIHPs can only supply data to States to the extent they are provided data by providers. This commenter suggested that this regulation require that providers give data to health plans.

Response: This regulation is directed to States and, by placing requirements on States for their contracts with MCOs,

PIHPs, PAHPs, and PCCMs, on these other entities. The regulation does not address the relationships of MCOs and PIHPs and their providers. Therefore, we are not including a provision to require data reporting by providers.

Comment: One commenter noted that it is important for States to negotiate price discounts with hardware and software vendors that can be passed on to providers and to develop guidance materials for practices preparing to install hardware and software.

Response: States are in the best position to identify means to assist providers with the electronic submission of data. We do not believe that this issue should be addressed in Federal regulations. We revised § 438.242(a) by adding the words "and appeals" after "grievances". This change was made to be consistent with § 438.416, which requires States to review information collected by MCOs and PIHPs as part of the State quality strategy.

E. Grievance System (Subpart F)

Proposed subpart F is based on section 1902(a)(3) of the Act, (which requires a State plan to provide an opportunity for a fair hearing to any person whose request for assistance is denied or not acted upon promptly), section 1902(a)(4) of the Act, (which authorizes the Secretary to specify methods of administration that are "necessary" for "proper and efficient administration"), and section 1932(b)(4) of the Act, (which requires that MCOs have an internal grievance procedure under which a Medicaid enrollee, or a provider on behalf of an enrollee, may challenge the denial of coverage of, or payment by, the MCO).

In this subpart, we proposed regulations that lay out the elements of the grievance system required under section 1932(b)(4) of the Act, and how it interfaces with the State fair hearing requirements in section 1902(a)(3). We defined terms, described what constitutes a notice of action, and addressed how grievances and appeals must be handled, including timeframes for taking action. We included a process for expedited resolution of appeals in specific circumstances; addressed the requirement for continuation of benefits; and laid out the requirements relating to record keeping, monitoring and effectuation of reversed appeal resolutions.

We proposed conforming amendments to part 431 to reflect changes in terminology and other new provisions enacted in the BBA. We also made conforming changes to the fair hearing regulations in subpart E of part

431, to reflect the MCO grievance and appeals process in subpart F of part 438. We note that we revised § 431.244(f)(3) to require State approval for direct access to an expedited State fair hearing for MCO and PIHP enrollees. Due to the close relationship of the subject matter with subpart F, comments and responses regarding part 431 are addressed in this subpart.

1. Statutory Basis and Definitions (Proposed § 438.400)

Definitions of terms used in proposed subpart F are found in proposed § 438.400 and have the following meanings:

Action means, in the case of an MCO or PIHP or any of its providers,

- The denial or limited authorization of a requested service, including the type or level of service;
- The reduction, suspension, or termination of a previously authorized service;
- The denial, in whole or in part, of payment for a service; or
- For a resident of a rural area with only one MCO or PIHP, the denial of a Medicaid enrollee's request to exercise his or her right to obtain services outside the network.

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

Grievance is defined as an expression of dissatisfaction about any matter other than an action. This term can also be used to refer to the overall system that includes grievances and appeals handled at the MCO or PIHP level and access to the State fair hearing Process. Possible subjects for grievances include, but are not limited to, the quality of care or services provided, aspects of interpersonal relationships such as rudeness of a provider or employee, or failure to respect the enrollee's rights.

Proposed § 438.400 contained the definition of a "governing body." We, however, had not proposed regulatory requirements for a governing body. Therefore, we are removing the definition of a governing body in the final rule.

We received the following comments on these definitions.

Comment: One commenter felt that having several potentially conflicting Federal statutes and State laws related to a health care plan's grievance system is troubling for the plans. They asked that, if a Patients' Bill of Rights is enacted, CMS review the provisions of this regulation to make it consistent with the mandate under that legislation, as well as ERISA rules.

Response: We agree with the commenter. If a Patients' Bill of Rights

is enacted, we of course would be required to conform to the new statute if it applied to Medicaid, but even if it did not, we would review the provisions and consider making changes if it is appropriate for the Medicaid program.

Comment: Many commenters believe that the definition of "action" must include the failure to furnish services in a timely manner, the failure to resolve an appeal in a timely manner, or the denial of an enrollee's request to disenroll. They argued that if a plan delays furnishing services or adjudicating a claim in a timely manner, no "action" is triggered. Therefore, the enrollee would be denied his or her right under section 1902(a)(3) to a fair hearing if a claim medical assistance is "not acted upon with reasonable promptness."

Response: We agree that section 1902(a)(3) of the Act requires access to a State fair hearing for those requests not acted upon in a timely manner, and therefore, in § 438.400(b) we have modified the definition of "action" to include unreasonable delays in services, or appeals not acted upon within the timeframes provided in § 438.408(b). However, we disagree that a denial of a request to disenroll constitutes an "action," as it addresses an issue separate from those specific denials, limitations, reductions, or suspensions of services that trigger fair hearing requirements.

Comment: Some commenters believe that the grievance and appeals provisions should apply to PAHPs as well as to MCOs and PIHPs.

Response: We agree that PAHP enrollees should have the right to appeal denials, but believe that direct access to the existing fee-for-service fair hearing process is the more appropriate vehicle for this in the case of PAHPs. Therefore, in response to this comment, we have revised the fair hearing regulations in subpart E of part 431 to expressly reference PAHP enrollees as having a right to a fair hearing under those provisions in the case of an "action." In general, we believe that the State should decide how best to address grievances involving PAHPs that do not involve an action, since they are often individual physicians or small group practices and cannot be expected to have the administrative structure to support a grievance process.

Comment: Several commenters disagreed that the independent professional judgment of providers should automatically trigger an action in the same manner as a denial from an MCO or PIHP. They believed that it is sometimes impossible for the MCO or PIHP to know when a provider has

denied a service, or offered an alternative form of treatment that may or may not be a denial. They requested that providers be removed from the "action" definition.

Response: We agree with the commenters. Since a provider is making independent professional judgments as to the care and treatment of enrollees, his or her denial of a particular request, or the suggestion of an alternative should not automatically trigger a formal notice of appeal rights from the MCO or PIHP. We have removed "or any of its providers" from the definition of an "action." However, anytime an enrollee challenges the decision of a provider to the MCO or PIHP, an action is triggered if the MCO or PIHP affirms the provider's decision, triggering a notice from the MCO or PIHP.

Comment: Many commenters wanted the regulations to provide expressly for a "quality of care" grievance in cases in which the enrollee believed that any aspect of his or her care was substandard, or could have caused them harm. These commenters recommended that the State be required to review any such "quality" grievance that was not disposed of to the enrollee's satisfaction. Some commenters wanted these grievances to be reviewable by a State fair hearing.

Response: We believe that those enrollee complaints not meeting the standard of an appeal should be treated uniformly under Federal statute. The definition of "grievance" includes "quality of care" and it should be up to the State to decide whether or not a review, or a mechanism allowing State review, is necessary. We also believe that an enrollee only has the right to a State fair hearing under section 1902(a)(3) in cases that involve an "action," since section 1902(a)(3) refers to a denial of medical assistance, or a case in which a claim for assistance is "not acted upon," and not a case in which there are concerns about the quality of the assistance. We believe that the quality assurance requirements in subpart D of part 438 address the commenter's concerns.

Comment: One commenter felt that appeal rights should be extended to providers in managed care systems. They argued that this is notable considering the appeal rights extended to MCOs in the right to pre-termination hearings.

Response: The grievance and appeal rights in this subpart implement statutory provisions that grant rights to Medicaid beneficiaries, not providers. The right to a fair hearing in section 1902(a)(3) applies to an "individual" whose claim for medical assistance is

denied or not acted upon. The statutory requirement in section 1932(b)(4) that MCOs have grievance procedures similarly applies to "an enrollee* * * or a provider *on behalf of an enrollee.* * * *" (Emphasis added.) While it is true that the statute provides for the right to a hearing before an MCO contract is terminated, there is no statutory provision for an appeal right for providers subcontracting with managed care plans. While States are free to provide such rights, and information must be provided about such rights where they exist (see section A. above), there are no such rights under Federal statute. We defer to congressional intent on this issue, and have not provided for any subcontracting provider appeal rights in this final rule.

2. General Requirements (Proposed § 438.402)

Proposed § 438.402 required each MCO and PIHP to have a grievance system in place for enrollees that includes a grievance process, an appeal process, and access to the State's fair hearing system.

Proposed § 438.402(b)(1) specified that an enrollee may file a grievance or an MCO or PIHP level appeal, and may request a State fair hearing. In addition, as provided in section 1932(b)(4), the proposed rule provides that a provider, acting on behalf of an enrollee (with the enrollee's written consent) may file an appeal of a "denial of coverage of or payment for" assistance, or an "action." However, under proposed § 438.402(b)(1)(ii), the provider could not file a grievance or request a State fair hearing on behalf of the enrollee.

Under § 438.402(b)(2), we proposed timeframes within which the enrollee or provider (on the enrollee's behalf) may file an appeal. Our intent was to mirror the filing timeframes for a State fair hearing, that is, a reasonable amount of time up to 90 days. In addition, we incorporated the longstanding policy at section 2901.3 of the State Medicaid Manual that beneficiaries be given a minimum of 20 days to file an appeal. We believe that this policy gives beneficiaries a reasonable amount of time to file an appeal. Therefore, the proposed regulation required that the State specifies a timeframe for filing an appeal that is no less than 20 days or more than 90 days from the date of the MCO's or PIHP's notice of action. Within this timeframe, the enrollee (or the provider on his or her behalf) may file an appeal, and in a State that does not require exhaustion of the MCO and PIHP level appeals, the enrollee may request a State fair hearing.

In proposed § 438.402(b)(3), we specified the manner in which enrollees may file grievances, and enrollees (or a provider on the enrollee's behalf) may file an appeal. For grievances, the enrollee may file either orally or in writing, either with the State or the MCO or PIHP, as determined by the State. The enrollee (or the provider on the enrollee's behalf) was permitted to file an appeal either orally or in writing, and unless he or she requests expedited resolution, was required to follow an oral filing with a written, signed, appeal. While enrollees were permitted to start the appeal clock with an oral request, under the proposed rule, they were required under the proposed rule to follow it with a written request, as we determined that a written appeal best documents the issue being appealed. In expedited situations, the proposed rule provided that the enrollee was not required to put the appeal in writing.

Comment: A few commenters believed that permitting States to require the exhaustion of internal MCO or PIHP appeals procedures was unwarranted, and favored appeal rights administered by a state agency using the Federal fair hearing regulations. Other commenters believed that since MCOs are responsible for coordinating care and making coverage decisions, enrollees should be required to utilize their internal appeals process first before filing for a State fair hearing.

Response: We disagree with both sets of commenters. With respect to the commenters opposing an internal grievance procedure, section 1932(b)(4) actually requires that such a procedure be available, and that enrollees be permitted to "challenge" a "denial of coverage of, or payment for" services under such procedures. Thus, using exclusively a State administered fair hearing mechanism was not even an option under the law. Furthermore, providing for an MCO/PIHP level of review is consistent with the appeals rules under the Medicare+Choice program, and most versions of Patients Bill of Rights legislation. We believe that as long as the timeframes and notice requirements conform with what is allowed under direct access, an internal system is a proper and efficient way to adjudicate appeals. However, we also believe that the State should have full discretion when it comes to whether to require the utilization of the required internal appeals process, or permit direct access to State fair hearing.

Comment: Some commenters found that the word "grievance," referring to the overall system as well as a particular avenue of adjudication, is inherently confusing. They recommended changing

"grievance system" to something such as the "dispute resolution process" or "complaint process." Others felt that the definition was too broad, triggering rights where a different avenue for resolution would make more sense.

Response: While we refer to the overall process as the "grievance system," States are free to call it by any name they prefer. We chose "grievance system" over terms such as "dispute resolution process" or "complaint process" because this is the term used in section 1932(b)(4), and the other terms suggested by the commenters were too informal. To some people, "complaint" conjures up ideas of more trivial matters, while "dispute resolution" is sometimes associated with arbitration, which connotes a less strict standard than we wanted to convey. While we based our reference to the overall system on the reference to "an internal grievance procedure" in section 1932(b)(4), our use of the term "grievance" to refer to disputes not resulting from an "action" tracks the approach in the Medicare+Choice regulations, and is based on the broad connotations of the word grievance to capture a variety of types of complaints. We believe that the timeframes and other administrative requirements in this final rule provide sufficient State flexibility to not be a burden on the grievance system.

Comment: Many commenters recommended additional general requirements for the grievance system. These recommendations included specific terms in the regulations requiring: (1) That all processes, policies, and procedures meet the conditions set forth in this subpart; (2) a State's written approval of an MCO's or PIHP's policies and procedures before implementation; (3) a governing body responsible for effective operation of the system including disposing of grievances and resolving appeals; (4) assurance that punitive action is neither threatened nor taken against a provider who requests or supports a grievance or appeal; (5) acceptance of grievances and appeals from the enrollee or his or her representative; (6) the provision of information required under this subpart; (7) the referral to the State of quality of care grievances in which the enrollee is dissatisfied; and (8) that providers be required to give notice in accordance with § 438.404(d).

Response: We believe that many of the above suggested requirements are already addressed in this final rule, either directly or implicitly. For example, we believe that while it would be clear without any explicit statement that grievance processes, policies and

procedures must be consistent with the regulatory requirements in part F, § 438.228 already expressly requires States to ensure, through its contracts, that MCOs and PIHPs have grievance systems that satisfy the requirements of this subpart. This includes the requirement on States to conduct random reviews of MCOs and PIHPs to ensure that they are notifying enrollees in a timely manner. The acceptance of appeals and grievances from the enrollee or a representative is similarly already provided for, as is the requirement, in § 438.10, for provision of information on appeals. We have addressed in section A of this preamble the commenters' suggestion for an assurance of no punitive action for requesting an appeal. Most of the other suggestions above would in our view most appropriately be addressed by the States without further Federal regulation.

Comment: Many commenters believed that a State should not be permitted to establish a deadline for appealing an adverse action that is less than 30 days, even though shorter periods are now permissible in the fee-for-service Medicaid program.

Response: As stated in the introduction, our intent was to mirror the filing timeframes for the State fair hearing; that is, a reasonable amount of time up to 90 days. In addition, we incorporated the longstanding policy at § 2901.3 of the State Medicaid Manual that beneficiaries be given a minimum of 20 days to file an appeal. We believe that this policy gives beneficiaries a reasonable amount of time to file an appeal, while providing States with the flexibility to tailor those timeframes to their particular internal and State procedures. Therefore, we will retain the requirement that the State specify a timeframe for filing an appeal that is no less than 20 days and does not exceed 90 days from the date of the MCO's or PIHP's notice of action.

Comment: One commenter objected to the fact that the proposed rule would allow providers, with written consent, to file an appeal on behalf of the enrollee, but prohibit providers from acting as an authorized representative for grievances or State fair hearings.

Response: As noted in section E. 1. above, we have limited the right to request a fair hearing, and the right to appeal a denial of coverage, to enrollees, and to providers on behalf of enrollees, in deference to our interpretation of congressional intent. In the case of grievances, since these are likely to involve a provider, we have limited the right to file a grievance to an enrollee. The commenter, however, correctly

notes that we have not just denied a provider the *right* to file a grievance or fair hearing request on behalf of an enrollee, but have affirmatively *prohibited* providers from doing so, through the second sentence in proposed § 438.402(b)(1)(ii). In considering this comment, we have determined that we do not wish to prohibit providers from acting as authorized representatives for grievances, appeals and state fair hearings, if the State wishes to provide them with this right. Since the current prohibition would pre-empt a State law to the contrary, we are, in response to this comment, changing the second sentence in proposed § 438.402(b)(1)(ii) to read, "A provider may file a grievance or fair hearing request on behalf of an enrollee if the State permits the provider to act as the enrollee's authorized representative in doing so."

3. Notice of Action (Proposed § 438.404)

Under the proposed rule, the notice MCOs and PIHPs are required to provide to enrollees under proposed § 438.404 would be the first step in the grievance system. It would serve as the enrollee's first formal indication that the MCO or PIHP will or has taken action, such as denying payment or denying, limiting, reducing, suspending or terminating a service through a service authorization decision. We proposed in § 438.404(a) that the notice meet the language and format requirements of proposed § 438.10(c) and (d) of this chapter to ensure ease of understanding. The notice must include the elements that are listed in proposed § 438.404(b), as follows:

- The action the MCO or PIHP or its contractor has taken or intends to take.
- The reasons for the action.
- The enrollee's or the provider's right to file an MCO or PIHP appeal.
- If the State does not require the enrollee to exhaust the MCO or PIHP level appeal procedures, the enrollee's right to request a State fair hearing.
- The procedures for exercising the rights specified in this section.
- The circumstances under which expedited resolution of an appeal is available, and how to request it.
- The enrollee's right to have benefits continue pending resolution of the appeal, how to request that benefits be continued, and the circumstances under which the enrollee may be required to pay the costs of these services.

In proposed § 438.404(c), we specified the timeframes in which the MCO and PIHP must mail the notices. Under proposed § 438.404(c)(1), timeframes for notices for the reduction, suspension, or termination of previously authorized

services are governed by the State fair hearing regulations found in 42 CFR part 431, subpart E. While some MCOs and PIHPs may find the advance notice requirement inappropriate, there are exceptions to advance notice that allow notice to be given on the date of the action (see § 431.213). These exceptions would cover the situation in which a provider believes an immediate change in care is appropriate for the health condition of the enrollee. For denial of payment, we required in proposed § 438.404(c)(2) that notice be given at the time of any action affecting the claim. Proposed § 438.404(c)(3) and (c)(4) required that for standard service authorization decisions that deny or limit services, notice must be given within the timeframes specified in § 438.210(d). Further, if the MCO or PIHP were to extend the timeframe in accordance with proposed § 438.210(d), it would have to give the enrollee written notice of the reason for the decision to extend the timeframe, inform the enrollee of the right to file a grievance if he or she disagrees with that decision, and issue and carry out its determination as expeditiously as the enrollee's health conditions requires and no later than the date the extension expires. In situations in which the service authorization decision is not reached within specified timeframes, and the failure to authorize a decision constitutes an adverse decision, we proposed at § 438.404(c)(5) that notice be mailed on the date that the timeframe for authorizing services expires without an authorization decision being made. Finally, for expedited service authorization decisions, under the proposed rule notice had to be given within the timeframes specified in proposed § 438.210(e) (recodified in this final rule at § 438.210(d)).

Comment: Several commenters believed that a strict application of the proposed notice requirement would be burdensome, especially if applied to decisions of primary care physicians (PCPs) made without involvement of the MCO or PIHP. Commenters also asked that CMS distinguish between claims that involve liability where the enrollee is actually billed, versus where there is no actual payment liability. Some commenters contended that MCOs and PIHPs do not always know when their providers deny services, making it difficult for them to comply with the notice requirements. Another commenter was concerned with § 438.404(b)(1) requiring a notice to explain the action the MCO or PIHP or its contractor has taken or intends to take. They felt that "contractor" could

be read as being a provider. They requested clarification.

Response: We agree with the commenters that a provider, using his or her professional judgement in making a determination of medical necessity, should not trigger a notice by reason of recommending against or preferring an alternative to a particular treatment. As discussed above, in response to comments received (including this comment), we have removed the word "provider" from the definition of "action" triggering notice obligations and appeal rights. As used in § 438.404(b)(1), a "contractor" would not include a provider, but rather any entity in which an MCO or PIHP delegated this particular authority/responsibility. However, an enrollee retains the right to request that the MCO or PIHP provide a particular service against the advice of a provider, triggering the requirement of a notice from that MCO or PIHP if the request results in a denial, reduction, or suspension. We disagree that notice rights are triggered only when a beneficiary is actually held liable for a particular claim. An action that may include a claim arising from a third party (such as, a hospital) because an MCO or PIHP refused to pay the claim. Even though the hospital may choose not to bill the beneficiary, a denial for payment of a service has occurred, triggering a notice to the beneficiary that the claim was denied. This ensures that a beneficiary is made aware of his or her appeal rights in case they are billed by a third party.

Comment: Several commenters noted that they do not believe that the expiration of an approved number of visits should be considered a termination. They noted that the enrollee is free to request that the service be continued, but that this request should be treated as a new request for a service. Other commenters expressed the opposite view; they believe that re-authorization of a service at a lower level than previously received, or a denial of re-authorization, is a termination or reduction of the service and should require notice and the continuation of benefits pending appeal.

Response: We agree with the first set of commenters that the expiration of an approved number of visits does not constitute a termination for purposes of notice and continuation of benefits. Likewise, when a prescription (including refills) runs out and the enrollee requests another prescription, this is a new request not a termination of benefits. In these circumstances, the MCO or PIHP would not need to send

a notice or continue benefits pending the outcome of an appeal or State fair hearing. If the enrollee requests a re-authorization that the MCO or PIHP denies, the MCO or PIHP must treat this request as a new request for service authorization and provide notice of the denial or limitation. We disagree with the second commenters that a denial of authorization for additional days is a "termination," since the enrollee had no expectation of coverage on those days, and this was thus simply a denial of a new request, not a termination of services the enrollee had a right to expect to continue.

We believe that the proposed rule already clearly reflected the above interpretation. In the definition of "Action," the reference to a "reduction, suspension, or termination" in the proposed rule was qualified by the phrase, "of a previously authorized service." Thus, the cessation of services because the authorization expired would not be an "action," because services after the date when the authorization expired would not be "previously authorized." In proposed § 438.404(c)(1), the reference to timeframes for a notice of a "termination, suspension, or reduction" was similarly qualified by "of previously authorized Medicaid-covered services." In proposed § 438.420(b), specifically governing the continuation of services, the right to continued benefits is expressly conditioned on the "[t]he appeal involv[ing] the termination, suspension, or reduction of a previously authorized course of treatment." Again, we believe it is clear that if additional days were not authorized, ending treatment as provided in the original authorization would not constitute a termination triggering the right to continued benefits. We have made one change in this rule in response to this comment, however. In a case in which services which were "previously authorized" are continued or reinstated at the request of the enrollee pending appeal, and during this continuation period, the period of authorization expires, services may be terminated as provided in the original authorization. We have added a new § 438.420(c)(4) to make this clear.

Comment: One commenter believed that CMS underestimated the true burden associated with MCO and PIHP notices, suggesting that it is closer to 20 minutes than 30 seconds per notice.

Response: We address this issue under the Collection of Information Requirements section of this preamble.

Comment: We received many comments regarding the elements of a notice. Several commenters suggested

that the written notice requirements of proposed § 438.404 be modified to mirror the existing State fair hearing regulations. Other commenters did not believe that there were sufficient protections in place to ensure that enrollees not only have rights, but have effective notice of those rights. These other commenters recommended additional requirements addressing the right to request a State fair hearing, the right to present evidence, how to contact the MCO or PIHP for assistance, how to obtain copies of enrollee records, the right of an enrollee to represent himself or herself or use counsel, and the right to be free from any negative impact from having filed an appeal. Several commenters were concerned that while oral requests for standard appeals must be followed up in writing, there was no requirement that enrollees be told this in the notice. They wanted to see this added.

Response: We agree that information given by MCOs and PIHPs should generally contain the information required by the State fair hearing notices. However, the provision of most of this information is required under the information requirements in § 438.10(g)(1) and the content requirements for a notice in § 438.404. These requirements will ensure that enrollees are informed, for example, that an oral request for a standard appeal will not be pursued unless it is followed up in writing, of the enrollee's right to a hearing, the method for having a hearing, and circumstances surrounding continuation of benefits, if applicable. We have previously addressed the comment on language concerning negative actions by an MCO or PIHP.

Comment: One commenter noted that § 438.404(c)(6) included an incorrect reference. The reference to § 438.210(e) should read "§ 438.210(d)."

Response: We agree with the commenter. We have made the appropriate change in § 438.404(c)(6) by correcting the cross reference to read § 438.210(d).

4. Handling of Grievances and Appeals (Proposed § 438.406)

Section 438.406 proposed to set forth how grievances and appeals must be handled. The general requirement for handling grievances and appeals would require MCOs and PIHPs to do the following:

- Give enrollees any reasonable assistance in completing forms and taking other procedural steps.
- Acknowledge receipt of each grievance and appeal.
- Ensure that individuals who make decisions on grievances and appeals are

individuals who were not involved in any previous level of review or decision making and who, if deciding an appeal of a denial that is based on lack of medical necessity, a grievance regarding denial of expedited resolution of an appeal, or a grievance or appeal that involves clinical issues, are health care professionals who have the appropriate clinical expertise in treating the enrollee's condition or disease.

We would require the MCO and PIHP, at proposed § 438.406(a)(1), that the "reasonable assistance" provided to enrollees include interpreter services and toll free numbers that have adequate TTY/TTD and interpreter capability. By including these as examples of types of assistance required to meet certain needs, we did not intend that other reasonable assistance need not be given. We believe, for example, that MCOs and PIHPs are required by this provision to provide reasonable assistance to meet other needs of enrollees, and assisting enrollees who have low-literacy abilities.

Proposed § 438.406(b) specified the following requirements that the appeals process would have to meet:

- Provide that oral inquiries seeking to appeal an action are treated as appeals and must be confirmed in writing, unless the enrollee or the provider requests expedited resolution. This is required in order to establish the earliest possible filing date for the appeal.
- Provide the enrollee a reasonable opportunity to present evidence, and allegations of fact or law, in person as well as in writing.
- Provide the enroll and his or her representative the opportunity, before and during the appeals process, to examine the enrollee's case file, including medical records, and any other documents and records considered during the appeals process.
- Include, as parties to the appeal, the enrollee and his or her representative or the legal representative of a deceased enrollee's estate.

Comment: One commenter was unclear whether the proposed rule permitted conducting State fair hearings using a video-conferencing system. The commenter noted that many states now use this technology, with videoconference facilities in numerous locations. Multiple sites can be linked to make it more convenient for all parties to participate in the hearing, reducing travel costs, and conserving time.

Response: Nothing in the statute or regulation prevents MCOs, PIHPs, or States from using videoconferencing equipment as long as they adhere to the

evidentiary rules described in parts 431 and 438.

Comment: Several commenters recommended that CMS establish more general standards regarding the qualifications of hearings officers. Commenters were concerned with the burden of finding providers with clinical expertise for a voluminous number of cases. They requested that it be permissible to either use physicians or other types of providers with appropriate clinical expertise. Other commenters recommended being more specific in linking certain cases to a particular area of expertise. For example, one commenter wanted language ensuring that all grievances and appeals involving care to a child be reviewed by pediatricians and pediatric specialists.

Response: We believe that it is important for adjudicators to have clinical training appropriate for the case in which they are presiding. However, we are leaving the definition of "appropriate clinical expertise" to be defined by the States. This allows States to decide what clinical expertise level is necessary to fit its particular appeals process and volume of cases.

Comment: Several commenters suggested adding "but not limited to" to § 438.406(a)(1) where it includes examples of enrollee assistance with grievance and appeals procedures. They believed that this addition would make the language of the regulation comport with the expressed intent of CMS.

Response: We agree with the commenters, and in response to this comment, we have added "but is not limited to" in § 438.406(a)(1).

Comment: Several commenters urged CMS to require MCOs and PHPs to have an adequately staffed office designated as the central point for enrollee issues, including grievances and appeals. This would ensure that the processing is someone's job, and not viewed as a chore that is handled on an ad hoc basis.

Response: We disagree with the commenters. As long as States can ensure that those requirements in § 438.406 are met, we believe that it should be their decision as to how best an MCO or PIHP can fulfill those requirements.

Comment: Several commenters questioned the impartiality of an internal appeals system, and felt that CMS should add language to the regulation preventing any employees of the MCO or PHP from being final decision makers on coverage decisions.

Response: In both the Medicare and Medicaid programs, the Congress has provided for an initial level of review of

enrollee appeals at the managed care organization level. We believe that the use of the words "internal grievance procedure" in section 1932(b)(4) indicates that the Congress contemplated that review be performed by MCO employees. Within this context, this final rule requires that the decision-makers not be individuals involved in any previous level of review, and either be physicians or have the clinical expertise needed to make a decision involving the enrollee's particular condition or disease. We believe that these requirements help insure that internal decisions will be as objective as possible. With respect to the "final decision" on a coverage question, all MCO or PIHP coverage decisions are subject to review by non-MCO employees at the State fair hearing level. We believe that those safeguards are reasonable and necessary at the internal appeals level.

Comment: Several commenters believed that we should require MCOs and PHPs to explicitly state that enrollees may obtain copies of their records.

Response: Section 438.406(b)(3) requires that MCOs and PIHPs provide the enrollee and his or her representative with the opportunity to examine the enrollee's case file, including medical records, and any other documents and records considered during the appeals process. However, we believe that the State is in the best position to decide in what way enrollees must be notified about this right.

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

In proposed § 438.408(a), we required that the MCO or PIHP dispose of each grievance and resolve each appeal, and provide notice, as expeditiously as the enrollee's health condition requires. In addition, this section required that the State establish timeframes for disposition of grievances and resolution of appeals, not to exceed the specific timeframes proposed in this section.

While we proposed timeframes to resolve appeals, we realize that the Congress, as part of proposals for a patient's bill of rights, is considering several other timeframes for internal MCO appeals. Some of these proposals would apply the timeframes to the Medicaid program. If these proposals were enacted, such statutory timeframes would supersede those set forth in this final rule.

Under proposed § 438.408(b), we established the specific maximum timeframes for disposition of grievances

and resolution of appeals. For the standard disposition of a grievance and notice to affected parties, the State may establish a timeframe for disposition that may not exceed 90 days from the day the MCO or PIHP receives the grievance. For standard resolution of an appeal and notice to affected parties, proposed § 438.408(b)(2) required that the State establish a timeframe no longer than 45 days from the day the MCO or PIHP receives the appeal. However, this proposed timeframe could be extended under proposed § 438.408(c), which specified that the MCO or PIHP may extend the timeframe by up to 14 calendar days if the enrollee requests the extension, or the MCO or PIHP shows (to the satisfaction of the State agency, upon its request) that there is need for additional information and how the delay is in the enrollee's interest.

Proposed § 438.408(b)(3) provided a maximum timeframe for expedited resolution of appeals and notice to affected parties. We required that the State establish a timeframe no longer than 3 working days after the MCO or PIHP receives the appeal. We believe that expedited resolution is necessary to ensure that appeals of situations that potentially place an enrollee's health in jeopardy are not delayed. Although States have historically instituted different processes to protect beneficiaries, we believe that a standardized expedited appeal process is needed to protect beneficiaries in a capitated health care delivery system. Further, this is an important beneficiary protection and is necessary to ensure that the overall timeframe of 90 days for a decision at the State fair hearing (excluding the time the beneficiary takes to file for a State fair hearing) can be met in all cases. However, similar to standard resolution of appeals, we proposed that this expedited timeframe can also be extended by 14 calendar days if the enrollee requests extension or the MCO or PIHP shows (to the satisfaction of the State agency, upon its request) that there is need for additional information and how the delay is in the enrollee's interest.

We proposed certain parameters for the extension process. Under proposed § 438.408(c)(2), if the MCO or PIHP grants itself an extension, it is required to notify the enrollee in writing of the reason for the delay. In § 438.408(d), we required the State to establish the method MCOs and PIHPs will use to notify an enrollee of the disposition of a grievance. Under proposed § 438.408(e), we specified that written notice of the appeal resolution must include the following:

- The results of the resolution process and the date it was completed.
- For appeals not resolved in favor of the enrollee, the enrollee's right to request a State fair hearing and how to do so, the right to request to receive continuation of benefits, and that the enrollee may be held liable for the cost of those continued benefits if the State fair hearing decision upholds the MCO's or PIHP's action.

Finally, at proposed § 438.408(f) (this paragraph was erroneously codified as a second paragraph (c), an error that has been corrected in this final rule), we outlined the requirements for State fair hearings. We required the State to permit the enrollee to request a State fair hearing within a reasonable time period specified by the State, but not less than 20 days or in excess of 90 days from the date of the MCO's or PIHP's notice of resolution (if the State requires exhaustion of the MCO or PIHP level appeal procedures) or from the date on the MCO's or PIHP's notice of action (if the State does not require exhaustion and the enrollee appeals directly to the State for a fair hearing). We also felt it was important to outline at proposed § 438.408(f)(2) that the parties to the State fair hearing include the MCO or PIHP as well as the enrollee and his or her representative, or the representative of a deceased enrollee's estate.

Comment: Several commenters felt that proposed § 438.408(a) should be revised to require that all notices of dispositions of grievances be provided in writing. These commenters argued that MCOs and PIHPs often confuse cases which should be treated as a grievance with those that should be handled as an appeal. Written dispositions of grievances would in the views of these commenters provide a mechanism for addressing this issue by revealing whether or not an MCO or PIHP is resolving a dispute pursuant to the appropriate mechanism.

Response: We believe that § 438.408 makes the difference between a grievance and an appeal very clear. An appeal is triggered through an action, while a grievance involves any dissatisfaction other than an action. If a State chooses to monitor its MCOs and PIHPs by requiring written notices, it may do so. However, we see no reason to require a written notice at the Federal level for all grievances, when many may not be of a nature for which such a notice is appropriate, and there is no Federal right to review by the State of such matters.

Comment: Comments on timeframes widely differed. Many commenters questioned the fact that the timeframes for appeals in the proposed rule were

longer than those in place under Medicaid fee-for-service, Medicare+Choice, and versions of Patients Bill of Rights legislation. The commenters apparently believed that departing from these standards failed to adequately protect beneficiaries, and raised constitutional due process questions. These commenters wanted standard internal appeals to be resolved within 30 days. However, several other commenters found the 45-day timeframe more reasonable. Still other commenters were confused about the timeframes in general, and wanted an explanation of how they worked.

Response: We realize that the proposed timeframes were confusing as proposed, and potentially would not give the State a reasonable amount of time—or under some scenarios, any time, to conduct a fair hearing. We believe that after an MCO or PIHP takes up to 45 days, plus a possible 14-day extension, to make a decision, the 90-day clock for a fair hearing decision should stop during the time the enrollee takes to file for a State fair hearing (which could be as long as 90 days itself). Therefore, in response to the above comments, we have clarified in § 431.244(f) that the State is required to resolve the State fair hearing within 90 days of the day the MCO or PIHP received the appeal, not including the number of days the enrollee took to subsequently file for a State fair hearing. We believe that this is a reasonable timeframe because it holds the State accountable within a 90-day timeframe as long as the enrollee takes prompt action to follow up any denial at the internal appeal level. This will guarantee a high level of commitment on both sides. We also believe that 45 days is a reasonable standard timeframe for an MCO or PIHPs, because an enrollee may request an expedited appeal if he or she feels that a standard timeframe could jeopardize his or her health. With respect to the comments raising constitutional due process issues, we believe that applying this timeframe in this situation is fully consistent with due process requirements.

Comment: Some commenters noted that most States already have a complex grievance system in place, with specified timeframes and other rules, and changing these requirements may be confusing for beneficiaries and may not provide any additional protections to enrollees. These commenters asked us to permit "deeming" of compliance with Medicaid rules when the State's system met certain standards.

Response: The grievance and appeals requirements in § 438.408 set forth

minimum standards that MCOs, PIHPs, and States must follow. As long as those standards are met, a State is free to tailor those to the system it operates. We believe that these timeframes, notice requirements, and other standards grant States flexibility (e.g., the State is granted the discretion to establish timeframes, within ranges), and constitute the minimum necessary to ensure reasonable beneficiary protections. We strongly believe that the established timeframes give States, MCOs and PIHPs adequate time to make an informed decision for enrollees at both the internal and State fair hearing levels.

Comment: Several commenters believed that the mandatory timeframes for the grievance and appeals process in § 438.408 might be difficult to meet if enrollees fail to submit timely information, or are not available for an in-person presentation to the MCO or PIHP. These commenters asked that a limit be placed on the number of days MCOs and PIHPs are responsible for providing continued services pending a final determination in the case of an appeal from a termination of benefits. Some commenters wanted the timeframes to begin when all documentation is received from providers, rather than the date of notice of the action being appealed, for fear that the timeframes would be impossible to meet in certain cases.

Response: We believe that the timeframes in § 438.408 will result in timely decisions based on all necessary evidence in the vast majority of cases. Enrollees have a strong incentive to cooperate fully with officials in an internal appeals process to facilitate timely coverage decisions. However, if some enrollees do not provide enough information to support their appeal, the MCO or PIHP is responsible for deciding the appeal on the basis of available information within the timeframes set out. Since continuation of benefits for authorized services being terminated may, at the beneficiary's request, continue throughout the appeals process until the final decision is made at the MCO, PIHP, or State level, we believe that it is reasonable to require MCOs and PIHPs to make decisions within the specified timeframes so they are not responsible for covering benefits due to another party's delay.

Comment: One commenter felt that the timeliness for grievance and fair hearing completions may be difficult to meet in the case of mental health enrollees. The commenter inquired as to whether decisions on an action could be made retroactively, still comply with the requirements.

Response: The timeframe for filing an appeal in a State will be between 20 and 90 days, as determined by that State. We believe that this should be sufficient time for all enrollees to request a hearing. MCO, PIHPs, and States are then responsible for assisting enrollees with any procedural barriers they may encounter. Once the appeal is filed, the MCO, PIHP, or State is responsible for ensuring that a fair decision is made within the mandated timeframes.

Comment: A few commenters noted that in proposed § 438.408, the paragraph titled "Requirements for a State fair hearing," which was identified in the preamble as paragraph (f), was inadvertently labeled paragraph (c) in the regulations text. The commenter assumed this was a typographical error.

Response: We agree with the commenter, and as noted above, we have made the appropriate change in § 438.408.

6. Expedited Resolution of Appeals (Proposed § 438.410)

In proposed § 438.410 we required each MCO and PIHP to establish and maintain an expedited review process for appeals when the MCO or PIHP determines or the provider indicates that taking the time for a standard resolution could seriously jeopardize the enrollee's life or health or ability to attain, maintain, or regain maximum function. Further, the MCO or PIHP was required under proposed § 438.410(b) to ensure that no punitive action is threatened or taken against a provider who requests an expedited resolution, or supports an enrollee's request for an expedited appeal.

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

Comment: One commenter contended that the definition of "expedited authorization decisions" can be applied to nearly any medical necessity determination. This commenter recommend removing language related to the "enrollee's ability to attain, maintain, or regain maximum function * * * could be jeopardized."

Response: We disagree with the commenter. If a standard appeals process is long enough to place an enrollee's health in jeopardy based on the definition above, we believe that an expedited appeal is warranted. Furthermore, the provider, MCO, PIHP,

or State has the final decision on whether or not that threshold has been met. Therefore, we believe that it does not add any unwarranted administrative burden to MCOs, PIHPs, or States during the process.

Comment: Comments on the timeframes in proposed § 438.410 again differed widely. Many commenters (again citing due process concerns and comparing the timeframes to other situations) wanted expedited internal appeals to be resolved within 72 hours, mirroring Medicare+Choice and State fair hearing timeframes.

However, several commenters found the timeframes unreasonable, unrealistic, subjective, and too prescriptive, and asked for more State flexibility to set timeframes. Some wanted the expedited process to be longer, such as a minimum of five working days, arguing that the present timeframe was unworkable. One commenter noted that most States already have timeframes, and suggested that changing these requirements may be confusing for beneficiaries while not providing any additional meaningful protections to enrollees.

Response: We continue to believe that the regulation should establish timeframes for steps in the internal appeal process, and that an expedited timeframe is necessary when the use of standard timeframes may jeopardize the enrollee's health. An expedited timeframe is an important beneficiary protection and ensures that those enrollees who need a quick decision will receive one. However, we believe that three working days for an expedited internal appeal makes the most sense. It provides for a very timely decision for those enrollees whose health may be in jeopardy, yet facilitates MCOs and PIHPs with the difficulty of operating during weekends and holidays. If an enrollee's health is jeopardized by an emergency medical condition, as defined in § 438.114(a), then he or she would go to the nearest emergency room. In § 438.408(a) we provide for States to establish timeframes that may not exceed the timeframes specified in this final rule. Thus, States may establish shorter timeframes. Again, with respect to the commenter's due process concerns, we are unaware of any legal basis for the suggestion that these regulations would violate due process.

Comment: Several commenters suggested that the regulations expressly allow the beneficiary to obtain an expedited review based on their primary care provider's opinion that the standard for expedited review has been met. They believed that MCOs and

PIHPs should not be given complete control over the situation, because their financial arrangements may provide an incentive to deny services.

Response: Under § 438.410(a), an MCO or PIHP must provide expedited review if it determines the standard for such review has been met, in the case of a request by an enrollee or if “the provider” makes such a determination. The preamble to the proposed rule did not specify whether “the provider” included the enrollee’s primary care provider, or only the provider who would be furnishing the service requested in connection with the appeal. In response to this comment, we are clarifying that “the provider,” as used in § 438.410(a), refers to the provider of the services requested, since this provider is in the best position to evaluate the enrollee’s need for those services. In some cases, this may be the primary care provider, in which case the current regulations would provide for the result the commenter seeks. In other cases, however, the primary care provider’s opinion would not be dispositive of whether expedited review would be granted. We assume that the primary care provider’s views would be taken into account by the MCO or PIHP in making their determination, or by “the provider” of the services sought, in deciding whether to request review or support the enrollee’s request as provided in § 438.410(a). If an enrollee disagrees with the MCO’s or PIHP’s decision, and the provider who would be furnishing the services does not support the enrollee’s request, nothing prevents him or her from contacting the State and asking for its involvement or assistance. Furthermore, States have the option to make a primary care provider’s decision binding in all cases as part of their contract requirements, or State law, if they choose.

Comment: Several commenters were concerned about the MCO’s and PIHP’s ability to extend the 3-day expedited timeframe for 14 more days in cases in which this extension was not requested by the enrollee, and with the fact that the enrollee does not have the right to appeal such an extension. These commenters argued that the State has no mechanism for knowing that an MCO or PIHP has given itself such an extension, making the expedited provision arguably an empty mechanism. Furthermore, it appears to these commenters that the MCO or PIHP could give itself extensions indefinitely because there is no requirement to resolve the appeal after the first extension. They recommended only allowing an extension in these cases if the enrollee requests it.

Response: We partially disagree with the commenters’ interpretation of the regulation. We state in § 438.408(b)(3) that an MCO or PIHP may extend the timeframe of 3 working days up to an additional 14 calendar days. This is intended to be the outer time limit before a decision is made or the enrollee is eligible to file for a State fair hearing. Thus, an MCO or PIHP could not continue “indefinitely” to grant additional 14 day extensions. With respect to cases in which an enrollee does not request the extension, the extension still must be in the enrollee’s interests, and an enrollee is free to argue to the State that this standard has not been met. The State then may decide if it should intervene. Moreover, we note that States have the option in contracts or in State law of permitting extensions only when requested by the enrollee.

Comment: One commenter expressed concern regarding the logistics of requiring MCOs and PIHPs to give prompt oral notice to an enrollee of any denial of an expedited request. They noted that some Medicaid enrollees may not be accessible by telephone.

Response: We are aware that some Medicaid enrollees may not have telephones, and that it therefore may be difficult in some cases to provide oral notice. Therefore, in response to this comment, we have revised § 438.410(c)(2) by requiring MCOs and PIHPs to make reasonable efforts to notify enrollees orally of decisions not to expedite an appeal, and to follow up with a written notice within two calendar days. MCOs and PIHPs should request information from enrollees about how and where they can be contacted.

Comment: Several commenters recommended that the State Medicaid agency be permitted 3 working days to hear expedited appeals that they receive, rather than 72 hours.

Response: We agree with the commenters. In response to this comment, the final rule, at § 431.244(f)(2) and (3), now requires the State to conduct a fair hearing and make its decision within 3 working days for service authorization denials that meet the criteria for expeditious handling. We have chosen to use the same 3-working-days standard that applies to MCO or PIHP review in expedited cases so that the State would not be required to complete review of all expedited cases during weekends or holidays.

Comment: Many commenters advocated a requirement that expedited internal appeals not decided wholly in the enrollee’s favor be automatically forwarded to the State fair hearing process. These commenters felt that

timing during an expedited process was essential, and that automatic forwarding would provide necessary speed to the process.

Response: We disagree with the commenters. We believe that the burden on MCOs, PIHPs and States, of automatic forwarding of appeal materials even in cases in which the enrollee may not wish to pursue a further appeal outweighs any benefits that might be achieved by such a policy. As in the case of when a beneficiary files an appeal during the 90 standard timeframe, it is reasonable to expect any enrollee who is seeking a particular service or benefit to promptly file for a State fair hearing if he or she is not wholly successful at the internal appeals level. We do not believe this would significantly add to the time it takes to handle the appeal. We note that the MCO or PIHP must give enrollees reasonable assistance in completing forms and taking other procedural steps.

Comment: One commenter noted that the proposed rule did not grant enrollees a right to a State fair hearing for an enrollee whose request for an expedited resolution is denied. Specifically, the commenter noted that this was not listed among the bases for a State fair hearing. The commenter wanted clarification on this point.

Response: The omission of a denial of a request for an expedited hearing from the ground for a fair hearing was intentional. As noted above, if a request for an expedited resolution is denied, the case is automatically treated as a standard appeal. However, if that internal appeal is not resolved wholly in favor of the enrollee, then the enrollee has a right to a State fair hearing.

Comment: One commenter objected to the fact that the proposed rule did not include a requirement for an expedited review process for grievances. They argued that this would be dangerous for enrollees with severe health problems who could not wait for the time frame of the standard review process.

Response: A grievance involves any dispute other than an “action.” Only an action should involve the possibility of a delay putting an enrollee with severe health problems at risk. We have an expedited provision for those type of disputes. Therefore, we do not believe that an expedited grievance process is a necessary mandate at the Federal level.

Comment: One commenter noted that proposed § 438.410(a) should have a period at the end rather than a semi-colon.

Response: We agree with the commenter, and we made the appropriate change in § 438.410(a) the final regulation.

7. Information About the Grievance System to Providers and Subcontractors (Proposed § 438.414)

Proposed § 438.414 required that the MCO or PIHP must provide the information specified at § 438.10(g)(1) about the grievance system to all providers and subcontractors at the time they enter into a contract.

Comment: One commenter requested that CMS require that information about the grievance system be provided to subcontractors as well as to contracting providers.

Response: Proposed § 438.414, which is unchanged in this final rule, already provided that this information must be provided to providers “and subcontractors.”

8. Recordkeeping and Reporting Requirements (Proposed § 438.416)

Proposed § 438.416 required the State to require MCOs and PIHPs to maintain records of grievances and appeals and review the information as part of the State quality strategy.

Comment: Commenters urged that the regulation require States to provide members of the public, upon request, with MCO and PIHP summaries of grievance and appeal logs.

Response: States have the authority to require that MCOs and PIHPs make available to the State, or at the State’s option, to members of the public, grievance and appeal logs or other MCO and PIHP grievance system documents. We do not agree that we should mandate this, however. In some cases, raw appeals data may be confusing to the public, or potentially misleading. We believe States are in the best position to decide how such information should be presented to the public. In designing their quality strategies, States should consider what information they and the public will need to support those strategies.

9. Continuation of Benefits When an MCO or PIHP Appeal of a Termination, Suspension, or Reduction, and State Fair Hearing on Such an Action, are Pending (Proposed § 438.420)

Proposed § 438.420 required that when the dispute involves the termination, suspension, or reduction of a previously authorized course of treatment, the MCO or PIHP must continue the enrollee’s benefits until issuance of the final appeal decision or State fair hearing decision, if all of the following occur:

- The enrollee or the provider files the appeal timely.
- The services were ordered by an authorized provider.

- The period covered by the authorization has not expired.
- The enrollee requests such an extension of benefits.

We specified that timely filing means filing on or before the later of either the expiration of the timeframe specified by the State (in accordance with § 438.404(c)(2)) and communicated in the notice of action or the intended effective date of the MCO’s or PIHP’s proposed action.

This provision would apply only when the MCO or PIHP physician initially authorized the services (that is, it would not apply to pre-service authorization requests that were denied) and when the beneficiary requests the services be continued (that is, the mere action of filing for an appeal or State fair hearing in a timely manner is not sufficient for benefits to be continued). The continuation of benefits provision would not require a further statement of authorization from the MCO or PIHP physician or affect benefits not originally authorized.

If the MCO or PIHP continues or reinstates the enrollee’s benefits while the appeal is pending, under proposed § 438.420(c), the benefits must be continued until one of the following occurs:

- The enrollee withdraws the appeal.
- The MCO or PIHP resolves the appeal against the enrollee, unless the enrollee has requested a State fair hearing with continuation of benefits until a State fair hearing decision is reached.
- A State fair hearing officer issues a hearing decision adverse to the enrollee.

Beneficiaries who have received continuation of benefits while they appeal to the MCO or PIHP are not obligated to pursue their appeal further, through the State fair hearing process, if the MCO or PIHP denies their appeal. It remains the beneficiaries’ choice. It is important to note, however, that enrollees who lose their appeal at either the MCO, PIHP or State fair hearing levels will be liable for the costs of all appealed services from the later of the effective date of the notice of intended action or the date of the timely-filed appeal, through the date of the denial of the appeal. As a result, in § 438.420(d), we proposed that if the final resolution of the appeal is adverse to the enrollee (that is, it upholds the MCO’s or PIHP’s action) the MCO or PIHP may recover the cost of the services furnished to the enrollee while the appeal was pending, to the extent that they were furnished solely because of the requirements of this section, and in accordance with § 431.230(b).

Comment: Many commenters pointed out that the proposed rule does not specify all the same circumstances set forth in §§ 431.230 and 430.231 as situations in which benefits must be continued or reinstated. These commenters specifically cited advanced notice requirements, and argued that this rewards MCOs and PIHPs that do not provide advanced notice.

Response: We disagree with the commenters. MCOs, PIHPs, and States have a strong incentive to notify enrollees timely of any reduction, limitation, or suspension of existing services. While enrollees have to actively request continuation of benefits while filing an appeal, they must be given the opportunity to do so before the benefits are reduced, limited, or suspended. And since enrollees have this right until an adverse State fair hearing decision (assuming of course that he or she follows the applicable rules), a delay in notice only gives enrollees benefits for a longer period of time. However, in response to this comment, we now state in the regulation text that the enrollee has 10 days after the MCO or PIHP mails the notice of action to request continuation of benefits. Therefore, even if the effective date of action has passed, an MCO or PIHP may not discontinue those benefits until 10 days after the notice is mailed. We believe that this sufficiently addresses the commenters’ concern.

Comment: We received many comments regarding enrollees’ rights to continuation of benefits during the MCO and PIHP appeal process. Several commenters thought that the regulations mandate that MCOs and PIHPs continue benefits in all cases in which the appeal involves services that are being terminated or reduced. Several commenters felt that continuation of benefits pending resolution of an appeal or State fair hearing, without financial risk, is one of the most important protections needed for managed care enrollees.

In contrast, several other commenters were opposed to extending continuation of benefits requirements to the MCO and PIHP appeal process. One commenter contended that this requirement would have significant cost implications for MCOs and PIHPs. Another commenter felt that benefits should be continued only at the point when an enrollee requests a State fair hearing.

One commenter thought that requiring MCOs and PIHPs to continue benefits would place them in an untenable position with their providers, compromising their ability to manage care and cost. This commenter expressed concern that this provision

may damage managed care programs, and believed it was unnecessary, given the requirement of expedited review of appeals in cases in which a delay could jeopardize health.

Response: Because we allow States to require exhaustion of the MCO and PIHP appeal before receiving a State fair hearing, we believe that, in order for the right to continued benefits during a State fair hearing to be meaningful, continuation of benefits must begin with the filing of an MCO or PIHP appeal, and continue until the State fair hearing decision. Given that, with few exceptions, the overall 90-day timeframe for a final fair hearing decision applies even when exhaustion is required, the amount of time benefits must be continued is the same under this final rule as under the longstanding fair hearing system. Continuation of benefits at the MCO and PIHP level thus is part of the same longstanding right to continuation of benefits that has existed for Medicaid beneficiaries when services are reduced or terminated.

As in fee-for-service, under managed care, the right to continuation of benefits is not exercised without financial risk to the beneficiary of payment for services provided should he or she lose the appeal. Otherwise, MCOs, PIHPs, or States would be unfairly liable for treatment in which they were correct in limiting, reducing, or suspending. It is because of this potential risk for enrollees that we require that the enrollee specifically request continuation of benefits. Under § 438.404(b)(7), the notice of adverse action must include an explanation of this choice.

While expedited appeals will decrease the amount of time MCOs and PIHPs are liable to continue benefits for enrollees with pending appeals, the expedited appeal process does not substitute for the protection provided to Medicaid beneficiaries of the right to continuation of previously authorized benefits pending the outcome of a State fair hearing decision.

If the benefit is a Medicaid covered service, but not an MCO or PIHP covered service, the State, not the MCO or PIHP is responsible for providing those services pending the outcome of the State fair hearing.

Comment: Several commenters requested that § 438.420 should clearly state that re-authorization of a service at a lower level than previously received, or a denial of re-authorization, is a termination or reduction of the service requiring the continuation of benefits pending appeal. Other commenters requested that we make clear in the regulation text that continuation of

benefits does not include the expiration of an approved number of visits through an authorized course of treatment.

Response: As noted above, we agree that the expiration of an approved number of visits does not constitute a termination for purposes of notice and continuation of benefits. If an enrollee requests re-authorization for services and the MCO or PIHP denies the request or re-authorizes the services at a lower level than requested, the MCO or PIHP must treat this request as a new service authorization request and provide notice of the denial. We have explained above that the language in the proposed rule already limited the right to continued benefits to services that were authorized. In response to this comment, in order to make clear that the continuation of benefits itself is not what we mean by "authorized," we have revised § 438.420(b)(4) by adding the word "original" to make clear that benefits are only continued to the extent they were originally authorized. As noted above, we also have added a new § 438.420(c)(4) in this final rule to make clear that when benefits are continued under § 438.420(b), they may be discontinued when the original authorization expires.

Comment: One commenter was concerned about the status of enrollees who received authorization for a course of treatment from a non-network physician but then had those benefits limited by a new MCO once the course of treatment had begun. They believe that these enrollees need protection for their benefits.

Response: An enrollee who has his or her existing benefits reduced, limited, or suspended by an MCO, PIHP, or State has the right to request a continuation of benefits regardless of the source as long as it originated from a Medicaid participating provider. It is the State's decision as to what entity is liable for those benefits during the appeals process.

Comment: One commenter argued that discontinuing services being provided by an MCO without a State fair hearing was unconstitutional.

Response: We do not believe that we need reach constitutional issues (such as, regarding whether a property interest or State action exist) because Medicaid beneficiary rights are directly addressed in section 1902(a)(3) and 1932(b)(4), and it is these statutory rights that are implemented in this final rule. As noted above, we believe that if services are discontinued on the date the authorization expires, this is not a "termination" of services that the enrollee had any right to expect to receive, and thus is not a termination

within the meaning of section 1902(a)(3) and the implementing regulations. In the case of a termination of authorized services prior to the expiration date of the authorization, we agree with the commenter that a beneficiary should have the right to have these benefits continue pending a hearing on the termination. We provide the enrollee with 10 days to request to have benefits continue under these circumstances, pending an appeal and State fair hearing. We believe that this process is fully consistent with the Medicaid statute and constitutional requirements, to the extent applicable.

Comment: Several commenters requested that we delete the requirement that the beneficiary must request continued benefits. They contended that this requirement was constitutionally defective in that they believed continued benefits, without pre-requisites to obtaining them, to be required under due process.

The commenters noted that while the existing regulation at § 431.230(b) provides for the possibility of recoupment, benefits are continued when an appeal is filed timely. The commenters found no reason to change this long-standing rule for beneficiaries who are receiving services through an MCO or PIHP. Also, several commenters believed that proposed § 438.420(c)(2) made it impossible for benefits to continue through a State fair hearing, because a beneficiary would have had to file for a State fair hearing before the MCO or PIHP had even made its internal appeal decision in order for benefits to continue.

Response: Again, we do not believe we need reach constitutional issues here, but that the final rule as proposed is fully consistent with any applicable constitutional requirements. It is not true that benefits continue under fee-for-service Medicaid "without pre-requisites to obtaining them." Benefits only continue under fee-for-service if the beneficiary timely files an appeal. We do not see the difference between requiring the filing of an appeal for benefits to continue and requiring that as part of such an appeal, the beneficiary request that benefits continue. Indeed, given the possibility of beneficiary liability in both cases, we believe that the approach in this final rule is more protective of beneficiary rights. Under this rule, after an action, the beneficiary will be notified both of this right to continuation of benefits and the possible liability for services if the final decision is not in his or her favor. Thus, we believe the general concern about continued benefits not being automatic with an appeal is unfounded.

However, we agree with the concerns expressed by several commenters' that proposed § 438.420(c)(2) could make it impossible for benefits to continue through a State fair hearing as proposed. Therefore, in response to these comments, we have revised § 438.420(c)(2) by requiring beneficiaries to re-request continuation of benefits within 10 days after the mailing of the internal appeal decision against the enrollee, in order to preserve continuation of benefits during a State fair hearing.

10. Effectuation of Reversed Appeal Resolutions (Proposed § 438.424)

Proposed § 438.424 required that if the MCO, PIHP, or the State fair hearing officer reverses a decision to deny, limit, or delay services that were not furnished while the appeal was pending, the MCO or PIHP must authorize or provide the disputed services promptly, and as expeditiously as the enrollee's health condition requires. Furthermore, if the MCO, PIHP, or the State fair hearing officer reverses a decision to deny authorization of services, and the enrollee received the disputed services while the appeal was pending, the MCO, PIHP, or the State would be required to pay for those services, in accordance with State policy and regulations.

Comment: Many commenters supported a time frame of no more than 10 days for an MCO or PIHP to provide or pay for services subsequent to a State fair hearing because enrollees with successful appeals should not have to adjudicate over the word "promptly."

Response: We disagree that MCOs and PIHPs should be held to a Federal timeframe to provide or pay for services, because such a timeframe may not be reasonable in the case of the circumstances of all States. Consistent with the State fair hearing policy in § 431.246, we are requiring that the services are provided promptly, or as expeditiously as the enrollee's health condition requires. We believe that the States are in the best position to decide whether to require specific time limits if they choose.

F. Certifications and Program Integrity (Subpart H)

Fraud and abuse can negatively affect both the quality of health care services rendered to Medicaid beneficiaries, and an MCO's, PIHP's, PAHP's, or PCCM's financial viability. Promoting program integrity within Medicaid managed care programs can protect against misspent Medicaid program funds, and promote quality health care services. Proposed

subpart H of part 438 contains safeguards against fraud and abuse and requires that organizations with Medicaid contracts make a commitment to a formal and effective fraud and abuse program.

In proposed § 438.600 we stated that the statutory basis for this subpart is under sections 1902(a)(4) and 1902(a)(19) of the Act. These sections require that methods be provided in the State plan for the proper and efficient operation of the plan and that safeguards are provided consistent with the best interests of the recipients.

In proposed § 438.602 we provided that the certification and program integrity requirements contained in subpart H apply to MCOs and PIHPs as a condition for contracting and for receiving payment under the Medicaid managed care program.

In proposed § 438.604 we provided that data, including enrollment and encounter data, must be certified and submitted to the State, if State payments are based on the data. We also specified that other information required by the State and information included in contracts, proposals, and other related documents must be certified. We also required in § 438.604(b) that the MCO or PIHP certify that they are in substantial compliance with the terms of the contract.

In proposed § 438.606 we required that certifications be provided concurrently with the data they relate to, and required that certifications be signed by the MCO's or PIHP's Chief Executive Officer, Chief Financial Officer, or an individual delegated authority to sign for one of these individuals. We proposed that the certifications must include attestations to the truthfulness, accuracy, and completeness of the data based on best knowledge, information, and belief.

In proposed § 438.608 we required that each MCO or PIHP have administrative and management arrangements or procedures, including a mandatory compliance plan, designed to guard against fraud and abuse. This section also outlined the required elements to be included in the arrangements and procedures.

In this final rule we are making a technical correction to add two additional sources of authority. First, we are adding a citation to section 1903(m), which establishes conditions for payments to the State with respect to contracts with MCOs. Second, we are adding a new § 438.610 to incorporate the requirements of section 1932(d)(1) of the Act. That provision of the statute is self-implementing, and therefore we did not include it in the proposed

regulation. However, we are including the substance of the requirement in this final regulation to make it easier for the public to find all the relevant provisions in one place. Under the authority of section 1902(a)(4) of the Act, we are also applying these provisions to PIHPs and PAHPs.

We believe it is in the best interests of State Agencies, MCOs, PCCMs, PIHPs, PAHPs, and CMS to significantly aid in the fight against fraud and abuse and the requirements of this subpart work to achieve that goal.

Comment: One commenter proposed that we develop a standard form for certifications since we are requiring certifications by the Chief Executive Officer or the Chief Financial Officer or other person who is delegated the authority of the MCO or PIHP to certify data submitted.

Response: We disagree with the commenter as we wish to maintain State flexibility in this area. In §§ 438.604 and 438.606 respectively, we provide that data certifications are required if data are being used to set payments. We have described the source, content, and timing required for certifications. We do not, however, wish to be overly prescriptive and therefore, we are not prescribing the format of the certifications. If the commenter is requesting a sample format that could be used as a model certification form, one can be found on the CMS website at <http://www.hcfa.gov/medicaid/letters/smd80700.htm> in the document entitled, "Guidelines for Addressing Fraud and Abuse in Medicaid Managed Care" at appendix 2.

Comment: One commenter suggested that it is unclear as to when certifications are required and if the certifications of data to set payments is meant to reference payments under the current contract year or for proposed contract years. The commenter also believes that the requirements for certifications for substantial compliance with the terms of the contract are unclear.

Response: In § 438.604(a) we require that MCOs and PIHPs provide certification of data requested by the State if payments to the MCOs and PIHPs are based on the data submitted, and in § 438.606(c) we require that MCOs and PIHPs submit the certification concurrently with the data. This applies regardless of whether the data are used for setting payments for current contract years, or for other contract years. If data are not being used to set payments, then certifications would not be required.

We agree with the commenter that clarification is necessary regarding

certification for substantial compliance with the terms of the contract. We previously proposed, in §§ 438.604(b), that an MCO or PIHP must certify that it is in substantial compliance with the terms of its contract.

We understand the commenter's confusion regarding this requirement since the statute and regulations already require States to monitor compliance with contracts executed under this rule and provides sanctions to be used where certain requirements are not met. Further we would expect to require corrective action plans in situations in which a State is found to be out of compliance with these rules. Consequently, we believe that the requirements on States, MCOs, PIHPs, PAHPs, and PCCMs contained in § 438.6 and elsewhere in this rule and the mechanisms for monitoring and enforcement are sufficiently clear that the requirements for "substantial compliance" in §§ 438.604 and 438.606 are unnecessary and we have deleted them from this subpart. Hence renumbering has taken place in these sections.

Comment: Several commenters believe that subcontractor certifications are necessary since MCOs could delegate functions to subcontractors including physicians, hospitals, and clinics as well as to administrative service organizations that collect data from network providers and report the data to the MCO and the State. The commenters argued that without accurate and complete data, States may not have the information necessary to set actuarially sound capitation rates. Commenters expressed opposing views on this issue with one commenter believing that this requirement would be burdensome to plans and providers because of the complexities involved in obtaining provider certifications. Other commenters stated that subcontractor certifications are necessary to protect CMS and others against being defrauded or paying an MCO more than the amount to which it should be entitled. We received further suggestions that not having subcontractor requirements could undermine federal enforcement of the False Claims Act.

Response: We have considered the commenters' suggestions and we agree that subcontractors play an important role in an MCO's network. We require MCOs and PIHPs to certify *all* data they submit, which would include any data produced by subcontractors. We believe that MCOs and PIHPs should be held accountable for their subcontractors and their subcontractors' data. We believe that States must be able to rely on the MCOs' and PIHPs' certifications if they

are to combat potential fraud and abuse, and continue to set capitation payments to MCOs and PIHPs appropriately. Therefore, we are only requiring in this subpart that data certifications be required of MCOs and PIHPs and not of their subcontractors. It is up to the State or the MCO or PIHP to determine whether subcontractor data is accurate. If data is not used to set payments, certifications by MCOs and PIHPs are not necessary.

Comment: We received opposing views about whether PAHPs should be exempt from the program integrity protections outlined in this subpart. One commenter suggested that PAHPs should be required to have fraud and abuse plans and data certifications to justify State payments, since fraud can be significant in ambulatory plans also. In contrast, another commenter believes we should require that fraud and abuse plans be implemented only by entities with 10,000 enrollees or more.

Response: We clearly intend that PAHPs should work to combat against fraud and abuse. However, we are recognizing that it may not be appropriate to require those organizations to implement formal fraud and abuse plans, given that they generally have relatively few enrollees and provide a relatively narrow range of services. We believe that the benefits of requiring PAHPs to comply with the formal measures of subpart H in order to protect against fraud and abuse is outweighed by the level of burden placed on these organizations, which could place some plans at financial risk.

Consequently, we are only requiring that §§ 438.600 through 438.610 apply to MCOs, to PIHPs, and only to PAHPs and PCCMs where specifically noted. Typically, MCOs and PIHPs, which include at least some inpatient hospital or institutional care services, are larger, more complex organizations, and will in most cases, have higher enrollment levels.

We believe the more comprehensive plans (such as, MCOs and PIHPs) are likely to need to provide for more sophisticated methods for combating fraud and abuse and may also need to provide for compliance officers as part of their staff. This is because they are more complex organizations, and need to contract with a large number, and greater variety of providers. These plans typically serve more enrollees and provide more services. Furthermore, more complex organizations are likelier to include administrative staff that collect and report data, and that need more in-depth monitoring. We disagree with the commenter that the applicability of these requirements

should depend on the PAHP's enrollment level, because enrollment can fluctuate, and we believe that approach would lead to arbitrary results.

Comment: A commenter suggested that we should not mandate the use of a compliance plan developed by a federal enforcement agency, that is, the OIG, that was intended for M+C plans.

Response: We agree with the commenter that to require the use of guidelines developed for a national program (such as, M+C) by a Federal enforcement agency would be overly prescriptive and could impede State flexibility in combating fraud and abuse. In § 438.608 we require MCOs and PIHPs to have administrative and management procedures, including a mandatory compliance plan, designed to guard against fraud and abuse; however, we have not mandated the use of the compliance plan developed by the OIG. The commenter is correct that the compliance plan developed by the OIG is intended for M+C plans and not for Medicaid managed care plans. Further, we agree that it is important for States to have flexibility in combating fraud and abuse in the Medicaid program and we believe States can maintain that flexibility by developing their own compliance plans.

G. Sanctions (Subpart I)

Section 1932(e)(1) of the Act requires, as a condition for entering into or renewing contracts under section 1903(m) of the Act, that State agencies establish intermediate sanctions that the State agency may impose on an MCO that commits one of six specified offenses: (1) Failing substantially to provide medically necessary items and services that are required by law, or are required under the MCO's contract with the State; (2) imposing premiums or charges in excess of those permitted under title XIX; (3) discriminating among enrollees based on health status or requirements for health care services; (4) misrepresenting or falsifying information; and (5) failing to comply with statutory requirements that apply to physician incentive plans. Under section 1932(e)(1)(A) a State may also impose sanctions against MCOs and PCCMs for distributing, directly or through an agent or contractor, marketing materials that contain false or materially misleading information. Proposed § 438.700 contained the above provisions from section 1932(e)(1) of the Act.

In section 1932(e)(2) of the Act, Congress described the types of sanction authority that would satisfy the State's obligation to have intermediate

sanctions. For the most part, the State has discretion to choose which of these sanctions to use. However, the State is required to have authority to appoint temporary management under section 1932(e)(2)(B), and to permit individuals to terminate without cause under section 1932(e)(2)(C). This is because section 1932(e)(3) requires the State to impose at least those two sanctions if an MCO repeatedly fails to meet the requirements of sections 1903(m) or 1932. The other provisions that would clearly satisfy the State's obligation to have intermediate sanction authority include authority to impose civil money penalties for specified violations, up to specified maximum amounts, and to suspend enrollment or payment for new enrollees. These provisions were reflected in proposed § 438.702(a).

Under section 1932(e)(2)(B), one of the sanctions that would satisfy section 1932(e)(1) is for the State to oversee the operation of the MCO "upon a finding by the State that there is continued egregious behavior by the organization or there is a substantial risk to the health of enrollees * * * or to assure the health of the organization's enrollees." Given the extraordinary nature of the sanction of taking over management of an MCO, we proposed in § 438.706 that this sanction be imposed only when those egregious circumstances exist.

The requirement in section 1932(e)(1), that the State have intermediate sanction authority as a condition of contracting, only applies to contracts with MCOs. It does not place a similar requirement on States with respect to PCCMs. However, subsections (e)(1)(A) and (e)(2)(D) and (E) refer to "managed care entities," and thus envision that the State would choose to apply those sanctions to PCCMs as well.

Section 1932(e)(4) of the Act authorizes State agencies to terminate the contract of any MCO or PCCM that fails to meet the requirements in sections 1932, 1903(m), or 1905(t) of the Act. This provision was included in proposed § 438.708. However, if the State chooses that remedy, under section 1932(e)(4)(B) the State is required to provide a hearing before terminating a contract. Proposed § 438.710 set forth requirements that apply to the notice to the MCO or PCCM, and to the pre-termination hearing. Under section 1932(e)(4)(C), enrollees may be notified of their right to disenroll immediately without cause in the case of any entity subject to a termination hearing. Proposed § 438.722 described the provisions for disenrollment during the termination hearing process. Finally, in § 438.724,

we proposed that States be required to notify CMS whenever it imposes or lifts a sanction.

Under section 1903(m)(5) of the Act, CMS has its own direct authority to impose sanctions when Medicaid-contracting MCOs commit offenses that are essentially the same as those identified in section 1932(e)(1) of the Act. Section 1903(m)(5) is currently implemented by regulations codified at 42 CFR § 434.67. We proposed to move those regulations to proposed § 438.730. However, we inadvertently made substantive changes, including omission of parts of the original regulation text dealing with denial of payment, and expanding the State plan requirement previously found in § 434.67(i). The final rule conforms the text of §§ 438.726 and 438.730 to the text of § 434.67. We proposed in § 438.726 to broaden the State plan requirements to include a plan to monitor for violations that involve the actions and failures to act that are specified in part 438 and to implement the provisions of part 438. We received no comments on this change and will maintain as it was proposed in this final rule. It also incorporates into § 438.726 the text of the existing § 434.22, which was cross-referenced by § 434.67(e), and which was inadvertently eliminated in the proposed changes to the regulation. Finally, there were certain ambiguities in the original regulation text which we are clarifying. In particular, § 434.67(c) was not clear with respect to who would forward the notice of sanction to the OIG at the same time it was sent to the MCO. We have clarified that it is sent by CMS.

Comment: One commenter requested clarification as to which sanctions were mandatory and which were discretionary.

Response: Section 1932(e)(1) of the Act requires, as a condition for entering into or renewing contracts under section 1903(m) of the Act, that State agencies must establish intermediate sanctions that the agency may impose on an MCO that commits one of the specified offenses in § 438.700(b). The type of sanction and the discretion to apply sanctions is generally up to the State agency. However, if it finds that an MCO has repeatedly failed to meet substantive requirements in section 1903(m) or section 1932 of the Act, or this Part, then the State must impose temporary management, must permit beneficiaries to disenroll without cause, and must notify them of the right to disenroll. See section 1932(e)(3) of the Act, and proposed §§ 438.706(b) and 438.702(a)(3).

Comment: Many commenters suggested that PIHPs and PAHPs be subject to the same sanctioning as MCOs.

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

Comment: A commenter requested clarification of whether the requirement for a pre-termination hearing in proposed § 438.710(b) applies if the State is terminating an MCO or PCCM contract under State authority and not the authority in § 438.708.

Response: A State that is not relying on the authority in § 438.708 to terminate an MCO or PCCM contract should follow only the State procedures related to the authority they are exercising to terminate the MCO or PCCM contract. To the extent the State is relying on the authority under § 438.708, the State must meet the requirements for a pre-termination hearing. The State may exercise the disenrollment options provided in § 438.722 regardless of the underlying authority on which they are basing termination.

Comment: One commenter was unclear about whether the notice to CMS under proposed § 438.724(a) was required only for sanctions specified in § 438.702(a) or if it also applied to State operated penalty systems such as a progressive penalty point accumulation system.

Response: Under § 438.724, notice to CMS is only required when a State imposes an intermediate sanction for one of the violations in § 438.700(b). To the extent the State has sanctions that it imposes for additional violations, notice to CMS is not required, but encouraged. We have added clarifying language to the regulation text.

Comment: Many commenters suggested notification to CMS was appropriate but that beneficiaries have the right to know when a plan has been sanctioned and that publication of the notice should be required in the

regulations. These commenters recommended that the State publish a notice describing the intermediate sanction imposed, explaining the reasons for the sanction and specifying the amount of any civil money penalty. Further, this notice should be published no later than 30 days after the State imposes the sanction, and the notice should be published in the newspaper of widest circulation in each city within the MCO's service area that has a population of 50,000 or more or in the newspaper of widest circulation in the MCO's service area, if there is no city with a population of 50,000 or more in that area. Several other commenters supported limiting the notification requirements to notifying CMS noting that publication is an unnecessary expense and inconsistent with current insurance practices.

Response: We agree that widespread publication would be an unnecessary expense. We also believe requiring public publication could discourage a State from imposing sanctions and could unnecessarily alarm enrollees. In addition, a State is not prohibited from publishing sanction information.

Comment: One commenter requested that we clarify in proposed § 438.726 that States can delegate certain functions to other entities as an acceptable way of accomplishing the goal of enrollee protection.

Response: The State agency is ultimately responsible for implementation of the provisions of this subpart but may delegate appropriate functions to other entities as part of their process.

Comment: One commenter indicated that it is crucial that the State's ability to delegate certain functions to other entities be explicitly recognized as an acceptable method for accomplishing the goal of enrollee protection through the use of sanctions and temporary management.

Response: We believe that the regulation, as written, maintains the State's ability to delegate functions. We recognize that with the imposition of temporary management, the State may need to delegate activities to another department within the State. We have maintained flexibility for States to determine what best fits their needs.

H. Conditions for Federal Financial Participation (Subpart J)

Subpart J of the proposed rule contains rules regarding the availability of Federal financial participation (FFP) in MCO contracts. In addition to setting forth recodified versions of existing regulations governing eligibility for FFP currently set forth in part 434, subpart

F, the regulations in proposed subpart J reflected new provisions in the BBA affecting FFP (such as., the new restrictions on FFP in enrollment broker contracts), and set forth a proposed new limitation on FFP related to the actuarial soundness requirements in proposed § 438.6(c).

1. Basic Requirements (Proposed § 438.802)

Proposed § 438.802 was based largely on the existing § 434.70, and provided that FFP is only available in expenditures under MCO contracts for periods for which (1) the contract is in effect and meets specified requirements, and (2) the MCO, its subcontractors, and the State, are in substantial compliance with specified contract requirements and the requirements in part 438.

Comment: One commenter requested that we clarify what we meant by the requirement in § 438.802 that the MCO and its subcontractors be in "substantial compliance" with physician incentive plan requirements and that the MCO and the State be in "substantial compliance" with the contract and these regulations, in order to qualify for FFP.

Response: Proposed § 438.802 was based on the existing § 434.70, which, in paragraph (b), specifically provided that FFP may be withheld for any period the MCO fails to comply with the physician incentive requirements, or the MCO or the State fail to comply with the terms of the contract between them or the provisions of this regulation. We understand the commenter's confusion regarding this requirement since this rule already requires states to monitor compliance with this rule and contracts executed under this rule and provides sanctions to be used where certain requirements are not met. Further we would expect to initiate penalties such as corrective action plans in these situations where a state is found to be out of compliance with these rules. Finally, in considering the commenter's question, we realize the difficulty in issuing useful guidance as to what constitutes "substantial compliance" for purposes of putting FFP at risk. Because we believe that the requirements on States and MCOs contained in § 438.6 and elsewhere in this rule, and the mechanisms for monitoring and enforcement are sufficiently clear, the requirement for "substantial compliance" in § 438.802 is potentially confusing and unnecessary, we have deleted it from this section.

2. Prior Approval (Proposed § 438.806)

Proposed § 438.806 was based on § 434.71 (as affected by new threshold amounts for prior approval enacted in

section 4708(a) of the BBA), and provided that FFP was not available in expenditures under contracts involving over a specified financial amount (\$1,000,000 for 1998, adjusted by the consumer price index for future years) unless the contracts were "prior approved" by CMS.

Comment: One commenter inquired whether § 438.806 precludes the availability of FFP for a period that a risk contract was under review by CMS, and whether the prior approval requirement applied to all MCOs or just new MCOs. If applicable to all MCOs, the commenter asked whether the FFP limitation applied to the entire amount paid or just the marginal difference from the previously approved contract amount?

Response: The requirement for prior approval of a new contract or new contract amendment applies to all comprehensive risk contracts, whether with a new or currently contracting MCO. FFP is not available for contracts that CMS has not approved. However, once we approve a contract, FFP is available for any period during which an approvable contract was under review. The limitation on FFP in this provision must be applied to the entire contract. FFP is not available for any portions of the contract unless it is approved.

Comment: One commenter questioned whether the requirement in § 438.806(a)(2) meant that a State would lose FFP should it not reach its quality strategy goals.

Response: Section 438.806(a)(2) requires that the written contract with the MCO meets the requirements specified as a condition for FFP. The contract would not be approved if it did not meet all the requirements of the law and regulations, including establishing the quality assessment and performance improvement program required by § 438.240. However, this is different from the issue of the MCO's or State's performance in implementing this contractually required program. A failure on the part of an MCO or State to meet a particular quality goal would not apply to the conditions in § 438.806(a)(2).

Comment: Several commenters pointed out that the reference in § 438.806(a)(1) to entities described in § 438.6 (a)(2) through (a)(5) should instead refer to § 438.6(b)(2) through (b)(5).

Response: We appreciate the commenters' assistance and have made the appropriate changes.

3. Exclusion of Entities (Proposed § 438.808)

Proposed § 438.808 reflects the limitation on FFP in section 1902(p)(2) of the Act, under which FFP in payments to an MCO is conditioned on the State excluding from participation as an MCO any entity that could be excluded from Medicare and Medicaid under section 1128(b)(8) of the Act, that—

- Has substantial contractual relationship with an entity described in section 1128(b)(8)(B) of the Act.

- Employs or contracts with individuals excluded from Medicaid.

We received no comments on this section.

4. Expenditures for Enrollment Broker Services (Proposed § 438.810)

Proposed § 438.810 reflects the conditions on FFP for enrollment broker services set forth in section 1903(b)(4) of the Act, which was added by section 4707(b) of the BBA. This section permits FFP in State expenditures for the use of enrollment brokers only if the following conditions are met:

- The broker is independent of any managed care entity or health care provider that furnishes services in the State in which the broker provides enrollment services (regardless of whether the entity or provider participates in Medicaid).

- No person who is the owner, employee, or consultant of the broker or has any contract with the broker:

- Has any direct or indirect financial interest in any managed care entity or health care provider that furnishes services in the State in which the broker provides enrollment services.

- Has been excluded from participation under title XVIII or XIX of the Act.

- Has been debarred by any Federal agency.

- Has been, or is now, subject to civil monetary penalties under the Act.

In addition to reflecting the above statutory requirements from section 1903(b)(4), proposed § 438.812 included the following proposed requirement:

- The initial contract or memorandum of agreement (MOA) or memorandum of understanding (MOU) for services performed by the broker must be reviewed and approved by CMS before the effective date of the contract or MOA.

Comment: One commenter felt that the proposed regulations were too broad for application in many States, and that States thus were required to create standards to ensure protective measures to support independent operations of enrollment brokers.

Response: We disagree with the commenter that the regulations are too broad. We believe that the language in section 1903(b)(4) of the Act, reflected in § 438.810, is very specific about limitations as to who can serve as an enrollment broker. A broker either is independent of “any” MCO, PIHP, or PCCM and of “any health care providers” that provide services in the State, or it is not. Similarly, a broker either does or does not have an owner, employee, consultant or contract with a person who (1) has a direct or indirect interest in an MCO, PIHP, PCCM or provider, or (2) has been excluded, debarred or subject to civil money penalties. While these standards are “broad” in their reach, this was a decision made by Congress. We do not believe that significant additional clarification is required. Moreover, § 438.810 does contain some additional clarification, in that paragraph (a) contains definitions of “choice counseling,” “enrollment activities,” “enrollment broker,” and “enrollment services.” It is not clear what additional clarification the commenter thinks would be needed. We also note that States may set rules more stringent than the Federal rules if they wish.

Comment: One commenter questioned whether there was a conflict between § 438.208(c), which provides for health screening assessments by an enrollment broker, and § 438.810(b)(1), which requires that enrollment brokers be independent.

Response: There is no conflict between these two sections. The independence of enrollment brokers from MCOs, PIHPs, PCCMs and providers of services is a separate issue from the activities of the enrollment broker in assessing and screening special needs individuals. The latter activities are performed by the broker for the State, as part of its activities as an enrollment broker, and not as the agents of an MCO, PIHP, PCCM or provider.

Comment: A commenter asked whether it was CMS’ intent to exclude all potential enrollment brokers who have any relationship with a health care provider, whether or not that health care provider serves the Medicaid population.

Response: CMS is bound by the statutory provision on enrollment brokers, and section 1903(b)(4)(A) of the Act specifically prohibits the availability of FFP for enrollment brokers who are not independent of any health care providers, “whether or not any such provider participates in the State plan under this title.” Congress presumably believed that such

independence was necessary to ensure that the Medicaid enrollment process was free from even potential bias.

Comment: Several commenters noted that the independence requirement could prevent employees of a county from serving as enrollment brokers that operates an MCO, PIHP, or PCCM, or provides services or is affiliated with providers, from serving as enrollment brokers, and contended that this result would be detrimental to the enrollment process. Commenters also felt that MCOs should be able to assist in enrollments. One commenter believed that it was not feasible for States to rely only upon community-based or non-profit organizations to process enrollments.

Response: First, with respect to the comments on MCO involvement in enrollment, States may permit MCOs to process enrollments in their own plans. This provision only involves a State contract with an enrollment “broker” which processes enrollments in multiple plans. With respect to the issue of employees of counties that operate managed care entities or provide health care services, we believe that such an employee would not meet the statutory standard of being “independent” of such providers, and that Congress has prohibited them from serving as enrollment brokers. An enrollment broker might be a public or quasi-public entity with a contract or MOA/MOU with the State or county, as long as the entity does not furnish health care services in the State. For example, a State may not claim FFP for a contract with, or have an MOU with, a county health department to do managed care enrollment or choice counseling because the health department provides health services. A community organization that provides health services in the State, for example, an organization providing health care to homeless individuals, may contract or subcontract to perform outreach and education, but not enrollment and choice counseling functions covered by the enrollment broker provisions in section 1903(b)(4).

Neither the statute nor these rules specifically address the use of non-profit or community-based organizations to fulfill the enrollment broker function, but these entities would be subject to the same requirements for independence and prohibitions on conflict of interest as any other prospective brokers. We note that the regulations also would permit for-profit enrollment brokers if they met the conditions in § 438.810.

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

Proposed § 438.812 was transferred in its entirety from previous §§ 434.74 and 434.75. It provides that States receive Federal matching for all costs covered under a risk contract at the medical assistance rate, while under a non-risk contract, only the costs of medical services are matched as medical assistance, while all other costs are matched at the administrative rate. We received no comments on this provision.

6. Limit on Payments in Excess of Capitation Rates (Proposed § 438.814)

Section 438.814 proposed limitations on the availability of FFP in contracts, which contain incentive arrangement or "risk corridors." As described in proposed § 438.6(c)(5) on rate setting for risk contracts, under this proposal, FFP was only available in contract payments to the extent they did not exceed 105 percent of the payment rate determined to be "actuarially sound." The theory for this limitation was that rates too far in excess of those established to be actuarially sound were not actuarially sound, and therefore did not meet the condition for FFP in section 1903(m)(2)(A)(iii).

Comment: Many commenters disagreed with the proposal to limit Federal matching at 105 percent of approved capitation rates in contracts with risk corridors. Some commenters questioned the rationale for setting the limit at 105 percent, while others questioned how it was determined that this limit would be appropriate for every contracting situation, State and contractor. Most commenters felt that the limit on risk corridors was inappropriate and arbitrary; would discourage States from using this mechanism, which the commenters felt could be an effective tool in setting rates for populations with little or no managed care experience, including the chronically ill and disabled; would prevent the State and Federal governments from sharing in profits and being protected from overpayments; and would discourage MCOs from taking the risk to cover these populations.

Other commenters pointed out that risk corridors are an important mechanism to address unforeseen costs to MCOs during contract periods from these factors as changes in case mix, enrollment patterns, utilization patterns, or provider networks, or coverage of populations with little or no managed care history. A 105 percent cap on these arrangements constrains States' flexibility to effectively address these

issues without administratively cumbersome mid-year rate adjustments and could, in the commenters' view, result in over-projection of capitation rates in order to remain under the ceiling. Commenters suggested CMS either: (1) Accept an actuarial certification that the amount paid to an MCO after settlement is actuarially sound, and permit FFP for that entire amount; (2) permit a "good cause" exception to the 105 percent limit; or (3) or raise the limit to 110 percent. One commenter supported CMS' acknowledgment of risk sharing and risk corridors as acceptable payment mechanisms up to 105 percent of capitation rates.

Response: We understand the commenters concerns and upon consideration of these comments, agree that the 105 percent limit on FFP on contracts, or portions of contracts with risk corridors, is too restrictive to permit the continued use of this important risk sharing mechanism. We agree that is inappropriate to place a specific percentage limitation on FFP where risk corridors are used in a contract. The purpose of this mechanism is to share both the risk and the profits between the contractor and the State (and the Federal government by virtue of its matching of State expenditures.) One potential risk that can be addressed in risk corridors is the risk of fluctuations in utilization based on the changing demographics of a population (such as, the high costs of an increased percentage of disabled enrollees.) A fixed percentage limit does not take such risks into account. In considering the commenters' concerns, we have determined that a more appropriate outer limit on the actuarial soundness of payments under a risk corridor methodology would be a limitation based on what Medicaid would spend for the specific services utilized, plus an amount to cover the managed care plan's reasonable administrative costs. Such a limit would be similar to the "non-risk upper payment limit" in § 447.362, except for the recognition of administrative costs. The reason we did not simply adopt the rule in § 447.362 is because the amount allocable to administrative costs under that section of the regulations is not based on a managed care entity's reasonable administrative costs, but rather on the amount the Medicaid agency "saves" in its administrative costs by not having to pay fee-for-service claims for the beneficiaries enrolled in the managed care plan. We believe this amount is likely to be much lower than even the

administrative costs of a well run managed care organization.

Thus, we are revising the requirement in proposed § 438.814 to impose an upper limit on payments under risk corridors that is based on "what Medicaid would have paid on a fee for service basis for the services actually furnished to recipients" plus an allowance for the managed care plan's reasonable actual administrative costs. This limit reflects the fact that a risk corridor extended to its ultimate extreme would become a nonrisk contract, and that the rule governing FFP in nonrisk contracts (with the modification noted) is the most logical limit to apply. We are also moving this requirement to § 438.6(c)(5) in order to have all of the payment provisions in one subpart of this rule.

Comment: Some commenters also believe the 105 percent limit was arbitrary and inappropriate for incentive arrangements, and could discourage programs intended to achieve quality-related goals (such as increases in EPSDT services and meeting quality improvement targets).

Response: We do not agree with commenters that the 105 percent limit is inappropriate and arbitrary for, and would discourage the use of, incentive arrangements. Under the new payment rules in § 438.6(c), capitation rates are to be established to reflect the level of State plan services to be delivered under the contract. Further, States are free to combine financial withholds and incentives for such things as quality improvement targets. Thus, we do not believe it is necessary to establish financial incentives above a level at which FFP would be available under this provision. As with the provision on risk corridors, we are moving this provision to § 438.6(c)(5).

Comment: One commenter asked that CMS define the term "risk corridors" as used in this section and in § 438.6(c).

Response: A risk corridor is a risk sharing mechanism in which States and MCOs share in both profits and losses under the contract outside of predetermined threshold amount. The amount of risk shared under this arrangement is usually graduated so that after an initial corridor in which the MCO is responsible for all losses or retains all profits, the State contributes a portion toward any additional losses, and receives a portion of any additional profits.

Comment: Several commenters asked whether this provision places a limit on any and all payments and payment mechanisms that are in excess of the capitation rate, or whether there are any

payment mechanisms which would be excepted from the cap?

Response: Section 438.6(c) sets forth the requirements for payments under all risk contracts, and requires that these payments be identified and computed on an actuarially sound basis. This requirement applies to reinsurance, stop-loss limits, or other risk sharing mechanisms. We believe that amounts payable under these other arrangements (except for incentives and risk corridors) will be offset by actuarially determined amounts in determining the capitation rate to be paid. Thus, the limit in any of these arrangements will be predetermined based on the amount of the offset or deduction from the capitation rate. Since the potential payments under these risk-sharing mechanisms are determined in this manner, the limits in this provision do not apply. Section 438.6(c) does not authorize any other payment in excess of the capitation rates.

Comment: Several commenters asked that CMS define what is included in the term “aggregate amount of approved capitation payments” as used in this section. Specifically, the commenters wanted to know whether this includes administration, profit and other expenditures. One commenter asked whether this provision applies when a State withholds a percentage of approved capitation rates and later distributes the pool of withheld funds based on some type of risk arrangement, and whether the amount of funds withheld would be considered part of the approved capitation amount, or would be capped under this provision.

Response: The term “aggregate amount of approved capitation payments” as used in this section refers to the total amount of the capitation rates approved under the contract that are attributable to the individuals and services covered by the incentive arrangement. This would include portions of the rate intended for administration, profit or any other purposes and would be determined prior to any withhold amount being deducted. Further, the 105 percent limit applies only to those portions of a contract, which apply to the individuals or services, governed by the incentive arrangement. For example, if the contract includes provisions to withhold a portion of the capitation payments for not meeting targets for initial screenings for enrollees, neither the payments nor any withheld amounts for these services would be part of the calculation for determining any incentive payments due the plan under a separate contract provision for meeting targets for childhood

immunizations. To further clarify this distinction, we have eliminated the provision in § 438.6(c)(5)(iii)(C) that required contracts with incentive arrangements to have withhold penalties for targets not met (proposed paragraphs (D), (E) and (F) have been redesignated as paragraphs (C)).

Comment: One commenter questioned whether the 105 percent limit is to be applied in the aggregate, or is it applicable to each individual rating cell.

Response: This would be determined by the specific arrangement under the contract. In most contracts, we would expect a target established for specific populations who may comprise their own rate cells under the contract. In this case, the limit would have to be applied to each individual or groups of cells covered by the arrangement. If the incentive applies to the entire population covered under the contract, the limit would be applied in the aggregate.

I. Revisions to Parts 435, 440, and 447; Miscellaneous Comments

In addition to the provisions set forth in the new part 438 and the fair hearing provisions in part 431 discussed in section II. E. of this preamble, the proposed rule contained amendments to parts 435, 440, and 447 that we discuss below. These provisions included amendments to §§ 435.212 and 435.326 to reflect the new terminology adopted by the BBA. We also proposed a new § 440.168 in part 440 to include a description of primary care case management services. Amendments to part 447 not already addressed above include a new § 447.46(f) implementing the timely claims payment requirements in section 1932(f), and a new § 447.60 regulating MCO cost-sharing, which was made permissible under BBA amendments to section 1916 of the Act. In this section, we discuss the comments we received on the above regulations. We received no comments on the revisions to § 447.60. In this section, we also address miscellaneous comments that did not relate to a specific section of the proposed regulations.

1. Guaranteed Eligibility (Proposed § 435.212)

Section 435.212 was revised in the proposed rule to implement section 1902(e)(2) of the Social Security Act. This change will permit State agencies, at their option, to provide for a minimum enrollment period of up to 6 months for individuals enrolled in a PCCM or any MCO. Previously, this option was only available to enrollees of Federally qualified HMOs.

Comment: One commenter expressed support for this provision.

Response: We thank the commenter for the support.

2. Definition of PCCM Services (Proposed § 440.168)

Section 4702 of the BBA added PCCM services to the list of optional Medicaid services in section 1905(a) of the Act. The BBA also added section 1905(t) to the Act. This subsection defines PCCM services, identifies who may provide them, and sets forth requirements for contracts between PCCMs and the State agency. This means that in addition to contracting with PCCMs under a section 1915(b) waiver program or section 1115 demonstration project, or under the new authority in section 1932(a)(1) to mandate managed care enrollment, States may add PCCMs as an optional State plan service. Regardless of the vehicle used, proposed § 438.6(k) set forth the minimum contract requirements States must have with their primary care case managers.

Proposed § 440.168(a), implementing section 1905(t)(1) of the Act, defined “primary care case management services” as case management related services that include locating, coordinating and monitoring health care services, and that are provided under a contract between the State and a primary care case manager. A PCCM was defined as including either (1) an individual physician (or, at State option, a physician assistant, nurse practitioner, or certified nurse-midwife), or (2) a group practice or entity that employs or arranges with physicians to furnish services. Proposed § 440.168(b) provided that PCCM services may be offered as a voluntary option under the State plan, or on a mandatory basis under section 1932(a)(1) or under a section 1115 or section 1915(b) waiver.

Comment: One commenter disagreed with the language designating it a “State’s Option” to qualify nurse practitioners as PCCM providers. The commenter believes nurse practitioners should be recognized as PCCM providers by the Medicaid program. It is critical that CMS ensure that Medicaid beneficiaries have the option to choose a nurse practitioner as their PCCM provider.

Response: The definition of a primary care case manager in § 438.2 of this part mirrors the statutory language in section 1905(t)(2) of the Act. The statute is clear that there are two categories of PCCMs. The first category is PCCMs that are physicians or physician groups, or that employ or arrange for the provision of physician services. The definition of a physician does not include a nurse

practitioner. (See sections 1905(a)(5)(A) and 1861(r)(1) of the Act.) The second category is non-physicians who are included as PCCMs “at State option.” The statute expressly provides for nurse practitioners to be PCCMs “at State option.”

3. Timely Claims Payment by MCOs (Proposed § 447.46)

Section 1932(f) of the Act specifies that contracts with MCOs under section 1903(m) must provide that, unless an alternative arrangement is agreed to, payment to health care providers for items and services covered under the contract must be made on a timely basis, consistent with the claims payment procedures described under section 1902(a)(37)(A) of the Act. Section 1902(a)(37)(A) of the Act requires that 90 percent of claims for payment (for which no further written information or substantiation is required in order to make payment) made for covered services provided by health care providers are paid within 30 days of receipt, and that 99 percent of the claims are paid within 90 days of receipt. These requirements were included in proposed § 447.46. We received no comments on this section.

4. Miscellaneous Preamble Comments

a. Effective Date of the Final Rule

Comment: Numerous commenters offered suggestions for the effective date and timeframe for implementation of the final rule. The commenters urged CMS to provide an adequate opportunity for MCOs and States to come into compliance with the regulation following its effective date as implementation will require both States and MCOs to make substantial changes to contracts, waivers, and other State procedures. One commenter recommended that the effective date be 180 days after the State’s MCO contract renewal date following publication of the final rule. A few commenters recommended that States be given 2 years to come into compliance with the final rule. Several other commenters recommended that a full year be given for all contracts, regardless of their renewal date, to come into compliance with the final rule.

Response: We agree with the commenters that adequate time needs to be given for implementation of this final rule. Therefore, we have established that the final regulation will become effective 60 days post publication, and must be fully implemented by 1 year from the effective date of the regulation. This would allow new provisions to be implemented without forcing States to

amend contracts in mid-term, although States would have the option to implement portions of the regulation in the interim period.

b. Violation of APA

Comment: A few commenters contended that the August 20, 2001 proposed rule did not comply with the Administrative Procedure Act (APA) as interpreted by the Supreme Court in *Motor Vehicle Manufacturers Assoc. v. State Farm Mutual Automobile Ins. Co.*, 463 U.S. 29 (1983). Specifically, the commenters suggested that we did not comply with the requirement in that case that agencies supply reasoned analysis in support of a change in policy. The commenters also quoted the U.S. Court of Appeals for the District of Columbia’s decision in *National Black Media Coalition v. FCC*, 775 F.2d 342, 356 n. 17 (D.C. Cir. 1985) for the proposition that “an agency may not repudiate precedent simply to conform with shifting political mood,” and that “the agency must demonstrate that its new policy is consistent with the mandate with which the Congress has charged it.” In citing these cases, these commenters were comparing the regulations in the August 20, 2001 proposed rule, to those in the January 19, 2001 final rule that never took effect. The commenters believe that we were required in the proposed rule to explain any differences between the rules proposed in the August 2001 proposed rule and those published on January 19, 2001 and find support in “the rulemaking record” for any such differences.

Response: The cases cited by the commenters concern changes made to existing regulations. In those cases, regulations had been published and taken effect, and the agencies were making changes to existing regulations. In this case, as noted in the previous comment, the effective date of the January 19, 2001 final rule was delayed, and those regulations had never taken effect. Thus, there are no “existing regulations” in part 438 that this proposed rule would “change.” Rather, the existing regulations governing Medicaid managed care are the regulations in part 434 which predate the earlier rulemaking that led to the January 19, 2001 final rule. We believe that the preamble to the proposed rule clearly articulates our reasons for proposing changes to these existing part 434 regulations. Most of the major changes in the proposed rule implement, or are based on, Medicaid managed care provisions in the Balanced Budget Act of 1997 (BBA), which was enacted after the existing

part 434 regulations were promulgated. When we proposed changes in policy not directly based on BBA provisions, the preamble explains the basis for the policy choice made, including discussion of inadequacies in the part 434 regulations, when appropriate.

We note that, while not required to do so by the cases cited by the commenters, we did explain in the preamble our rationale for the departures in this proposed rule from the approach taken in the January 19, 2001 regulations. We indicated that in developing this proposed rule, we were “guided by several considerations” set forth in detail in the preamble. (See 66 FR 43616.) For example, we indicated that the proposed rule was designed to recognize that Medicaid is a “Federal-State partnership” under which “States are assigned the responsibility of designing their State programs” and need the flexibility to “employ different approaches to achieving the same goal within their varying State marketplaces and health care delivery systems.” We also noted “new advances and findings in health care, health quality assessment and improvement” that “unfold on an almost daily basis,” and noted that regulations containing too rigid a structure are not able to adapt to these changes. The extent to which some aspects of the proposed rule differed from those in the January 19, 2001 rule is attributable to our reassessment, described above.

c. Applicability of BBA Provisions and Other Parts of This Final Rule To Waiver Programs

Section 4710(c) of the BBA specifies that the requirements in sections 4701 through 4710 do not affect the terms and conditions of any demonstration projects or waiver programs approved by the Secretary under the authority of sections 1115 or 1915(b) of the Act. We have consistently interpreted this to be a “grandfather” provision that applies only to waivers or demonstration projects that were in effect, or already approved, as of August 5, 1997, the date of enactment of the BBA. Thus, when the waiver or demonstration project expires, the grandfather provision in section 4710(c) no longer applies.

Under section 4710(c), the grandfather provision applies to the “terms and conditions” of a waiver. Any provisions of a State’s section 1115 demonstration project or section 1915(b) waiver program that were specifically addressed in the State’s waiver proposal, statutory waivers, special terms and conditions, operational protocol, or other official State policy or procedures approved by us, are

considered to be the “terms and conditions” of the waiver. To the extent the terms and conditions of the State’s approved waiver program covered the same subject matter as any of the BBA requirements, that portion of the State’s program would not have to comply with the BBA until the waiver expired. For example, if the State’s waiver program included enrollment and disenrollment rules, the enrollment and disenrollment rules in section 1932 of the Act would not apply while the waiver was still in effect. For any part of the State’s Medicaid managed care program that was not within the scope of the waiver, the BBA provisions applied immediately, with certain exceptions specified below, dealing with newly submitted or amended waivers.

As noted above, under our interpretation, the exemption from the BBA requirements applied to section 1915(b) waiver programs only until the date that the waiver authority that was approved or in effect as of August 5, 1997 expired. Because none of those waivers exceeded two years, all of them expired no later than 1999. After the waiver expired, the State was required to comply with all BBA requirements. Similarly, in the case of section 1115 demonstration projects, the “grandfather” provision in 4710(c) only applies until the demonstration expires, as established by the expiration date that appears in the waiver documents that were approved or in effect on August 5, 1997. However, section 1115(e) of the Act provides a State with a statutory right to extend any waiver previously approved under 1115(a), on the same “terms and conditions,” unless the Secretary specifically disapproves the extension. This extension can be for up to three years. As long as the State applies for an extension under section 1115(e) while its demonstration project is still subject to the “grandfather” provision described above, the statutory requirement that the waiver continue under the “same terms and conditions” means that those waiver provisions cannot be subject to the BBA requirements until the extension expires. The Medicare, Medicaid, and State Child Health Insurance Program Benefits Improvement and Protection Act of 2000 (BIPA), enacted on December 21, 2000 (Pub. L. 106–554) added section 1115(f) of the Act, to provide for additional extensions of section 1115 health care reform demonstrations. Unlike section 1115(e), section 1115(f) does not require that the demonstration project be extended under the same terms and conditions, providing, instead, for the negotiation of

new terms and conditions. Therefore, unless the Secretary uses his discretionary authority to waive the requirements, as explained below, the BBA requirements apply to all demonstration projects approved under section 1115 except during the “grandfather” period and any subsequent extension under section 1115(e)(2).

For newly submitted or amended section 1115 waivers, the Secretary of DHHS retains the discretionary authority to exempt the State from specific BBA managed care provisions. Generally, exemptions are granted to allow States some flexibility in operating their Medicaid programs, while promoting the proper and efficient administration of a State’s plan. However, particularly for those BBA provisions related to increased beneficiary protections and quality assurance standards, we anticipate that we would not approve an exemption unless a State can demonstrate that the waiver program has beneficiary protections or quality standards that would equal or exceed the BBA requirements.

In addition, the Secretary may use his discretionary authority (to the extent permitted by the specific waiver provision) to waive other requirements in this rule which do not implement provisions of the BBA, such as the new rate setting requirements, requirements that apply to PIHPs and PAHPs, and requirements that were redesignated from part 434 or other parts of 42 CFR.

Comment: Several commenters questioned the applicability of these rules to waiver programs. One commenter wanted CMS to confirm the belief that the proposed rule does not apply to States with current section 1115 demonstrations, while another wanted CMS to specify in the text of final rule that these regulations do not apply to waiver programs under section 1115 or 1915(b), to be consistent with section 4710(c) of the BBA. Another commenter supported CMS’ decision to apply the final rule to both new and renewed section 1115 and 1915(b) waivers.

Response: As stated in the proposed rule and reiterated above, section 4710(c) of the BBA is time-limited, has expired for all section 1915(b) waiver programs, and only applies to section 1115 health care reform demonstrations during the period of approval that was in effect as of August 5, 1997 and any 3-year extension periods granted under the authority in section 1115(e)(2) of the Act. We disagree with the suggestion that the provisions of this part should

never apply to programs conducted under these waivers.

Comment: One commenter asked that CMS grant States flexibility in applying these rules through 1915(b) waivers, but another commenter opposed the decision to consider granting any new waivers of these requirements.

Response: As indicated above, waiver authorities in section 1915(b) and 1115 remain in effect. If a State requests a waiver in order to implement an alternative approach for its Medicaid program that requires a waiver of provisions contained in this rule, while maintaining necessary beneficiary protections and meeting the specific requirements of the waiver authority requested, we may grant the waiver. We believe granting these waivers reflects the intent of the Congress which did not modify or limit the authority in either of these waiver provisions.

Comment: One commenter asked to what extent the provisions in this rule apply to section 1915(c) waiver programs.

Response: To the extent any provisions of these rules are relevant to the contract requirement, payment mechanisms, enrollment, or any other aspect of a program operating under a section 1915(c) waiver authority, the requirements apply. While we do not believe that most current 1915(c) programs would be subject to any of these requirements, any program operating under a combined 1915(b) and (c) authority which includes such things as an enrollment lock-in period, a capitated reimbursement methodology, or a provider that qualifies as a PAHP, would have to comply with the provision of this final rule as applicable.

See section I.E. of this preamble for further discussion regarding the applicability of the BBA requirements to States with waivers.

d. Education of MCOs, PIHPs, PAHPs, and PCCMs About Special Health Care Needs

Comment: Many commenters believe that there should be language stating that the “State agency must have in effect procedures for educating MCOs, PIHPs, PAHPs, PCCMs, and any subcontracting providers about the clinical and other needs of enrollees with special health care needs.” The commenters stated that this is an essential way for the State to ensure that health plans, that have not traditionally served Medicaid enrollees or enrollees with special health care needs, understand those needs. Another commenter stated that managed care must be sensitized to the needs of special needs beneficiaries, for whom

disruptions in service and impediments to access can be serious.

Response: While we understand the need for awareness of special health care needs, we want to give States the flexibility to decide at what level this should happen. Many States may not have the capability or feel that it is appropriate for the State to provide education to MCOs, PIHPs, PAHPs, PCCMs, and providers on what is often a clinical issue. Public health departments and local medical societies are often doing this type of work in the State.

e. Miscellaneous Comments

Comment: Numerous commenters applauded CMS for amending the Medicaid managed care regulations with the proposed rule published on August 20, 2001. Commenters appreciated that the proposed regulation removed much of the prescriptiveness of the requirements and acknowledged the expertise and work that continues at the State level. Most commenters were pleased to see a renewed emphasis on State flexibility. The proposed rule changed the focus from detailing how States and MCOs should operate to laying out the basic requirements for Medicaid managed care and allowing States the authority to implement them in a manner appropriate for each State. Further, commenters stated that the new rule simplified many of the provisions and eliminated redundancy so that requirements are stated only once. Commenters believe that the simplification of the regulation and removal of duplicative and redundant provisions will help States to accurately interpret, follow, and enforce this regulation.

Other commenters stated that the proposed rule will permit innovation and support program growth under standards that respond to the needs of the full spectrum of enrollees and implementation of the January 2001 rule would have seriously undermined the availability of the benefits of MCOs to Medicaid beneficiaries. Another commenter believes that removal of much of the highly detailed language contained in the January 2001 rule will enhance the ability of both the Federal and State governments to exercise responsibilities as purchasers and regulators effectively. Further, States have proven their ability to innovate in the quality arena and will continue to strive towards providing the highest quality care to Medicaid beneficiaries. Several other commenters noted that the proposed rule is a significant improvement over the rules published in January 2001, many provisions of

which would have significantly raised health plan compliance costs without meaningfully improving patient care. One commenter urged immediate implementation of the proposed rule.

Response: We thank the commenters for their support. We will continue to work with States during the implementation period of the final rule.

Comment: Numerous commenters expressed their dissatisfaction with the proposed rule published on August 20, 2001. These commenters strongly support the immediate implementation of the January 19, 2001 final rule. Most of these commenters stated that the January rule reflected a true balance between providing States additional flexibility and providing Medicaid beneficiaries, including those with disabilities, the protections they need to ensure that Medicaid managed care meets their needs; that the revised proposed rule and the accompanying delays in implementation demonstrate that the Administration is more attuned to the desires of the States and managed care industry than to the needs of the people who are supposed to benefit from the Medicaid program; that the proposed rule pays too little attention to the special needs of children and adults with mental retardation and other disabilities. These commenters believe that the January rules establish important new protections for beneficiaries with respect to access to care, grievance and appeal procedures, and mandatory enrollment requirements.

Other commenters stated that more specific requirements are warranted related to transitioning children into and out of managed care, and the identification, screening and assessment of children with special health care needs. Some commenters urged CMS to strengthen the proposed rule to ensure safeguards for children with special health care needs, consistent with the waiver criteria for children with special health care needs. These commenters also called upon CMS to incorporate the recommendations of the Department's November 2000 Report to the Congress entitled "*Safeguards for Individuals with Special Health Care Needs Enrolled in Medicaid Managed Care*" into the regulation.

Another commenter expressed concern that many provisions of the proposed rule do not provide adequate protections for consumers of mental health and substance abuse services enrolled in managed care plans through the Medicaid program. The commenter further suggested that the proposed rule unjustifiably undermines the consumer safeguards established in the January

2001 final rule. Another commenter specified that the proposed rule represents a profound failure to implement the statutory provisions of the BBA and does not provide even basic patient protections. These commenters urged CMS to reinstate many aspects of the January rule, which they believe better effectuate the BBA. Many other commenters believe that if the proposed rule is implemented it will be extremely harmful to Medicaid beneficiaries with special health care needs, including people living with HIV/AIDS.

Response: In development of the proposed and final rules we gave serious attention to all of the concerns raised to us. We believe the final rule reflects the path chosen by the Congress to strike an appropriate balance between State flexibility and beneficiary protections. We believe that this final rule reflects that balance and appropriately implements the beneficiary protections established by the BBA. We believe all commenters have expressed the same goal, namely: strong, viable, State Medicaid managed care programs that deliver high quality health care to Medicaid beneficiaries. We believe that the final rule will help States achieve this goal. The Congress drafted the statute in full recognition of the Medicaid program as a Federal-State partnership and we share that recognition. States are assigned the responsibility of designing their State programs. We drafted this regulation to recognize the responsibilities of the States and the need to employ different approaches to achieving the same goal within their State marketplaces and health care delivery systems. We heard from some key stakeholders in Medicaid managed care, including States, provider organizations, and advocates for beneficiaries. Some of these stakeholders expressed serious concerns about the regulation, including changes made to the January 2001 final rule that had not been included in the September 1998 proposed rule. Other stakeholders strongly supported the January 2001 final rule and urged us to continue with implementation. We decided that the best approach was to make some modifications to the January 19, 2001 final rule and republish it as a proposed rule in order to give everyone the opportunity to comment on all of the provisions.

We believe we have created a set of requirements that appropriately balances the necessary protections for all beneficiaries enrolled in Medicaid managed care plans, including individuals with special health care needs, and States' flexibility to manage

their managed care programs. We have not reduced the emphasis on requiring States to provide high quality care to beneficiaries, especially those with special needs. The rule requires States to identify managed care enrollees with special needs to make sure that they will receive appropriate access to quality care. States retain the flexibility to develop these mechanisms and define the special needs populations. This approach enables States to better target their Medicaid resources to those most in need. We believe this is a far more efficient approach than imposing regulatory burdens that may not have their intended effects.

Comment: One commenter expressed concern that the August 20, 2001 proposed rule did not contain important regulatory language that was included in the 1998 proposed rule supportive of protections for the mentally ill in Medicaid managed care. The commenter pointed out that a number of its recommendations were not included and the commenter requests an explanation for these negative decisions.

Response: The regulation, as now written, is intended to address the needs of, and protections for, all Medicaid beneficiaries in managed care, including persons with disabilities and those who suffer from mental illness. The regulation is written in a manner to establish a general framework for States to use when developing managed care programs to serve all of its enrolled populations. Therefore, we do not believe it is necessary to list specific medical conditions within the regulation text. As far as comments received on the September 28, 1998 proposed rule, responses to all of the comments and rationale for changes can be found in the January 19, 2001 final rule preamble.

Comment: A few commenters, while supportive of the fact that CMS delayed implementation of the January 2001 final rule and then made substantial revisions in the August proposed rule, were still concerned that the proposed rule will increase the cost and administrative burden associated with Medicaid managed care. The commenters believe that health plans serving members other than Medicaid beneficiaries will be placed at a disadvantage. The commenters also urged CMS to take steps to encourage commercial plans and providers to participate in Medicaid managed care programs and to regulate the program in a manner that allows States to continue moving forward with managed care. Another commenter expressed concern regarding the overall impact on access, quality of care and cost effectiveness of

applying the regulations to specialty mental health programs. And to the extent CMS does not provide more flexibility to States in these regulations, it should seriously consider providing reasonable flexibility to States in the section 1915(b) waiver process. Another commenter stated that the speed with which these rules have been rewritten has led to a proposed rule that shows a lack of clarity and careful consideration. The regulatory process did not provide for adequate participation by the States with the knowledge and experience to help draft effective and efficient rules for managed care. The commenter urged CMS to involve State representatives in a final rewrite of the rule. In addition, when considering the imposition of every new administrative requirement, CMS needs to be cognizant that each of those requirements costs the States' increasingly limited resources that could better be focused on provision of care. Further, every new requirement on MCOs and providers can affect their continued participation in managed care. Another commenter advised CMS to keep in mind that as regulations are designed with particular focus on enrollee protections, it is critical to keep in mind that overly prescriptive requirements that shift potentially unnecessary administrative costs and burdens to plans and providers may result in the unintended consequence of provider and/or plan withdrawal from the Medicaid program. This could then lead to impeded access to quality care for vulnerable populations.

Response: The regulation was developed to provide States with an appropriate level of flexibility that we believe to be consistent with necessary beneficiary protections.

State flexibility had to be balanced against the statutory requirements of the BBA. Further, the regulation has been designed to provide a framework that allows CMS and States to continue to incorporate further advances for oversight of managed care, particularly as they pertain to beneficiary protection and quality of care. We recognize that States are unique and have different needs for their enrolled populations. This final rule was designed to promote State flexibility as much as possible so that States can implement managed care programs that meet the needs of their beneficiaries. With respect to MCO and provider participation, we further believe that the new rate-setting provisions will allow States to set rates that more appropriately reflect the costs of health services for the variety of Medicaid populations served, especially those with special health care needs.

Comment: One commenter stated that changes should be made to the proposed rule to ensure that providers are compensated in a timely manner, so they can continue to provide needed services to low-income patients.

Response: Section 1932(f) of the Act specifies that contracts under 1903(m) must provide that, unless an alternative arrangement is agreed to, payment to health care providers for services covered under the contract be made on a timely basis, consistent with the claims payment procedures described under section 1902(a)(37)(A) of the Act. These procedures require that 90 percent of claims for payment (for which no further written information or substantiation is required in order to make payment) made for services covered under the contract and provided by health care providers are paid within 30 days of receipt, and that 99 percent of the claims are paid within 90 days of receipt. These requirements are included in § 447.46. We do not believe that additional changes need to be made.

Comment: One commenter noted that the proposed rule does not take into consideration the frontier nature of some States. Many of the provisions would be difficult to meet even for the non-Medicaid population.

Response: We believe this final rule affords States the flexibility to implement these requirements for Medicaid managed care in all areas of their State. Further, the final rule provides for an exception to the choice requirements (§ 438.52) for residents in rural areas.

Comment: One commenter stated that these rules continue to require monitoring and oversight on issues that would result in higher requirements for Medicaid enrollees than for fee-for-service Medicaid or the general population. The commenter noted that it remains a distressing tendency to enforce things for managed care that are not enforced for the fee-for-service population.

Response: While CMS agrees that beneficiary protections are also important for beneficiaries receiving care under fee-for-service arrangements, this rulemaking implements Chapter 1 of Subtitle H of the BBA, titled "Managed Care." These statutory provisions do not apply to fee-for-service Medicaid, and cannot be extended to fee-for-service arrangements in this final rule. However, States do have the flexibility to develop beneficiary protections similar to those presented in this regulation for those still receiving care through fee-for-service. States may establish similar

standards that can be monitored on the same scale as those standards established for Medicaid managed care. We agree that it is important to recognize that beneficiaries are afforded additional assistance in managed care than may be afforded in fee-for-service.

Comment: One commenter noted that when establishing protections for Medicaid managed care beneficiaries, CMS should recognize that oral health is an inseparable part of an individual's overall health and the formation of an effective Medicaid dental delivery system is just as important as the creation of an adequate Medicaid medical delivery system. The commenter stated that all dental patients, whether they are in private plans, Medicaid fee-for-service or any Medicaid managed care arrangement, deserve equal access to health services and equal protections under the law.

Response: We recognize the importance of oral health and the importance of serving the dental needs of the Medicaid population. The final rule is designed to address access issues related to all Medicaid managed care services. For example, an MCO or PAHP that delivers dental services to Medicaid beneficiaries must comply with the access requirements in this regulation. The MCO or PAHP must ensure that it offers an appropriate range of services and that it maintains a network of providers that is sufficient to meet the needs of enrollees. Further, each State must ensure that all of the covered services are accessible for all beneficiaries enrolled. We are also optimistic that managed care will facilitate increased utilization in the area of dental services.

Comment: One commenter expressed concern regarding some of the regulatory provisions, as they may pose or have a different effect in the territories, particularly since Medicaid funds are capped.

Response: We recognize the commenter's concern, however territories are required to meet all Medicaid requirements except for provisions specified in Federal law and regulation.

Comment: Several commenters stated that none of the Medicaid managed care rules has included any discussion of the need for State Medicaid programs to develop incentives for physicians to participate in Medicaid managed care plans. The commenters specified that lack of sufficient physician participation may pose a significant barrier to high quality care for Medicaid beneficiaries. Development of incentives for physician participation should be a central issue for Federal and State governments as

they design, implement and evaluate managed care programs. One commenter recommended that State agencies be required to consult with State medical societies early on in the process of designing Medicaid managed care programs and continue to seek input from the physician community throughout implementation. The commenter cited a recent report from the American Academy of Pediatrics that concluded "in order to ensure that expanding insurance coverage for children translates into viable access to care, States must provide incentives for pediatricians to extend their resources to serve new Medicaid and SCHIP enrollees."

Response: We realize that physician consultation is an important factor in the development of Medicaid managed care initiatives and encourage stakeholder input at all stages of managed care development. However, we are not specifically requiring stakeholder involvement since States, based on the uniqueness of their Medicaid managed care programs, are in the best position to determine how this involvement should be structured. Each State is required to have a Medical Care Advisory Committee (MCAC) established for the purpose of advising the Medicaid agency about health and medical services. This committee, by regulatory definition, is required to include physicians. We encourage States to continue to use the MCAC as a mechanism for obtaining input on managed care issues. Likewise, under § 438.202, we require public consultation in development of the State's quality strategy.

Comment: One commenter disagreed with the deletion of the requirement that no more than 75 percent of enrollees in risk contracts be eligible for Medicare or Medicaid.

Response: This change was made by the Congress in the BBA, and we thus had no discretion in this rulemaking to retain it. We note that this requirement was previously used as a rough "proxy" to ensure quality services by requiring that an MCO attract commercial consumers. This "proxy" has been replaced in the BBA with more direct quality requirements implemented in this final rule.

III. Summary of Changes to the Proposed Rule

For reasons discussed above in the preamble, we have made the following changes to the proposed rule:

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

Section 431.200

We have added language to include PAHP actions to suspend, terminate, or reduce services such as those that would result in access to the State fair hearing.

Section 431.220

We have included a new paragraph (a)(6) requiring that any PAHP enrollee who has an action must be granted the opportunity for a State fair hearing.

Section 431.244

We have added language in paragraph (f)(1)(i) to specify that the 90-day timeframe for resolution of the State fair hearing begins the date the enrollee filed an MCO or PIHP appeal, not including the number of days the enrollee took to subsequently file for a State fair hearing. In paragraph (f)(1)(ii) we clarify the regulation text to State that if permitted by the State, the date the enrollee filed for direct access to a State fair hearing.

In paragraphs (f)(2) and (f)(3) we have changed the limit for appeals of a denial of service by an MCO or PIHP 72 hours to three working days.

PART 438—MANAGED CARE PROVISIONS

Subpart A—General Provisions

Section 438.1

In paragraph (b), we have included PIHPs in the scope of contracted entities provided in part 438.

Section 438.2

We moved the definition of "health care professional" from § 438.102 to § 438.2, as it applies to all of part 438.

We have clarified the definition of "health insuring organization" to reflect language in section 1932(a)(3) of the act.

Section 438.6

In paragraph (c)(3)(ii), we have added language to clarify that we are referring to data factors such as medical trend inflation, incomplete data, and MCO, PIHP, or PAHP administration.

In paragraph (c)(4)(ii), we have added language to clarify that payment rates are based only upon services covered under the State plan, or costs directly related to providing these services (such as, MCO, PIHP, or PAHP administration.)

We removed proposed § 438.6(c)(5)(ii) that referred to limitations on payment for risk corridors and incentive arrangements in proposed § 438.814. We

added new paragraph c)(5)(ii), which contains revised limitations on payment for risk corridors.

We added a new paragraph c)(5)(iii) that contains the payment limitations for incentive arrangements that were originally in proposed § 438.814.

We have redesignated proposed paragraph (c)(5)(iii) as (c)(5)(iv).

We have removed proposed paragraph (c)(5)(iii)(C), which required that for all incentive arrangements, the contract must provide that the arrangement is designed to include withholds or other payment penalties if the contractor does not perform the specified activities or does not meet the specified targets.

We have included a new paragraph (c)(5)(v) to require that if a State makes payments to providers for graduate medical education costs under an approved State plan, the State must adjust the capitation rates to account for the aggregate amount of the graduate medical education payments to be made on behalf of enrollees covered under the contract.

We have included a new paragraph (i)(2) specifying that all PAHP contracts must also provide compliance with the advance directive requirements if the PAHP includes, in its network, any of those providers listed under requirements on advance directives in § 489.102(a).

Section 438.8

We have made revisions in paragraph (b)(1) to specify that PAHPs must meet the contract requirements of § 438.6, except for those that pertain to HIOs and the requirements for advance directives unless the PAHP includes any of the providers listed in § 489.102.

We have revised paragraph (b)(6) to require PAHPs to meet all designated portions of subpart D (Quality Assessment and Performance Improvement).

We have added a new paragraph (b)(7) to specify that PAHP enrollees have the right to a State fair hearing under subpart E of part 431 (State Organization and General Administration).

Section 438.10

We have added paragraph (b)(2) requiring that the State must have in place a mechanism to help enrollees and potential enrollees understand the State's managed care plan. We also added paragraph (b)(3) requiring each MCO and PIHP to have in place a mechanism to help enrollees and potential enrollees understand the requirements and benefits of the plan.

We have revised paragraph (c)(2) to require that the State must make

available written information in each prevalent non-English language.

In paragraph (f) we rephrased the introductory language to require that information be furnished to MCO, PIHP, PAHP, and PCCM enrollees. In paragraph (f)(1) we have added language to clarify that for those States that choose to restrict disenrollment for periods of 90 days or more, notice of the enrollees disenrollment rights must be sent no less than 60 days before the start of each enrollment period. In paragraphs (f)(2) and (3) we now include references to paragraphs (g) and (h) of this section to specify the information certain enrollees have a right to request and obtain at least once a year.

We have included, in paragraph (f)(4) that the State, its contracted representative, or the MCO, PIHP, PAHP, or PCCM must give each enrollee written notice of any change that is deemed significant in the specified information in paragraphs (f)(6) of this section and paragraphs (g) and (h) of this section, if applicable.

In paragraph (f)(6) we have clarified that the information in this section must be provided by the State, its contracted representative, or the MCO, PIHP, PAHP, or PCCM. We have revised paragraph (f)(6)(i) to clarify that information on the names, locations, telephone numbers of, and non-English languages spoken by current contracting providers in the enrollees service area, including identification of providers that are not accepting new patients be provided to all enrollees. For MCOs, PIHPs, and PAHPs this includes, at a minimum, information on primary care physicians, specialists and hospitals. Further, in paragraph (f)(6)(iv) we add that for PAHP enrollees, the information specified in § 438.10(h) must be provided.

We have revised paragraph (g)(3) to provide that detailed information of physician incentive plans is available upon request.

We have added a new paragraph (h) that requires specific information that must be provided for PAHP enrollees. The State, its contracted representative, or the PAHP must provide information to their enrollees on the right to a State fair hearing, including the right to a hearing, the method for obtaining a hearing, and the rules that govern representation. In paragraph (h)(2), we have specified that information must be provided on advance directives, as set forth in § 438.6(i)(2) and in paragraph (h)(3) that, upon request, information must be provided on physician incentive plans as set forth in § 438.6(h). We have redesignated the previous

paragraph (h) as paragraph (i) in the final rule.

We have clarified in paragraph (i)(2)(i) the timeframes for when information must be furnished to all enrollees of a State plan program under § 438.50. For these enrollees, the timeframe is annually and upon request and for potential enrollees within the timeframe specified in § 438.10(e)(1). In paragraph (i)(3), we have clarified that the information provided is only for each contracting MCO or PCCM in the potential enrollee and enrollee's service area. Finally, in paragraph (i)(3)(v), we have removed reference to disenrollment rates as defined by the States as information that must be included.

Subpart B—State Responsibilities

Section 438.60

We have included language allowing for payment exceptions when the State has adjusted the capitation rates paid under the contract, in accordance with § 438.6(c)(5)(v), to make payments for graduate medical education.

Subpart C—Enrollee Rights and Protections

Section 438.100

We have moved paragraph (b)(3)(iii) regarding requests for medical records to new paragraph (b)(2)(vi). We have revised paragraph (b)(3) to specify that an enrollee of an MCO, PIHP, or PAHP (consistent with the scope of the PAHP's contracted services) has the right to be furnished health care services in accordance with §§ 438.206 through 438.210. We have removed paragraph (b)(3)(ii), regarding the right to obtain a second opinion.

Section 438.102

We have moved the definition of health care professional to § 438.2.

Section 438.104

We have revised paragraph (b)(1)(iv) to clarify that the requirement regarding the sale of other insurance applies to "private" insurance.

In paragraphs (b)(2) and (c) we have corrected cross-references to paragraphs (e) and (f) of § 438.10.

Section 438.114

In paragraph (a) we have removed references to § 422.113(b) and (c) and included the full text of definitions of emergency medical condition, emergency services and post-stabilization care services. In paragraph (d)(1)(ii) we have revised language to specify that entities may not refuse to

cover emergency services based on the emergency room provider, hospital, or fiscal agent not notifying the enrollee's primary care provider, MCO, or applicable State entity of the enrollee's screening and treatment within 10 days of presentation for emergency services.

Subpart D—Quality Assessment and Performance Improvement

In subpart D, §§ 438.200, 438.206, 438.207, 438.208, 438.210, 438.214, 438.224, 438.230, and 438.236 have been amended by adding PAHPs to allow this network to have the same services.

Section 438.202

In paragraph (b) we replaced the words "provide for" with "obtain" and the words "including making" to "and make." In paragraph (c) we replaced the word "compliance" with the words "The MCOs, PIHPs, and PAHPs comply."

Section 438.204

In paragraph (b)(1) we have removed the word "including" and clarified that procedures must assess the quality and appropriateness of care and services furnished to Medicaid enrollees under the MCO and PIHP contracts, and to all individuals with special health care needs. In paragraph (b)(3), we have clarified that the procedures must regularly monitor and evaluate the MCO and PIHP compliance with the standards. In paragraph (c) we have added, "For MCOs and PIHPs, any national" before "performance" and "that may be" before "identified." In paragraph (e) we have added the phrase "For MCOs," before "appropriate."

Section 438.206

In paragraph (a) we reversed the words "services" and "covered," and added the words "under the State plan" after "covered."

In paragraph (b)(1)(ii) we revised the second clause to read "taking into consideration the characteristics and health care needs of specific Medicaid populations represented in the particular MCO, PIHP, and PAHP."

In paragraph (c)(1)(i) we added the word "the" between the words "of" and "need."

In paragraph (c)(1)(iv) we added at the end, the words "by providers."

In paragraph (c)(1)(v), we added the word "providers" after the word "Monitor" and replaced "continuously" with "regularly" to clarify that each MCO, PIHP, and PAHP must monitor regularly to determine compliance.

Section 438.207

In paragraph (a), we added the words "and providers supporting documentation that demonstrates" after the word "State."

In paragraph (b), we changed the title from "Nature of assurances" to "Nature of supporting documentation" and removed the words "acceptable to CMS."

In paragraph (c), we removed the words "and specifically" and replaced them with "but no less frequently than."

In paragraph (d) we replaced the word "submission" to "certification" in the title.

Section 438.208

Section 438.208 is revised. We have made significant changes to the organization of this section.

Section 438.210

In paragraph (a), we have reorganized and revised language for clarity.

Section 438.214

In paragraph (b) we have added a requirement that each State must establish a uniform credentialing and recredentialing policy that each MCO, PIHP, and PAHP must follow.

Section 438.240

In paragraph (a)(2) we have removed "standardized quality measures" and replaced it with "performance measures." We have revised paragraph (b)(1) to require that performance improvement projects must be designed to achieve, through ongoing measurements and intervention, significant improvement, sustained over time, in clinical care and non-clinical care areas that are expected to have a favorable effect on health outcomes and enrollee satisfaction. We redesignated paragraph (b)(2) as (b)(3) and we redesignated paragraph (b)(3) as (b)(4). We added a new paragraph (b)(2) to specify that each MCO and PIHP must submit performance measurement data, as described in paragraph (c) of this section.

In paragraphs (c) and (d)(2) we have clarified that each MCO and PIHP must annually measure and report to the State its performance (including requirements under § 438.204(c) and § 438.240(a)(2)), submit to the State data to enable the State to calculate measures, or perform a combination of the above activities.

Section 438.242

In paragraph (a) we have added "and appeals" after "grievances" to clarify that a health information system must provide information on appeals.

Subpart E—[Reserved]

Subpart F—Grievance System

Section 438.400

We have removed "or any of its providers" from the definition of "action." We have clarified the definition of "action," to include unreasonable delays in services or appeals not acted upon within the necessary timeframes provided in § 438.408(b).

Section 438.402

In paragraph (b)(1)(ii) we clarified that a provider may file a grievance or request a State fair hearing on behalf of an enrollee, if the State permits the provider to act as the enrollee's authorized representative in doing so.

Section 438.404

In paragraph (c)(6) we have corrected the cross-reference to § 438.210(d)—timeframes for expedited service authorizations.

Section 438.406

We have revised paragraph (a)(1) to clarify that giving enrollees any reasonable assistance in completing forms and taking other procedural steps is not limited to providing interpreter services and toll-free numbers that have adequate TTY/TTD and interpreter capability.

In paragraph (a)(3)(ii) we have clarified that the individuals who make decisions on grievances and appeals are individuals who are health care professionals who have the appropriate clinical expertise, as determined by the State, in treating the enrollee's condition or disease.

Section 438.408

In paragraph (d)(2)(ii) we have added language clarifying that the MCO or PIHP must also make reasonable efforts to provide oral notice.

Section 438.410

In paragraph (c)(2) we have added language clarifying the MCO or PIHP must make reasonable efforts to give the enrollee prompt oral notice of the denial.

Section 438.420

In paragraph (b)(4) we have included the word, "original" to describe the type of authorization.

In paragraph (c), we have added language to clarify the duration of continued or reinstated benefits. If, at the enrollee's request, the MCO or PIHP continues or reinstates the enrollee's benefits while the appeal is pending, the

benefits must be continued until one of the following occurs:

- The enrollee withdraws the appeal.
- Ten days have passed after the

MCO or PIHP resolves the appeal against the enrollee, unless the enrollee, within the 10-day timeframe, has requested a State fair hearing with continuation of benefits until a State fair hearing decision is reached.

We have added a new paragraph (c)(4) to specify that benefits must be continued until the time period or service limits of a previously authorized service has been met.

Subpart G—[Reserved]

Subpart H—Certifications and Program Integrity

Section 438.600

We have added sections “1903(m)” and “1932(d)(1)” to the statutory basis to establish conditions for payments to the State with respect to contracts with MCOs and to incorporate the BBA provisions prohibiting affiliations with individuals debarred by Federal agencies.

Sections 438.604 and 438.606

We deleted the requirement for “substantial compliance” with the terms of the contract and for submitting certifications for “substantial compliance” respectively in order to prevent unnecessary lawsuits against MCOs and States. In addition, the statute and regulations already require States to monitor compliance with contracts executed under this rule.

Section 438.610

We added a new section to incorporate language from section 1932(d)(1) of the Act to the regulation to implement the BBA provisions prohibiting affiliations with individuals debarred by Federal agencies. This self-implementing provision has not been published previously, but was added in the final rule to include all of the relevant protections against fraud and abuse in one section.

We added application to PCCMs and to PAHPs to this section. (The BBA provided that section 1932(d)(1) of the Act be applied to MCEs; therefore we included application to PCCMs. We applied this section to PAHPs under the authority of section 1902(a)(4) of the Act.

Subpart I—Sanctions

Section 438.724

We have clarified that the notice that must be given to the CMS Regional

Office whenever a State imposes or lifts a sanction is only applicable to those sanctions under § 438.700.

Section 438.726

We have added a new paragraph (b) which states that a contract with an MCO must provide that payments provided for under the contract will be denied for new enrollees when, and for so long as payment for those enrollees is denied by CMS.

Section 438.730

We have reorganized this section so that it conforms to removed § 434.67.

Subpart J—Conditions for Federal Financial Participation

Section 438.802

We have removed the requirement for substantial compliance with physician incentive plans, the MCO’s contract, and the provisions of part 438 as a condition for FFP.

Section 438.806

We have made technical revisions to correct erroneous cross-references in paragraph (a)(1). We now correctly refer back to paragraphs (b)(2) through (b)(5) of § 438.6.

Section 438.814

We have revised and moved the provisions of this section to paragraphs (c)(5)(ii) and (c)(5)(iii) of § 438.6.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval.

In order to fairly evaluate whether OMB should approve an information collection, section 3506(c)(2)(A) of the PRA of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comments on each of these issues for the information collection requirements discussed below.

The following information collection requirements and associated burdens are subject to the PRA. For purposes of this requirement, we incorporated pertinent managed care data from the 2000 Medicaid enrollment report. As of June, 2000, there were 339 managed care organizations (MCOs) (this includes three HIOs that must adhere to the MCO requirements of this regulation), 37 primary care case management (PCCM) systems, 376 managed care entities (MCOs and PCCMs combined), 123 mental health and substance abuse prepaid health plans (PIHPs) and 34 dental, primary care and transportation prepaid health plans (PAHP), all of which have previously been regulated as PHPs. There were a total of 25,821,196 beneficiaries enrolled in these plans (some beneficiaries are enrolled in more than one plan) in forty-eight States and the District of Columbia (Wyoming and Alaska do not currently enroll beneficiaries in any type of managed care).

A. Section 438.6 Contract Requirements

Section 438.6(c) Payments Under Risk Contracts

1. Requirement. Section 438.6(c) modifies the rules governing payments to MCOs, PIHPs, and PAHPs by doing the following: (1) Eliminating the upper payment limit (UPL) requirement; (2) requiring actuarial certification of capitation rates; (3) specifying data elements that must be included in the methodology used to set capitation rates; (4) requiring States to consider the costs for individuals with chronic illness, disability, ongoing health care needs, or catastrophic claims in developing rates; (5) requiring States to provide explanations of risk sharing or incentive methodologies; and (6) imposing special rules, including a limitation on the amount that can be paid under FFP in some of these arrangements.

2. Burden. It is difficult to quantify the burden on States of providing information to support the actuarial soundness of the capitation rates for their risk-based, managed care contracts, because the rate setting methodologies and data sources vary widely from State to State. Under the UPL requirements, States were required to provide the capitation rates and any requested supporting documentation for all rate cells used which may vary from 5 to 10 cells on one end to 60 or more on another. In addition, States needed to generate data to meet the UPL requirement using historical fee-for-service (FFS) data trended forward to

the contract year. This would be a relatively simple process for a State initiating its managed care program, where it can rely on a very recent full year of FFS data for this purpose. However, almost all States have been operating risk-based managed care programs for at least 5 to 10 years and must make numerous adjustments to that data so that it can be used for this purpose. We estimate the average burden on States to comply with the current rate setting and UPL rules to be 16 hours per contract for documenting the capitation rates (setting out and explaining rate cells, risk sharing mechanisms, etc) and 40 hours per contract for generating a UPL for comparison purposes. This results in a total burden of 56 hours per contract for 496 risk contracts, resulting in a total burden of 27,776 hours.

Under the new requirements for actuarial soundness, States will need to provide an actuarial certification and additional documentation not previously required, including: specific data elements used to set capitation rates; methodologies to consider the costs for individuals with chronic illness, disability, ongoing health care needs, or catastrophic claims; explanations of risk sharing or incentive methodologies; and documentation supporting special contract provisions. We estimate the burden to comply with these requirements to average approximately 32 hours per contract for the 496 risk contracts, resulting in a total burden of 15,872 hours. This amount is limited to the time required for the State to compile documentation the State and its actuaries would already have developed in determining the capitation rates and submitting this documentation, as required, to CMS. Since, under this new rule, States will no longer need to generate a UPL in addition to the rate setting burden, this change results in a net reduction in burden of 11,904 hours.

Section 438.6(i)(3) Advance directives

1. Requirement. This paragraph requires that MCOs, PIHPs, and certain PAHPs provide adult enrollees with written information on advance directives policies and include a description of applicable State law.

2. Burden. The burden associated with this requirement is the time it takes to furnish the information to enrollees. We assume that this information would be furnished with the rest of the information required by § 438.10 and is therefore subsumed under those requirements.

There is also an implied recordkeeping requirement associated

with contracts; i.e., that would be documented. Maintaining documentation is a usual and customary business practice and does not add to the burden.

B. Section 438.8 Provisions That Apply to PIHPs and PAHPs

1. Requirement. This section specifies which of the contract requirements contained in § 438.6 apply to PIHPs and which apply to PAHPs. Requirements for advance directives apply only to PIHPs and certain limited numbers of PAHPs.

2. Burden. PHPs (now designated as PIHPs and PAHPs) have not previously been required to maintain written policies and procedures with respect to advance directives. This rule requires the PIHP and some PAHPs to provide written information to enrollees of their rights under this provision and the PIHPs policies with respect to the implementation of those rights. We project 8 hours of time for each of 123 PIHPs and 2 PAHPs to establish this policy and 2 minutes per enrollee for provision of this information, and acceptance of this right to each of approximately 6.3 million individuals enrolled in PIHPs and the specified PAHPs. The total time for this is approximately 212,000 hours.

1. Requirement. Under the physician incentive plan provision, PIHPs and PAHPs, like MCOs, will be required to provide descriptive information to States and CMS to determine whether or not there is substantial financial risk in their subcontracts. In addition, enrollees must be surveyed and provided information on the risk arrangements when substantial risk exists.

2. Burden. We are basing our projections of burden upon information published in the **Federal Register** on March 27, 1996 and December 31, 1996 (61 FR 13445 and 61 FR 69049) which contained the original regulatory provisions on physician incentive plans for Medicare and Medicaid HMOs.

Based on those assumptions, we believe no more than 1/3 of the approximately 157 PIHPs and PAHPs use incentive or risk payment arrangements with their subcontracting providers. Affected PIHPs and PAHPs would be required to provide detailed responses to State surveys regarding their payment mechanisms and amounts. At the projected 100 hours per response for approximately 53 PIHPs and PAHPs the total burden would be 5,300 hours. For those PIHPs and PAHPs with substantial financial risk, there are other requirements such as stop/loss insurance and beneficiary surveys. We believe there would be minimal

additional burden as a result of these requirements (because many already comply with these requirements) and that this would apply to no more than 1/4 of those PIHPs and PAHPs with risk or incentive payments, or a total of 13. We estimate an additional 10 hours per plan for a total of 130 hours. Altogether, we estimate 5,430 hours of burden through imposition of this requirement on PIHPs and PAHPs.

C. Section 438.10 Information Requirements

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

1. Requirement. In summary, § 438.10 requires that each State, its contracted representative, or at the option of the State, each MCO, PIHP, PAHP, and PCCM furnish information to enrollees and potential enrollees to meet the requirements of this section. Paragraph (c)(4) requires that the State and each MCO, PIHP, PAHP, and PCCM, make oral interpretation available in languages other than English. Paragraph (c)(5) requires that beneficiaries be informed how to access those services. Paragraph (d)(2) requires that all enrollees and potential enrollees must be informed that information is available in alternative formats and how to access those formats. The basic information listed in paragraph (e)(2) must be provided to each potential enrollee by the State or its contracted representative.

The State, its contracted representative or the MCO, PIHP, PAHP, or PCCM must provide the information in paragraph (f)(6), and for MCOs and PIHPs, in paragraph (g) at least once a year. The information that must be provided includes the following:

(a) Information for potential enrollees:

(1) General information must be provided about the basic features of managed care, which populations are excluded from enrollment, subject to mandatory enrollment, or free to enroll voluntarily in an MCO or PIHP, and MCO and PIHP responsibilities for coordination of enrollee care.

(2) Information specific to each MCO, PIHP, PAHP, and PCCM serving an area that encompasses the potential enrollee's service area must be provided in summary form, or in more detail, upon request of the enrollee. This includes information on benefits covered; cost sharing if any; service area; names, locations, and telephone numbers of current network providers, including at a minimum, information on primary care physicians, specialists, and hospitals, and identification of providers that are not accepting new

patients; and benefits that are available under the State plan but are not covered under the contract, including how and where the enrollee may obtain those benefits, any cost sharing, and how transportation is provided.

(b) Information for enrollees:

(1) The State must notify enrollees of their disenrollment rights annually. The State, or the MCO, PIHP, PAHP, and PCCM, if delegated this responsibility by the State, must provide certain information to new enrollees and notify enrollees annually of their right to request additional information. The State must give each enrollee written notice of any change (that the State defines as "significant") in the information specified at least 30 days before the intended effective date of the change and make a good faith effort to give written notice of termination of a contracted provider, within 15 days after receipt or issuance of the termination notice, to each enrollee who received his or her primary care from, or was seen on a regular basis by, the terminated provider.

(c) General information for all enrollees of MCOs, PIHPs, PAHPs, and PCCMs:

(1) Names, locations, and telephone numbers of, and non-English languages spoken by, current network providers, including information at least on primary care physicians, specialists, and hospitals, and identification of providers that are not accepting new patients.

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

(3) Enrollee rights and responsibilities as specified in § 438.100.

(4) Information on grievance and fair hearing procedures, and for MCO and PIHP enrollees, the information specified in § 438.10(g)(i).

(5) The amount, duration, and scope of benefits available under the contract in sufficient detail to ensure that enrollees understand the benefits to which they are entitled.

(6) Procedures for obtaining benefits, including authorization requirements.

(7) The extent to which, and how, enrollees may obtain benefits, including family planning services from out-of-town network providers.

(8) The extent to which, and how, after-hours and emergency coverage are provided.

(9) What constitutes emergency medical condition, emergency services, and post-stabilization services, with reference to the definitions in § 438.114, and the fact that prior authorization is not required for emergency services.

(10) The post-stabilization care services rules set forth at § 438.113(c) of this chapter.

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

(12) Cost sharing, if any.

(13) How and where to access 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.

(14) For a counseling or referral service the MCO, PIHP, PAHP, or PCCM does not cover because of moral or religious objections, the MCO, PIHP, or PCCM need not furnish information on how and where to obtain the service. The State must furnish information about how and where to obtain the service.

(d) Specific information requirements for enrollees of MCOs and PIHPs:

(1) In addition to the requirements in § 438.10(e), MCOs and PIHPs must provide to their enrollees the following information specified in § 438.10(g):

(i) Grievance, appeal, and fair hearing procedures and timeframes, as provided in § 438.400 through 438.424, in a State-developed or State-approved description, which includes:

(ii) The right to a State fair hearing and the method for obtaining a hearing,

(iii) The rules governing representation at the hearing,

(iv) The right to file grievances and appeals

(v) The filing requirements, timeframes, and availability of assistance with the filing process,

(vi) The toll-free numbers enrollees can use to file a grievance or appeal by phone,

(vii) The fact that when requested by the enrollee, benefits will continue if the enrollee files an appeal or a request for a State fair hearing within the specified timeframes,

(viii) The possibility that the enrollee may be required to pay the cost of services furnished during the appeal process, if the final decision is adverse,

(ix) Any appeal rights that the State chooses to make available to providers to challenge the failure of the organization to cover a service,

(x) Information on advance directives, as set forth in § 438.6(i)(2) and physician incentive plans, as set forth in § 438.6(h) and

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

2. Burden. We believe the burden placed on States, MCOs, PIHPs, PAHPs,

and PCCMs, and enrollment brokers as a result of these requirements is the time associated with modifying the content of existing information materials, as well as the time associated with distributing the materials to enrollees as specified by the regulation. We estimate that it will initially take 12 hours for each MCO, PIHP, PAHP, or PCCM system to modify existing information materials to conform to the requirements above. We further estimate that there are approximately 533 MCOs, PIHPs, PAHPs, and PCCM systems equating to an initial modification burden of approximately 6,396 hours. After the initial modification, we estimate that it will take MCOs, PIHPs, and PAHPs approximately 4 hours each to annually update the information materials, equating to an annual total burden of approximately 2,132 hours.

We estimate that that it will take MCOs, PIHPs, PAHPs, and PCCM systems approximately 5 minutes per enrollee to mail a packet of materials to potential enrollees and enrollees. We estimate that each year approximately 15 percent of the Medicaid managed care enrollee population are new enrollees. This equates to approximately 3.9 million potential enrollees a year for a total burden on the States of 65,000 hours. Mailing the annual packet of information to the 25,731,040 enrollees, at 5 minutes a packet, will result in a burden to the State, or the MCOs, PIHPs, PAHPs, and PCCMs, if delegated this responsibility by the State, of 2,144,253 hours.

We similarly estimate that it annually will take MCOs, PIHPs, PAHPs, and PCCMs 5 minutes per enrollee to supply information requested by potential enrollees and enrollees. We estimate that 10 percent of potential enrollees and enrollees will request information each year. For the 390,000 potential enrollees requesting information, this results in a burden on States of 6,500 hours. For the 2,573,104 enrollees requesting information, this results in a burden on States, or MCOs, PIHPs, PAHPs, and PCCMs if delegated this responsibility by the State, of 214,425 hours.

Section 438.10(i) Special Rules: States With Mandatory Enrollment Under State Plan Authority

1. Requirement. Under (h), if the State plan provides for mandatory MCO or PCCM enrollment under section 1932(a)(1)(A) of the Act, the State or its contracted representative must provide information in a comparative, chart-like format, to potential enrollees. The information must include the MCO's or PCCM's service area, the benefits covered under the contract, any cost

sharing imposed by the MCOs or PCCMs and, to the extent available, quality and performance indicators, including but not limited to disenrollment rates and enrollee satisfaction.

2. Burden. For the requirement to provide information in a chart-like format, we believe that the additional burden on States (i.e., not yet captured in the above provisions) is the length of time associated with creating the comparative chart. We estimate that it will take States approximately 8 hours each to create the comparative chart. Currently, 10 States per year have approved managed care under the State Plan Option, for a total annual burden of approximately 80 hours.

D. Section 438.12 Provider Discrimination Prohibited

1. Requirement. This section requires that if an MCO, PIHP, or PAHP declines to include individual or groups of providers in its network, it must give the affected providers written notice of the reason for its decision.

2. Burden. The burden associated with this requirement is the time it takes the MCO, PIHP, or PAHP to draft and furnish the providers with the requisite notice. We estimate that it will take 1 hour to draft and furnish any given notice. We estimate that on average each MCO, PIHP, and PAHP will need to produce 10 notices per year for a total of 4,960 hours.

E. Section 438.50(b) State Plan Information

1. Requirements. Each State must have a process for the design and initial implementation of the State plan that involves the public and must have methods in place to ensure ongoing public involvement once the State plan has been implemented.

2. Burden. The burden associated with this section includes the time associated with developing the process for public involvement, including annual updates. We estimate that it will take 10 current States 40 hours per State to develop the process for involving the public for a total burden of 400 hours. We estimate that ensuring ongoing public involvement will take another 20 hours per State annually for a total annual burden of 200 hours.

The recordkeeping burden involved in maintaining documentation that the requirements are met is a usual and customary business practice and imposes no additional burden.

F. Section 438.56 Disenrollment: Requirements and Limitations

Section 438.56(d)(1)

1. Requirement. In order to disenroll, the beneficiary (or his or her representative) must submit an oral or written request to the State agency (or its agent) or to the MCO, PIHP, PAHP, or PCCM where permitted.

2. Burden. We believe that the burden associated with this requirement is the length of time it would take enrollees to submit in writing a disenrollment request, if they choose to use the written format. We estimate that it will take approximately 10 minutes per enrollee to generate a written disenrollment request. We estimate that approximately 5 percent of MCO, PIHP, PAHP, and PCCM enrollees will request that they be disenrolled from an MCO, PIHP, PAHP, or PCCM. Approximately one-fourth of the enrollees will choose a written rather than an oral request. This equates to an annual burden of approximately 10 minutes multiplied by 321,638 affected enrollees (one-fourth of the 1,286,552 enrollees requesting disenrollment), or approximately 53,606 hours. We estimate a burden of 3 minutes per oral request for disenrollment (for 3/4ths of the 1,286,552 enrollees, or 964,914 enrollees) for a total burden of 48,246 hours.

Section 438.56(f)

1. Requirement. Under paragraph (f), a State that restricts disenrollment under this section must provide that enrollees and their representatives are given written notice of disenrollment rights at least 60 days before the start of each enrollment period.

2. Burden. The burden for this section is addressed in § 438.10(f).

G. Section 438.102 Enrollee-Provider Communications

1. Requirement. Section 438.102(a)(2) states that the general rule in paragraph (a)(1) of this section does not require the MCOs, PIHPs, and PAHPs to cover, furnish, or pay for a particular counseling or referral service if the MCO, PIHP, or PAHP objects to the provision of that service on moral or religious grounds; and makes written information on these policies available to (1) prospective enrollees, before and during enrollment and, (2) current enrollees, within 90 days after adopting the policy with respect to an any particular service.

2. Burden. We believe the burden associated with this requirement will affect no more than 3 MCOs or PIHPs annually since it applies only to the

services they discontinue providing on moral or religious grounds during the contract period. We estimate that it takes 4 hours to devise a notice and 5 minutes to mail, affecting 52,000 enrollees, for a total burden of 4,345 hours. $[12 \text{ hours} + (52,000 \times \frac{1}{2})]$ The burden for notification of prospective enrollees of the services not covered by the MCO, PIHP, or PAHP on these grounds is included in the overall burden arising from the Information Requirements in § 438.10.

H. Section 438.202 State Responsibilities

1. Requirement. Each State contracting with an MCO or PIHP must have a written strategy for assessing and improving the quality of managed care services offered by the MCO or PIHP, make it available for public comment before adopting it in final, and conduct periodic reviews to evaluate the effectiveness of the strategy. We expect States will conduct these periodic reviews every 3 years. Each State must also submit to CMS a copy of the initial strategy and a copy of the revised strategy whenever significant changes are made. In addition, States are required to submit to CMS regular reports on the implementation and effectiveness of the strategy, consistent with the State's own periodic review of its strategy's effectiveness.

2. Burden. The burden associated with this section is limited to those States offering managed care through MCOs or PIHPs (41) and includes the time associated with developing the proposed strategy, publicizing the proposed strategy, incorporating public comments, submitting an initial copy of the strategy to CMS prior to its implementation and whenever significant changes are made, and submitting regular reports on the implementation and effectiveness of the strategy. We estimate that it will take 40 hours per State to develop the proposed strategy for a total burden of 1,640 hours. We estimate that publicizing the proposed strategy will take 2 hours per State for a total burden of 82 hours. We estimate that incorporating public comments for the final strategy will take another 40 hours per State for a total burden of 1,640 hours. We estimate it will take 1 hour per State to submit an initial copy of the strategy to CMS prior to implementation and whenever significant changes are made for a total of 41 hours. We estimate it will take 40 hours per State to create and submit a report on the implementation and effectiveness of the strategy and that these reports will be submitted at

approximately every 3 years for a total annual burden of 546 hours.

I. Section 438.204 Elements of State Quality Strategies:

1. Requirement. In the final rule we require at § 438.204(b)(2) that a State identify the race, ethnicity, and primary language spoken by each MCO and PIHP enrollee and report this information to each MCO and PIHP in which each beneficiary enrolls at the time of their enrollment.

2. Burden. We believe that most States currently track race and ethnicity data in their eligibility systems. If States do not, minor changes in their software will be needed. With respect to primary language of enrollees, there will likely be additional programming needed for all States. We estimate that this would require 4 hours of programming for each of the 41 jurisdictions for a total of 164 hours.

J. Section 438.207 Assurances of Adequate Capacity and Services

1. Requirement. Section 438.207(b) requires that each MCO, PIHP, and PAHP (where applicable) submit documentation to the State, in a format specified by the State, to demonstrate that it has the capacity to demonstrate that it complies with specified requirements and that it has the capacity to serve the expected enrollment in its service area in accordance with the State's standards for access to care and meets specified requirements.

Section 438.207(c) requires that this documentation be submitted to the State at the time the MCO, PIHP, or PAHP enters into a contract with the State and at any time there has been a significant change (as defined both by the State and this regulation) in the MCO's, PIHP's, or PAHP's operations that would affect adequate capacity and services.

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

2. Burden. We believe that MCOs, PIHPs, and PAHPs already collect and provide this information to State agencies as part of their customary and usual business practices and that the only additional burden on MCOs, PIHPs, and PAHPs is the length of time required for these entities to compile this information in the format specified by the State agency, and the length of time to mail the information to the State and to CMS. We estimate that it will take each MCO, PIHP, and PAHP

approximately 20 hours to compile the information necessary to meet this requirement, for a total of 20 hours multiplied by 486 MCOs, PIHPs, and PAHPs with networks, or approximately 9,720 hours. In addition, we estimate that it will take MCOs, PIHPs, and PAHPs approximately 5 minutes each to mail the materials associated with this burden to the State for an annual burden of approximately 5 minutes multiplied by 486 of these entities, or approximately 4 hours.

We estimate that obtaining information on: (1) The numbers and types of persons with special health care needs that could be anticipated to enroll in the MCO or PIHP; (2) the types of experienced providers they would require; (3) the experience of the existing providers in the MCO's or PIHPs network; and (4) the numbers and types of additional experienced providers needed, would require an estimated 40 hours of work for each of the 462 MCOs, PIHP, and PAHP for a total estimated burden of 18,480 hours.

K. Section 438.208 Coordination and Continuity of Care

1. Requirement. Under paragraph (b)(3) of this section requires MCOs, PIHPs, and PAHPs to share with other MCOs, PIHPs, and PAHPs serving the enrollee the results of its identification and assessment of any enrollee with special health care needs so that those activities need not be duplicated.

2. Burden. The burden associated with this information collection requirement is the time it will take to disclose information on enrollees. We estimated that it will be necessary to disclose information on 619,709 enrollees and take it will take 45 minutes for each one, for an annual total of 464,782 hours.

L. Section 438.210 Coverage and Authorization of Services

1. Requirement. Under paragraph (b) of this section, for the processing of requests for initial and continuing authorizations of services, each contract must require that the MCO, PIHP, or PAHP and its subcontractors have in place written policies and procedures.

2. Burden. The burden associated with this requirement is the time required to develop the policies and procedures. We do not believe that this requirement will increase an entity's burden as it part of usual and customary business practices.

1. Requirement. Under paragraph (c) of this section, each contract must provide for the MCO, PIHP, or PAHP to notify the requesting provider, and give the enrollee written notice of any

decision by the MCO, PIHP, or PAHP to deny a service authorization request, or to authorize a service in an amount, duration, or scope that is less than requested.

2. Burden. The burden associated with this requirement will be the time required to notify the requesting provider and the enrollee. We believe that there will be approximately 100 notifications under this provision and that it will take 60 minutes to complete the notification (including writing it) per MCO or PIHP. There are approximately 339 MCOs and 123 PIHPs for a total of 462 for a total of 46,200.

M. Section 438.214 Provider Selection

1. Requirement. Under this section, each State must ensure, through its contracts, that each MCO, PIHP, or PAHP implements written policies and procedures for selection and retention of providers.

2. Burden. The burden associated with this requirement is the usual and customary recordkeeping collection associated with maintaining documentation.

N. Section 438.230 Subcontractual Relationships and Delegation

1. Requirement. Under paragraph (b), there must be a written agreement that specifies the activities and report responsibilities delegated to the subcontractor and provides for revoking delegation or imposing other sanctions if the subcontractor's performance is inadequate.

2. Burden. The burden associated with this requirement is the time required to write the agreement and the time required to maintain documentation of the agreement. We believe that these activities and usual and customary business practices and do not affect the entities' burden.

O. Section 438.236 Practice Guidelines

1. Requirement. Under paragraph (c) of this section, each MCO, PIHP, and PHAP must disseminate guidelines to its affected providers and, upon request, to enrollees and potential enrollees.

2. Burden. The burden associated with this requirement is the time required to disseminate the guidelines. We believe that these will be rare requests and will occur infrequently.

P. Section 438.240 Quality Assessment and Performance Improvement Program; Performance Improvement Projects

1. Requirement. Section 438.240(c) states that each MCO and PIHP must annually measure its performance using

standard measures required by the State and report its performance to the State. In addition to using and reporting on measures of its performance, § 438.240(d)(1) requires States to ensure that each MCO and PIHP have an ongoing program of performance improvement projects. In § 438.240(d)(2) each MCO and PIHP is required to report the status and results of each such project to the State as requested.

2. Burden. This regulation requires States to require each MCO and PIHP to have an ongoing program of performance improvement. Based on discussions with the 17 States with the largest Medicaid managed care enrollments, all 17 States are already doing so. Because the use of performance measures in managed care has become commonplace in commercial, Medicare, and Medicaid managed care, we do not believe that this regulatory provision imposes any new burden on MCOs, PIHPs, or States.

With respect to the requirements for ongoing performance improvement projects in § 438.240(d), we expect that, in any given year, each MCO and PIHP will complete two projects, and will have four others underway. We further expect that States will request the status and results of each MCO's and PIHP's projects annually. Accordingly, we estimate that it will take each MCO and PIHP 5 hours to prepare its report for each project, for an annual total burden of 30 hours per MCO and PIHP. In aggregate, this burden equates to 30 hours multiplied by an estimated 462 MCOs and PIHPs, or approximately 13,860 hours.

Q. Section 438.242 Health Information Systems

1. Requirement. Section 438.242(b)(1) requires the State to require each MCO and PIHP to collect data on enrollee and provider characteristics as specified by the State, and on services furnished to enrollees, through an encounter data system or other such methods as may be specified by the State. Paragraph (3) requires that the data be made available to the State and, upon request, to CMS.

2. Burden. The above information collection requirement is subject to the PRA. However, we believe that the burden associated with these information collection requirements is exempt from the Act in accordance with 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons in the normal course of their activities.

R. Section 438.402 General Requirements

1. Requirement. In summary, § 438.402 requires each MCO and PIHP to have a grievance system, sets out general requirements for the system, and establishes filing requirements. It provides that grievances and appeals may be filed either orally or in writing, but that oral appeals (except those with respect to expedited service authorization decisions) must be followed by a written request.

2. Burden. We estimate that it will take approximately 5.5 hours for each MCO and PIHP to conform their existing general grievance system requirements to those in the regulation. It will take approximately 2.5 hours to create or change the filing requirements, including developing or revising templates for a notice of action and a notice of disposition or resolution. The total burden for 462 MCOs and PIHPs is 3,696 hours.

We estimate that approximately 1 percent of 23.7 million MCO and PIHP enrollees (237,000) annually will file a grievance with their MCO or PIHP and that approximately .5 percent (118,000) annually will file an appeal. For these cases, we estimate that the burden on the enrollee filing a grievance or appeal is approximately 20 minutes per case. The total annual burden on enrollees is 118,500 hours.

S. Section 438.404 Notice of Action

1. Requirement. In summary, § 438.404 states that if an MCO or PIHP intends to deny, limit, reduce, or terminate a service; deny payment; deny the request of an enrollee in a rural area with one MCO or PIHP to go out of network to obtain a service; or fails to furnish, arrange, provide, or pay for a service in a timely manner, the MCO or PIHP must give the enrollee timely written notice and sets forth the requirements of that notice.

2. Burden. We estimate that the burden associated with this requirement is the length of time it would take an MCO or PIHP to provide written notice of an intended action. We estimate that it will take MCOs and PIHP 30 seconds per action to make this notification. We estimate that approximately 5 percent (1,185,000) of the approximately 23.7 million MCO and PIHP enrollees will receive one notice of intended action per year from their MCO or PIHP for a total burden of approximately 9,875 hours.

T. Section 438.406 Handling of Grievances and Appeals

1. Requirement. In summary, § 438.406 states that each MCO and

PIHP must acknowledge receipt of each grievance and appeal.

2. Burden. The above information collection requirement is not subject to the PRA. It is exempt under 5 CFR 1320.4(a) because it occurs as part of an administrative action.

U. Section 438.408 Resolution and Notification: Grievances and Appeals

1. Requirement. In summary, § 438.408 states that for grievances filed in writing or related to quality of care, the MCO or PIHP must notify the enrollee in writing of its decision within specified timeframes. The notice must also specify that the enrollee has the right to seek further review by the State and how to seek it. All decisions on appeals must be sent to the enrollee in writing within specified timeframes and for notice of expedited resolution, the MCO or PIHP must also provide oral notice. The decision notice must include the MCO or PIHP contact for the appeal and the results of the process and the date it was completed. For an oral grievance that does not relate to quality of care, the MCO or PIHP may provide oral notice unless the enrollee request that it be written.

2. Burden. The above information collection requirements are not subject to the PRA. They are exempt under 5 CFR 1320.4(a) because they occur as part of an administrative action.

V. Section 438.410 Expedited Resolution of Appeals

1. Requirement. Paragraph (c), Action following denial of a request for expedited resolution, requires each MCO and PIHP to provide written notice to an enrollee whose request for expedited resolution is denied.

2. Burden. The above information collection requirement is not subject to the PRA. It is exempt under 5 CFR 1320.4(a) because it occurs as part of an administrative action.

W. Section 438.414 Information About the Grievance System to Providers and Subcontractors

1. Requirement. Under this section, the MCO or PIHP must provide the information specified at § 438.10(g)(i) about the grievance system to all providers and subcontractors at the time they enter into a contract.

2. Burden. The burden associated with this requirement is the time required to include the necessary language in the contract. We believe that this is usual and customary business practice and does not add any burden.

X. Section 438.416 Record Keeping and Reporting Requirements

1. Requirement. This section requires the State to require MCOs and PIHPs to maintain records of grievances and appeals.

2. Burden. We estimate that approximately 95,000 (.5 percent) of the approximately 19 million MCO and PIHP enrollees will file a grievance or appeal with their MCO or PIHP (205 per MCO or PIHP). The recording and tracking burden associated with each grievance is estimated to be 1 minute per request (3.4 hours per MCO or PIHP), for a total burden of 1,583 hours (1 minute multiplied by an estimated 95,000 enrollees who would file a grievance or appeal).

Y. Section 438.604 Data That Must Be Certified

1. Requirement. The data that must be certified include, but are not limited to, enrollment information, encounter data, and other information required by the State and contained in contracts, proposals, and related documents.

2. Burden. While the requirement for MCOs and PIHPs is to certify all documents required by the State, the burden associated with these requirements is captured during the submission of such information. Therefore, we are assigning 1 token hour of burden for this requirement

Z. Section 438.608 Program Integrity Requirements.

1. Requirement. Under this section, the MCO or PIHP must have administrative and management arrangements or procedures that are designed to guard against fraud and abuse. The arrangements or procedures must include written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable Federal and State standards and the designation of a compliance officer and a compliance committee that are accountable to senior management.

2. Burden. The burden associated with this requirement is the time required to file a copy of the written procedures. We believe that this is a normal business practice and does not add any burden.

AA. Section 438.710 Due Process: Notice of Sanction and Pre-Termination Hearing

Section 438.710(a) Due Process: Notice of Sanction and Pre-Termination Hearing

1. Requirement. Section 438.710(a) states that before imposing any of the

sanctions specified in this subpart, the State must give the affected MCO or PCCM written notice that explains the basis and nature of the sanction.

2. Burden. The above information collection requirement is not subject to the PRA. It is exempt under 5 CFR 1320.4(a) because it occurs as part of an administrative action.

Section 438.710(b)(2) Due Process: Notice of Sanction and Pre-Termination Hearing

1. Requirement. Section 438.710(b)(2) states that before terminating an MCO's or PCCM's contract, the State must:

(i) Give the MCO or PCCM written notice of its intent to terminate, the reason for termination, the time and place of the hearing;

(ii) After the hearing, give the entity written notice of the decision affirming or reversing the proposed termination of the contract and, for an affirming decision, the effective date of termination; and

(iii) For an affirming decision, give enrollees of the MCO or PCCM notice of the termination and information, consistent with § 438.10, on their options for receiving Medicaid services following the effective date of termination.

2. Burden. The above information collection requirement is not subject to the PRA. It is exempt under 5 CFR 1320.4(a) because it occurs as part of an administrative action.

BB. Section 438.722 Disenrollment During Termination Hearing Process

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

2. Burden. States already have the authority to terminate MCO or PCCM contracts according to State law and have been providing written notice to the MCOs or PCCMs. States are now given, at their discretion, the option of notifying the MCO's or PCCM's enrollees of the State's intent to terminate the MCO's or PCCM's contract. While it is not possible to gather an exact figure, we estimate that 12 States may terminate 1 contract per year. We estimate that it will take States 1 hour to prepare the notice to enrollees, for a total burden of 12 hours. In addition, we estimate that it will take States approximately 5 minutes per beneficiary to notify them of the termination, equating to a burden of 5 minutes multiplied by 12 States

multiplied by 46,194 beneficiaries per MCO or PCCM, for a burden of approximately 46,194 hours. The total burden of preparing the notice and notifying enrollees is 46,206.

CC. Section 438.724 Notice to CMS

1. Requirement. Section 438.724 requires that the State give the CMS Regional Office written notice whenever it imposes or lifts a sanction. The notice must specify the affected MCO, the kind of sanction, and the reason for the State's decision to impose or lift a sanction.

2. Burden. We anticipate that no more than 36 States would impose or lift a sanction each year and that it would take each one 30 minutes to give the regional office notice. Thus the annual burden would be 18 hours.

DD. Section 438.730 Sanction by CMS: Special Rules for MCOs With Risk Contracts

1. Requirement. Section 438.730(b), Notice of Sanction, requires that if CMS accepts a State agency's recommendation for a sanction, the State agency gives the MCO written notice of the proposed sanction.

Paragraph (c) of this section, Informal reconsideration, requires that if the MCO submits a timely response to the notice of sanction, the State agency gives the MCO a concise written decision setting forth the factual and legal basis for the decision. In addition, if CMS reverses the State's decision, the State sends a copy to the MCO.

2. Burden. These requirements are exempt under 5 CFR 1320.4(a) because they occur as part of administrative actions.

EE. Section 438.810 Expenditures for Enrollment Broker Services

1. Requirement. Section 438.810(c) requires that a State contracting with an enrollment broker must submit the contract or memorandum of agreement (MOA) for services performed by the broker to CMS for review and approval.

2. Burden. The burden associated with this requirement is the length of time for a State to mail each contract to CMS for review. We estimated that the burden associated with this requirement is 5 minutes per enrollment broker contract, for a total annual burden of approximately 3 hours per year (5 minutes multiplied by an estimated 35 enrollment broker contracts in the States using brokers).

We have submitted a copy of this final rule to OMB for its review of the information collection requirements described above in §§ 438.6, 438.8, 438.10, 438.12, 438.50, 438.56, 438.102,

438.202, 438.204, 438.207, 438.208, 438.210, 438.214, 438.230, 438.236, 438.240, 438.242, 438.402, 438.404, 438.406, 438.408, 438.410, 438.414, 438.416, 438.608, 438.710, 438.722, 438.724, 438.730, and 438.804. These requirements are not effective until they have been approved by OMB.

If you comment on these information collection requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Information Services, DCES, SSG, Attn: Julie Brown, CMS-2104-F, Room N2-14-26, 7500 Security Boulevard, Baltimore, MD 21244-1850;

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

V. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub.L. 104-4), and Executive Order 13132. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year.) We project the cost of this rule to be between \$221 and \$295 million annually. The burden of these costs will be shared between States, MCOs, PIHPs, PAHPs, PCCMs, and the Federal government. It should be noted that a large portion of these costs will be born by the Federal government through its matching payments to States for Medicaid expenditures.

This rule will implement new requirements for Medicaid managed care programs which have not been previously implemented through either the previous Part 434 of the CFR or the State Medicaid Director Letters listed in section I.A. of the Preamble, or self-implemented through the BBA. The new provisions implemented under this rule

are requirements governing: (1) Payments under risk contracts; (2) PIHPs and PAHPs; (3) information that must be provided to beneficiaries; quality assessment and performance improvement for managed care programs; and (4) grievances and appeals.

The RFA requires agencies to analyze options for regulatory relief of small entities. We have provided an analysis of alternatives to these rules in section V.C. of the Preamble.

This final rule primarily impacts beneficiaries, State agencies, enrollment brokers, MCOs, PIHPs, PAHPs, and PCCMs. Small entities include small businesses in the health care sector that are HMO medical centers or health practitioners as prepaid health plans with receipts of less than \$8.5 million, nonprofit organizations, and other entities. (See 65 FR 69432). For purposes of the RFA, individuals and State governments are not included in this definition. In the proposed rule we invited comments on alternatives to provisions of the proposed rule that would reduce burden on small entities. We did not receive any comments in response to this invitation.

As of June 2000, there were 339 MCOs, 123 PIHPs, 34 PAHPs, and 37 PCCM systems. We believe that only a few of these entities qualify as small entities. Specifically, we believe that 16 MCOs, 14 PIHPs, 11 PAHPs, and most managed care entities in the 37 PCCM systems are likely to be small entities. We estimate that there are 4.8 million beneficiaries enrolled in these small entities. We believe that the remaining MCOs, PIHPs, and PAHPs have annual receipts from Medicaid contracts and other business interests in excess of \$8.5 million.

The primary impact on small entities will be through the requirements placed on PIHPs and PAHPs by § 438.8. Under this rule, PIHPs will be subject to nearly all of the requirements for MCOs, including the requirements for quality assessment and improvement and grievances and appeals. PAHPs are not subject to the grievance and appeals requirements, but will be subject to quality requirements like network adequacy and coverage and authorization of services where it is determined to be applicable. The impact on these entities from these provisions is discussed later in this section.

However, we are identifying additional burden on the 14 PIHPs and 11 PAHPs, which we project to be small entities of 2,000 hours from the requirement for advance directives and 900 hours on information on solvency requirements, for a total burden of 2,900 hours. Using

the mean hourly wage the average wage for the health care service sector of \$16.34 (Bureau of Labor Statistics, March 2001), this will result in a total cost to these small entities of \$47,386.

The most significant burden relates to providing information to enrollees. Specifically, MCOs, PIHPs, PAHPs, and PCCMs are required to make written materials available in languages that are prevalent in its service area (as determined by the State) and provide oral interpretation services when needed. The final rule requires MCOs, PIHPs, PAHPs, and PCCMs to make oral interpretation services available to each potential enrollee or enrollee requesting them. This requirement is actually derived from the provisions of Title VI of the Civil Rights Act of 1964 and Executive Order 13166, and not created by this rule. We estimate that less than 1% of the enrollees of these entities (or 48,000 individuals) will require this service an average of 2 times per year. Using the baseline commercial language line charges of \$2.20 per minute with a one hour minimum, we estimate the cost of providing oral interpretation services to be \$12.7 million annually. We believe that this estimate may overstate the impact of this requirement, because: (1) Many providers are bilingual or have staff that are bilingual (particularly in areas with relatively a large percentage of non-English speaking individuals); (2) there are less costly alternatives than the example we have used to provide oral interpretation; (3) many enrollees in need of oral interpretation will prefer to use a friend or relative; and (4) these specific costs should be mitigated by the costs of complying with current civil rights requirements to provide translation services.

We do not believe that there is significant burden as a result of the remainder of this section. PCCMs or PAHPs do not normally provide much written material directly to enrollees since, in the final rule, we place the responsibility on States, rather than PCCMs and PAHPs. We believe that States will usually prepare this information so that the only burden on PCCMs and PAHPs will be to distribute the information when it is requested by an enrollee. For the small entities who must perform this function themselves, including those MCOs and PIHPs identified as such we have projected a burden of 36,000 hours for compliance with the requirements in the information section. This results in an additional burden of \$588,240.

The final rule also imposes requirements for quality assessment and improvement in subpart D on all MCOs

and PIHPs and those PAHPs designated by the State. Based on the estimates in the Collection of Information section of this preamble, we project a burden of 3,800 hours or \$62,092.

In addition, Subpart F of this rule requires the 16 MCOs and 14 PIHPs that are small entities to develop and implement a grievance system as described in that section. While most of these entities would have had a system in place already, they will, at a minimum, need to modify the current system to comply with the requirements of this section. We project the burden for these modifications and operation of the grievance systems by these entities to be a total of 8 hours per entity for the development and modification of the current system and an average of 4 hours each for the resolution of the expected 1440 grievances and appeals filed by the enrollees of these entities (based on the estimates contained in section IV of this preamble on Information Collection Requirements). This results in a total burden of 6,000 hours at the mean hourly wage of \$16.34, for a total cost of \$98,040.

We do not believe that the remaining impact of the provisions of this final rule are great on the small entities that we have identified. These small entities must meet certain contract requirements, however, these are consistent with the nature of their business in contracting with the State for the provision of services to Medicaid enrollees. They, likewise, must meet requirements related to disenrollment of enrollees for cause, including receipt and initial processing of disenrollment requests if the State delegates this function to the entity. However, all enrollees have an annual opportunity to disenroll, and historically the number of disenrollment requests for cause are small. In addition, these entities must submit marketing material to the State for review and approval, and those MCOs, PIHPs, and PAHPs which are at risk for emergency services must cover and pay for emergency services based on the prudent layperson standard. However, the provisions governing marketing materials and emergency services have already been implemented through State Medicaid Director Letters.

We have clarified that PAHP enrollees have the right to a State fair hearing under subpart E of part 431, although this is not a new requirement. Additionally, PAHPs may not discriminate against providers seeking to participate in the plan. This requirement imposes no burden as it would reflect their usual and customary business operations.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a Metropolitan Statistical Area and has fewer than 100 beds.

We do not anticipate that the provisions in this final rule will have a substantial economic impact on most hospitals, including small rural hospitals. The BBA provisions include some new requirements on States, MCOs, and PIHPs, but no new direct requirements on individual hospitals. However, the prudent layperson standard for emergency services should benefit these hospitals by providing a uniform standard on which to determine the potential for coverage of these services across all MCOs. The impact on individual hospitals will vary according to each hospital's current and future contractual relationships with MCOs and PIHPs, but any additional burden on small rural hospitals should be negligible.

We have determined that we are not preparing analysis for either the RFA or section 1102(b) of the Act because we have determined, and we certify that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals in comparison to total revenues of these entities.

B. Anticipated Effects

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

Specific provisions of the regulation include the following:

- Permitting States to require in their State plan that Medicaid beneficiaries be enrolled in managed care. (This provision was implemented through a State Medicaid Director (SMD) Letter dated December 17, 1997, but this rule adds requirements for public involvement in the process.)

- Eliminating the requirement that no more than 75 percent of enrollees in an MCO or PHP be Medicaid or Medicare enrollees. (This provision was implemented through an SMD Letter dated January 14, 1998.)

- Specifying a grievance and appeal procedure for MCO and PIHP enrollees.

- Providing for the types of information that must be given to enrollees and potential enrollees, including requirements related to language and format.

- Requiring that MCOs, PIHPs and PAHPs document for the States that they have adequate capacity to serve their enrollees and that States certify this to us.

- Specifying quality standards for States, MCOs, and PIHPs.

- Increasing program integrity protections and requiring certification of data by MCOs and PIHPs.

- Increasing the threshold for prior approval of MCO contracts. (This provision was implemented through an SMD Letter dated January 14, 1998.)

- Permitting cost sharing for managed care enrollees under the same circumstances as permitted in fee-for-service. (This provision was implemented through an SMD Letter dated December 30, 1997.)

- Expanding the managed care population for which States can provide 6 months of guaranteed eligibility. (This provision was implemented through an SMD Letter dated March 23, 1998.)

- Revising the rules for setting capitation rates.

It is extremely difficult to accurately quantify the overall impact of this regulation on States, MCOs, PIHPs, PAHPs, and PCCMs because there is enormous variation among States and these entities regarding their current regulatory and contract requirements, as well as organizational structure and capacity. Any generalization would mask important variations in the impact by State or managed care program type. The Lewin Group, under a contract with the Center for Health Care Strategies, released a study of the cost impact of the earlier proposed regulation published on September 29, 1998 the **Federal Register** (63 FR 52022). Because this new final rule addresses the same areas as the September 29, 1998 proposed rule and includes many similar provisions, the Lewin study remains the best information we have available on the potential incremental impact of this final rule. However, the provisions discussed in the study were more prescriptive, and thus more costly to implement, than the provisions contained in this final rule.

Consequently, we believe that these

estimates are higher than the actual costs will be to implement these requirements.

The Lewin study did not analyze the original proposed regulation in total, but focused on four areas within the original proposed regulation: individual treatment plans, initial health assessments, quality improvement programs, and grievance systems/State fair hearings. These areas are discussed in more detail in the specific section of the Impact Analysis addressing that provision. While the study's focus is limited to selected provisions of the previous regulation, and some of the details of the provisions in this final rule differ from the earlier proposed rule, nevertheless, we believe that the overall cost conclusions are relevant to this final rule. In addition to examining the four regulatory requirements, the Lewin study cited the need to evaluate both the incremental and aggregate effects of the rule; the affect on different managed care environments (for example, overall enrollment; the Medicare, commercial, and Medicaid mix; geographic location); and differing regulatory requirements of the State (for example, State patient rights laws, regulation of noninsurance entities). The Lewin report also points out that many of the BBA provisions were implemented through previous guidance to the States, so the regulatory impact only captures a subset of the actual impact of the totality of BBA requirements.

In summary, according to the Lewin Study, States and their contracting managed care plans have already implemented many provisions of the BBA. While there are incremental costs associated with these regulatory requirements, they will vary widely based on characteristics of individual managed care plans and States. Finally, the BBA requirements are being implemented in an increasingly regulatory environment at the State level. Therefore, States, MCOs, and PIHPs will likely face additional costs not related to these regulatory requirements absent these new regulations. Thus, the incremental impact of these requirements on costs to be incurred would be difficult if not impossible to project.

We believe that the overall impact of this final rule will be beneficial to Medicaid beneficiaries, MCOs, PIHPs, PAHPs, PCCMs, States, and CMS. Many of the BBA Medicaid managed care requirements merely codify the Federal statute standards widely in place in State law or in the managed care industry. Some of the BBA provisions represent new requirements for States,

MCOs, PIHPs, PAHPs, and PCCMs, but also provide expanded opportunities for participation in Medicaid managed care.

It is clear that all State agencies will be affected by this final Medicaid rule but in varying degrees. Much of the burden will be on MCOs, PIHPs, PAHPs, and PCCMs contracting with States, but this will also vary by existing and continuing relationships between State agencies and MCOs, PIHPs, PAHPs, and PCCMs. This regulation is intended to provide important beneficiary protections while giving States flexibility and minimizing the compliance cost to States, MCOs, PIHPs, PAHPs, and PCCMs to the extent possible consistent with the detailed BBA requirements. We believe the final rule provisions will result in improved patient care outcomes and satisfaction over the long term.

Recognizing that a large number of entities, such as hospitals, State agencies, MCOs, PIHPs, PAHPs, and PCCMs will be affected by the implementation of these statutory provisions, and a substantial number of these entities may be required to make changes in their operations, we have prepared the following analysis. This analysis, in combination with the rest of the preamble, is consistent with the standards for analysis set forth by both the RFA and RIA.

1. State Options To Use Managed Care

Under this provision, a State agency may amend its State plan to require all Medicaid beneficiaries in the State to enroll in either an MCO or PCCM without the need to apply for a waiver of "freedom of choice" requirements under either section 1915(b) or 1115 of the Act. However, waivers will still be required to include certain exempted populations in mandatory managed care programs, notably dual Medicare-Medicaid eligibles, Indians, and groups of children with special needs. Federal review will be limited to a one-time State plan amendment approval, while States will no longer need to request waiver renewals every 2 years for section 1915(b) of the Act and 3–5 years for section 1115 of the Act waivers. State agencies may include "exempted" populations as voluntary enrollees in the State plan managed care programs or as mandatory enrollees in State waiver programs. Currently, ten States use State plan amendments to require beneficiary enrollment in MCOs and PCCMs. In short, the new State plan option provides State agencies with a new choice of method to require participation in managed care. The ability of States to require enrollment in managed care through their State plans

rather than through a waiver will not alter the standards of care practiced by MCOs and health care providers and, therefore, will not change the cost of providing care to managed care enrollees.

Pursuing the State plan amendment option rather than a waiver under section 1915(b) or 1115 of the Act waiver may reduce State administrative costs because it will eliminate the need for States to go through the waiver renewal process. Likewise, we will benefit from a reduced administrative burden if fewer waiver applications and renewals are requested. However, we believe the overall reduction in administrative burden to both the States and Federal government of approximately 40 hours annually per State will be offset by an additional burden of approximately 40 hours annually to develop and maintain the public process required by this rule.

2. Elimination of 75/25 Rule

Before the passage of the BBA, nearly all MCOs, and PHPs contracting with Medicaid were required to limit combined Medicare and Medicaid participation to 75 percent of their enrollment, and State agencies had to verify enrollment composition as a contract requirement. Elimination of this rule allows MCOs, PIHPs, and PAHPs to participate without meeting this requirement and eliminates the need for States to monitor enrollment composition in contracting MCOs, PIHPs, and PAHPs. This will broaden the number of MCOs, PIHPs, and PAHPs available to States for contracting, leading to more choice for beneficiaries. This provision results in no additional burden on States since it merely eliminates a previous statutory requirement and has already been implemented through the BBA amendment and the State Medicaid Director Letter in 1998.

3. Increased Beneficiary Protection—Grievance Procedures

The BBA requires MCOs to establish internal grievance procedures that permit an eligible enrollee, or a provider on behalf of an enrollee, to challenge the denials of medical assistance or denials of payment. Prior to the enactment of the BBA, the regulations at 42 CFR 434.59, required MCOs and PHPs to have an internal grievance procedure. While the regulations do not specify a procedure for MCOs or PIHPs to follow for their grievance process, we believe that these entities have grievance systems that are similar in their processes to the requirements of this final regulation. This belief is supported