

information that identifies a particular enrollee. In addition, we require the State to ensure that MCOs and PHPs have procedures in place that address how the information will be used and disclosed. We would expect that these procedures would specifically address when the MCO or PHP would use enrollee information for research and under what circumstances it would disclose the information to outside researchers. As noted above, the forthcoming HIPAA regulation will address this issue in more detail.

10. Enrollment and Disenrollment (Proposed § 438.326) and Grievance Systems (Proposed § 438.328)

These proposed sections required that a State agency include as part of its quality strategy ensuring compliance with the enrollment requirements in § 438.56, and, consistent with section 1932(c)(1)(A)(ii) of the Act, with the grievance requirements in subpart F. We received no comments on proposed § 438.326, and one comment relating to proposed § 438.328.

Comment: One commenter requested that we mandate that States conduct random reviews of service denial notifications, and other forms of non-coverage to ensure that MCOs and PHPs are notifying members in a timely manner.

Response: We agree with this comment. In § 438.228(b) of the final rule with comment period, we have added a requirement that States must conduct random reviews to ensure that each MCO and PHP and its providers and contractors are notifying enrollees in a timely manner. We have further added at § 438.228(c) a requirement that State must review, upon request of the enrollee, grievances not resolved by an MCO or PHP to the satisfaction of the enrollee.

11. Subcontractual Relationships and Delegation (Proposed § 438.330)

Proposed § 438.330 set forth requirements specifying that the State must ensure that an MCO or PHP entering into a contract with the State oversees and remains entirely accountable for the performance of any activity it delegates to a subcontractor. Under proposed § 438.330, it is the sole responsibility of the MCO or PHP to ensure that the delegated activity or function is performed in accordance with applicable contractual requirements. Specifically, under proposed § 438.330, the MCO or PHP should: (1) Evaluate the ability of the prospective contractor to perform the functions delegated; (2) enter into a written agreement that specifies the

delegated activities and reporting requirements of the subcontractor, and provides for revocation of the delegation or imposition of other sanctions if the subcontractor's performance is inadequate; (3) monitor the subcontractor's performance on an ongoing basis, and subject the subcontractor to formal review at least once a year; and (4) if deficiencies or areas for improvement are identified, take corrective action. These provisions are consistent with the CBRR as they relate to consumer choice of provider networks that are adequate to serve the needs of consumers, and in particular, these provisions ensure that States hold MCOs and PHPs accountable for the availability and adequacy of all covered services.

Comment: One commenter recommended requiring certifications to the State that payments under a subcontract are sufficient for the services required. Commenters recommended that all subcontracts should be made available for public inspection, so that they are available to the State, enrollees, and advocates.

Response: While we are not requiring a direct certification to the State, it is the MCO's or PHP's responsibility under § 438.230(b)(1) to evaluate, before delegation occurs, the prospective subcontractor's ability to perform the activities that are to be delegated. This evaluation may include evaluation of the subcontractor's financial stability and financial ability to deliver services. Subsequently, the MCO or PHP is held accountable for any functions it delegates, and therefore, has ultimate responsibility for oversight of the subcontractor. In addition, there is nothing in this provision that would preclude a State from requiring such a certification if it so chooses.

Moreover, we do not review subcontracts and normally do not become involved in the relationship between MCOs and PHPs and their subcontractors, with the exception of physician incentive rule arrangements, which must be disclosed. The law imposes requirements on MCOs, not on their subcontractors. We do not believe that we should be involved because the MCO or PHP (with whom there is a direct relationship) is ultimately responsible that requirements are met. Therefore, we will not in this final rule with comment period require public access to subcontracts. However, public access to subcontracts is subject to State procedures and policies governing their disclosure.

Comment: Several commenters requested clarification on the definition of subcontractor. The commenters

questioned whether we intended for this provision to apply to individual providers or solely to organizations. One commenter expressed the view that if an individual physician/provider is considered to be a subcontractor, the requirement for annual recertification would be unreasonable. Another commenter suggested that we give States the flexibility to define subcontractor as it applies to these provisions, while other commenters recommended that we define the term so that these provisions would apply solely to organizations.

Response: Any entity, whether an individual or organization, that is not an employee of the organization, but who assumes responsibility on behalf of the MCO or PHP, would be considered to be a subcontractor. While we are not specifically defining subcontractor, we do intend for it to include any non-employee individuals or organizations within the MCO's or PHP's network.

Comment: One commenter believes the requirement that the MCO subject each subcontractor's performance to formal review on an annual basis is unnecessarily prescriptive. The commenter notes that there is considerable overlap between this requirement and the provider credentialing requirements, and that States should have flexibility in this area.

Response: The intent of this provision was not to require recertification once a year. Proposed § 438.330 was designed to hold MCOs and PHPs accountable for the availability and adequacy of all covered services delivered through their subcontracts. As a result of this comment, we have revised § 438.230(b)(3) of the final rule with comment period to require that the MCO or PHP monitor the subcontractor's performance on an ongoing basis, and subject it to formal review according to a periodic schedule established by the State, consistent with industry standards or State laws and regulations.

Comment: One commenter expressed the view that the proposed rule did not go far enough in protecting an enrollee's rights when Medicaid services are delegated to subcontractors. The commenter believed that the enrollee has the right to know what to expect of a subcontractor, and that the State should be much more involved in making sure the subcontractor complies with the requirements of the contract and State and Federal law. The commenter recommended that, at a minimum, all subcontracts should be directly monitored by the State with the

monitoring procedures applicable to the MCO also applied to subcontractors.

Response: Section 438.230(a) of the final rule with comment period requires that the MCO or PHP oversee, and be held accountable for, any functions and responsibilities that it delegates to any subcontractor. Therefore, it is the MCO's or PHP's responsibility to ensure that its subcontractors are in compliance with all applicable laws, including those identified under § 438.100 (Enrollee Rights). It is the sole responsibility of the MCO or PHP to ensure that the delegated function is performed in accordance with applicable contractual requirements. However, there is nothing in this provision that precludes States from monitoring subcontracts if they so choose.

Comment: One commenter recommended that regulatory language be revised so that it is the same as that used in the Medicare+Choice regulations. The commenter believes that this will reduce the regulatory burden on managed care organizations that contract under both programs. The commenter recommends that the Medicaid final rule with comment period require that subcontractors comply with all applicable Medicaid laws, regulations, and our guidance.

Response: For the most part, the requirements contained in the Medicare regulations for subcontractors are reflected in the Medicaid regulatory language. However, in response to this comment, we have added a new provision at § 438.6(l) to require that all subcontracts fulfill the requirements of part 438 that are appropriate to the service or activity delegated under the subcontract.

Comment: One commenter suggested that the final rule with comment period address the obligation of States and MCOs to certain subcontractors, specifically Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs). They recommended that the rule reflect the statutory requirement that MCOs that enter into contracts with FQHCs and RHCs are required to provide payment that is not less than the level and amount of payment which would be made for services from a provider which is not an FQHC or RHC. These commenters also believed that the final rule with comment period should reflect the requirement that States directly compensate FQHCs and RHCs if they receive less compensation than that to which they are entitled. The commenters believe that an FQHC's or RHC's ability to provide high quality services, such as HIV services, in a managed care environment depends

upon linkages with MCOs that include adequate compensation.

Response: The rules cited by the commenter are "transitional" in nature, as the payments provided for thereunder are to be phased out over the next several years. We do not believe it appropriate to promulgate regulations that will be obsolete in a relatively short period of time. Moreover, we do not believe regulations are necessary, as the statutory requirements are straightforward and self-implementing, and we have provided guidance to all States on FQHCs and RHCs, through State Medicaid Director Letters on April 21, 1998, October 23, 1998, and September 27, 2000. We will continue, as necessary, to clarify FQHC and RHC payment policies.

Comment: One commenter expressed the view that subcontractual relationships may not be advantageous between Indian Health Service (IHS) and tribally operated programs and MCOs, if they are only reimbursed at a capped rate that does not give them the ability to recoup the costs of providing services in reservation communities located in rural and isolated locations. However, the commenter believed that some contracts may be desirable in communities where a local relationship with an MCO provider provides a network of support services not available in the Indian health care system. Another commenter cited a Memorandum of Agreement between IHS and HCFA, and Federal legislation, which each provide that IHS is compensated at a special rate, and that tribally operated programs may also choose to be compensated at the IHS rate. Furthermore, services furnished by these entities are entitled to a 100 percent Federal matching rate. The first commenter requested that we require that IHS or tribal providers operating as subcontractors be allowed to bill States or their fiscal intermediaries directly for American Indian Medicaid beneficiaries. The second commenter recommended that IHS, tribal providers, and urban Indian clinics receive payment for services to IHS beneficiaries who are also Medicaid beneficiaries from States or their fiscal intermediaries directly and not be required to bill MCOs, regardless of whether the facility is a subcontractor or providing "off-plan" services.

Response: As also noted in section II. H. below, policies concerning IHS or tribal providers, the rates paid to such providers, or the Federal matching applicable to such providers, are unaffected by, and are outside the scope of, this rulemaking.

12. Practice Guidelines (Proposed § 438.336)

Proposed § 438.336 required that States ensure that each MCO and PHP develop or adopt and disseminate practice guidelines that met standards set forth in proposed § 438.336(a), which required that the guidelines: (1) Be based on reasonable medical evidence or a consensus of health care professionals; (2) consider the needs of MCO and PHP enrollees; (3) be developed in consultation with contracting health care professionals, and (4) be reviewed and updated periodically. MCOs and PHPs were required under proposed § 438.336(b) to disseminate the guidelines to providers and enrollees where appropriate, or when they request them. Proposed § 438.336(c) required that decisions with respect to utilization management, enrollee education, coverage of services, and other areas be consistent with the guidelines.

Comment: Several commenters requested clarification of the regulatory language requiring MCOs and PHPs to "develop" (or adopt) practice guidelines. One commenter assumed that § 438.336 did not require the development of "new" practice guidelines, but only that if practice guidelines currently exist, they should be disseminated according to the language in this section. Another commenter was unclear if the provision required MCOs to adopt guidelines, or required MCOs, if using practice guidelines, to use them in accordance with this section.

Other commenters requested that MCOs be allowed to "develop" their own practice guidelines instead of "utilizing" existing practice guidelines developed by governmental agencies. Some commenters believed that practice guidelines should not be required. These commenters believed a blanket requirement for practice guidelines in all disease management areas is unwise, as not all areas have developed guidelines. Also, the commenters noted that the Medicare+Choice regulations do not mandate the development of guidelines.

Response: We realize that the words "develops" and "development" were misleading in that they appeared to suggest that we were encouraging MCOs and PHPs to develop their own practice guidelines, instead of using those already established by expert panels. We have removed those words from § 438.236 of the final rule with comment period. Since a number of practice guidelines already exist for a variety of clinical areas, we do not specify how

many or which practice guidelines MCOs and PHPs must adopt. Rather, each MCO and each PHP will need to establish a process for identifying and reviewing guidelines that are relevant to the health conditions of its enrolled population and implement a process, in conjunction with its providers, for the adoption and implementation within the MCO or PHP. This is consistent with industry standards in the private sector. NCQA's 1999 accreditation standard Q18, "Clinical Practice Guidelines," states, "The MCO is accountable for adopting and disseminating practice guidelines for the provision of acute and chronic care services that are relevant to its enrolled membership."

Comment: Multiple commenters recommended that the final rule with comment period specifically mention or require MCOs to use the following specified Federal Practice Guidelines: (1) Federal "Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents," (2) Federal "Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection," and (3) the "USPHS/IDSA Guidelines for the Prevention of Opportunistic Infections in Persons with Human Immunodeficiency Virus," and update as appropriate.

Several commenters felt this section should be clearer and more specific to the unique health care needs of children, for example, specifically referencing the American Academy of Pediatrics (AAP) immunization guidelines.

One commenter believed that MCOs should be required to report on compliance with scientifically grounded clinical practice guidelines where they exist for persons with disabilities.

Response: Many evidence-based practice guidelines exist that would be beneficial for MCOs and PHPs to adopt as tools for improving the quality of health care provided to enrollees. Because of the growing number of such guidelines, the variation in the strength of the evidence base supporting these guidelines, and the need for ongoing review and updating of guidelines, we are reluctant to single out a subset of practice guidelines as superior to all others and preferentially require adherence to them in this regulation. We do, however, reference the Adult and Pediatric Guidelines for use of Antiretroviral Agents in Treatment of HIV Disease as examples of the type of guidelines that should be adopted. We did not specifically require that the guidelines be adopted due to the reasons stated above. However, we have referenced HIV guidelines in the text of § 438.236(b) as examples of guidelines

that could be adopted consistent with this final rule with comment period, to reflect our strong belief that adherence to the HIV guidelines is essential to providing quality HIV care. We would continue to hold this position as long as the guidelines continue to meet the criteria in § 438.236(b). In addition to the guidelines referenced in the regulations text, we also strongly recommend that MCOs and PHPs adopt the following HIV guidelines if they continue to meet the criteria in § 438.336(b): USPHS/IDA Guidelines for Prevention of Opportunistic Infections in Persons Infected with HIV, Public Health Task Force Recommendations for the Use of Antiretroviral Drugs in Pregnant Women Infected with HIV-1 for Maternal Health and Reducing Perinatal HIV-1 Transmission in the United States, and US Public Health Service Recommendations for Human Immunodeficiency Virus Counseling and Voluntary Testing of Pregnant Women. We did not include references to any immunizations schedules, because current law requires State Medicaid agencies to provide all immunizations recommended by the Advisory Committee on Immunization Practices as part of the EPSDT program.

Comment: One commenter expressed the view that practice guidelines should take into consideration the needs of populations with special health care needs. One other commenter believed that a lack of medical evidence cannot be taken as a sign of a lack of efficacy. People with disabilities have limited access to clinical trials, and would suffer if practice guidelines based on clinical proof of efficacy were needed to ensure coverage. One commenter felt that guidelines should not be required to be based on "reasonable medical evidence," because in some specialty areas, including mental health, there is not an established base of published clinical trial outcomes. The commenter also noted Federal case law, that requires the provision of appropriate treatment, even if the treatment is not supported by clinical studies.

Two commenters agreed that MCOs should use practice guidelines that are evidence-based and developed by clinicians with training and expertise in a field, but they believed that some guidelines are not developed in an empirical framework, and if implemented, could jeopardize both children's access to and types of treatments received.

One commenter agreed that practice guidelines can be helpful, but found that the area of mental health has not developed sufficient guidelines for all courses of treatment. The commenter

believed that use of guidelines in the area of mental health may result in the denial of treatment as new treatment methods are developed.

Response: Some commenters have interpreted the regulation as requiring practice guidelines to be based on clinical trials, and were concerned about the potential lack of clinical trials including populations with special health care needs. In fact, this regulation does not require the use of practice guidelines for all conditions, or restrict the use of guidelines to those based on clinical trials. Section 438.236(b)(1) of the final rule with comment period requires that the guidelines be based on "reasonable clinical evidence or a consensus of health care professionals in the particular field," which does not necessitate that a clinical trial have been conducted; for example, guidelines for Perinatal Care, developed by the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists.

The commenters are also concerned over the lack of practice guidelines for some conditions, such as mental health, and fear that treatment may be denied. The regulation does not specify the number of practice guidelines that must be adopted, nor does it mandate for which conditions practice guidelines must be developed. The lack of practice guidelines for a particular condition does not provide a basis for an MCO or PHP to fail to treat conditions for which there is no guidance.

Comment: Two commenters suggested that we only permit practice guidelines developed by licensed health care providers in a particular field. Another commenter wanted to give greater weight to the requirements that guidelines be based on "reasonable medical evidence or a consensus of health care professionals in the particular field (§ 438.336(a)(1))," and that they "consider the needs of the MCO's enrollees (§ 438.336(a)(2))" than the requirement that they be developed "in consultation with contracting health care professionals (§ 438.336(a)(3))." The commenter believed that guidelines developed in accordance with § 438.336(a)(3) could lead to "garden variety" practice guidelines. One commenter believed that professional specialty organizations have adopted many national standards and practice guidelines that should be used.

Response: Because there is variation in the evidence base that supports all medical interventions, we believe we must be flexible and accept the use of guidelines developed both by clinical evidence or a consensus of health care professionals in the particular field. We

have replaced the word "reasonable" with the words "valid and reliable" to better describe the type of clinical evidence that should serve as a basis for practice guidelines that MCOs and PHPs are to adopt. The language we have used in the proposed rule and final rule with comment period at § 438.236 is consistent with industry standards.

Comment: One commenter suggested that practice guidelines be based on reasonable "clinical" evidence instead of reasonable "medical" evidence. Two commenters believe that if medical evidence does not exist, it may be due to the rarity of the disease, inadequate research infrastructure, or the fact that people with disabilities do not have as much access to clinical trials.

Response: We agree with the commenters. The term "medical" typically refers to actions and treatments related to physician practices, while "clinical" extends to health care researchers, as well as other health care providers, such as dentists, pharmacists, and nurses. Because of this, in response to this comment, we have substituted "clinical" for "medical" in § 438.236(b)(1). By replacing "medical" with the broader term, "clinical," we are also being more consistent with the following examples. The Institute of Medicine (IOM) discusses practice guidelines in the context of "clinical practice." For example, "Practice guidelines must include statements about when they should be reviewed to determine whether revisions are warranted, given new clinical evidence or professional consensus (or the lack of it)." The IOM also points out that two of the key attributes of practice guidelines include "clinical applicability" and "clinical flexibility."

One source of clinical practice guidelines on a variety of topics and that can help interested parties compare different practice guidelines on the same topic is the Agency for Healthcare Research and Quality's (AHRQ) National Guideline Clearinghouse, available at www.AHRQ.gov.

Comment: One commenter believed that MCOs should be required to report on compliance with scientifically grounded clinical practice guidelines where they exist for persons with disabilities. The same commenter also believed that the regulation should require that the amount, duration, and scope of coverage for covered benefits be reasonably sufficient to achieve the purpose of the service.

Response: We have decided not to require reporting on, or State monitoring of, compliance with the guidelines adopted by each MCO and PHP due to

excessive cost and administrative burdens. Instead we have chosen to emphasize the adoption and dissemination of evidence-based and widely accepted practice guidelines by MCOs and PHPs to their providers. We also believe that compliance with those practice guidelines adopted by States and MCOs and PHPs can be monitored through the quality assessment and performance improvement project requirements in § 438.240.

The commenter's second concern about the amount, duration, and scope of coverage for covered benefits was addressed in the response to comments on § 438.310.

Comment: One commenter believed that MCOs need to require their providers to use practice guidelines through a MOA or linkage agreements.

Response: We do not believe it is appropriate for the regulation to specify how MCOs and PHPs are to promote adherence to the guidelines by their contracted providers. We note that the state-of-the-art of information dissemination, technology transfer, and changing provider practice patterns is complex and continues to be the subject of much study.

Comment: One commenter believed that decisions about medical care should be based on medical necessity and medical judgement, and that these may not in individual cases, be consistent with the guidelines. Several commenters stated that practice guidelines are guidelines only, and should not restrict access and should be consistent with individual needs.

Many commenters expressed a concern that no requirement exists requiring individual coverage decisions to conform to government practice and care guidelines, especially in the area of HIV/AIDS treatment.

One commenter expressed a concern regarding how MCOs contracting with Medicaid will apply EPSDT standards and guidelines to children being served, and specifically to children with special health care needs.

Response: Our intent is not to substitute practice guidelines for professional judgement in the care of individuals. Practice guidelines are guidelines, not mandates, and should be applied consistent with the needs of the individual.

Comment: One commenter expressed a concern that MCOs will not reimburse subcontractors for services that are not recognized as medically necessary, or not consistent with nationally recognized practice guidelines.

Response: As noted above, there are many evidence-based practice guidelines that would be helpful to

MCOs and PHPs in undertaking efforts to improve the quality of health care provided to enrollees. However, we are not prescribing a uniform set of guidelines that must be used, or specifying that guidelines must be used whenever they are available. Rather, we are requiring that MCOs and PHPs consider relevant guidelines and choose those they find appropriate. Because it is not practical for an MCO or PHP to focus its quality assessment and improvement efforts simultaneously on all areas for which there are practice guidelines, it is not our expectation that MCOs and PHPs will adopt practice guidelines for all areas of treatment.

For those clinical areas for which an MCO or PHP has adopted a clinical practice guideline, if an enrollee requests services that contradict the practice guideline, the MCO or PHP may have grounds for withholding the services or refusing to pay for the service. Similarly, if an MCO or PHP found a requested service not to be medically necessary, the MCO or PHP would have grounds for withholding the service or refusing to pay for the service. However, there are two means of recourse for beneficiaries who believe that they have been inappropriately denied a service based on a practice guideline. First, the enrollee may appeal the denial of services on an individual basis. Second, the enrollee may request that the Medicaid agency review the guideline to see that it meets the regulation requirements that guidelines be evidence-based and up-to-date. We believe this will protect enrollees from the misuse of practice guidelines.

Comment: One commenter believed that guidelines should also be disseminated to enrollee representative, advocates, and the general public. Several commenters agree that enrollees, as well as the public, should have a right to obtain a copy of the practice guidelines.

In contrast, many other commenters voiced concern over the dissemination of guidelines to anyone other than appropriate providers. Some stated that the dissemination of guidelines intrudes on the practice of medicine and exceeds BBA requirements. One commenter believed that the administrative effort and expense would be too high if guidelines were to be disseminated "as appropriate." Two commenters were unclear about the meaning of "as appropriate." One commenter stated that disclosure of practice guidelines to enrollees may present problems around inclusion of proprietary information directly related to the conduct of business between providers and the MCO. Two commenters question the

value/usefulness of guidelines being disseminated to individual enrollees, as the information may be too confusing for them to comprehend. Finally, several commenters agree that guidelines should be disseminated to practitioners, but not to enrollees. These commenters believed the provider could give the guidelines to the enrollee as part of a treatment plan.

One commenter feared that the requirement to disseminate guidelines to all providers may result in MCOs collecting or creating guidelines in cases where medical outcomes are uncertain, expert preferences are mixed, or no justification is needed when following a treatment option. Another commenter believed that guidelines should only be disseminated to providers affected by the guidelines.

Response: Concerns over the dissemination of practice guidelines fell into two opposing views. Some commenters believed that guidelines should be available not only to enrollees, but also to enrollee representatives, advocates, and the general public. Other commenters believed that the current dissemination language is too broad, and that it would create a burden on MCOs to have to disseminate guidelines to all providers and all enrollees. Others were simply unclear as to what the words disseminate "as appropriate" entailed. We believe that guidelines should be disseminated to all providers who are likely to deliver the type of care that is the subject of the guideline (e.g. an MCO need not disseminate guidelines on childhood immunizations to its adult specialty surgeons). We also believe that enrollees with particular health concerns; e.g., asthma, may reasonably want to know if an MCO or PHP has adopted any particular guidelines on asthma care (such as those promulgated by the National Institutes of Health), and if so, would want to receive a copy of the guidelines. To clarify this section, and the intentions of the regulatory language regarding dissemination, we are revising the regulation at § 438.236(c) to read as follows: "Each MCO and PHP disseminates the guidelines to all affected providers, and upon request to enrollees and potential enrollees."

13. Quality Assessment and Performance Improvement Program (Proposed § 438.340)

Proposed § 438.340 required each MCO and PHP that contracts with a State Medicaid agency to have an ongoing quality assessment and performance improvement program, and specified the basic elements of such a

MCO and PHP program. Under proposed § 438.340(b), MCOs and PHPs were required to: (1) Achieve minimum performance levels on standardized quality measures, using standard measures required by the State; (2) conduct performance improvement projects; and (3) have in effect mechanisms to detect both underutilization and overutilization of services. Proposed § 438.340(c) provides for minimum MCO and PHP performance levels to be established by the State. Proposed § 438.340(d) established criteria for performance improvement projects, requiring, among other things: (1) the State to establish contractual obligations for the number and distribution of projects among specified clinical and non clinical areas; and to specify certain non clinical focus areas to be addressed by performance improvement projects; (2) that each MCO and each PHP assess its performance for each project based on systematic, ongoing collection, and analysis of valid and reliable data on one or more quality indicators; (3) that each MCO's and each PHP's interventions result in improvement that is significant and sustained over time; and (4) that each MCO and each PHP report the status and results of each project to the State agency as requested. Proposed § 438.340(e) required the State to review, at least annually, the impact and effectiveness of each MCO's and each PHP's quality assessment and performance improvement program; and authorized the State agency to require each MCO and each PHP to have in effect a process for its own evaluation of the impact and effectiveness of its quality assessment and performance improvement program.

Comment: Several commenters believed that States could be faced with the loss of FFP when MCOs fail to achieve minimum performance levels, since meeting these levels is a requirement under proposed § 438.340(b)(1), and section 1903(m) of the Act requires that requirements under section 1932 of the Act be met as a condition for FFP. These commenters believed that this would give States an incentive to set performance levels that are low enough to be easily achieved. The commenters felt that the States needed the flexibility to make exceptions for MCOs and providers with high-risk patient caseloads.

Response: We would not expect to deny FFP to any State that establishes a Quality Assessment and Performance Improvement Program that meets the requirements in the regulations, even if an individual MCO or PHP might not achieve required performance levels in

a single instance. Therefore, we do not agree that States will establish low minimum performance levels because of fear of loss of FFP. States are responsible for judging MCO and PHP performance in meeting the levels. We intend that the minimum performance levels be set at levels that can realistically be achieved. We require States to consider data and trends in managed care and fee-for-service in setting the levels. This is key to the process of quality improvement that we establish in this regulation.

Comment: One commenter believed that phase-in of full compliance with the imposed standards, and ongoing improvement over time should be allowed.

Response: As stated above, we believe that these regulations allow for flexibility. We believe that all MCOs and PHPs should be responsible for measuring their performance using standard measures set by the State, meet State-established minimum performance levels and conduct performance improvement projects. These are basic elements of a quality improvement program.

Comment: Several commenters were concerned that the proposed rule did not expressly require States to study care across the spectrum of enrolled populations, or to establish minimum quality measures relevant to all enrollees.

Response: For performance improvement projects, the regulation specifies four clinical areas that must be addressed over time. We intend that these areas (that is, prevention and care of acute and chronic conditions, high-volume services, high-risk services, and continuity and coordination of care) to apply to all enrolled populations. We do not specify that States must use measures of performance that address all conditions affecting all enrollees, because the state-of-the-art and limitations on resources do not allow this. However, in response to this comment, and other comments discussed in section II. C. above, we have added a provision at § 438.240(c)(2)(ii)(A) that permits us to specify standardized quality measures to be used by MCOs and PHPs. This provides us with the opportunity to specify measures for subpopulations of Medicaid enrollees and we could use this authority if a State failed to address certain subpopulations of enrollees. In addition, also in response to this and other comments, we have added at § 438.240(b)(4) a requirement that MCOs and PHPs must have in effect mechanisms to assess the quality and

appropriateness of care furnished to enrollees with special health care needs.

Comment: Several commenters believed that minimum performance levels should not be set below established compliance levels, for example in EPSDT, even if the State/MCOs are well below these standards at present.

Response: While we permit States to set minimum performance levels for their MCOs and PHPs, this authority does not diminish the responsibility of States to meet performance levels established by law, such as conducting EPSDT screening and providing EPSDT services.

Comment: Several commenters believed that the Federal government should develop over time performance measures, and set minimum performance levels, based on an aggregation of data submitted by the MCOs.

Response: We agree with this comment. In the final rule with comment period, in response to this comment and other comments discussed in section II. C. above, we have added a provision (§ 438.204(c)) that requires States to include among their strategies, performance measures and levels prescribed by us. This does not reduce the State's authority to set minimum levels for MCOs and PHPs. We expect that States will pass on to MCOs and PHPs responsibility to meet Federally-established performance levels in order for the States to meet their own targets.

Comment: One commenter read proposed § 438.340(c)(2)(i) to imply that States cannot impose standards on MCOs in addition to those specifically allowed by this regulation. The commenter also believed that proposed § 438.340(c)(6), which allows States to require the MCO to undertake performance projects specific to the MCO, and to participate annually in statewide performance improvement projects, could be read to prevent the State from being able to go further. The commenter suggested deleting §§ 438.340(c)(2)(i) and (c)(6).

Response: Section 438.240(c)(2)(i) of the final rule with comment period permits States to choose how many performance measures and performance measurement projects to require from their MCOs and PHPs. It sets as a minimum requirement that MCOs and PHPs measure, report to the State, and conduct performance improvement projects (PIPs). This regulation does not prohibit a State from imposing standards in addition to those specifically provided for in the regulation. Neither does it prohibit the

State from imposing a greater number or diversity of performance improvement projects specific to a given MCO or PHP or on a statewide basis.

Comment: One commenter believed that the level of detail for quality assessment and performance improvement left little flexibility for States to accommodate the special needs of newly formed MCOs that may have limited resources and experience with such activities required during their initial contract period.

Response: States have considerable flexibility in determining how many projects an MCO or PHP must conduct, the areas to be addressed by the projects, the scope of the projects, and the amount of improvement expected. We believe this latitude is sufficient for States to address the circumstances of new MCOs or PHPs and those with fewer resources than others.

Comment: Several commenters were concerned that prospectively determined, quantifiable quality improvement goals could be difficult for MCOs and PHPs to achieve, as they do not control all factors impacting such improvement. They believed that circumstances outside the control of the MCO could make it difficult or impossible to complete a study and collect clean data. These commenters felt that States needed flexibility to accommodate these problems appropriately, without facing sanctions, when noncompliance occurs as a result of factors beyond the control of the MCO.

Response: As stated in the responses to several comments above, we believe these regulations provide States with considerable flexibility to set requirements for their MCOs and PHPs. States also have flexibility in deciding when sanctions should be imposed on MCOs and PHPs. Also, while we agree that some factors that affect quality improvement may be outside of the MCO's or PHP's control, we believe that many factors are within the control of MCOs or PHPs, and that MCOs and PHPs should be held accountable for quality improvement.

Comment: Several commenters believed that we should require States to allow MCOs sufficient time to implement programs and systems. They were concerned about the total administrative burden being imposed by the proposed rule (for example, the requirement that MCOs maintain health information systems that collect, analyze, integrate, and report necessary data).

Response: We do not agree that States should be able to postpone the Quality Assessment and Performance

Improvement (QAPI) provisions to give MCOs or PHPs the time to develop programs and systems. MCOs and PHPs now have the responsibility to monitor care, and to do this requires that they have programs and data that can be used to measure their performance.

Comment: One commenter did not believe new requirements on MCOs should be imposed unless specific additional funding covering the costs of such requirements is made available.

Response: In this final rule with comment period we are replacing the upper payment limit on payments to MCOs and PHPs with a different mechanism to contain managed care costs. This new method will allow for additional costs to be considered in setting capitation rates including the costs of complying with QAPI requirements.

Comment: Another commenter wanted us to review existing QI projects that MCOs are conducting as part of HEDIS reporting and NCQA accreditation, so as not to duplicate measures and increase administrative costs.

Response: The relationship in Medicaid is between the State and the MCO or PHP, not between us and the MCO or PHP. In establishing these requirements, nothing in the regulation prohibits States from considering other QI projects their MCOs are conducting, and we would encourage States to do so.

Comment: Several commenters believed that State agencies should consider historical MCO and FFS Medicaid performance data and trends to determine the appropriateness of quality measures. They also believed that performance levels adopted by States should be reasonably attainable. They asked that the following preamble language be inserted into the regulation text, "In establishing minimum performance levels, the State agency should ensure that the targets are achievable, meaningful, and equitable. The State agency must consider historical plan and FFS Medicaid performance data and trends."

Response: Section 438.240(c)(2)(ii)(B) of the final rule with comment period provides that States should "consider data and trends for both the MCOs and PHPs and fee-for-service Medicaid in that State," in setting minimum performance levels. This addresses the issues of achievability and equity.

Comment: Several commenters believed that a predefined percentage, like QISMC's standard of a 10 percent reduction in deficient care, would stifle creative approaches to QI. They also object to the 10 percent standard because it is inconsistent with NCQA's

“meaningful” standard for improvement, based on effort. The same commenters also believed that the 10 percent standard could cause MCO not to pursue QI projects for which a 10 percent reduction was difficult to predict. The commenters would like to see the defined percentages removed from the preamble, and in its place have NCQA’s “meaningful” improvement standard inserted.

Response: The 10 percent reduction rule from QISMC is in the preamble as an example only and is not a requirement. However, we believe that the true test of quality improvement is measurable improvement. This requires that a numeric benchmark or percentage improvement goal be in place. Therefore, we do not agree that a standard of “meaningful” improvement is sufficient. The regulation does not require the use of the 10 percent reduction standard. States have the discretion to establish specific numeric, objective improvement levels themselves.

Comments: Many commenters believed that without specific instructions from us, stating that MCOs must identify and monitor care delivered to populations with special health care needs enrolled in an MCO, it is unlikely that results from QAPI will reflect the experiences of these groups. They also believed that HEDIS for Medicaid does not include many measures specific to children or adults with special health care needs. The commenters would like to see specific quality assurance activities and outcome measures, focusing on the various populations with special health care needs, to be developed in conjunction with advocates and experienced providers in these areas.

Response: We agree that populations with special health care needs should not be left out of MCO and PHP quality assessment and performance improvement activities. Section 438.240(d)(2) of the final rule with comment period requires that performance measurement and quality improvement projects address the entire Medicaid enrolled population in an MCO or PHP to whom the measure is relevant. The regulation also requires that all enrolled populations be measured over time. As discussed above, we have added provisions permitting the Secretary to specify annual quality measures and performance improvement project topics for MCOs and PHPs. Through this mechanism, we have the authority to direct States, MCOs, and PHPs to address subgroups of enrollees should the States fail to do so. To make explicit

the requirement that populations with special health care be included in MCO and PHP quality assessment and performance improvement activities, we have added a new item at § 438.240(b)(4) requiring that MCOs and PHPs have in effect mechanisms to assess the quality and appropriateness of care furnished to enrollees with special health care needs. We note however that more effective and plentiful quality indicators to measure the quality of care delivered to individuals with special health care needs are still needed.

Comment: One commenter believed that in addition to reporting performance measures, States or medical auditors should also target and access medical records to study overall treatment of specified conditions and adherence with treatment protocols.

Response: We do not agree that we should require States (in addition to using performance measures and quality assessment and performance improvement projects) to separately review medical records to study overall treatment of specific conditions and monitor the use of treatment protocols. While States are free to undertake this activity, we believe that the elements of State quality assessment and performance improvement strategy will be sufficient to monitor health care quality (including adherence to treatment protocols).

Comment: One commenter favored outcomes measured through both process indicators and “quality of life” indicators.

Response: The term performance measure, as we are using it, provides the option for States to use process and outcome measures, including quality of life indicators.

Comment: A commenter recommended a requirement that HEDIS be the standardized tool for QAPI, instead of leaving this up to States.

Response: We believe that the choice of performance measures and measurement tools should be left to the discretion of individual States. Many States now use a number of HEDIS measures; however, we note that HEDIS as a measurement set has limitations and may not serve the complete needs of States or fully address the Medicaid population.

Comment: A commenter believed that the statement, “projects are representative of the entire spectrum of clinical and non-clinical areas,” should be qualified so that projects are not required to cover the entire spectrum every year, but should focus on one area each year, as long as the subject varies over time.

Response: The proposed rule did not, and the final rule with comment period does not, require that all areas be addressed each year. States may specify the number of projects its MCOs and PHPs must conduct, and the requirement would be met if the State requires only one project. We have clarified the final rule with comment period to state at § 438.240(d)(3) that States must require each MCO and each PHP or more to initiate one or more performance improvement projects per year.

Comment: One commenter asked if a successful NCQA review would be acceptable in lieu of the required yearly audit, since this would save administrative efforts and expense.

Response: As discussed above in section II. C., while section 1932(c)(2) of the Act provides for external quality review (EQR) requirements to be met based on other accreditations, there is no such authority for the requirements under section 1932(c)(1) of the Act (as is the case with respect to similar requirements under the Medicare+Choice program).

Comment: A commenter was concerned about the fact that many subpopulations served by an MCO were small in number, and believed it may be difficult to produce any meaningful results for quality assurance and performance measurement. The commenter asked if aggregate results of a performance project across several MCOs of a national company would be acceptable.

Response: States are accountable for the quality of care for their Medicaid beneficiaries, and must be permitted to set the requirements for the MCOs and PHPs with which they contract. Therefore, we will not modify the regulation to permit MCOs or PHPs to aggregate data across States.

Comment: Several commenters wanted States to publish performance measurement tools and results of assessments. The commenters were concerned that no requirement exists that requires MCOs to provide information about quality assurance programs to enrollees and potential enrollees in Medicaid.

Response: While we have not provided in this final rule with comment period for the provision of information on MCO or PHP quality measures, this will be provided for in the final EQR regulation, as it is required under section 1932(c)(2)(A)(iv) of the Act.

Comment: Several commenters believed that self-reported quality measures should be subject to external validation by the State, and that State-

defined measures and performance improvement projects should be required to use audited data.

Response: This type of external review is provided for in section 1932(c)(2) of the Act, which is being implemented in a separate rulemaking.

Comment: Some commenters did not believe that the use of the word benchmark in the preamble discussion of proposed § 438.340(d)(9) was clear. Yet they believed that benchmarking is one of the key terms for QI, and needs to be expanded in the final rule with comment period.

Response: We agree that the term "benchmarks" can have many connotations, and have deleted it from the final rule with comment period.

Comment: A commenter requested that we include a definition of "high-volume" or "high-risk" services. The commenter believed this should be defined to require the review of mental health services, and did not believe that mental health services would be considered high-volume or high-risk without these services being expressly included in the definition.

Response: We have chosen not to define "high-volume" or "high-risk" services, as they differ relative to individual MCOs or PHPs and the populations they serve. For example a PHP behavioral health carve-out would only include mental health services. We believe States are in the best position to define this for their MCOs and PHPs.

Comment: One commenter urged that cultural competence be included as a nonclinical area of performance measurement in the regulation.

Response: We agree that cultural competence is a nonclinical area that may be a topic of a performance improvement project. In response to this comment, in § 438.240(d)(5)(iii) of the final rule with comment period, we have added "cultural competence" as a non-clinical area.

Comment: Several commenters asked that we establish a process for detailed discussions with MCOs to better understand the operational issues associated with implementing the proposed standards of the regulation. Two of the commenters desired discussions with us to define short- and long-term goals for Medicaid managed care quality oversight and to arrive at a focused strategy. For example, they believed that HEDIS was undermined by the ability of States to establish an independent system of quality improvement strategies.

Response: We are working to provide technical assistance tools to the States. In turn, the States will be able to work with MCOs and PHPs, and MCOs and

PHPs will have an opportunity to provide public input to the quality strategy in their respective State.

Comment: A commenter believed that more "horizontal" lines of communication regarding performance improvement and measurement needed to occur, in addition to the current "vertical" lines of communication between the States, MCOs, and HCFA. For example, they would like to see communication take place across MCOs and across State agencies.

Response: We agree that communication across organizational components is of considerable value, and this function is currently addressed through membership organizations, such as the American Public Human Services Association (APHSA). These organizations can assist with the exchange and gathering of information through conferences and publications.

14. Health Information Systems (Proposed § 438.342)

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

In proposed § 438.342, we provided that the State ensure that each MCO and PHP maintain a health information system that collects, analyzes, integrates, and reports data that can achieve the objectives of this part. Under the proposed rule, we specified that the system should provide information on areas including, but not limited to, utilization, grievances, disenrollments and solvency. Furthermore, we proposed that the State ensure through its contracts with MCOs and PHPs that each MCO and PHP be required to: (1) Collect data on enrollee and provider characteristics, as specified by the State, and on services furnished to enrollees; (2) ensure that the data received from providers are accurate and complete by verifying the accuracy and timeliness of reported data, screening the data for completeness, logic and consistency, and by collecting service information in standardized formats to the extent

feasible and appropriate; and (3) make available all collected data to the State and HCFA. An MCO or PHP was permitted to use any method or procedure for data collection, so long as it could demonstrate that its system achieves the objectives of this standard.

Comment: Several commenters believed that the regulation should specifically require appropriate acquisition of data by MCOs concerning race, ethnicity, sex, age, disability, and primary language. These commenters believed that without the collection of such data, compliance and enforcement with civil rights laws including Title VI and the ADA would be difficult.

Response: All of the above, with the exception of age and sex, are explicitly addressed in this final rule with comment period. Information on disability will be captured through the initial and ongoing assessment provisions of § 438.208. Primary language spoken is addressed in the language requirement of § 438.10(b). As discussed previously, race and ethnicity are addressed in § 438.204(b)(1)(iii). However, sex and age are fundamental pieces of demographic information that are essential if MCOs and PHPs are to be able to comply with the information system requirements in § 438.242. Age and sex are such routinely collected demographic information, that we do not believe it necessary to expressly mandate their collection in the regulation.

Comment: Several commenters urged that the timing and costs associated with implementing the regulations be evaluated. These commenters suggested that we allow more time to comply with the regulation, because of millennium activities that are utilizing the majority of State and MCO resources. Several other commenters questioned how funding for this activity would occur, as they did not believe they had the resources to meet the requirements.

Response: Given the passage of time since January 1, 2000, "Y2K" activities should no longer be utilizing State systems resources. We will work with States to assist them in implementation of this final rule with comment period. As for the funding for implementing the requirements, new Medicaid State agency system development design and implementation is funded at 90 percent and maintenance to existing systems is matched at 50 percent.

Comment: Several commenters questioned the logic of including solvency information in the same system as enrollee-specific data such as utilization, grievances and disenrollments. These commenters did not believe solvency information should

be included as a mandatory element of a health information system. The commenters believed that a State's current standards for reporting and format should be sufficient.

Response: We agree that this is not the appropriate place to capture solvency information. In response to this comment, we have removed the reference to solvency from § 438.342(a).

Comment: Several commenters found the requirement that MCOs make all collected data available to both the State and HCFA excessive and redundant since the State must also submit data to us. The commenters noted that it is the MCO's business to manage their population and to report required data to the State. Duplicative reporting requirements could increase the administrative expenses of MCOs, and make contracts with State Medicaid programs less attractive to commercial HMOs.

Response: We agree that it is burdensome to request all information to be sent to both the State and to HCFA. In response to this comment we have provided in § 438.242(b)(3) of this final rule with comment period that MCOs and PHPs make all collected data available to the State as required in subpart D, and to us upon request.

Comment: Several commenters recommended that we establish national data collection standards for States to use for the collection of encounter data, EPSDT, and network information. These commenters specified that these standards should be based on current data elements that could be systematically produced by providers, and captured by MCOs and PHPs.

Response: We desire to have consistency of information, and to have national standards in those cases where it makes sense to do so. However, we must also balance that desire with providing States with the necessary flexibility to implement their individual Medicaid programs. We are working on several initiatives to standardize data collection on a national level. The Health Insurance Portability and Accountability Act (HIPAA) requires us to work toward the goals recommended by several of the commenters.

E. Grievance Systems (Subpart F)

Background

Proposed subpart F was based on section 1902(a)(3) of the Act (requires a State plan to provide an opportunity for a fair hearing to any person whose request for assistance is denied or not acted upon promptly), section 1902(a)(4) of the Act (authorizes the Secretary to specify methods of

administration that are "necessary" for "proper and efficient administration"), and section 1932(b)(4) of the Act (requires that MCOs have an internal grievance procedure under that a Medicaid enrollee, or a provider on behalf of an enrollee, may challenge the denial of coverage of or payment by the MCO).

In this subpart, we proposed regulations that lay out the required elements of the grievance system required under section 1932(b)(4) of the Act, and how it interfaces with the State fair hearing requirements in section 1902(a)(3) of the Act; describing what constitutes a notice (that is, the first step in the grievance system); addressing complaints and grievances, including timeframes for taking action; the process for actions; how grievances are to be handled; and how enrollees are to be notified of the resolution of grievances. In addition, the proposed rule provided for expedited resolution of grievances and appeals in specific circumstances; addressed the requirement for continuation of benefits; included the requirement that MCOs and PHPs clearly and fully inform enrollees of the entire system so that they are aware of it and how to use it; specified what materials must be provided when notifying an enrollee, and the requirements for those materials; and lay out the requirements relating to record keeping, monitoring, and the consequences of noncompliance.

1. Statutory Basis and Definitions (Proposed § 438.400)

Definitions of terms that would apply for purposes of proposed subpart F are found in § 438.400 of the proposed rule, in that the following terms have the indicated meanings:

Complaint was defined as any oral or written communication made by or on behalf of an enrollee to any employee of either the MCO, PHP, its providers, or to the State, expressing dissatisfaction with any aspect of the MCO's, PHP's, or provider's operations, activities, or behavior, regardless of whether the communication requests any remedial action.

Enrollee was defined for purposes of subpart F, as an enrollee or their authorized representative.

Governing body was defined as the MCO's or PHP's Board of Directors, or a designated committee of its senior management.

Grievance was defined as a written communication, submitted by or on behalf of a Medicaid enrollee expressing dissatisfaction with any aspect of the MCO's, PHP's, or providers's operations, activities, or behavior that pertains to

the following: (1) The availability, delivery, or quality of health care services, including utilization review decisions that are adverse to the enrollee; (2) payment, treatment, or reimbursement of claims for health care services; or (3) issues unresolved through the complaint process provided for under the proposed rule.

Comment: Some commenters questioned HCFA's statutory authority to promulgate the detailed requirements in proposed subpart F, given the limited amount of text in section 1932(b)(4) of the Act.

Response: As noted above, these rules are based only in part on section 1932(b)(4) of the Act. We believe that those portions of subpart F that address an MCO's internal grievance system constitute a reasonable implementation of authority under section 1932(b)(4) of the Act. This rule is also based on our general authority under section 1902(a)(4) of the Act, and on the State fair hearing requirements in section 1902(a)(3) of the Act, that prior to this final rule with comment period have not been implemented in regulations that apply to managed care enrollees. We believe that the requirements in subpart F of this final rule with comment period are warranted in order to ensure that MCOs have an effective and useful internal grievance process, as required under section 1932(b)(4) of the Act, and in order to ensure that MCO and PHP enrollees have access to the same State fair hearing process that fee-for-service enrollees have under subpart E of part 431. This final rule with comment period applies the general rights in section 1902(a)(3) of the Act to managed care enrollees both in MCOs and PHPs. In the case of PHPs, the requirements in subpart F are based both on section 1902(a)(3) of the Act and, in the case of longstanding PHP regulations, they are generally on our broad authority under section 1902(a)(4) of the Act to specify methods necessary for proper and efficient administration. In the case of MCOs, we are also implementing the requirements in section 1932(a)(4) of the Act, and setting forth what we believe is necessary to adequately meet these requirements as we have interpreted them. The analysis of key court decisions has also guided the development of these final regulations, just as the Supreme Court's *Goldberg v. Kelly* decision was incorporated in the State fair hearing regulations under part 431, subpart E to which the MCO and PHP grievance system is linked.

Comment: Some commenters believed that while we took case law into account in proposed subpart F, HCFA did not go far enough to protect

Medicaid managed care enrollees' rights in the following three areas: (1) Continuation of benefits; (2) direct access to State fair hearings; and (3) time frames for action.

Response: We have carefully considered all comments on these three issues and address each issue below in the context of our discussion of regulation language that pertains to the issue. In general, we recognize that we have a responsibility to protect Medicaid enrollees and ensure their rights. To meet this responsibility, we have established a set of Federal protections that apply to Medicaid enrollees regardless of their State of residence. This will ensure a minimum degree of consistency with the level of protection afforded Medicare beneficiaries. States may choose to add to these protections by exceeding the minimum levels required by this regulation.

In developing these regulations, we relied heavily on the Consumer Bill of Rights and Responsibility (CBRR). We also examined the grievance procedures of many States, and considered all comments on these issues. We have carefully documented, tracked, and analyzed each decision we have made with respect to our consideration of commenters' suggestions in light of the guiding principles in the CBRR.

Comment: We received comments that suggested that we specify a different grievance process for enrollees with addiction or mental health issues or, at a minimum, make specific mention of these concerns in the regulation, and adopt the principles of the Model Managed Care Consumer Protection Act proposed by the President's Commission on Model State Drug Laws. Under this Act, the patient, family, or program must be permitted to appeal directly outside the MCO or PHP. These commenters also suggested that there be a separate office responsible for the addiction and mental health grievance process and to advocate for patients and families.

Response: We do not agree that there should be separate grievance processes, procedural requirements, or offices based on diagnosis-specific or population-specific criteria. The grievance system set forth in this regulation is designed to address the needs of all Medicaid enrollees, including those with special health care needs. PHPs providing mental health or substance abuse services are also subject to these provisions, that we believe adequately protect individuals with these conditions.

Comment: Many commenters strongly recommended that we eliminate the

"complaint" category set forth in the proposed rule, while others supported the broad definition of "complaint" as separate from "grievances" subject to a State fair hearing, but recommended changes to better distinguish these categories. The comments advocating the elimination of a separate complaint category are first presented below followed by the comments supporting retention of the two categories but recommending changes related to these categories.

In support of eliminating separate categories, one commenter contended that it has been well documented that Medicare+Choice organizations misidentify what should be appeals under the Medicare+Choice appeals system as "grievances," are not subject to external administrative and judicial review under that system. The commenter believed that HCFA should eliminate the "complaint" level, because the commenter saw it as the equivalent of "grievances" under Medicare+Choice, and in order to avoid confusion and prevent the potential mishandling of appeals. One commenter noted that under the proposed rule, an MCO or PHP could fail to acknowledge an appeal and provide the required notice to enrollees simply because the enrollees failed to "use the magic words" when filing their dispute.

Another commenter believed that because the NPRM does not require that complaints be monitored and tracked as closely as grievances, MCOs and PHPs have an incentive to categorize a dispute as a complaint. The commenter stated that this could benefit the MCO or PHP because complaints would not be reflected in the MCO's or PHP's performance ratings, and MCOs and PHPs should not be given the authority to decide whether an issue is a complaint or grievance.

Another commenter expressed the view that a complaint process does not protect the enrollee and, therefore, should be deleted from the regulation. This commenter believed that MCOs and PHPs would be able to resolve complaints on a more informal basis through the customer service department, while enrollees' rights to a formal appealable grievance would remain.

One commenter noted that many States have a single definition for a "grievance" in order to avoid confusion for MCOs, PHPs and enrollees. The commenter felt that this simplifies reporting and facilitates the resolution of a complaint. One commenter said that all issues should be tracked as grievances whether submitted orally or in writing. Another said that enrollees

should be able to address any problem that they have with the MCO, PHP, or a provider without getting trapped or confused by a labeling and tracking process. Several commenters said the documentation of all complaints as well as grievances should be required.

A commenter felt that allowing both an informal complaint and a formal grievance process has led to confusion of enrollees, MCOs and PHPs, as well as to inappropriate transfers and unnecessary delays. This commenter believed that there have been many instances of MCOs and PHPs re-classifying grievances as "complaints" in order to evade review or to slow the dispute resolution process, and that an enrollee's rights may hinge on this classification process.

One commenter believed that enrollees should be given the right to request expedited resolution of complaints and these should be treated in the same manner as grievances were under the proposed rule, for when expedited resolution is requested by the enrollee or the provider.

One commenter noted that under existing fee-for-service regulations, all disputes are dealt with in a uniform manner and all that is required to obtain a hearing is a "clear expression by the applicant or recipient, or his authorized representative, that he wants the opportunity to present his case to a reviewing authority." According to this commenter, this [42 CFR 431.201] definition allows for differences in presentation of disputes and does not require beneficiaries to refer to rules and definitions when presenting them. In the commenter's opinion, many beneficiaries do not have the capacity to distinguish between a "complaint" and a "grievance."

Other commenters agreed that there should be distinct categories for complaints and grievances subject to appeal, but suggested changes to how these categories are defined and the provisions applying to each. These comments follow.

One commenter believed that complaints that are not resolved to the beneficiary's satisfaction within 30 days after filing should automatically become appealable grievances.

Another commenter stated that if the complaint process is not eliminated, it should be regulated to the same extent as the grievance process was under the proposed rule. The commenter suggested that the regulation should provide more guidance on how complaints are to be handled. The regulation should also specify who distinguishes a complaint from a grievance and the qualifications of this

decision-maker. The distinction between a complaint and grievance, as used in the proposed rule, needed to be clarified with examples, in the commenter's view. Matters do not always squarely fit within one category.

One commenter said that the terms "complaint" and "grievance" should be clarified in the regulation, and that the complaint process would address those communications that were not grievances under the proposed rule. The commenter provided examples of topics that would likely be addressed as complaints in this process for example, waiting times, operating hours, demeanor of health care personnel, and the adequacy of facilities.

A commenter noted that the preamble's characterization of complaints differs from the regulatory definition. The commenter stated that the regulation defines complaints but includes no guidance on how they are to be handled. One commenter noted that the preamble says that complaints include problems involving waiting times and operating hours. However, the commenter noted, if a beneficiary must wait three weeks for an appointment during limited afternoon hours, this clearly is an availability and quality problem which should be defined as an appealable grievance.

One commenter believed that the distinction made in the proposed rule between complaints and grievances was subjective and suggested that the proposed rule's requirement that grievances be in writing would greatly reduce the number of disputes handled through the grievance process, because of the difficulty enrollees may have in filing a written appeal. The commenter further noted that some problems require immediate response, which a telephone communication allows.

One commenter thought that grievances which result from unresolved complaints should apply only to unresolved complaints that are related to service delivery or treatment. This commenter believes that appeals should be available only for "actions" (that is, the denial, reduction, or termination of services), and that frivolous complaints not resolved to the enrollee's satisfaction should not be entitled to a State fair hearing. This commenter was concerned that the proposed regulation opens up the State fair hearing process to virtually any expression of dissatisfaction with the operation of the MCO or PHP.

A final commenter recommended that we use the terms used in the Medicare+Choice regulations to simplify MCO and PHP documentation, and MCO and PHP enrollee education.

According to the commenter, consistent use of terms would also make life easier for providers and for enrollees who participate in both the Medicare and Medicaid programs.

Response: We agree with the commenters who were confused by the way the term "grievance" was used in the proposed rule, particularly in light of Medicare+Choice's use of the term "grievance" as a complaint that is not subject to external review or a State fair hearing. Our use of the term "grievance" in the proposed rule was based on the fact that the Congress, in section 1932(b)(4) of the Act, referred to an internal "grievance procedure under that an enrollee could challenge a denial of payment or coverage." The Congress used the term "grievance" to refer to a type of appeal that under the Medicare+Choice program was subject to appeal and was under that program's terminology not a grievance. It was for this reason that we used the term "complaint" to refer to the type of problem labeled a "grievance" in the Medicare+Choice program. In order to adopt an approach more consistent with Medicare's (to avoid confusion for organizations that participate in both programs). In this final rule with comment period, we are deleting the use of the word "complaint," and using the term "grievance" to refer to the same types of enrollee problems. Also, in this final rule with comment period, like in the Medicare+Choice program, we establish two mutually exclusive categories: (1) a "grievance," that is not subject to the State fair hearing process (called a "complaint" in the proposed rule), and (2) an "appeal," that is subject to a State fair hearing (encompassed in the term "grievance" in the proposed rule). Because the Congress employed the term "grievance procedure" in section 1932(c)(4) of the Act, we continue to use the term "grievance system" to refer to the overall grievance and appeal system provided for in subpart F.

Specifically, in response to the above comments, we have in this final rule with comment period: (1) dropped the definition of "complaint;" (2) changed the definition of "grievance" to roughly track the definition of "complaint" used in the proposed rule; and (3) added a new definition of "appeal" to § 438.400 so that grievance and appeal are two mutually exclusive categories. We agree with the commenters favoring the employment of two distinct categories because we believe that certain disagreements between the MCO or PHP and its enrollees should have a higher standard of review, and should be subject to a State fair hearing if the MCO

or PHP decision is adverse to the enrollee. The term "appeal" also is used by most States for State fair hearing requests. In this final regulation, the term "appeal" is used to refer to requests for an MCO or PHP hearing, as well as, for a State fair hearing. As just noted, it is also the term used in Medicare and will reduce the burden on MCOs and PHPs for educating providers and dually-eligible enrollees.

To clearly distinguish between a grievance and an appeal, in this final rule with comment period, we have added a definition of "action" as the event that entitles an enrollee to file an appeal and defined a grievance as involving a matter other than an action. An action includes the following: (1) the denial or limited authorization of a requested service; (2) the reduction, suspension, or termination of previously authorized services; (3) the denial of payment, in whole or in part for a service, for a resident of a rural area with only one MCO or PHP; (4) the denial of a Medicaid enrollee's request to exercise their right to obtain services out of network; (5) the failure to either furnish, arrange or provide for payment of services in a timely manner; and (6) the failure of an MCO or PHP to resolve an appeal within the timeframes provided in the regulation. In addition, for a State agency, the denial of a Medicaid enrollee's request to disenroll is an action.

In response to comments that we should set out additional requirements for MCOs and PHPs when they are addressing complaints (now called grievances), we have added several requirements. In this final rule with comment period, we require that MCOs and PHPs ensure correct classification of grievances. We also provide examples of grievance issues in the regulation text (in a parenthetical in the revised definition of grievance). We specify maximum timeframes for MCOs and PHPs to dispose of grievances. We provide in § 438.406(a)(7)(ii) that grievances involving clinical issues and those regarding denials to expedite resolution of appeal be decided by a health care professional with appropriate clinical expertise. We also provide that while grievances are not subject to review at the State fair hearing level, they are subject to further review by the State at the request of the enrollee. We also provide that MCOs and PHPs must work with the State to dispose of grievances if the State considers the MCO or PHP response to be insufficient. In addition, the State must monitor these processes and incorporate that monitoring into its overall quality improvement strategy.

Overall, we believe that this new approach will streamline the grievance and appeal process, eliminate confusion on the part of enrollees and providers, be more consistent with Medicare, and provide protection for enrollees.

Comment: Some commenters believed that the grievance and appeals provisions should apply to PCCMs, as well as, to MCOs and PHPs.

Response: We do not agree with the commenter's suggestion that the grievance and appeal provisions should apply to PCCMs. PCCMs are often individual physicians or small group practices and can not be expected to have the administrative structure to support a grievance process. Because PCCMs that are not capitated (capitated PCCMs would be subject to subpart F as PHPs) are reimbursed through the fee-for-service system, they are subject to the State fair hearing process described in 42 CFR 431 Subpart E. Moreover, as noted above in section II. D. with respect to the quality requirements in section 1932(c)(1) of the Act, the Congress made a conscious decision in section 1932(b)(4) of the Act to apply the grievance requirements only to MCOs in that section, notwithstanding the fact that other requirements in section 1932 of the Act apply to PCCMs. We believe it would be inconsistent with Congressional intent to apply grievance requirements to PCCMs. In the case of PHPs, the Congress was silent in section 1932 of the Act. We believe that because PHPs are paid on a risk basis like MCOs and have a financial incentive to deny care like MCOs, grievance and appeal protections are as important for PHP enrollees as they are for MCO enrollees.

Comment: One commenter urged that grievances and appeals be classified according to the type of denial (for example, a clinical determination should be subject to appeal). The commenter stated that this differentiation is important because denials of service may have a critical impact on the patient's health, unlike denials of payment and general grievances.

Response: In this final rule with comment period (§ 438.400(b)) the definition of "action" distinguishes what is subject to appeal from what is addressed as a grievance. In addition, we also distinguish between grievances involving quality of care issues and other grievances. Section 438.406(a)(7)(ii) of this final rule with comment period provides that grievances involving a clinical issue or a grievance of a denial of a request for expedited appeal must be decided by a health care professional who has

appropriate clinical expertise in treating the enrollee's condition or disease.

2. General Requirements (Proposed § 438.402)

Proposed § 438.402 stated the general requirements of the MCO and PHP grievance system, and required MCOs and PHPs to have a grievance system that includes a complaint (now referred to as grievance) process, a grievance (now called appeal) process, and a link to the State's fair hearing system.

Proposed § 438.402 required the MCO and PHP to—

- Base its complaint (now grievance) and grievance (now appeal) process on written policies and procedures that, at a minimum, meets the conditions set forth in this subpart.

- Obtain the State's written approval of the grievance (now appeal) policies and procedures before implementing them.

- Provide for its governing body to approve and be responsible for the effective operation of the system;

- Provide for the governing body to review and resolve complaints (now grievances) and grievances (now appeals) unless it delegates this responsibility to a grievance committee.

- Provide through its grievance (now appeal) process clearly explained steps that permit the enrollee to appeal to the MCO, PHP, and to the State.

- Allow the enrollee a reasonable time to file an appeal, include for each step timeframes that take into consideration the enrollee's health condition and provide for expedited resolution of grievances (now appeals) in accordance with § 438.410, not substitute for the State's fair hearing system.

- Permit enrollees to appear before the MCO and PHP personnel responsible for resolving the grievance (now appeal), and provide that, if the grievance (now appeal) resolution decision is wholly or partly adverse to the enrollee, the MCO or PHP submits the decision and all supporting documentation to the State as expeditiously as the enrollee's health condition requires but no later than the following for—

- ++A standard resolution, no later than 30 days after receipt of the grievance (now appeal) or the expiration of any extension; and

- ++An expedited resolution, no later than 24 hours after reaching the decision.

Additionally, the State must either permit the enrollee to request a State fair hearing on a grievance (now appeal) at any time, or provide for a State fair hearing following and MCO or PHP

adverse decision on the matter that gave rise to the grievance (now appeal).

Comment: Given the provision in proposed § 438.402(a) requiring a link between the grievance system under section 1932(b)(4) of the Act and the State fair hearing system, the right under proposed § 438.402(d) to a fair hearing (either directly, or following an adverse MCO or PHP decision), and language in the preamble to the proposed rule requesting comments on whether fair hearing timeframes should be revised, several commenters were prompted to comment generally on the State fair hearing process. Many of these commenters recommended substantial revisions to HCFA's State fair hearing regulations, and requested that HCFA convene a meeting to discuss proposed changes to those recommendations. The commenters agreed that the State fair hearing process needs to be revised, but there was no consensus on how it should be revised. Several commenters wanted Medicaid to adopt the same standards for the State fair hearing process that were proposed for the MCO and PHP internal grievance process. Other commenters wanted an expedited State fair hearing. Commenters suggested various timeframes which ranged from 24 hours to 15 days. Finally, one commenter wanted HCFA to eliminate extensions for State fair hearings provided for in the Medicaid manual.

Response: We have decided to postpone consideration of major modifications to the State fair hearing regulations generally and to develop an NPRM to propose changes to the State fair hearing rules. At that time we will also review the provisions in the Medicaid Manual related to fair hearings. We will consider using the negotiated rule-making process in developing this NPRM.

In response to these and other comments, however, this final rule with comment period does require, under §§ 438.408(j)(3)(ii) and 431.244(f)(2), expedited State fair hearings when a service has been denied and a delay in receipt of that service could jeopardize the enrollee's health. States must conduct a State fair hearing and issue a final decision on these cases as expeditiously as the enrollee's health condition requires, but no later than 72 hours from receipt of the appeal.

Comment: Several commenters requested modifications to the State fair hearing regulations to allow MCOs and PHPs to become a party to the hearing. The commenters believed that the MCO or PHP should have an opportunity to present its position on the dispute at the hearing. Other commenters noted that

several States have not recognized MCOs and PHPs as parties to State fair hearing.

Response: We agree that MCOs and PHPs should be parties to the State fair hearing and in response to this comment, have provided for this in the final rule with comment period at § 438.408(j)(2). As parties to the hearing, we believe it is clear that MCOs and PHPs are subject to the hearing decision. As parties to the hearing it will also be clear that an MCO or PHP can present its position at a State fair hearing which we think is appropriate because the MCO or PHP will be liable for providing and paying for a service if the State fair hearing officer overturns the decision.

Comment: Several commenters noted that some State fair hearing officers do not believe that they have jurisdiction over MCOs and PHPs and believe they lack authority to order MCOs and PHPs to take a particular action. These commenters believed it would be very helpful for the regulations to provide that both the agency and the State fair hearing officer have authority to order the MCO or PHP to provide a required service or perform a corrective action, including reimbursing for services.

Response: We agree with commenters that State fair hearing officers should have jurisdiction over Medicaid MCOs and PHPs. As just noted, we have provided at § 438.408(j)(2) that MCOs and PHPs are parties to a State fair hearing appealing their decisions. With this addition, we think it will be clear that the presiding officer of the proceeding has jurisdiction over a party to the hearing.

Comment: One commenter recommended that an expedited State fair hearing be available to Medicaid beneficiaries who are not enrolled in managed care. The commenter noted that increasingly, fee-for-service arrangements use prior authorization processes, and as in managed care, the care under review may be urgently needed.

Response: While we believe there is merit in the commenter's suggestion from a policy perspective, we are not amending the State fair hearing regulations to provide an expedited hearing in fee-for-service situations, because the proposed regulation addressed Medicaid managed care, not the fee-for-service delivery system. We plan to develop an NPRM to revise the State fair hearing regulations as they pertain to fee-for-service and managed care. When this NPRM is published, the public will be invited to comment on these proposed rules. In this final rule with comment period we revise the State fair hearing regulation only to

provide an expedited timeframe for resolution of appeals involving MCO or PHP denials of services in situations that require expedited resolution. This matter was put before the public in our proposed rule.

Comment: Several commenters recommended that HCFA establish more specific standards for the State fair hearing processes, including specific standards regarding the qualifications of hearing officers. Commenters were concerned with State use of hearing officers who lack adequate understanding of clinical issues when a hearing involves a denial based on lack of medical necessity.

Response: We have not addressed this concern in this final rule, comment period. As with judicial review, the presiding officer is usually not medically trained. It is the responsibility of both parties to explain the matter in a way that can be understood by the adjudicator. Parties may retain experts to present technical issues. In addition, as provided in section 431.420, provides that if the hearing officer finds it necessary, they may order an independent medical assessment to be performed at State expense.

Comment: Several commenters recommended that we require States to consult with beneficiaries, advocates, and the State MCAC when developing State grievance requirements.

Response: In § 438.202(c) we require that States provide for the input of beneficiaries and stakeholders in the development of their quality strategies. Grievance and appeal procedures must be addressed as part of State quality strategies. This provides an opportunity for beneficiary and stakeholder input. We are not specifying the mechanisms States must use to receive input. Therefore, States may, but are not required to, consult with their MCAC on grievance requirements.

Comment: Several commenters supported the requirement in proposed § 438.402(b)(3) that the MCO and PHP grievance process must be approved by the MCO's or PHP's governing body. Other commenters were concerned that requiring the governing body to approve and be responsible for the operation of the process was unnecessary and inefficient. They believed that the State should determine whether MCOs and PHPs have appropriate staff to handle the grievance process.

Response: Our intent is to ensure the involvement of individuals with authority to direct corrective action should systemic changes be required. The regulations at § 434.32, that this regulation replaces, required that the

MCO ensure the participation of individuals with authority to require corrective action. We retain this requirement in this final rule with comment period. The actual processing of grievances and appeals can be delegated to a grievance committee of less senior employees.

Comment: Several commenters thought that the 90-day period for filing appeals following the notice of action was burdensome to MCOs and PHPs, because MCOs and PHPs need more timely filing by enrollees in order to assess their potential payment liabilities. Another commenter noted that § 431.221 of the current regulation, that is cited in proposed § 438.402(c)(1)(ii) provides that the State must allow for a reasonable time, not to exceed 90 days for beneficiaries to file an appeal. One commenter implied that the proposed rule states that the State must allow a minimum of 90 days for filing of appeals is inconsistent with the current regulation and that application of the proposed rule would result in different standards for managed care and fee-for-service appeals.

Response: Our intent in the NPRM was to mirror the filing timeframes for the State fair hearing, that is, a reasonable amount of time up to 90 days. This is reflected in the parenthetical in proposed § 438.402(c)(1)(ii) stating "as provided under the fair hearing process at proposed § 431.221." Our reference to 90 days was incorrect because it did not reflect the fact that the regulation we intended to incorporate provided for "up to" 90 days. We therefore have revised this final rule with comment period to mirror § 431.221. In addition, we have incorporated in the regulation the longstanding policy at § 2901.3 of the Medicaid Manual that beneficiaries be given a minimum of 20 days to file an appeal. We believe that this policy more specifically defines the requirement in the current regulation that beneficiaries be given "a reasonable amount of time" to file an appeal. We believe that placing this requirement in this final rule with comment period will increase public awareness of this standard.

In the notice of action, MCOs and PHPs must include information on the deadline for filing an appeal. Further, in States that do not require that enrollees appeal first through the MCO or PHP grievance system, the notice of action must also state that the enrollee may appeal directly to the State for a fair hearing.

Comment: We received several comments concerning the manner in

which grievances and appeals may be filed.

One commenter recommended that an enrollee be permitted to submit a grievance or appeal either orally or in writing. If the decision is made to require that grievances and appeals be submitted in writing, the commenter urged that MCOs and PHPs be required to provide assistance in the process. The commenter believed that requiring Medicaid enrollees to submit grievances and appeals in writing may deprive some beneficiaries of their rights if they are not proficient in English, have little formal education or a low level of literacy, or have disabilities that prevent or make writing difficult.

Another commenter suggested that staff designated to receive and resolve grievances or appeals (proposed § 438.406(a)) be charged with reducing to writing any oral request for official review or remedial action. The commenter felt that the regulations should require MCOs and PHPs to record oral grievance and appeal requests.

One commenter suggested that we clarify whether the enrollee or the MCO or the PHP must put in writing the request for expedited resolution. Another commenter noted that the requirement for written confirmation of an oral request for expedited resolution can be a barrier to an enrollee who has severe and persistent mental illness, and who is in a period of cognitive deficit. This commenter recommended that an oral request should be allowed to suffice in this circumstance.

One commenter stated that we should delete all reference to oral requests because information received orally may be misconstrued. Another commenter stated that the regulation should include language requiring MCOs and PHPs to record oral grievances.

Response: For standard appeals, as is the case for State fair hearing requests, in this final rule with comment period, we are providing in § 438.402(c)(2) that enrollees may start the appeal clock with an oral request but must follow it with a written request. A written appeal best documents the issue being appealed. This requirement cannot be used to limit enrollees' rights. MCOs and PHPs are required in § 438.406(a)(3) to provide reasonable assistance to enrollees who file grievances or appeals, including assistance with the completion of forms. Our requirement should not preclude Medicaid enrollees with legitimate claims from pursuing those claims because of language or physical barriers. In expedited situations, this final rule with comment period provides that the enrollee is not

required to place the appeal in writing. In § 438.410(c)(3) we require that MCOs and PHPs record all expedited oral appeals in writing.

Comment: Some commenters interpreted the NPRM to require that all denials of service authorization be automatically transferred to the MCO and PHP grievance system for processing as an appeal. They believed that a requirement would be too burdensome.

Response: We did not intend that all service authorization denials automatically become appeals. Proposed § 438.402(c)(1)(i) provides for the "enrollee to appeal" to the MCO and to the State. Even the expedited appeal process under proposed § 438.410 provided in paragraph (a)(1) apply only when "an enrollee makes the request". In this final rule with comment period, we continue to provide that the enrollee must appeal service authorizations denial.

Comment: We received many and varied comments on proposed § 438.402(c)(4), that required MCOs and PHPs to forward information to the State on appeal decisions that were adverse to the beneficiary (in whole or part).

Several commenters believed that the regulation should not only require the transfer of information to the State, but that this should automatically start the process for a State fair hearing.

Similarly, several commenters thought that HCFA should provide that a denial of a request for expedited appeal be automatically appealed to the State agency for a fair hearing. Several commenters noted that the 90-day limit for completion of the State fair hearing would be difficult to meet unless the State starts the fair hearing process upon receipt of the information from the MCO or PHP. Other commenters felt that this requirement would create an overwhelming amount of paperwork and that States would prefer to receive the information at the time a State fair hearing is requested. Several commenters thought that the 24-hour turnaround timeframe for an MCO or PHP to forward the paperwork for an expedited hearing decision is too short and unrealistic given holidays. Several commenters believed that a complex system would be costly and prone to error. One commenter supported the practice of one State that requires MCOs to report only those grievances that are unresolved after 30 days, noting that the State reviews other grievances as part of the annual MCO audit process. One commenter thought that beneficiaries should have to affirmatively request a State fair hearing and that this is sufficient to guarantee the appeal rights

of enrollees. One commenter noted that the States are already able to get this type of information through the audit process.

Response: We have revised the requirement for MCOs and PHPs to automatically forward information to the State on appeal decision adverse to the beneficiary to require this only in the case of decisions that are expedited. For these cases, we believe that it is necessary for the State to receive the file and supporting documentation so that it can begin the State fair hearing process as soon as an appeal is filed. Because we have included a requirement for States to expedite the fair hearing process in these cases and decide the appeal within 72 hours of receiving the request, it is essential that they not lose time by needing to request the appeal file from the MCO or PHP. Also, because of the requirement for an expedited fair hearing, we continue to require that the file be forwarded within 24 hours.

For standard appeals, we have removed the requirement that the file be forwarded automatically. We are persuaded by the comment that this requirement would be burdensome on MCOs, PHPs, and States, and is not necessary to protect beneficiaries. In this final rule with comment period, we require MCOs and PHPs to forward within 72 hours files requested by the State. States will request these files upon receipt of a request for a fair hearing or for a standard appeal.

Comment: Several commenters expressed the view that in proposed § 438.402(c), HCFA has taken an important step by recognizing the need for uniform timeframes across managed care programs, and that setting timeframes recognizes the need for MCOs and PHPs to conclude their reviews promptly. However, these commenters recommended that the final rule with comment period should explicitly provide that MCOs and PHPs must resolve appeals within a timeframe that would allow the State agency to proceed with a State fair hearing, if applicable, and ensure a final decision within 90 days of the initial appeal. The commenter believes that this is needed so that beneficiaries, States, and MCOs and PHPs will clearly understand that the timeframe for final administrative action is not affected by the appeal process at the MCO and PHP level. One commenter expressed the opposite view and requested that the regulations clarify that the time allowed for State fair hearing decisions under 42 CFR 431.244(f) does not begin until a Medicaid beneficiary requests a State fair hearing following the conclusion of the MCO and PHP appeal process. This

commenter expressed the opinion that if both the MCO and PHP appeal process and the State fair hearing process are to have sufficient time to meet all the requirements imposed on each of them, then both should not have to be completed in the time allowed for one.

Response: We believe that it is important to maintain a total maximum time period for appeals to be resolved at the MCO and PHP level and by the State at the fair hearing level. However, we recognized that the 90-day timeframe for the completion of both reviews discussed in the preamble of the proposed rule is not workable because the time allowed the MCO or PHP to complete action (30 days with a possible 14 day extension), together with the time allowed by the State for a beneficiary to file a fair hearing request (up to 90 days), may exceed 90 days. Therefore, in this final rule with comment period, we have retained a total of 90 days for consideration of an appeal, but we are providing that this period be interrupted between the time the MCO issues its notice of decision and the beneficiary files for a State fair hearing. We provide that the State has 90 days to complete the State fair hearing process minus the number of days taken by the MCO or PHP to resolve the initial appeal. In addition, in order to ensure that MCO and PHP review does not unduly delay the appeal process, we have provided that if an MCO or PHP does not complete its review within the required timeframes that this becomes an adverse action.

Comment: Several commenters agreed with our statement that the MCO and PHP grievance process is not a substitute for the State fair hearing process.

Response: We agree with the commenter that it is critical that all beneficiaries, including those enrolled in MCOs or PHPs, have access to the State fair hearing process rights provided for under section 1902(a)(3) of the Act.

Comment: Several commenters wanted specific mention of members' right to a second opinion, and would like that right mentioned in adverse action notices. The commenters believed that members should have a right to out-of-plan, unbiased second opinions.

Response: In response to this and other comments, we explicitly provide in § 438.206(d)(3) of this final rule with comment period for the right to a second opinion in the network, or outside the network if an appropriate provider is not available within the network, and this right is referenced in § 438.100(b)(3). We do not provide the

right to a second opinion out of network if there is another provider within the network qualified to provide a second opinion. We believe that this is consistent with the concept of holding the MCO or PHP accountable for services to their enrollees. This final rule with comment period provides that enrollees must be informed of the right to a second opinion as part of enrollment information and we therefore, do not believe it is necessary to require that it be included in the notice of action.

Comment: Several commenters supported allowing the State to choose whether to require that enrollees exhaust MCO and PHP grievance procedures prior to appealing to the State for a fair hearing. Other commenters believed that the regulations should not permit States to require the exhaustion of the internal MCO and PHP grievance process prior to permitting access to the State fair hearing process. These commenters felt that requiring the exhaustion of an MCO's and PHP's internal grievance process would inevitably lead to delays, confusion about timing, and a denial to the right to a timely State fair hearing. Commenters also believed that the internal MCO and PHP process was not impartial because the MCO or PHP has a financial interest in the outcome. Finally, one commenter argued that forcing individuals with disabilities to navigate the administrative procedures of the grievance process would be inconsistent with the provisions of the Americans with Disabilities Act (ADA), because in this commenter's view, the ADA prohibits requiring qualified individuals with disabilities to complete administrative processes that cannot be directly linked to the provision of the services offered.

Response: We continue to believe that a State should be permitted to require Medicaid managed care enrollees to exhaust MCO and PHP appeal remedies prior to accessing the State fair hearing process. This not only gives the MCO or PHP an opportunity to reconsider its decision, if the decision is reversed, it reduces the burden on the fair hearing system. We do not understand the commenter's contention that requiring exhaustion in the case of people who have disabilities necessarily would violate the ADA. While we would agree that exhaustion would not be required in the case of a claim under the ADA itself, the exhaustion requirement at issue here involves an appeal of an "action" (for example, a denial of payment or coverage). It is true that the ADA requires that reasonable accommodations be made for people

who have disabilities in the conduct of the MCO or PHP level grievance process, and the extent of an obligation is based on the facts and circumstances of the individual case. It is not clear, however, why it would be any more of a burden for an individual who has a disability to file an appeal with their MCO or PHP than it would be to file a request for a State fair hearing. If anything, it might be easier, because the enrollee would have an existing relationship with the MCO or PHP. MCOs and PHPs should be aware of their obligations under the ADA to accommodate people who have disabilities in the grievance process. We do not believe that requiring enrollees who have disabilities to use the same process as other enrollees violates the ADA.

Comment: One commenter questioned HCFA's statutory authority for the requirement that the State fair hearing process be available to review MCO and PHP determinations. This commenter noted that the BBA does not mention the State fair hearing process and infers that the Congress intended that the MCO and PHP appeal process alone address enrollee appeals. Another commenter believed that open access to State fair hearings essentially would negate the grievance procedures within an MCO or PHP.

Several commenters applauded HCFA for providing detailed guidance to MCOs and PHPs on establishing grievance processes. One commenter felt that there also is currently little, if any, link between the MCO and PHP appeal process and the State fair hearing process. Beneficiaries are informed of both options, but are not advised as to whether they must exercise these options in a particular order or whether one "trumps" the other. One commenter believed that allowing the State to choose to provide a fair hearing only after running the course of the MCO's and PHP's grievance system could be the equivalent of denying a fair hearing, which is a beneficiary right. This commenter stated that better mechanisms to coordinate simultaneous participation in both the MCO and PHP and State systems should be devised.

Response: As discussed above, the requirements in subpart F are based only in part on the internal grievance requirements in section 1932(b)(4) of the Act. To the extent these regulations apply to the MCO internal grievance process, they are grounded on section 1932(b)(4) of the Act. To the extent these regulations involve the State fair hearing process, however, including the requirement that MCO and PHP internal grievance processes interface with the

State fair hearing process, they are based on the fair hearing requirements in section 1902(a)(3) of the Act. The State fair hearing process guarantees all Medicaid beneficiaries an independent hearing. At the time the original fair hearings regulations were promulgated, beneficiaries were not enrolled in managed care arrangements as they are today. Even if the BBA had never been enacted, there would have been a need to promulgate regulations applying the fair hearing rights that all beneficiaries have in the managed care context. We took the opportunity to do so in the proposed rule implementing the grievance requirements in section 1932(b)(4) of the Act. We believe that these regulations are clearly authorized. With respect to the commenter's argument that allowing States to require exhaustion could be "the equivalent" of denying a fair hearing, which is a beneficiary right, this is clearly not the case. As noted above, in cases that exhaustion is required, if the MCO or PHP does not favorably resolve the case by the timeframe provided, the case is automatically forwarded to the State for a fair hearing, and a decision must be made within the same 90-day timeframe that would apply if the fair hearing was requested directly. States should work with MCOs, PHPs, and enrollees to ensure that enrollees understand the linkage between the MCO and PHP grievance processes and the State fair hearing process.

Comment: Several commenters thought that the proposed regulations should preserve beneficiaries' State fair hearing rights, not expand them to include appeals from unresolved complaints, that these commenters saw as a burden on State fair hearing systems. They requested that proposed § 438.402(d) be amended to restrict the right to a State fair hearing to enrollees appealing MCO and PHP decisions denying, reducing, or terminating medical care for an enrollee. Other commenters requested that HCFA confirm that the State fair hearing process applies only to issues that involve claims for services or denials of coverage. These commenters noted that current regulations at § 431.200 provide that the hearing right arises when the "Medicaid agency takes action to suspend, terminate, or reduce services." In the commenter's view, quality or access grievances that do not also involve the denial of services should not be appealed through the State fair hearing process and should be pursued through the MCO's and PHP's internal grievance process or with the External Quality Review Organization with

which the State contracts. These commenters also stated that medical treatment decisions made by providers should not be subject to the State fair hearing process.

Response: We agree that the scope of issues subject to the State fair hearing process should not be as broadly defined as in the NPRM. This final rule with comment period specifies that actions, as defined in the regulation, are subject to appeal at the MCO or PHP, and to the State for a fair hearing. This includes a denial of a service, a limitation on receipt of a service, or the reduction, suspension, or termination of a service. We recognize that a provider may deny a requested service for a variety of reasons, including that the provider does not believe the service is medically appropriate for the enrollee. However, because of the financial arrangement that provides a capitated payment to an MCO or PHP for services provided to an enrollee, we believe that the enrollee needs to have recourse through an appeal if a requested service is not provided.

Comment: One commenter contended that the option for the State to require exhaustion at the MCO and PHP level or allow for direct appeal to a State fair hearing could be interpreted to allow an enrollee to file an appeal after the conclusion of the 90-day timeframe for filing.

Response: As discussed above, this final rule with comment period clearly provides that the enrollee has a reasonable time period specified by the State, not less than 20 days and not to exceed 90 days, to file an appeal with the MCO or PHP, or with the State following an unsuccessful appeal to the MCO or PHP, or initially with the State if the State does not provide for exhaustion. If an enrollee does not file an appeal with the MCO, PHP or State, the enrollee would have waived their right to an appeal.

Comment: Several commenters asked for clarification on how Medicare-Medicaid dual eligible enrollees would access the Medicare and Medicaid external hearing processes.

Response: As in the fee-for-service system, dually eligible Medicare-Medicaid beneficiaries have the appeal rights provided for under both programs, to the extent the particular program has paid for the service in question. If a dually-eligible enrollee is enrolled in a Medicare+Choice plan, then the Medicare+Choice appeals process would apply to benefits covered under that program, including otherwise non-Medicare benefits covered under the Medicare+Choice plan. When a dually eligible beneficiary is enrolled in

a Medicaid MCO or PHP, and is denied a service covered by Medicare, the beneficiary similarly has Medicare appeal rights, as well as Medicaid rights to the extent that Medicare applies a different standard from Medicaid. In the case of an MCO or PHP denial of a Medicaid service not covered by Medicare, the appeal rights in subpart F apply. In all cases, the notice of action will inform the beneficiary of how to file an appeal.

Comment: Commenters requested that HCFA amend the language in the regulation to say that the MCO and PHP must "have," rather than "provide for," a link to the State fair hearing process.

Response: In this final rule with comment period at § 438.402(a) we define "grievance system" as including the MCO and PHP grievance and appeal processes, and access to the State's fair hearing system. We believe this change clearly establishes the link from the MCO and PHP processes to the State fair hearing process.

Comment: Several commenters asked that HCFA require States to allow providers the right to challenge MCO and PHP decisions on behalf of enrollees.

Response: Section 1932(b)(4) of the Act expressly requires that MCOs have a grievance procedure in place under that an enrollee "or a provider on behalf of an enrollee" can "challenge the denial of coverage or payment" by an MCO. We agree with the commenters that States are required to allow providers the right to do so, on behalf of an enrollee. In response to this comment, we have added at § 438.402(c)(1) a provision to permit the provider to file a grievance or appeal or request a State fair hearing on behalf of an enrollee with the enrollee's written consent. This condition that the enrollee provide written consent for the provider to act on their behalf reflects policy communicated in a letter to the State Medicaid Directors dated February 20, 1998 that stated, the enrollees' consent is needed if a provider submits an appeal on their behalf. We note that enrollees may be financially liable for the costs of services when provided as a continued benefit during appeal. Therefore, it is important that enrollees understand the possible implications of an appeal and consent to the appeal.

Comment: Commentators urged that HCFA require States to establish a system for administrative appeals that providers could appeal adverse network selections, payments, or other administrative actions that directly affect providers but that only indirectly affect beneficiaries.

Response: The Congress spoke to issues involving MCO relationships with subcontracting providers in provisions: (1) regulating physician incentive arrangements in section 1903(m)(2)(A)(x) of the Act, (2) prohibiting discrimination based on licensure in section 1932(b)(7) of the Act, prohibiting restrictions of provider-enrollee communications in section 1932(b)(3) of the Act, and in section 1932(b)(4) of the Act providing for a provider to file a grievance on behalf of an enrollee. We believe that if the Congress had intended that providers have specific appeal rights under Federal law, these would have been provided for in section 1903(m) or section 1932 of the Act. We believe that this is best left for providers and MCOs or PHPs to negotiate. However, this regulation does not prohibit a State from granting providers the right to challenge MCO and PHP decisions affecting them.

Comment: One commenter suggested that if a decision to deny an item or service is reversed, the MCO or PHP should be required to review all similarly situated beneficiaries and make the item or service available to them as well, regardless of whether the beneficiaries have filed appeals.

Response: We believe that decisions on appeals are so fact-specific that it would not be practical to apply an across the board rule. However, where a State requires MCOs and PHPs to extend the benefit of a hearing decision or court order to individuals in the same situation as those directly affected by the decision or order. Under § 431.250(d), FFP may be claimed for such expenditures.

3. Notice of Intended Action (Proposed § 438.404)

Under proposed § 438.404, MCOs and PHPs were required to provide enrollees timely written notice of a decision to deny, limit, reduce, delay or terminate a service, within timeframes specified in § 438.310, and in the notice explain the action the MCO or PHP intends to take, the reasons for the action, any laws and rules that support the action, the enrollee's right to file a grievance with the MCO or PHP, the enrollee's right to request a State fair hearing, the circumstances under which expedited grievance review is available and how to request it, how to file grievances (called complaints in proposed § 438.404), appeals (called grievances in proposed § 438.404), and State fair hearing requests; that if an appeal is filed, the enrollee has a right to appear in person before the MCO or PHP personnel assigned to resolve the appeal; the circumstances under which benefits

will continue pending resolution, how to contact the designated office described in § 438.406(a), and how to obtain copies of enrollee's complete records.

Comment: We received many comments regarding notice to enrollees. Several commenters believed that a strict application of this principle would be burdensome, especially if applied to the following: (1) Prescription drugs; (2) decisions of primary care physicians (PCPs) made without involvement of the MCO or PHP utilization control unit; (3) MCO and PHP decisions to authorize a limited number of visits; and (4) denials of payment to a specialist when the visit was without a referral by a PCP. One commenter pointed out that denials are typically the result of provider administrative issues involving coding practices, contractual fee schedules, and timely filing. The commenter recommended that the regulation not require that notice be sent to members as a result of provider administrative issues.

One commenter found this provision fairly consistent with current Medicaid fee-for-service requirements, except for the requirement to give notice of a "delay of service." This commenter expressed concern that a notice would be required when a utilization management representative asks for additional information or tests prior to approving a service, as this would confuse the member and create an administrative burden for the MCO or PHP. Several commenters strongly agreed that notice should be provided in all instances when an enrollee's authorization is denied or limited or a service already provided to the enrollee is reduced, terminated, suspended, or delayed.

Several commenters wanted the definition of grievance in the proposed rule (containing grounds for a grievance now included in the definition of "action" in this final rule with comment period) to be expanded to include a determination by the MCO or PHP to deny a service because the MCO or PHP believes that the service is not included in its contract. Similarly, the commenters wanted a State's denial of a service included if the State's reason for denial is because the service is to be provided by the MCO or PHP.

Response: In this final rule with comment period, we define "action," and specify that notice must be sent to enrollees any time an action occurs. We believe that it is an essential enrollee protection that they be sent a notice of all actions, including those that the commenter believes to be burdensome

to the MCO and PCP. We define "action" as a denial or limitation of a service authorization request; a reduction, suspension, or termination of a service previously authorized; a denial of payment for a service by an MCO, PHP, or its providers; the failure to furnish, arrange, or provide for payment in a timely manner; or a decision by the State not to grant an enrollee's request to disenroll from the MCO or PHP. In addition, an action includes, for residents of rural areas with only one MCO or PHP, the denial of an enrollee's request to go out of plan. Actions may be taken by the MCO, PHP, or its providers.

The terms "deny or limit" apply when the service requested by the enrollee or provider on behalf of the enrollee is not yet authorized or referred by either the MCO's or PHP's primary care physician, or otherwise authorized by the MCO or PHP in whole or in part. Under this final rule with comment period, a notice of service denial must be sent to the enrollee even if the MCO or PHP believes that its contract does not require that it provide the service. Without this requirement, the enrollee would have no recourse if the MCO or PHP denied the service in error. In this final rule with comment period, we have deleted the reference to a "delay" in service. We provide in § 438.210 that requested services must be approved or denied within 14 days. A request not acted on within this timeframe is considered a denial and a notice of denial must be sent to the enrollee. Extensions to the 14-day time period to act on a service authorization can be requested by the enrollee or by the MCO or PHP when taking additional time is in the best interest of the enrollee. The terms "reduction, suspension, or termination of services or denial of payment" are the same as the traditional fee-for-service definitions of those terms, that is, when a service has been authorized or is being provided and the MCO, PHP, or its provider reduces the number or frequency of the service, stops providing the service prior to the end of the time that was originally authorized, stops providing the service for a period of time, or refuses to pay for a covered or authorized service. The final two criteria in the definition of an action give managed care enrollees a remedy when the State denies a request for disenrollment or the State, MCO or PHP denies the request of an enrollee who is enrolled in a single rural MCO or PHP to go out-of-plan.

Comment: Some commenters contended that MCOs and PHPs do not always know when their providers deny

services, making it difficult for them to comply with the notice requirements.

Response: MCOs and PHPs must have a system in place to identify these situations, and to ensure that notice is provided. In this final rule with comment period, we allow providers of MCOs and PHPs to provide only general information in the notices they give to enrollees. When this option is chosen, the MCO or PHP must send the enrollee another notice that provides information specific to the enrollee's situation. (See § 438.404(d)(2)). To meet this requirement, MCOs and PHPs will need to have systems in place to find out from their providers when an enrollee has been denied a service or had a service reduced, suspended, or terminated.

Comment: Several commenters believed that Medicaid beneficiaries do not file grievances and appeals very often because of the complex requirements imposed by States, MCOs and PHPs. These commenters further stated that a system established to facilitate resolution of grievances or appeals should ensure that beneficiaries are encouraged to voice their dissatisfaction without fear of reprisal or consequences of any kind.

Response: To ensure beneficiary rights to appeal, in response to this comment, in this final rule with comment period at § 438.404(b), we specify what must be included in the notice of action. This includes information about the right to appeal, how to file an appeal, how to obtain assistance with filing, and that filing an appeal will not negatively affect the way enrollees are treated by MCOs, PHPs, their providers, or the State.

Comment: Several commenters were concerned that enrollees' rights to notice may be violated if HCFA did not prohibit States from delegating responsibility for State fair hearing notices to MCOs and PHPs. They believed that until States, MCOs, and PHPs can better ensure timeliness in processing appeals as well as full constitutional protections, there should be no delegation of the State's responsibility for providing a due process notice to beneficiaries.

Response: We have not accepted this recommendation because we believe that States may find MCO or PHP issuance of State fair hearing notices the most efficient and timely way to get the information about State fair hearing rights to enrollees when an action is taken by the MCO or PHP.

Comment: Several commenters requested that § 438.404 be amended to specifically address situations in which an MCO or PHP intends to deny, limit,

reduce, delay, or terminate a service, or deny payment for a service in whole or in part.

Response: The current appeal notice requirements require a notice any time there is an "action", that can include the reduction of services for a Medicaid-eligible individual. Similarly, the notice requirements in this regulation apply when MCOs or PHPs intend to deny, limit, reduce, suspend, or terminate a service, or deny payment for a service in whole or in part. The terms "reduce" and "limit" were included in the notice requirements to cover instances in which already authorized services or requested services, respectively, were decreased or diminished in part.

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

Response: We believe that the expiration of an approved number of visits does not constitute a termination for purposes of notice and continuation of benefits. When a prescription (including refills) runs out and the enrollee requests another prescription, this is a new request not a termination of benefits. In these circumstances, the MCO or PHP would not need to send a notice or continue benefits pending the outcome of an appeal or State fair hearing. If the enrollee requests a re-authorization that the MCO or PHP denies, the MCO or PHP must treat this request as a new request for service authorization and provide notice of the denial or limitation. However, in this situation, if the enrollee appeals the action, benefits would not be continued.

Comment: Several commenters pointed out that HCFA exclusively relies on a written notice to meet the enrollees' needs. They found this policy insufficient, given language, literacy, and disability barriers. Other commenters noted that some States require MCOs and PHPs to send notices by certified mail, and believed that this

was very costly, and often unsuccessful in reaching enrollees.

Response: We recognize that Medicaid beneficiaries often face language, literacy, and disability barriers. To address this issue, we have applied the information requirements found at § 438.10, including the language requirements in § 438.410(b) to the notice requirements. We also require that MCOs and PHPs mail notices to an authorized representative designated by the enrollee. We are not requiring States to provide notice in formats other than in writing, except in the case of notices about expedited hearings, that must be provided orally due to time considerations. In this final rule with comment period, we do not prohibit States from setting additional requirements for MCOs and PHPs concerning notices.

Comment: One commenter believed that HCFA has underestimated the true burden associated with MCO and PHP notices.

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

Comment: One commenter requested that we adopt the notice timeframes in part 431, subpart E for the situations covered by those sections, and allow States to set other notice timeframes. Several commenters disagreed with the use of a 10-day notice period prior to the date of action. They found that period to be too long because the medical condition of the enrollee may require quicker action. They also suggested that HCFA disregarded the exceptions to the 10-day rule set forth in § 431.213(h). That regulation allows for notice to be sent on the date of the action when a change in the level of medical care is prescribed by the beneficiary's physician. This exception should be interpreted to give MCO's and PHP's the flexibility to give notices, in specified cases, immediately prior to the action being taken.

Response: This final rule with comment period does not change the current regulation at § 431.213 and is consistent. Under § 438.404(c)(1) of this final rule with comment period, timeframes for notices for the reduction, suspension, or termination of previously authorized services are governed by the State fair hearing regulations found in 42 CFR 431 subpart E. While some MCOs and PHPs may find the advance notice requirement inappropriate, there are exceptions to advance notice, that allow notice to be given on the date of the action (see § 431.213). These exceptions would cover situations that a provider believes an immediate change in care is appropriate for the health

condition of the enrollee, for example, the reduction in dosage of a prescription drug.

Comment: We received several comments regarding the elements of a notice. Several commenters suggested that the written notice requirements of proposed § 434.404 be modified to mirror the existing State fair hearing regulations. Other commenters pointed out that HCFA is requiring a great deal of information in the notices required under proposed § 434.404. They suggested deleting some of the requirements. One commenter believed that information on continuation of benefits should be provided if a service is terminated or reduced. Commenters requested that information be provided in the notice about how to contact the MCO or PHP to receive help in filing an appeal. One commenter requested that the rule require MCOs and PHPs to notify the enrollee of their right to expedited review.

Several commenters wanted the content and time line requirements clarified in the notice and a full explanation to be provided of the laws and rules that support the action, rather than a citation to a particular statute or regulation. These commenters requested clarification that the enrollee has a right to obtain other relevant information germane to the resolution of the enrollee's issue. These commenters further requested a clarification that notices must specify the reasons or criteria used in determining that the request was not medically necessary.

Response: We agree that notices given by MCOs and PHPs should, at a minimum, contain the information required by the State fair hearing notices. We have provided for this in this final rule with comment period. However, we have retained the requirements specified in the NPRM concerning the content of the notice, including information about the circumstances under which an enrollee may receive expedited review, and the reason for the action. We believe that requiring the inclusion of the reason for the action will provide the enrollee with information to understand why it occurred, and help the enrollee to decide whether to appeal. We made one change to the NPRM requirements to remove the requirement that the notice specify that the enrollee may appear before the person assigned by the MCO or PHP to resolve the appeal, as we have deleted this requirement for MCOs and PHPs in this final rule with comment period.

In response to the commenter who favored inclusion of information in the notice about continuation of benefits

when benefits are being terminated or reduced, we have added a requirement that the notice state that an enrollee may be held liable for payment for services if the enrollee requests continuation of benefits during appeal. This provides the enrollees with a more complete picture of what the continuation of benefits provision means to them. We also agree with the commenter favoring a requirement that the notice contain information on how to obtain assistance from the MCO or PHP in filing an appeal, and have provided for this in § 438.404(b)(8) of this final rule with comment period.

Comment: Several commenters believed that we should require MCOs and PHPs to provide enrollees with copies of their records within 24 hours of the request and, if the member (or authorized representative) is unable to pick up the copies, that they be mailed the next business day.

Response: In § 438.224 we provide that MCOs and PHPs must ensure that enrollees may request and receive a copy of their medical records and information. MCOs and PHPs should allow members to obtain copies of their medical records in a timely manner to allow the enrollee to submit information in support of their appeal. However, we have not accepted the commenter's suggested deadline, as we believe that this would be impractical and create too great a burden for MCOs and PHPs. We believe that States should have the flexibility to decide whether to establish deadlines in this area.

Comment: Several commenters believed that the notice should explain that the enrollee may be represented by counsel or a legal representative during the grievance process and include the address and phone number for free legal assistance. They noted that the right to be represented by counsel is required under the *Goldberg v. Kelly* ruling and that this right is given to fee-for-service Medicaid beneficiaries in the State fair hearing process.

Other commenters believed that it is sufficient to provide enrollees information regarding free legal services in a Medicaid brochure or other enrollee notification materials. Another stated that providing this information on a routine basis would be burdensome and that it may not be accurate because assistance is not available in all areas.

Response: In response to these comments at § 438.404(b)(1) of this final rule with comment period, we provide that the notice must inform the enrollee of the right to represent themselves or to use legal counsel, a relative, a friend, or other spokesperson. We do not believe it is necessary to require that the

notice itself include information about free legal assistance, and we leave it to States to decide how this information is to be made available to beneficiaries.

Comment: Several commenters urged us to require each State to develop a uniform notice to be used by MCOs and PHPs. They contended that requiring use of a State-developed uniform notice is a simple, common sense way to assure consistency in the grievance and State fair hearing process across MCOs and PHPs, and would best protect the constitutional rights of the beneficiary.

Response: We believe that due process and notice requirements can be observed without requiring each State to develop a uniform notice for MCO and PHP use. States are expected to review MCO and PHP notices to ensure that all required elements, including those listed in § 431.200 et seq., are included. Nothing in our regulations prohibits States from developing a uniform notice for use by their MCOs and PHPs if they choose.

Comment: Several commenters suggested that the notice should explicitly inform the beneficiary that filing an appeal or State fair hearing request would not affect the way the member is treated by the provider, MCO, PHP, or the State.

Response: In response to this comment, we have provided under § 438.404(b)(11) of this final rule with comment period that the notice must inform the enrollee that filing an appeal or requesting a State fair hearing (where an enrollee is permitted to do so directly) will not negatively affect or impact the way the MCO or the PHP and their providers, or the State agency, treat the enrollee.

Comment: Several commenters believed that providing for an in-person hearing before the MCO or PHP would significantly increase the time and expense involved, without substantially improving the quality of the system. They also questioned if this requirement is realistic for appeals that are expedited. Finally, commenters noted that the appearance of disgruntled enrollees before MCO and PHP personnel may pose a security risk to MCO and PHP staff.

Response: We agree that due process does not require an in-person hearing at the MCO and PHP. However, we believe that enrollees should have an opportunity to present evidence and allegations of fact or law related to the issue in dispute, in person as well as in writing. In this final rule with comment period (§ 438.406(b)(4)), we provide enrollees the opportunity to present their cases in person but do not require a formal hearings process. We have also

removed the requirement that the in-person presentation must be before the decision maker for the MCO or PHP. We do this because of the burden this would place on MCOs and PHPs. Appeals requiring expedited resolution, MCOs and PHPs must notify enrollees of the limited time available for them to appear in person.

4. Handling of Complaints (Grievances) (Proposed § 438.406)

Proposed § 438.406 set forth how grievances or appeals (called complaints and grievances in the proposed rule) must be handled. The general requirement for handling grievances and appeals required MCOs and PHPs to have an adequately staffed office, acknowledge receipt of each grievance and appeal, give enrollees any assistance with completing forms or taking other steps necessary to obtaining resolution at the PHP level, and conduct appeals using impartial individuals who were not involved in any previous level of review. Proposed § 438.406(d) required that in the case of a denial based on lack of medical necessity, the individual must be a physician with appropriate expertise in the field the encompasses the enrollees condition.

Comment: One commenter advocated deleting proposed § 438.406 altogether. Other commenters believed that requirements should be added to those in § 438.406. Among the suggested additions, one commenter wanted the regulation to prohibit MCOs and PHPs from using internal appeal timeframes and procedures to avoid the medical decision process, or to discourage or prevent members from receiving medically necessary care in a timely manner. Another commenter asked that we include a clear explanation of the role of personnel provided by the MCO or PHP to advocate for the enrollee, provide customer service, or assist in resolving grievances. Another suggested that we require MCOs and PHPs to give consumers written notice of a hearing and a description of the hearing procedures, at least fifteen days in advance. One suggested that we require MCOs and PHPs to hold internal hearings at mutually convenient times. Another said we should require MCOs and PHPs to postpone hearings at the request (for just cause) of the enrollee. When enrollees have cause, one commenter wanted us to provide that enrollees need not appear at a hearing and that the hearing be conducted in the same manner regardless of the consumer's presence. Another asked that we forbid all ex parte discussions. One commenter wanted us to require MCO and PHP staff to attempt,

whenever possible, to resolve grievances informally pending a decision, but that resolution should not permit the MCO or PHP to consider the grievance "withdrawn" in order to evade State review. Another asked that formal rules of evidence not be used, but rather that enrollees be allowed to submit written information in support of their claims, arrange for a physician or other expert to testify on the enrollee's behalf, and compel the appearance of MCO or PHP staff to answer questions concerning the dispute. Commenters believed that if the MCO or PHP has an attorney present at the hearing, the role of the attorney should be to ensure that a fundamentally State fair hearing takes place and all issues in dispute are adequately addressed. The attorney should not, in these commenters' view, be permitted to argue the MCO or PHP position in the dispute. These commenters believed that consumer representatives should be trained and certified by the State on a periodic basis, that MCOs and PHP should be required to document how they select the consumer representatives on the internal hearing committee, and that this selection process should be approved by the State on a yearly basis.

Response: The proposed rule did not propose to require a formal hearing at the MCO and PHP level. We believe that commenters misconstrued the provision in the proposed regulation concerning the in-person appearance of the enrollee to be a requirement for a formal hearing. This was not our intent. The proposed rule only addressed the presentation of evidence by the enrollee in person to the MCO or PHP. We do not believe a hearing is necessary at the MCO and PHP level and therefore, do not require it in this final rule with comment period. Because we did not propose a hearing and are not providing for a hearing before the MCO or PHP in this final rule with comment period, we are not addressing the comments relating to the nature of a hearing. We believe that the provisions remaining in this section strike an appropriate balance between proscribing sufficient provisions to protect beneficiaries and retaining some flexibility for MCOs and PHPs to design, with State approval, the procedures for their appeal processes.

Comment: One commenter was concerned that proposed § 438.406(b) did not specify a time period within that the MCO or PHP must transmit its acknowledgment of receipt of a grievance or appeal. The commenter believed that an enrollee who files a grievance or appeal needs to know in a timely manner whether the MCO or PHP has received it. Consequently, the

commenter suggested that § 438.406(b) indicate that the MCO or PHP must acknowledge receipt within a specified time period, perhaps 24 hours after receiving a grievance or appeal. One commenter believed that the regulation was intended to require the MCO or PHP to acknowledge receipt of grievances or appeals in writing.

Response: We require MCOs and PHPs to acknowledge the receipt of grievances and appeals, but we do not specify that the acknowledgments be in writing, nor do we specify the timeframes in which they must be provided. We believe that requirements would be burdensome for MCOs and PHPs. States, at their option, may consider adding these requirements.

Section 438.416(b) of this final rule with comment period requires that MCOs and PHPs track the date of acknowledgment and report it to the State as part of the annual disclosure report under § 438.416(d). State monitoring should include tracking this activity.

Finally, if the appeal was oral and is not expedited, the acknowledgment must tell the enrollee that although the timeframe for resolution has begun, the appeal must be submitted in writing. The MCO or PHP must assist the enrollee with the written request, if asked.

Comment: Several commenters requested that HCFA modify the language in proposed § 438.406(c) to change the requirement that MCOs and PHPs must provide enrollees "any assistance" to "reasonable assistance" with the completion of forms or other procedural steps in the grievance process. These commenters were concerned that the phrase "taking other steps necessary to obtain resolution of the grievance" may require the MCO or PHP to pay for a second opinion on the disputed service in order to "obtain resolution." Other commenters wanted this provision clarified so that MCOs and PHPs would not be required to pay for attorney representation or other unreasonable assistance.

Other commenters urged that the following be required elements of MCO and PHP assistance to beneficiaries during the grievance process: (1) A toll-free number with adequate interpreter capability including TTY; (2) outreach to beneficiaries with limited English proficiency, in accordance with Title VI of the Civil Rights Act of 1964; (3) an ombudsman program; and (4) a State established consumer assistance program to assist enrollees (especially homeless persons) to navigate the grievance process.

Response: In response to the above comment, we have revised the language to require MCOs and PHPs to provide "any reasonable assistance" for the completion of forms or other procedural steps in the grievance and appeal process. Also in response to the above comments, we have deleted the phrase "to obtain resolution of the complaint or grievance at the MCO level," as we do not intend for this provision to require MCOs and PHPs to do more than assist enrollees during the grievance process.

In response to the above suggestions to specify required elements of assistance, in § 438.406(a)(3) of this final rule with comment period, we require MCOs and PHPs to make interpreter services available to enrollees, as well as, toll-free numbers that have adequate TTY/TTD and interpreter capability. By including these as examples of types of assistance required to meet certain needs, we do not intend that other reasonable assistance need not be given. We believe, for example, that MCOs and PHPs are required by this provision to provide reasonable assistance to meet other needs of enrollees, and assisting enrollees who have low-literacy abilities.

In this section, we do not address outreach to beneficiaries with limited English proficiency, but we note that the information requirements in § 438.10(b) and (c), in the section on Notice of Action (§ 438.404), and in the section on Information about the Grievance System (§ 438.414) require that information and assistance be provided to these enrollees.

The remaining comments relate to State responsibilities. This section addresses MCO and PHP requirements. We have not revised § 438.404 to address these points.

Comment: One commenter urged HCFA to create an affirmative duty of the provider to assist the enrollee in registering an appeal.

Response: We do not agree that the provider should be required to assist the beneficiary in filing a grievance or an appeal. We believe that this is appropriately the responsibility of the MCO and PHP, and we are requiring in this regulation that they provide this assistance. They are free, however, to use their contracting providers to provide this assistance on their behalf.

Comment: Several commenters commended HCFA for specifying that individuals making decisions on appeals must not have been involved previously in the claim, but requested that § 438.406 omit the word "impartial" when referring to individuals employed by a MCO or PHP who serve as decision makers. These

commenters believed that MCO and PHP employees involved in appeal decisions can never be impartial.

Response: The requirement is that the MCO and PHP decision makers not have played a role in the original decision. Therefore, the term "impartial" is unnecessary and in response to this comment, we have removed it in § 438.406(a)(7) of this final rule with comment period.

Comment: Several commenters requested that enrollees receive access to hearings presided over by independent panels of clinical peer professionals. One commenter believed that enrollees should be able to seek review by an external panel and receive a de novo determination if the decision denies or limits a covered benefit, denies payment of services deemed not medically necessary or experimental, involves services that exceed a significant threshold, or puts the patient's life or health in jeopardy.

Response: The regulations provide for external review through the State fair hearing process that is available to all beneficiaries as required under section 1902(a)(3) of the Act. These regulations link the internal grievance procedures required under section 1932(b)(4) of the Act with the existing State fair hearing process that implements section 1902(a)(3) of the Act. Under the State fair hearing process, Medicaid beneficiaries are guaranteed due process through an independent hearing meeting the standards set forth in the Supreme Court's *Goldberg v. Kelly* decision. While the hearing officer is not required to be a health professional, we would expect medical evidence to be presented by clinicians to support an enrollee's appeal.

While the State fair hearing provides beneficiaries with an independent review of their appeals and is a beneficiary right that cannot be denied, we are aware that some States have established independent panels to review MCO and PHP decisions unfavorable to enrollees, and have made these available to Medicaid managed care enrollees. This regulation does not prohibit use of this review process by Medicaid enrollees. However, any process cannot be substituted for the grievance process and fair hearing process that is required under this final rule with comment period and the regulations at 42 CFR part 431, subpart E. If an enrollee chooses to appeal through the grievance and State fair hearing process, the decisions under this process would be controlling over any inconsistent determination made by another State body.

Comment: We received several comments concerning our decision, stated in the preamble, not to require the establishment of ombudsman programs. One commenter suggested that an enrollment broker may effectively serve as an initial unbiased contact for grievances and appeals and assist beneficiaries through the grievance process or refer them for appropriate assistance from an ombudsman or other outside source. One commenter suggested that States should establish centralized advocacy and customer service programs available to all citizens enrolled in MCOs (not just Medicaid enrollees).

Several commenters requested that ombudsman programs be established and have sign language, interpreters, and TTYs. The commenters stated that the need for an external agency, as an ombudsman program, is well proven and should be required by the regulation.

Commenters noted that the Medicaid population includes individuals with limited education, linguistic and cultural barriers to care, and frequent negative experiences in accessing entitlements and challenging bureaucratic institutions. They stated that enrollees should have designated points of contact to receive counseling on grievances or appeals if managed care is to be successful as a quality health delivery system for the Medicaid program.

Response: We encourage States to establish consumer assistance programs to assist enrollees in navigating the grievance and appeal system. After careful consideration, we have decided not to include a requirement that MCOs, PHPs, or State agencies establish ombudsman programs to assist beneficiaries. We believe that each State agency should establish its own approach to how enrollees obtain assistance during the grievance process, including the State fair hearing process. We require that MCOs and PHPs assist enrollees in completing forms and taking other procedural steps. Other assistance could be provided through a more comprehensive ombudsman program. We encourage States, MCOs, and PHPs to work with the ombudsman programs currently operating through State Medicaid Agencies, Departments on Aging, and Insurance Commissioners. In many instances, States may be able to expand existing State ombudsman programs with few additional resources. As noted in 42 CFR 431.250, FFP is available for transportation costs and other expenses of Medicaid enrollees during the appeals process.

Comment: One commenter pointed out that the word “contracts” in the first paragraph of the preamble to proposed § 438.406 should be “contacts”.

Response: This commenter is correct. However, because this language did not appear in proposed regulations text, and the preamble to this final rule with comment period controls the meaning of the final regulations, no action was required in response to this comment.

Comment: Several commenters suggested that all appeals be filed by enrollees on a form developed by the State. They further suggested that MCOs and PHPs submit these to the State Medicaid agency, and that the Medicaid agency log in the appeals and return them to the MCO and PHP within 72 hours.

Response: We do not agree with this suggestion. We are not requiring use of a State-developed form for filing appeals, as this would require that enrollees obtain these forms, possibly delaying the process, and may be an impediment to enrollees wishing to file appeals. We note that States may wish to develop forms to guide and assist enrollees in filing appeals. However, their use must be at the option of the enrollee. As for filing appeals with the State, we are aware that a similar process is required by the State of Tennessee. We are concerned that the central log-in system used by that State agency would not work well in other States. A log-in procedure would require a well-developed infrastructure that could be costly and burdensome to many States, and that would add another layer (and, even under the commenter’s proposal add 72 hours) to the appeals process. Furthermore, we believe that other parts of this rule will result in many of the same benefits noted by advocates of the approach used by Tennessee. For example, under § 438.416, we require that MCOs and PHPs keep a log of grievances and appeals and that its contents be reported to the State. This will provide the State the same information obtained through the commenters’ suggested approach. Additionally, State on-site reviews can monitor appeal processes to determine if MCOs and PHPs are meeting required timeframes.

Comment: Several commenters requested that the person investigating the grievance should receive training on the Medicaid statute, regulations, and contractual provisions; on confidentiality and patient protections; and on the grievance process.

Response: We agree that MCOs and PHPs should provide this training to their personnel. States should consider making this a requirement of their

MCOs and PHPs. However, we do not think it necessary to require specific MCO and PHP training programs in Federal regulations.

Comment: Several commenters urged that this final rule with comment period require that grievances and appeals involving application of medical standards should be reviewed by an appropriately trained physician.

Response: This final rule with comment period at § 438.406(a)(7)(ii) provides that the individual making a decision must be a health professional; with appropriate clinical expertise in treating the enrollee’s condition or disease for—(1) an appeal of a denial that is based on lack of medical necessity, (2) a grievance regarding denial of expedited resolution of an appeal, and (3) a grievance or appeal that involves clinical issues.

Comment: Several commenters pointed out that the NPRM referred to “physicians” when describing individuals with appropriate medical expertise to make decisions on grievances and appeals concerning clinical issues. They noted that other health care professionals, not just physicians, are competent to make decisions and commonly perform these services in the private market. They stated that Medicaid beneficiaries are best served by having service denials reviewed by qualified health care professionals with appropriate expertise.

Response: We agree that health providers, other than physicians, may be appropriate to make decisions when the area of expertise required is other than a physician (for example, a dentist). In § 438.406(a)(7)(ii) of this final rule with comment period we have removed the term “physician” and replaced this with “health care professionals who have the appropriate clinical expertise in treating the enrollee’s condition or disease.”

5. Grievance (Appeal): Resolution and Notification (Proposed § 438.408)

Proposed § 438.408 required MCOs and PHPs to investigate each appeal (called grievance in the proposed rule) to base the decision on the record of the case, including any MCO or PHP hearing provided under § 438.402(c)(3), and relevant program laws, regulation and policies; and to resolve each as expeditiously as the enrollee’s health condition requires, within State established time-frames, but no later than 30 days after it receives the appeal. The MCO or PHP would be permitted to extend the 30 day timeframe by up to 14 days if the enrollee requests the extension, or if the MCO or PHP justifies

a need for additional information on how the delay is in the interest of the enrollee. For an appeal that requires an expedited resolution under § 438.10, proposed § 438.408(a)(3) required that it be resolved as expeditiously as the enrollee’s health condition requires, within timeframes established by the State, but no later than 72 hours after it receives the appeal. The MCO or PHP again would be permitted to extend the timeframe by up to 14 days if the enrollee requests the extension, or if the MCO or PHP justified a need for additional information or how the delay is in the best interest of the enrollee. Proposed § 438.408 also set forth requirements for notification if the decision is adverse or partially adverse to the enrollee. For a standard resolution the timeframe was no later than 30 days after it received the appeal, and for an expedited resolution, no later than 24 hours after it reaches the decision. The content of the notice must include the name of the MCO or PHP contact, the results of the appeal and the date completed, a summary of the steps taken on behalf of the enrollee to resolve the issue, a clear explanation of the right to a State fair hearing, circumstances under which benefits would continue if a State fair hearing request was filed, and the potential for enrollee liability for services furnished during the pending appeal if an adverse decision is reached.

Comment: One commenter believed that HCFA underestimated the burden associated with the grievance system timeframes.

Response: We address the burden imposed by this provision elsewhere in this preamble, in the section titled Collection of Information Requirements.

Comment: Several commenters believed that extensions to the appeals timeframes benefit the MCOs and PHPs more than the enrollee, and recommended that we eliminate them.

Response: We believe that extensions may be necessary to provide additional time to decide appeals when information necessary to the decision cannot be obtained in time to meet the timeframes, and that extensions may be in the enrollee’s interest. In expedited cases, however, we agree with the commenter that giving MCOs and PHPs the discretion to extend timeframes may be problematic because this is by definition a case that the enrollee’s health is at risk. Therefore, we believe that unless the enrollee actually has determined that an extension is in their interests and requests an extension, there should be no extensions in expedited cases, and we accept the commenters’ recommendation that

extensions be eliminated to this extent. In this final rule with comment period, therefore, for appeals that are expedited, only the enrollee may request an extension. This is an added protection for enrollees who are appealing to receive services without which their health may be jeopardized.

Comment: Several commenters strongly favored the adoption of standardized timeframes for Medicaid that conform with those for Medicare.

Response: We have retained the same timeframes for Medicaid that are used for Medicare. Appeals must be resolved as quickly as the enrollee's health condition requires, or no later than 30 days for standard appeals, and 72 hours for expedited appeals. As under the Medicare+Choice program, we permit 14 day extensions for both standard and expedited appeals when requested by the enrollee. In the case of a standard appeal a 14-day extension may also be obtained if the MCO or PHP justifies to the State Medicaid agency that it is in the enrollee's interests. As noted in response to the previous comment, we have eliminated extensions in expedited cases unless requested by the enrollee.

In response to the above comment favoring the adoption of Medicare timeframes, we are extending the extent to which this final rule with comment period follows Medicare timeframes by providing in §§ 438.408(j)(3)(ii) and 431.244(f)(2)(ii) and (iii), for an expedited State fair hearing in cases of expedited appeals. Specifically, we require that the State fair hearing decision be made within 72 hours, that is the same timeframe used for Medicare for expedited appeals to the Center for Health Dispute Resolution (CHDR), the current Medicare contractor for external independent review under Medicare+Choice. The fair hearing process is the Medicaid counterpart of CHDR review, in that in both cases it is the first "independent" and "external" review of a managed care organization's decision.

Comment: Comments on standardized timeframes differed. Some commenters believed that consistent timeframes are especially important in expedited appeals when the enrollee's health condition needs to be taken into consideration. Other commenters supported the adoption of standardized timeframes, but called for them to be shorter. One commenter believed that the timeframes in the proposed rule might violate Constitutional due process because the timeframes outlined do not adequately protect beneficiaries.

Other commenters criticized the standardized timeframes. Several commenters found the timeframes

unreasonable, unrealistic, subjective, and too prescriptive and asked for more State flexibility to set timeframes. One commenter wanted the timeframes to begin when all documentation is received from providers. One commenter noted that most States already have expedited timeframes and changing these requirements may be confusing for beneficiaries and may not provide any additional protections to enrollees. One commenter found the extensive and varying timeframes for resolutions confusing and believed that it would be difficult to administer.

Response: We continue to believe that the regulation should establish timeframes for steps in the internal appeal process and that an expedited timeframe is necessary when the use of standard timeframes may jeopardize the enrollee's health. This is an important beneficiary protection and is necessary to ensure that the overall timeframe of 90 days for a decision at the State fair hearing (excluding the time the beneficiary takes to file for a State fair hearing) can be met in all cases. In § 438.408(a) we provide for States to establish timeframes that "may not exceed" the timeframes specified in this final rule with comment period. States may establish shorter timeframes.

Comment: Several commenters believed that mandatory timeframes might be difficult to meet if enrollees fail to submit timely information, or are not available for an in-person presentation to the MCO or PHP. These commenters asked that a limit be placed on the number of days MCOs and PHPs are responsible for providing continued services pending final determination.

Response: We believe that the timeframes included in the regulation will result in timely decisions on appeals. Enrollees must be informed of the timeframes, and provided an opportunity to present evidence and appear in person before an MCO or PHP representative. However, if they do not provide information to support their appeal, the MCO or PHP is responsible for deciding the appeal on the basis of available information within the timeframes set out. Continuation of benefits for already authorized services must continue throughout these periods until the final decision at the MCO, PHP, or State is made, whichever is later. Given the limits on timeframes for decision in this rule, we do not believe that "time limits" are necessary. We note that there are no such limits under fee-for-service Medicaid.

Comment: Several commenters thought that MCOs and PHPs should be required to receive written approval

from the State before extending the timeframes.

Response: We are not requiring that MCOs and PHPs receive prior approval from the State for extensions, as we do not believe that this would be practical, given the number of cases and the timeframes involved. However, States are required to monitor MCO and PHP use of extensions and may require that MCOs and PHPs provide justification for any extension.

Comment: Several commenters believed that the enrollee should be forwarded a concurrent copy of the MCO's or PHP's written request given the opportunity to respond to the MCO's or PHP's request for a time extension, and provided a concurrent copy of the State's response. One commenter warned that requiring prior approval would be burdensome.

Response: We agree that enrollees should be informed when an MCO or PHP grants an extension, and in response to this comment have provided for this in § 438.408(d)(2) of this final rule with comment period. The MCO or PHP notice must include the reasons for the delay and inform the enrollee of the right to file a grievance if the enrollee disagrees with the decision to extend the timeframes. We do not believe that this requirement will unduly burden MCOs and PHPs, as we believe that most appeals will be decided within the time period allowed before an extension is needed. We note that our decision to not permit MCOs or PHPs to extend the timeframe for an expedited appeal absent a request by an enrollee is also responsive to the commenters' concerns about an enrollee being informed of extensions and having the opportunity for input.

Comment: One commenter requested that we require the MCO or PHP to give a written justification to the enrollee whenever the MCO or PHP extends the 14-day timeframe, and that a copy be included in the case file. Another commenter noted that the MCO or PHP does not need to obtain prior approval before granting itself an extension, and as currently drafted, the enrollee appears to have no recourse other than to file a grievance with the MCO or PHP, even in situations when the enrollee's life may be jeopardized. They believe that due process and fundamental fairness require MCOs and PHPs to provide notice to the enrollee, and that the enrollee should have the right to object and have the dispute immediately decided by an impartial decision maker. A delay in decision making constitutes a delay in providing the service, and is subject to Constitutional requirements

and *Goldberg v. Kelly* in this commenter's view.

One commenter also requested that physicians (in addition to enrollees) should have a right to request a 14-day extension.

Response: We agree that MCOs and PHPs, upon granting themselves an extension, should notify the enrollee in writing of the extension and of the enrollee's right to file a grievance if the enrollee disagrees with an extension of the timeframes. We do not believe that providers need to be given the right to seek an extension. The provider is associated with the MCO or PHP that can grant itself an extension in a non-expedited case if the standard is met. The MCO or PHP must also provide justification for the extension to the State, if required. We note that the commenter's concern about "situations when the enrollee's life may be jeopardized" by an MCO or PHP-initiated extension has been addressed by our decision to eliminate the opportunity for the MCO or PHP to extend the deadline in expedited cases absent an enrollee request.

Comment: One commenter believed that the timeframes should begin when the appeal initially is made, not when it is submitted in writing.

Response: We agree that timeframes should begin when the enrollee first appeals the action, regardless of whether the appeal is made orally or in writing. When setting the timeframe for resolving appeals in § 438.406(b)(3) of this final rule with comment period, we refer to the date that the MCO or PHP first "receives" an oral or written appeal as the point that the time for resolving the appeal has begun. We note, however, that the enrollee must follow a standard oral appeal for a request with a written request.

Comment: Several commenters recommended that the timeframe for making a decision on a request to authorize a service should be less than the 14 days proposed.

Response: We continue to believe that 14 days is an appropriate outer limit for the time allowed for an MCO or PHP to authorize a service. We have retained the provision of the NPRM that requires this decision to be made more quickly if required by the enrollee's health needs. In addition, in this final rule with comment period, when a determination is made that a case meets the standards for an expedited appeal, the MCO or PHP must decide an appeal of this decision no later than 72 hours after the appeal is filed.

Comment: One commenter agreed with our decision stated in the preamble to the proposed rule not to require

MCOs and PHPs to automatically resolve any dispute in the enrollee's favor that the MCO or PHP did not resolve within a defined timeframe. Other commenters supported requiring that appeals be resolved automatically in the favor of the enrollee if not completed within a specific time period. These commenters reported ongoing problems of MCOs and PHPs denying services for months while multiple requests for information are made.

Several commenters reported that some State laws provide safeguards when decisions on medical care are not made within required timeframes, including deeming the failure to make a timely decision an adverse decision subject to appeal or automatic approval of the service.

Several commenters pointed out that in HCFA's Medicare+Choice regulations, the failure of a Medicare+Choice organization to meet initial determination and reconsideration timeframes is automatically considered an adverse decision and automatically referred to the next level of review.

Response: We are not requiring that appeals be resolved automatically in the favor of the enrollee if not completed within a specific time period. Instead, non-compliance will be considered an adverse decision, and automatically referred to the next level of review (the State fair hearing process). For service authorization requests, an MCO or PHP not completing authorizations within the specified timeframes would be required to send a notice of adverse action explaining the enrollee's appeal rights. As the commenters noted, this is consistent with Medicare's policy for reconsiderations not acted upon within the required timeframes. That is, the Medicare+Choice organization's failure to act is considered an affirmation of its adverse decision and the file must be sent to the independent entity for an independent outside review. This first level of independent review under Medicare+Choice is analogous to fair hearing review under this final rule with comment period.

Comment: One commenter asked that the words "title of staff person" be substituted for "name of staff person" to protect MCO and PHP staff members from possible retaliation by enrollees.

Response: We agree and have changed "name" to "title" in this final rule with comment period.

6. Expedited Resolution of Grievances and Appeals (Proposed § 438.410)

Proposed § 438.410 required that each MCO and PHP establish and maintain an expedited review process for appeals

(called grievances in the proposed rules) and set forth requirements for the resolution of expedited grievances and appeals including, responses to oral or written requests if the MCO or PHP determines, or the provider indicates that the time for a standard resolution could seriously jeopardize the enrollee's life, health, or ability to regain maximum function.

Comment: Some commenters applauded our inclusion of an expedited grievance process similar to that under Medicare+Choice and then-proposed the Department of Labor regulations. Others argued for State flexibility and contended that prescriptive Federal requirements preclude States from taking into account other expedited processes that they have implemented with respect to clinical aspects of appeals, for example, preauthorizations.

Response: We believe that expedited resolution is necessary to ensure that appeals of situations that potentially place an enrollee's health in jeopardy are not delayed. The Consumer Bill of Rights and Responsibilities (CBRR) and beneficiary advocates have both recommended the adoption of expedited procedures. Although States have historically instituted different processes to protect beneficiaries, HCFA believes that standardized expedited appeal processes are needed to protect beneficiaries in a capitated health care delivery system.

Comment: One commenter requested that "retain function" be added to the criteria for expedited grievances and appeals. The commenter stated that retention of less than full function is often the goal for beneficiaries with long-term disabilities who cannot expect to regain full function but should be protected against further loss of function. Other commenters wanted the expedited process to apply when the enrollee has significant pain or side effects, and for children with special health care needs.

Response: In response to this comment, we have revised the language for expedited appeals to include all instances for which the time needed for standard resolution could "seriously jeopardize the enrollee's life or health, or the ability to attain, maintain, or regain maximum function." With this revision, the Medicaid criteria are more inclusive than those for Medicare. We believe that these criteria are sufficient to address situations that the enrollee is in significant pain or is having significant side effects. Finally, we do not agree that children with special health care needs should automatically receive expedited appeals in all cases

solely on the basis of being in that category. We believe that the criteria we have established will ensure that expedited appeals will be available when they are needed.

Comment: Several commenters suggested that the regulations allow the beneficiary to obtain an expedited review based on the beneficiaries' own attestation that the standard for expedited review has been met. They believed that MCOs and PHPs should not be given control over the situation because their financial arrangements with physicians may provide an incentive to deny services. One commenter supported the ability of an enrollee to obtain an expedited resolution if the enrollee obtains the support of a physician.

Response: We do not agree that an enrollee's attestation should be sufficient to require an expedited appeal. The enrollee may not be objective in this determination or may not have the knowledge to draw a correct conclusion. It is not clear what would preclude enrollees under this approach from attesting that the standard is met in every case simply to get faster action on all appeals. We are including in this final rule with comment period a provision that if a provider makes the request, or supports the enrollee's request for expedited review, the review must be expedited. We believe this sufficiently protects enrollees.

Comment: Several commenters noted that the rule should prohibit retaliation by the MCO or PHP against physicians who support their patients' requests for expedited appeals.

Response: We intend that providers who advocate on behalf of their patients should be protected against retaliation by MCOs and PHPs in all circumstances. In response to this comment, we expressly prohibit any retaliation in § 438.402(b)(5) of this final rule with comment period.

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

Response: We are aware that some Medicaid enrollees may not have telephones. Nevertheless, MCOs and PHPs must make reasonable efforts to notify enrollees orally of decisions not to expedite the appeal and follow up with a written notice within two calendar days. MCOs and PHPs should request information from enrollees about how and where they can be contacted.

Comment: Several commenters recommended that the State Medicaid agency be required to hear all expedited appeals and issue decisions within specified timeframes. One commenter recommended we include a requirement that decisions be made within 24 hours; another suggested two days.

Response: This final rule with comment period requires the State to conduct a fair hearing and make its decision within 72 hours for service authorization denials that meet the criteria for expeditious handling. We have limited this requirement to initial denials of authorization for a service because in the case of a decision to reduce or terminate benefits, benefits continue through the State fair hearing decision. The enrollee's health is protected during the time it takes for the State fair hearing decision to be made. We have chosen to use the same 72-hour standard that applies to MCO or PHP review in expedited cases because we do not believe it would be reasonable to expect the State to complete review of all expedited cases in 24 hours. We also note that this 72-hour timeframe is employed in Model guidelines established by the National Association of Insurance Commissioners (NAIC), in Department of Labor regulations governing Retirement Income Security Act (ERISA) health plans, and at both the Medicare+Choice organization and independent external review levels in the Medicare+Choice program.

Comment: Several commenters pointed out that proposed § 438.410(c)(2) allowed a physician to request an expedited appeal. They suggested that we broaden this provision to allow other health care professionals to make these requests.

Response: We agree that all health care professionals who provide services to Medicaid beneficiaries should be permitted to request expedited appeals. As discussed above, we have made this change in this final rule with comment period.

7. Information About the Grievance System (Proposed § 438.414)

Proposed § 438.414 required that MCOs and PHPs provide information about the grievance system to enrollees, potential enrollees (as provided by the State), and all providers at the time they enter into a contract with the MCO and PHP. It also specified that the content of the information include a description of the grievance process that is developed or approved by the State, and that it include the following: (1) specification of what constitutes grounds for a complaint (now grievance) grievance (now appeal) or State fair hearing; (2) an

explanation of how to file for each; (3) an explanation of the assistance available; (4) toll-free numbers (with TTY and interpreter capability) for enrollees to register grievances and appeals; (5) titles and telephone numbers of persons responsible for the functioning of the grievance process and with authority to require corrective action; (6) assurance that filing an appeal or requesting a State fair hearing will not negatively affect or impact the way the MCO or PHP, their providers, or the State agency treat the individual; and (7) information on how to obtain care or services during the grievance or fair hearing processed. Section 438.414 also requires that the MCO or PHP to provide enrollees and potential enrollees with aggregate information regarding the nature of enrollee appeals and their resolution.

Comment: One commenter believed that we underestimated the true burden associated with MCO and PHP grievance information requirements.

Response: We address the issue of burden in the Burden Statement to this final regulation.

Comment: Several commenters requested that we explicitly require notices and information about the grievance system to be written at a fourth grade level, translated into prevalent languages, and accessible to persons with hearing and sight impairment.

One commenter requested us to require MCOs, PHPs, and PCCMs to use at least one of the following reference materials: (1) Fry Readability Index; (2) PROSE: The Readability Analyst; (3) Gunning FOG Index; or (4) McLaughlin SMOG Index.

Response: In this final rule with comment period, we require that notices meet the formatting and language requirements at § 438.10. We believe that it is appropriate that we include a general requirement for material to be written in easily understood language and formatted likewise. We also provide that material must be translated into the prevalent languages in the MCO's or PHP's service area. In the preamble to the proposed rule, we provided examples of standards States can use to determine prevalence. We are not requiring that material be written at a specific grade level because no single level is possible or appropriate for all material.

Comment: One commenter believed that additional State flexibility was necessary regarding how and when information should be distributed to enrollees. Another commenter asked for more clarification about the detail of the information that must go to all enrollees

and the time that information must be sent. One commenter requested that States develop standard language that MCOs and PHPs be required to use in their member handbooks. Several commenters supported the amount of detail in the regulation regarding information because it ensures that information about beneficiary protections is provided more uniformly to enrollees.

Response: We are not mandating that States require the use of standard language because, we believe that States should be permitted to decide this based on State circumstances. With respect to the timing of the provision of information, § 38.10(d), (e), and (f) set forth requirements as to when information about the grievance system must be provided to enrollees and potential enrollees. With respect to the information on grievances and appeals addressed in § 438.414, for enrollees, § 438.10(e)(1) requires that this information (referenced in § 438.10(e)(2)(x)) be provided within a reasonable time after the MCO or PHP receives notice of enrollment, and once a year thereafter. In the case of potential enrollees, § 438.10(f)(7) requires that the information described in paragraphs (d) and (e) of § 438.10 (including the grievance information described in § 438.10(e)(2)(x)) be provided only upon request. In § 438.414(a)(1) and (3), we require MCOs and PHPs to provide information about the grievance system to enrollees, and to providers and subcontractors (at the time of entering into a contract). In section 438.414(a)(2), we require that the State, a State contractor, or MCOs and PHPs provide this information to potential enrollees. In § 438.404 we require that information about the grievance system be sent to enrollees as part of the notice of action.

Comment: One commenter believed that the State fair hearing process should be explained clearly to enrollees at the time of enrollment, and annually thereafter. Several commenters asked that MCOs and PHPs be required to give enrollees information on the right to be represented by counsel, and the availability of free legal assistance. One commenter requested that beneficiaries be informed of their rights during the grievance process at every stage.

Response: We have revised this regulation to clarify that the beneficiary's State fair hearing rights must be explained, including the fact that enrollees have the right to represent themselves, or be represented by legal counsel, a relative, a friend, or other spokesperson. We do not require MCOs and PHPs to inform beneficiaries about the availability of free legal counsel.

This is consistent with the current policy in fee-for-service. In the State Medicaid Manual (SMM 2900.3), we require States to maintain a list of available free legal services and to notify beneficiaries of their right to legal assistance, including free legal assistance. States may, at their option, require MCOs and PHPs to maintain copies of this list and make it available to enrollees.

Comment: Several commenters thought that we should require MCOs and PHPs to provide grievance, appeal, and State fair hearing information to potential enrollees, upon request, and to enrollees upon initial enrollment, and whenever the grievance system is changed by the MCO, PHP, or the State. Several commenters wanted aggregate information on grievances and their resolution to be given to consumers as part of their initial and annual enrollment choice information. Several commenters wanted grievance data to be available to the general public, as well as, to enrollees and potential enrollees. One commenter encouraged us to have consistent requirements for Medicaid and Medicare.

Response: As noted above, we require the State to ensure that information on grievances and appeals is provided to potential enrollees upon request, either by the State or its contractor (for example, an enrollment broker), or by the MCO or PHP. MCOs and PHPs also are required to provide this information to enrollees at the time of enrollment, and annually thereafter. Information will also be provided as part of notices of actions. We believe that this will provide enrollees with the information they need to exercise their rights.

We agree with the commenter that MCOs and PHPs should provide aggregate information on grievances and appeals to enrollees, potential enrollees, and the general public upon request. In response to this comment, § 438.414(d) of this final rule with comment period provides that aggregate information be released to the public upon request.

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

Response: In § 438.414(a)(3) of this final rule with comment period, we specify that this information must be provided to subcontractors as well as to contractors.

8. Recordkeeping and Reporting Requirements (Proposed § 438.416)

Proposed § 438.416 required that MCOs and PHPs comply with specified record keeping requirements, that also

had to be done in compliance with confidentiality requirements in § 438.324. Specifically, MCOs and PHPs were required to—

- Maintain a log of all grievances and appeals (called complaints and grievances in the proposed rule).

- Track each appeal until its final resolution.

- Record any disenrollment and the reason for it, even if it occurs before the appeal process is complete.

- Retain the records of grievances and appeals (including their resolution) and disenrollments for three years, and make them accessible to the State or if any litigation, claim negotiation, audit or other action is started before the end of this three year period, the MCO or PHP must retain the records until completion of the action and resolution of the issues, if later than three years.

- Analyze the collected information and prepare and send to the State a summary as often as the State requests, but at least annually—

- ++ The number and nature of all complaints and grievances.

- ++ The timeframes within which they were resolved, and the decisions.

- ++ A listing of all grievances that have not been resolved to the satisfaction of the affected enrollee.

- ++ The number and nature of grievances for which the MCO or PHP provided expedited resolution, and the decisions.

- ++ Trends relating to a particular provider or a particular service.

Comment: One commenter believed that HCFA underestimated the true burden associated with MCO and PHP record keeping and reporting requirements.

Response: We address the issue of burden in the section of the preamble titled Collection of Information Requirements.

Comment: Several commenters suggested that the State be allowed to determine the specific data elements to collect on grievances and appeals, and how and when reports are to be submitted to the State. Other commenters supported the inclusion of the elements included in the proposed rule.

Response: We believe that a minimum set of data should be available from all MCOs and PHPs to facilitate monitoring. We have changed this final rule with comment period to remove the requirement in proposed § 438.416(e)(3) that MCOs and PHPs submit a list of all appeals not resolved to the satisfaction of the enrollee. We believe that this requirement is unnecessary now that MCOs and PHPs will be required to forward all appeals not resolved to the

satisfaction of the enrollee to the State for a fair hearing. We note that States have the flexibility, at their option, to set record keeping and reporting requirements in addition to these Federal minimums. For example, States may establish a minimum number of categories of grievances and appeals that MCOs and PHPs must report (for example, delays in receiving referrals, delays in access to specialists or services, dissatisfaction with quality of care, and waiting times for appointments).

Comment: Several commenters wanted the regulation to specify that MCOs and PHPs should collect and report information on the number and nature of requests for expedited review.

Response: We agree that we should require that MCOs and PHPs collect and report information on the number of requests for expedited review, and in response to this comment have provided in § 438.416(b) of this final rule with comment period that grievances and appeals must be classified in terms of whether the disposition was standard or expedited. We have retained the requirement in proposed § 438.416(e)(1) (now § 438.416(d)(1)) that information be reported on the "nature of all grievances and appeals," whether expedited or standard.

Comment: Several commenters wanted grievances to be tracked, sorted by type, number and resolution, and reported to the same extent as appeals. They believed that this would be useful in identifying problems with education and outreach.

Response: This final rule with comment period requires that grievances, as well as appeals, be tracked and reported. In response to the comment favoring additional tracking, we have added a requirement to the regulation that MCOs and PHPs must track and report on the time frames for acknowledging to the enrollee the receipt of grievances and appeals.

Comment: Several commenters objected to the requirement in proposed § 438.416(c) that MCOs and PHPs record any disenrollments and the reason for them, because these commenters believed that the State controls the disenrollment process and maintains data regarding disenrollments. Therefore, these commenters believed that States, not MCOs and PHPs, should be required to maintain disenrollment records. One commenter noted that requiring the collection of disenrollment information is good and that it should also be classified

Response: We have removed the requirement for an MCO or PHP to "record any disenrollment and the

reason for it" from the proposed provisions at § 438.416 because this was duplicative of the requirement at proposed § 438.342(a) that the State ensure that each MCO and PHP maintain a health information system that collects, integrates and reports data on areas including disenrollments. However, in response to this comment, we recognize that there is a distinction between disenrollments from an MCO or PHP due to loss of Medicaid eligibility and other disenrollments initiated by the enrollee of the MCO or PHP. Given that information regarding disenrollments due to loss of Medicaid eligibility is not typically known by MCOs or PHPs, in response to this comment, we have modified the reference to disenrollment in § 438.242 to refer to "disenrollment for other than loss of Medicaid eligibility."

Comment: One commenter requested that we clarify that the regulation requires MCOs and PHPs to provide the State only with information about grievances and appeals of Medicaid enrollees, not all enrollees.

Response: We believe that the regulation is clear that this information must be supplied only for Medicaid enrollees, as it references grievance and appeal mechanisms that are only available to enrollees.

Comment: We received several comments regarding the annual disclosure of information. One commenter believed that annual disclosure of aggregate data was appropriate, but that reporting trends relating to a particular provider or particular service was not. Commenters urged us not to require such information to be reported. They were very concerned that these reports would have a detrimental effect on existing quality improvement and peer review processes.

Response: We agree that Federal reporting of trends relating to particular providers may not be appropriate, and in response to this comment have deleted this requirement from this final rule with comment period. States, at their option, may develop provider grievance and appeal profiling requirements consistent with State laws.

Comment: Several commenters asked that State Medicaid agencies and ombudsman programs have access to MCO and PHP logs. In addition, commenters urged that the regulation require States to provide members of the public, upon request, with MCO and PHP summaries. Another commenter recommended that HCFA require MCOs and PHPs to identify trends on grievances and appeals for particular enrollee sub-populations. One

commenter wanted the regulation to require MCOs and PHPs to computerize their grievance and appeal logs and report to the State on a quarterly rather than annual basis.

Response: States have the authority to require that MCOs and PHPs make available to the State grievance and appeal logs or other MCO and PHP grievance system documents. In the final regulation we are requiring that States must make information on MCO and PHP grievances and appeals available to the public. We do not agree that we should be more prescriptive in the regulation about reporting requirements. States, at their option, may require MCOs and PHPs to provide ombudsman programs access to grievance and appeal logs, to include information about all systemic issues that emerged from grievances and appeals, to report on their response to systemic problems, to report grievance and appeal data on particular subpopulations of enrollees including persons with special needs, to computerize logs, or to report on a more frequent basis. In designing their quality strategies, States should consider what additional information they or others will need to support those strategies.

9. Continuation of Benefits Pending Resolution of a State Fair Hearing Decision (Proposed § 438.420)

Proposed § 438.420 set forth requirements for MCOs and PHPs, in the case of an appeal from the termination or reduction of services currently being provided to continue services upon a timely appeal while the MCO or PHP considers the appeal, and through the end of any State fair hearing. As used in this section, "timely" means filing on or before the time limit specified by the State and communicated in the notice of intended action, or before the effective date of the MCO's or PHP's proposed action, whichever is later. Although the benefit is to be continued during the resolution process, enrollees who lose their appeal at either the plan or State fair hearing levels will be liable for the cost of all appealed services from the later of the effective date of the Notice of Intended Action or the date of the timely filed appeal, through the date of the denial of the appeal.

Comment: Commenters expressed concern that the regulation may be read to permit benefits to be stopped after the appeal to the MCO or PHP, but before the State fair hearing.

Response: We intend for benefits to continue through the enrollee's final appeal at the State fair hearing when requested by the enrollee. Section 438.420(d)(1) of this final rule with

comment period makes it clear that benefits must continue without interruption, if elected by the enrollee, through the conclusion of the State fair hearing process if the case is not favorably resolved at the MCO or PHP level.

Comment: One commenter thought that requiring continuation of benefits through the State fair hearing decision was inappropriate because the enrollee may be liable for payment for services provided during this period if the appeal is ultimately denied at the State fair hearing.

Response: We provide that enrollees must request to have benefits continue during the appeal process because of their potential financial liability in the event that they are unsuccessful. In § 438.404(b)(7) of this final rule with comment period, we require that the notice of action inform the enrollee of the potential financial liability for services continued during appeal. Likewise, in § 438.408(g)(4)(iii), we require a written notice to the enrollee that the enrollee may request that benefits be continued and of the potential financial liability if the benefits continue.

Comment: We received many comments regarding enrollees' rights to continuation of benefits during the MCO and PHP appeal process. Several commenters thought that the regulations should include a provision to require MCOs and PHPs to continue benefits when the appeal involves services that are being terminated or reduced. Several commenters felt that continuation of benefits pending resolution of an appeal or State fair hearing without financial risk, is one of the most important protections needed for managed care enrollees.

Several commenters were opposed to extending continuation of benefits to the MCO and PHP appeal process. One contended that this requirement would have significant cost implications. Another believed that benefits should be continued only at the point when an enrollee requests an external fair hearing.

One commenter thought that requiring MCOs and PHPs to continue benefits would place them in an untenable position with their providers, compromising their ability to manage care and cost. They expressed concern that this provision may damage managed care programs and believed it unnecessary given the requirement of expedited review of appeals in cases in which a delay could jeopardize health.

One commenter argued that requiring continuation of benefits during an MCO or PHP appeal, as opposed to a State fair

hearing, was not consistent with this commenter's interpretation of the statute and case law. It appeared to this commenter that a beneficiary would obtain double benefits in this situation. The commenter requested clarification to explain the duration of continuation of benefits when they are provided during the MCO and PHP appeal process. The same commenter also felt that continuation of benefits would make it difficult for the State to track the case and determine the beneficiary's eligibility for continuation of benefits at the point of the State fair hearing.

Response: Because we allow States to require exhaustion of the MCO and PHP appeal before receiving a State fair hearing, we believe that, in order for the right to continued benefits during a fair hearing to be meaningful, that continuation of benefits must begin with the filing of the appeal and continue until the State fair hearing decision. Continuation of benefits at the MCO and PHP level thus is not a "double" benefit, but part of the same longstanding right to continuation of benefits that has existed for Medicaid beneficiaries when services are reduced or terminated.

As in fee-for-service, under managed care, the right to continuation of benefits is not exercised without financial risk to the beneficiary of payment for services provided should he or she lose the appeal. The enrollee may choose not to request continuation of benefits because of the potential liability. The notice of adverse action must include an explanation of this choice.

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

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

It is not clear why the last commenter believes that providing continued benefits through the fair hearing level is inconsistent with the statute or case law. We believe that it simply gives MCO and PHP enrollees the same Medicaid fair hearing rights that all other enrollees have under the program. To the extent that we are aware of case law on this issue, courts have supported continuation of benefits in the managed care context.

Comment: One commenter requested that this section should make clear that re-authorization of a service at a lower level than previously received, or a denial of re-authorization, is a termination or reduction of the service requiring the continuation of benefits pending appeal.

Response: We believe that the expiration of an approved number of visits does not constitute a termination for the purposes of notice and continuation of benefits. If an enrollee requests re-authorization for services and the MCO or PHP denies the request or re-authorizes the services at a lower level than requested, the MCO or PHP must treat this request as a new service authorization request and provide notice of the denial or limitation. The MCO or PHP is not obligated to provide continuation of benefits in this circumstance. This policy is consistent with that in fee-for-service.

Comment: One commenter objected to requiring MCOs and PHPs to cover the service pending appeal if the enrollee is no longer eligible for Medicaid and there is no emergency.

Response: The policy for continuation of benefits does not apply when an enrollee loses Medicaid eligibility.

Comment: We received many comments regarding the requirements in proposed § 438.420(b) that a MCO or PHP physician with authority under the MCO or PHP contract must have authorized the enrollee's services in order for them to be continued.

Several commenters believed that benefits should be continued in all cases in which a dispute involves a service covered under the Medicaid State plan. They argued that conditioning continuation of benefits on the benefits having been authorized was inconsistent with constitutional due process requirements. They contended that the rule could lead to an interruption in services when services are prescribed by an out-of-plan emergency room physician or by an out-of-network provider who is treating a Medicaid beneficiary because the MCO or PHP does not have an available provider in the network; the MCO or PHP pays for the service although it is prescribed by an out-of-network provider; a beneficiary is receiving out-of-network family planning services; or an enrollee, while continuously eligible for Medicaid, either changes MCOs or PHPs or joins an MCO or PHP (from fee-for-service or PCCM) during a course of treatment.

Several commenters recommended that the regulation be amended to trigger continued services regardless of whether the provider requests the

service. They contended that there is a direct financial conflict of interest between a provider employed by a MCO or PHP (or contracting with a MCO or PHP) and the patient. These commenters also said that MCO and PHP doctors base treatment decisions, in part, on MCO and PHP guidelines and receive bonuses if they meet performance goals that may include utilization criteria.

Response: For continuation of services to apply, the services must have been previously authorized. This final rule with comment period uses the term "authorized provider" rather than "MCO or PHP physician" to address some of the concerns expressed by the commenters. We note, with respect to the example of emergency services cited by the commenters, that in section 1932(b)(2)(A)(ii) of the Act, the Congress has provided MCOs with the right to decide whether to authorize out of network "post-stabilization services" once an emergency medical condition has been stabilized. The Congress contemplated that services would only be covered by Medicaid if authorized by the MCO, or covered under the post-stabilization guidelines in cases in which the MCO does not respond timely to a request for coverage authorization. To the extent the MCO or PHP does not authorize continued services by a non-network provider, it must assume responsibility for the services through a network provider, so there would be no interruption in needed services.

Where services were not covered in the first place because they were not authorized or covered as emergency services or post-stabilization services, there could be no "right" to continuation of coverage, even if the services would be covered under the State plan for a beneficiary not enrolled with an MCO or PHP. We therefore disagree with the commenters who suggested that it violated due process to require MCOs and PHPs to provide continuation of services only when the services in question were authorized in the first place.

However, if services are covered under Medicaid, under this final rule with comment period, benefits must be continued if the beneficiary timely appeals a decision to terminate, reduce or suspend the services, regardless of whether or not the beneficiary is enrolled in a MCO or PHP. We note that this includes instances in which the services were begun by a provider under the fee-for-service system, but a MCO or PHP made a decision to terminate, reduce, or suspend them. These beneficiaries' rights to continued care are addressed under regular fee-for-

service rules, and it is the State that is obligated to ensure that these rights are enforced. States should specify in their contracts with MCOs and PHPs whether the MCO, PHP, or the State will assume financial responsibility for these services under these circumstances. We note that § 438.62(b) requires that States have a mechanism in effect to ensure continued access to services when an enrollee with "ongoing" health care needs is transitioned from fee-for-service to managed care.

Benefits must be continued by the MCO or PHP in the following situations, (this assumes that the benefits are included in the MCO or PHP contract): (1) the MCO or PHP pays for services prescribed out-of-plan; (2) services are prescribed by an outside specialist who is treating the enrollee with the MCO's or PHP's knowledge and consent; (3) family planning services are being received from a provider who is not part of the MCO or PHP network, and family planning services are covered under the MCO or PHP contract; and (4) in rural areas, where individuals are, by law, permitted to seek out-of-network services/providers, for example when the service or provider is not available within the MCO or PHP. If the benefit is not included in the MCO or PHP contract, the State must pay to continue the benefits.

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

The commenters noted that the existing regulation at 42 CFR 431.230(b) provides for the possibility of recoupment, yet benefits are continued when an appeal is filed timely. The commenters found no reason to change this long-standing rule for beneficiaries who are receiving services through an MCO or PHP.

Response: We do agree with the commenters view that beneficiaries should not be required to specifically request continuation of benefits. We continue to believe that beneficiaries should have to request continuation as they may be held liable for services if the final decision is not in their favor. We have provided that enrollees be notified that they may incur a financial liability if their appeal is unsuccessful. As in the case of the fee-for-service regulations, benefits will only be continued if the enrollee files a timely appeal. This is a "prerequisite" to obtaining them which has been upheld

in the courts as consistent with due process.

Comment: Several commenters expressed concern that beneficiaries may request continuances of State fair hearings, and extend the period during which benefits will continue. They recommended that the final regulation specify the grounds on which an enrollee may request a hearing continuance. If a continuance is granted for reasons other than good cause, these commenters believed that the MCO or PHP should not be obligated to continue to provide services during the period of the continuance.

Response: We do not agree that we should specify when a State fair hearing officer may grant a continuance, as we believe that this should be left to the hearing officer's discretion, as is the case under fee-for-service Medicaid. The State Medicaid Manual at 2900 permits the State fair hearing officer to grant one continuance of up to 30 days.

Comment: Several commenters recommended that we establish parameters for the liability of MCOs and PHPs for care provided pending the outcome of the hearing. Commenters wanted to work with HCFA to develop this provision. They stated that MCOs and PHPs should be compensated appropriately if they are required to provide services, and the hearing decision upholds the MCO's or PHP's determination.

Some commenters believed that it would be unrealistic to assume that an MCO or PHP would be able to collect payment for services from an enrollee if the final decision is not in their favor. They noted that Medicaid beneficiaries generally do not have the financial resources to pay, and MCOs and PHPs thus should be able to recoup payment from a provider, with the provider then billing the enrollee. They believed that this process would add to the administrative burden of the MCO or PHP and the provider.

One commenter recommended that MCOs and PHPs should be paid their costs for providing services during the hearing process if the enrollee is unsuccessful at the State fair hearing and the MCO or PHP is unsuccessful in collecting from the enrollee.

Another commenter recommended that MCOs and PHPs be reimbursed on a fee-for-service basis for services provided during the time taken for the appeal and State fair hearing.

One commenter asked that this section be amended to limit the responsibility of enrollees for services provided that are the subject of the appeal, rather than all services provided during this time period.

Several commenters were concerned that MCOs and PHPs would use the requirement that enrollees be told of their potential liability for payment for services continued to intimidate enrollees from using the grievance process. These commenters noted that, under the fee-for-service system, States seldom try to recover the cost of services from a beneficiaries, but under a managed care system, the MCOs and PHPs are more likely to attempt recovery to avoid financial losses.

Response: States, in their contracts with MCOs and PHPs, have the flexibility to determine what entity is responsible to cover costs of services continued through an appeal. We believe that States are in the best position to decide what entity should pay. They may prefer to take this into account in setting capitation rates for MCOs and PHPs or may prefer to pay for these services directly.

The current requirement in the Medicaid fee-for-service program is that beneficiaries who lose their appeal at the State fair hearing level are liable for the costs of the services continued during the appeal. Enrollees must be told of their potential liability in order for them to make an informed choice about whether or not to accept continued services. Section 438.408(i)(4) of this final rule with comment period thus requires written notice of this potential liability, and the option to refuse continued benefits. Enrollees are not liable for all services provided during this time period, but only for services continued because of their appeals. We have clarified the language on this point in the regulation (§ 438.420 (e)). FFP is available to States for payments for services continued pending a State fair hearing decision. Likewise, if the MCO or PHP is unable to collect from the enrollee after a good faith effort, FFP is available to the State under § 431.250(a) for payments for services continued pending a hearing decision.

10. Effectuation of Reversed Grievance Resolutions (Proposed § 438.421)

Proposed § 438.421(a) provided that if the MCO or PHP decides an appeal (called a grievance in the proposed rule) in favor of the enrollee, the MCO or PHP was required to authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days after the date the MCO or PHP receives the request for reconsideration. Furthermore, under proposed § 438.421(b), if the MCO's or PHP's decision on a appeal was reversed under the State fair hearing process, the MCO

or PHP must authorize or provide the disputed service as expeditiously as the enrollee's health condition requires within time frames established by the State, but no less than 60 calendar days from the date the MCO or PHP receives notice reversing the MCO's or PHP's decision to deny.

Comment: Several commenters disagreed with the time frames in the proposed rule for providing a service, which depended on whether the beneficiary won the appeal at the MCO or PHP (30 days to provide the service), or at the State fair hearing (60 days to provide the service). Another commenter believed that the time frames should take into consideration the appropriateness of the procedure or treatment for the individual, as there may be cases in which providing the service within 30 days may not be clinically appropriate for the enrollee. The commenter further noted that external factors for example, scheduling and bed availability may affect the time frame for providing treatment. Several commenters supported the elimination of time frames because in the view of these commentators, beneficiaries with successful appeals should not have to wait at all following the decision.

Response: We agree that MCOs and PHPs should remove barriers to receipt of the services and take into account the needs of the individual. Therefore, in response to the above comments, we are eliminating the time frames in proposed § 438.421 (§ 438.424 in this final rule with comment period), and requiring that the services be provided as soon as required to meet the needs of the beneficiary. This is consistent with the State fair hearing policy in 42 CFR 431.246.

Comment: One commenter asked that we hold States, MCOs, and PHPs financially responsible for the cost of services inappropriately withheld if the enrollee obtains them outside the network and their appeal is upheld. The commenter believed that failure to provide for this remedy could encourage States, MCOs, and PHPs to refuse expensive care until after an appeal is resolved.

Response: We agree with these commenters. In response to this comment, we have provided in § 438.424(b) of this final rule with comment period that the State, MCO, or PHP must pay for services denied to an enrollee when the enrollee received the services and later won an appeal of the denial.

11. Monitoring the Grievance System (Proposed § 438.422)

In proposed § 438.422, we required the MCO, PHP, and the State to use the grievance and appeal logs (called complaint and grievance logs in the proposed rule) and annual appeal summary required under § 438.416 for contract compliance and quality monitoring. At a minimum, proposed § 438.422 required that the contract between the State and the MCO or PHP require that logs be reviewed and summarized for trends in grievances and appeals by provider or by service, and the requirement that MCOs and PHPs conduct follow up reviews, report results to the State, and take corrective action when necessary.

Comment: One commenter requested that HCFA either define the term "undesirable trend" or delete the term.

Response: We agree that the term "undesirable trend" is vague. We now require in § 438.426(b) that when the MCO or PHP identifies through trends in the data collected in § 438.416(b) that systemic changes are needed, the MCO or PHP must investigate, report the results to the State, and take corrective action.

Comment: One commenter requested that we mandate that States conduct random reviews of service denial notifications to ensure that MCOs and PHPs are notifying members in a timely manner.

Response: We agree that States should monitor service denial notifications to ensure that MCOs and PHPs are notifying members in a timely manner. This should be an integral part of each State's Quality Improvement Strategy and contract compliance monitoring. We believe that States are in the best position to determine the timing for this monitoring.

Comment: Several commenters requested that we modify this section to require States to require MCOs and PHPs to take corrective action if numerous grievances are filed concerning the same issue.

Response: As part of the State's quality strategy, which includes monitoring MCO and PHP grievances and appeals, States are required to take corrective action when needed to remedy problems.

Comment: Several commenters felt that the requirement to identify trends by provider constitutes a serious breach under State law of the peer review processes and legal privileges. They believed that these issues can be monitored appropriately by the States without requiring reports.

Response: We agree that Federal requirements that require MCOs and

PHPs to report on undesirable trends relating to providers is not appropriate, and we have revised the rule to delete this requirement. States, at their option, may develop provider grievance and appeal profiling requirements that are consistent with State laws concerning peer review.

12. Consequences of Noncompliance (Proposed § 438.424)

Comment: We received many comments that this section confused readers, particularly with respect to the types of sanctions States could impose on MCOs and PHPs.

Response: We have eliminated this proposed section from this final rule with comment period. This section was intended to emphasize the importance of MCOs' and PHPs' compliance with the provisions of this Subpart. It did not convey any authority or responsibility to the States, MCOs, or PHPs.

F. Certifications and Program Integrity Protections (Subpart H)

Background

We believe it is important for MCOs to develop effective internal controls to fight fraud and abuse and to ensure quality of health care services to Medicaid beneficiaries. Administrative and management procedures, including a compliance plan, address specific areas of concern or potential areas of risk for MCOs. It is in the best interest of MCOs, State agencies, and HCFA to make a commitment to an effective administrative and management arrangement that will significantly aid in the elimination of fraud and abuse.

By requiring certification of the accuracy of data used to determine payments, of information contained in contracts, proposals, and other related documents submitted to State agencies, and of administrative and management procedures designed to prevent fraud and abuse, we are working to promote program integrity, protect Medicaid managed care enrollees, and protect Medicaid government funds.

Subpart H of proposed part 438, Certifications and Program Integrity Provisions, contains safeguards to promote program integrity within Medicaid managed care programs. We have proposed that these rules apply only to MCOs, as they were not made applicable to PHPs under proposed § 438.8.

Proposed § 438.600 sets forth the statutory basis for the requirements in subpart H, which is based on section 1902(a)(4) of the Act. Proposed § 438.600 permits us to find methods of administration that are "necessary for

proper and efficient administration" of the plan. The requirements in subpart H are also based on section 1902(a)(19) of the Act, which requires that States provide safeguards necessary to ensure that eligibility will be determined and to provide services in a manner consistent with simplicity of administration and the best interests of recipients.

Proposed § 438.602 requires that when State payments to an MCO are based on data submitted by the MCO, which include enrollment information and encounter data, the MCO must, as a condition for receiving payment, attest to the data's accuracy, completeness, and truthfulness. Proposed § 438.606 requires that an entity seeking an MCO contract have administrative and management arrangements or procedures designed to prevent fraud and abuse, which include reporting to the State, HCFA, or OIG (or both) credible information on violations of laws by the MCO or its subcontractors or enrollees. In the case of enrollee's violations, this proposed requirement only applies if the enrollee's violations pertain to his or her enrollment, or to provision or payment for health services.

Proposed § 438.608 sets forth a separate certification requirement, requiring that MCOs certify the accuracy, completeness, and truthfulness of information in contracts, requests for proposals, and other related documents specified by the State.

Comment: One commenter suggested that the program integrity requirements in subpart H apply to all MCOs/primary care case managers (PCCMs), not just MCOs.

Response: We agree with the commenter that the requirements in subpart H should have applicability beyond MCOs. The commenter suggested that primary care case managers should be subject to these requirements. We agree with this recommendation to the extent the PCCM is paid on a risk basis as the MCOs that were the subject of subpart H. In this case, payments may also be based on encounter data submitted by the entity, and the same types of incentives and potential for fraud and abuse apply. However, in the case of a PCCM paid a fixed monthly case management fee, payments for services furnished to an enrollee are paid under the existing State plan payment process, which is subject to existing fraud and abuse protections that apply generally to providers that bill Medicaid. In order to identify only those PCCMs and other non-MCO entities that are paid on a risk basis, we are revising § 438.8 to require

that PHPs comply with the program integrity requirements in subpart H.

Comment: One commenter requested clarification as to whether subpart H applies only to MCOs operated under a State plan option or to both those operated under a State plan option and those operated under a waiver program.

Response: The requirements of subpart H apply to MCOs, whether the MCO or PHP operates under a waiver program, a mandatory managed care program, or a voluntary program.

Comment: Several commenters believe that requiring certification of data as 100 percent accurate and complete is unworkable and not customary. The commenters suggested that this provision does not recognize the impossibility of meeting an absolute standard, that this provision should be changed to correlate with more commonly accepted standard language on certifications and to correlate with the language adopted by the Medicare+Choice program.

Response: We recognize that requiring attestation that data is 100 percent accurate may not be feasible. We believe that it is important to ensure accurate data submissions. Because this information may directly affect the calculation of payment rates, we are amending the regulation to be consistent with the current language being adopted in the Medicare+Choice provisions; that is, we will require that attestations be "based on best knowledge, information, and belief." We have restructured and recodified some of the provisions of proposed subpart H. The revised certification requirement containing the Medicare+Choice language is now in § 438.606(b). These certifications will assist HCFA, State agencies, and OIG in combating fraud and abuse and in investigating and prosecuting suspected cases of fraud as authorized by the False Claims Act.

Comment: One commenter believes that the relationship between the submission of data and Medicaid payments is neither clear nor uniform and that there may be a tenuous connection between the State's reliance on the substance of the data and its payments to the MCO. The commenter also believes that certification of data fails to address incentives for underutilization and permits Medicaid payment for coverage of services that the MCO may not actually be providing. This commenter recommended that the MCO's payments be based upon filing a "claim" for these payments, certifying the data on which payments may be based, and whether the MCO substantially meets its contract requirements.

Response: Not all States base payments to MCOs on encounter data or on enrollment data submitted by the MCO. In this case, the certification requirement in proposed § 438.604(a) would not apply as it only applies to data when payments are based on the data. If it is not clear that there is a connection between given data and payment, those data may not have to be certified. We believe it is important that data are certified as accurate, at least to the best of the MCO's belief, if payment to that MCO will be based on these data. Submission of data that are complete and accurate will provide the State with information needed to set actuarially sound capitation rates. We disagree with the commenter that underutilization is not addressed at all, as encounter data can be used by States to identify and address underutilization and the potential for payments made for services not furnished. While we do not require States to collect encounter data from MCOs, we believe this is becoming a State requirement. It is unclear how the commenter's first recommendation concerning basing payment on filing a claim and certifying data associated with the claim relates to the commenter's concern for underutilization or how the recommendation differs from the requirements in subpart H. We agree with the commenter that MCOs should be required to certify that services are being provided in substantial compliance with their contracts, since under § 438.802(c) of this final rule (discussed in section II.H of this final rule) FFP is only available in contract payments if the MCO is in substantial compliance with its contract. We have revised §§ 438.604 and 438.606 to provide for this certification.

Comment: Several commenters believe the data should be certified by the Chief Executive Officer (CEO) or the Chief Financial Officer (CFO) whom they believe would have actual knowledge of the accuracy, completeness, and truthfulness of the data and believe that this requirement would force the MCOs to establish procedures and protocols to ensure that the information is correct. These commenters believe that problems arise when the person signing the certification may not have direct information concerning these facts, and that the CEO or CFO should certify the accuracy of the data on a document, a requirement similar to that in the Medicare+Choice program.

Response: We agree with these commenters that an accountable individual such as the CEO or CFO should sign the certification, and we

accept the commenters' suggestion that the Medicare+Choice requirement be adopted. Under § 422.502(l) of the Medicare+Choice regulations, certifications must be signed by "the CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer." We have adopted this language in § 438.606(a)(2) of this final rule.

Comment: Several commenters urged that related entities, contractors, or subcontractors that generate these data should be required to certify the accuracy, completeness, and truthfulness of the data.

Response: We agree with these commenters, and we are providing (1) in § 438.602 that an MCO "and its subcontractors" must comply with the certification requirements in subpart H; and (2) in § 438.606(a)(1) that MCOs must require subcontractors to certify the data they submit to MCOs if the data are used in determining the MCO's payment.

Comment: Another commenter believes that the large majority of data on which payment is based is determined by the State agency and not by the MCO. Regardless of the billing data submitted by the plan, the commenter believes the State determines the payment to the MCO based on information within the State system and the certification of the accuracy of the data should be applied equally to the State agency.

Response: The purpose of the certification requirement with respect to data submitted to the State by the MCO is to ensure that MCOs do not submit false or inaccurate data that might result in inappropriate higher payment amounts. It is a protection for the State and HCFA against being defrauded, or paying an MCO more than the amount to which it should be entitled. The State has no incentive to pay more than the amount dictated by accurate information, and has existing incentives to use accurate data. A major purpose of the certification requirement is to facilitate possible cases under the False Claims Act. States are not subject to the False Claims Act. States are subject to detailed requirements in § 438.6(c) requiring that payments are accurate and appropriate. We do not believe that States should have to certify data. However, if payment is based solely on State data, and an MCO does not submit any data upon which its payment is based an MCO would not have to sign certifications under subpart H.

Comment: One commenter believes that data integrity is critical but was still unclear on certification requirements.

Response: We believe that this final rule clearly spells out which data must be certified (§ 438.604), who must certify the data (§ 438.606(a)), and to which data the certifying individual is attesting (§ 438.606(b)). We believe that the requirements of these regulations are clear. We believe that imposing more detailed requirements than already set forth in this final rule would be overly prescriptive and that States should have flexibility in applying these requirements.

Comment: One commenter believes that the State Medicaid Fraud Control Units (MFCUs) should be added to the list of parties to whom the MCO must submit the reports required in § 438.606.

Response: We did not identify the MFCUs as a recipient of the reports on the violations of law because States are already required under 42 CFR 455.21 to refer to the MFCU all cases of suspected provider fraud, including such materials as records or information kept by the State Medicaid Agency or its contractors, computerized data stored by the Agency, and any information kept by providers to which the State Medicaid Agency is authorized access. States already have established relationships with MFCUs relative to referring cases of suspected fraud and abuse. We believe this requirement is already sufficiently addressed, and we have not revised this aspect of the proposed rule.

Comment: One commenter suggested that administrative and management arrangements or procedures should include specific plans for the method by which the MCO intends to discover and discourage fraud and abuse and that these specific plans should be submitted to the State Medicaid Agency for review and prior approval before execution of any contract. The commenter believes that specific plans would eliminate subjective determinations by each MCO of that which constitutes effective arrangements and management procedures.

Response: We believe that it is appropriate to allow States flexibility in determining their requirements for MCOs in this regard. We also note that States may have laws that govern this authority, and we wish to respect those laws.

Comment: One commenter noted differences between the language in proposed § 438.606 requiring only that MCOs have a process for reporting violations of law and language in § 422.501(b)(3)(vi) of the Medicare+Choice interim final rule published on June 28, 1998 requiring that Medicare+Choice organizations have a comprehensive compliance plan

that includes an “adhered-to” process for reporting credible information to HCFA and/or OIG. The commenter recommended that HCFA adopt the Medicare+Choice language in §422.501(b)(3)(vi). The commenter believes consistency between Medicare and Medicaid will reduce the regulatory burden on managed care plans that elect to participate in both programs by eliminating any uncertainty as to what standard of conduct applies. A few commenters raised concerns about the general requirement that MCOs have “administrative and management arrangements or procedures designed to guard against fraud and abuse.” Instead of imposing Federal requirements in this area, such as self-reporting, the commenter believes the rule should allow States to take the lead in working with MCOs to combat fraud and abuse in the Medicaid program.

Response: We agree with the first commenter that maintaining consistency with Medicare+Choice will eliminate unnecessary burden on plans and that administrative and management procedures that include a compliance plan will work toward that end. We have included a compliance plan that includes the same elements as those listed in the Medicare+Choice final rule published on June 29, 2000 (65 FR 40170). We disagree with the second commenter that there should be no Federal requirements, but, consistent with the commenter and consistent with the Medicare final rule, which deleted the mandatory self-reporting requirement in §422.501(b)(3)(vi)(H), we have deleted this requirement. The Medicaid MCO requirements and Medicare+Choice requirements are now consistent on this issue.

Comment: A few commenters raised concern over the term “credible” information. One commenter believes the word “credible” should be replaced with the standard contained in §455.15, specifically that if there is “reason to believe that an incident of fraud or abuse has occurred,” MCOs are required to report this to the State. One commenter believes the word “credible” should be eliminated entirely so that MCOs are not penalized for reporting in good faith information that is later found not to be credible.

Response: We have deleted the Federal self-reporting requirement containing the word “credible,” so these comments are moot.

G. Sanctions (Subpart I)

Section 1932(e)(1) of the Act requires, as a condition for entering into or renewing contracts under section 1903(m) of the Act, that State agencies

establish intermediate sanctions that the State agency may impose on an MCO that commits one of six specified offenses: (1) Failing substantially to provide medically necessary services; (2) imposing premiums or charges in excess of those permitted; (3) discriminating among enrollees based on health status or requirements for health care services; (4) misrepresenting or falsifying information; (5) failing to comply with physician incentive plan requirements; and (6) distributing marketing materials that have not been approved or that contain false or materially misleading information. In the case of violation number 6, the statute imposes sanctions against PCCMs as well as MCOs. Proposed §438.700 contains the above provisions from section 1932(e)(1) of the Act.

In section 1932(e)(2) of the Act, the Congress provided specific sanction authority under which State agencies may impose civil money penalties in specified amounts for specified violations, take over temporary control of an MCO, suspend enrollment or payment for new enrollees, or authorize enrollees to disenroll without cause. These provisions are reflected in proposed §438.702(a). Given the extraordinary nature of the sanction of taking over management of an MCO, we proposed in §438.706 that this sanction be imposed only in the case of “continued egregious behavior,” in situations in which there is “substantial risk” to enrollee health, or when the sanction is “necessary to ensure the health of enrollees.”

Although these sanctions are referenced in section 1932(e)(1) of the Act as sanctions to be imposed on MCOs and on PCCMs only in the case of marketing violations, section 1932(e)(2)(C) of the Act refers to a “managed care entity,” while paragraphs (D) and (E) that follow refer to “the entity” and provide for suspension of enrollment or suspension of payment after the date the Secretary notifies “the entity” of a determination that it has violated “section 1903(m) or * * * section [1932].” While only an MCO could violate section 1903(m) of the Act, a PCCM could violate requirements of section 1932 of the Act that apply to MCOs and PCCMs generally or to PCCMs specifically. In proposed §438.702(b)(2), we interpret the foregoing language to mean that the sanctions in sections 1932(e)(2)(D) and (E) of the Act are available in the case of a PCCM that violates “any requirement” in section 1932 of the Act. The general intermediate sanction authority in paragraphs (D) and (E) of section 1932(e)(2) of the Act is reflected

in §438.702(b)(1) with respect to MCOs. In light of the foregoing interpretation, paragraphs (b)(4) and (b)(5) of §438.702 use the term MCO or PCCM rather than MCO only, even though the only “determinations” that apply to PCCMs are terminations under proposed §438.700(a)(6) (marketing violations) or the general violations of section 1932 of the Act that are addressed in §438.702(b)(2). Under the codification in the proposed rule, these latter determinations technically are not “determinations under §438.700,” and are not included under paragraphs (b)(4) and (b)(5) of §438.702. As recodified in this final rule, these determinations are addressed in §438.700(d).

Section 1932(e)(3) of the Act requires that, for MCOs with chronic violations, the State impose temporary management and allow disenrollment without cause. This provision is implemented in proposed §438.706(b).

Section 1932(e)(4) of the Act authorizes State agencies to terminate the contract of any MCO or PCCM that fails to meet the requirements in sections 1932, 1903(m), or 1905(t) of the Act. This authority is implemented in proposed §438.708. Under section 1932(e)(4)(B) of the Act, before terminating a contract, the State is required to provide a hearing. Proposed §438.710 sets forth this hearing requirement as well as procedures for the hearing. Under section 1932(e)(4)(C) of the Act, enrollees must be notified of their right to disenroll immediately without cause in the case of any enrollee subject to a termination hearing. Proposed §438.722 reflects this provision.

Section 1932(e)(5) of the Act contains a general requirement that States provide “notice” and “such other due process protections as the State may provide” in the case of sanctions other than terminations, which are governed by section 1932(e)(4)(B) of the Act. Section 1932(e)(5) of the Act also provides that “a State may not provide a managed care entity with a * * * hearing before imposing the sanction” of temporary management. Proposed §438.710(b) reflects this statutory language.

In proposed §438.724, we proposed that States be required to notify HCFA whenever they impose or lift a sanction.

The new sanction authority in section 1932(e) of the Act represents the first time that the Congress has granted Medicaid sanction authority directly to State agencies. Under section 1903(m)(5) of the Act, which the Congress has left in place, HCFA has authority to impose sanctions when Medicaid-contracting MCOs commit

offenses that are essentially the same as those identified in section 1932(e)(1) of the Act. In proposed § 438.730, we retain the existing regulations implementing section 1903(m)(5) of the Act, which is currently codified at § 434.67.

Comment: A few commenters recommended that we add the requirement: "States shall develop criteria to guide them in their determinations of when and how to use specific sanctions individually or in conjunction with each other."

Response: While section 1932(e) of the Act mandates that States establish intermediate sanctions, it grants States flexibility to determine which sanctions to impose and when to impose them, stating that State sanctions "may include" those identified in section 1932(e)(2) of the Act and that the State "may impose" these sanctions. We believe that the Congress intended to give States discretion and flexibility in this area. While we would expect that most States would establish specific criteria to guide their exercise of sanction authority, we believe it should be a State decision whether or to what extent it imposes sanctions. We are not including the suggested Federal criteria requirement.

Comment: One commenter suggested that we provide expressly in subpart I that sanctions be imposed for violations of proposed § 438.100, which require that contracts specify what services are included in the contract and require that States make arrangements for those not covered through the contract. The commenter believes that this would help ensure access to all Federally mandated benefits and services, including nurse-midwifery services.

Response: The Congress intended that States have flexibility in imposing sanctions, requiring only that States have sanctions in place for the specific violations in paragraphs (i) through (v) of section 1932(e)(1)(A) of the Act. Our authority under section 1903(m)(5) of the Act is similarly limited. Even under our broad interpretation of paragraphs (D) and (E) of section 1932(e)(2) of the Act, under which States may impose intermediate sanctions for any violation of sections 1903(m) or 1932 of the Act, the sanctions suggested by the commenter would not be provided for since neither of these sections mandate the inclusion of the contract terms required under proposed § 438.100(a) or impose the obligation on States under proposed § 438.100(b). If services that are included in the contract are not provided, sanctions are authorized under § 438.700(a)(1).

Comment: One commenter supported the provisions in subpart I but suggested that misrepresentation to any member of the public should also be cause for sanction.

Response: Sections 438.700(b)(4) and (5) allow States to impose sanctions on MCOs for misrepresenting or falsifying information that they furnish to HCFA, the State, an enrollee, potential enrollee, or health care provider. This provision implements section 1932(e)(1)(A)(iv) of the Act, which specifies these entities. It is not clear how a misrepresentation to a member of the public who is not a provider, enrollee, or potential enrollee would be relevant. We believe that this list covers any individual, government agency, or entity that could be affected by a misrepresentation. States are free to develop, under State law, a policy to require sanctioning for misrepresentation to any member of the general public.

Comment: One commenter had serious concerns about what the commenter perceived to be the absence of adequate Federal, as opposed to State, standards on the rights to be afforded to MCOs to contest sanctions. Although this aspect of the rule reflects section 1932(e)(5) of the Act, which leaves the decision on what due process protections to provide to MCOs to the States, the commenter believes that States should be encouraged to provide MCOs the same procedural protections that HCFA has provided to Medicare+Choice organizations before HCFA imposes sanctions.

The commenter was also concerned about potential conflicts between the intermediate sanctions required under the Act and the provisions of State law. This commenter also applauded the proposed rule allowing MCOs to be sanctioned for not providing medically necessary services to Medicaid enrollees. Regarding discrimination among enrollees on the basis of health status or need for health care services, the commenter recommended that all health insurance policies fulfill the following requirements: (1) no waiting periods for enrollment; (2) no limitation of coverage or reimbursement because of severe chronic or common recurring illnesses; (3) no premium rate increases based on experience only on community rating; and (4) guaranteed renewability and portability.

Response: The statute requires timely written notice, a hearing before terminating an MCO contract, and in the case of other sanctions for "such other due process protections as the State may provide." The commenter recognizes that the Congress has expressly granted States the discretion to determine what

procedures to afford to MCOs in the case of intermediate sanctions and civil money penalties. We agree with the commenter that States should be encouraged to consider offering the types of procedures offered to Medicare+Choice organizations under the Medicare regulations. We do not agree that there is a risk of conflict between the intermediate sanctions authority in subpart I and provisions of State law, because these sanctions have to be established only if State law does not cover the specified situations. With regard to the commenter's suggestion concerning discrimination, we believe that the regulations address these issues. In the case of the "waiting period" issue, § 438.6(c)(1) requires that enrollees be accepted in the order in which they apply without restrictions. With respect to the issues of coverage limits or premium increases based on a health condition, § 438.6(c)(1) addresses the provision prohibiting discrimination based on health status or need for health services. Section 438.6(c)(1) also addresses the issue of renewability to the extent that the individual remains Medicaid eligible and the contract remains in place. Since Medicaid only covers people who meet financial eligibility requirements, it is impossible to guarantee renewability. "Portability" of Medicaid benefits is similarly impossible.

Comment: A commenter suggested that subpart I should address the issue of inadvertent balance billing of Medicaid enrollees. There are no guidelines that would enable the State agency or contracting MCOs to differentiate minor technical violations from those that should result in sanctions and fines of several thousand dollars. The regulations should develop criteria to guide this kind of decision making and to protect MCOs from arbitrary State action.

Response: Under section 1932(e) of the Act, imposition of sanctions is almost entirely at a State's discretion, other than termination and temporary management rules. We believe that States are in the best position to develop criteria for when they will impose sanctions for balance billing violations, which could be sanctioned under section 1932(e)(1)(A)(ii) of the Act and § 438.700(b)(2) (codified at § 438.700(a)(2) in the proposed rule) as "charges on enrollees" in "excess of" the charges permitted under title XIX.

Comment: A commenter stated that section 438.700, which specifies the basis on which States may impose intermediate sanctions on an MCO, should include discrimination based on race, ethnicity, or language. This would

be in keeping with Title VI of the Civil Rights Act which states that "no person in the United States shall, on ground of race, color or national origin, be excluded from participation, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance." Several of the commenters stated that the omission of Title VI requirements from the list of sanctionable activities reduces the likelihood that MCOs will comply with cultural competency requirements. It is also very important that the rules strengthen the requirements for both State Medicaid agencies and their managed care plans to collect data regarding the race/ethnicity of the enrollees and the care of patients with limited proficiency and/or low literacy. The commenter recommended amending proposed § 438.700(a)(3) (recodified at § 438.700(b)(3) in this final rule) to read, "Acts to discriminate among enrollees on the basis of their health status, race, color or national origin, or requirements for health care services."

Response: Section 438.700(b)(3) reflects the language in section 1932(e)(1)(A)(iii) of the Act, which addresses only discrimination based on health status. Since § 438.700(b) reflects the specified violations for which the Congress in section 1932(e)(1)(A) of the Act said States must have sanctions, we believe that we do not have authority under section 1932(e) of the Act to add additional grounds. The civil rights law cited by plaintiffs has its own enforcement provisions, which are administered by the HHS Office for Civil Rights. We believe that it is appropriate to inform MCOs of their obligations under this and other civil rights laws and have required under revised § 438.6(d)(4) that contracts expressly reflect these obligations. Also, § 438.100(d) specifies that the State must require MCOs to comply with Title VI of the Civil Rights Act and other civil rights laws. In addition to the Federal enforcement remedies under civil rights laws, States are free to impose sanctions on an MCO that denies services on the basis of race, color, or national origin, or establish their own rules under State law.

Comments: In general, several commenters wanted the regulation to be clear that States have the authority to impose sanctions for violations beyond those that are listed in the regulation. These commenters do not believe that the six violations listed in this section should be seen as exhaustive and that States should not be precluded from establishing and imposing separate State

sanctions or from imposing other types of sanctions. These commenters believe that while our intent may have been clear in the preamble, we should set forth our policy with respect to sanctions in the regulations text. Specifically, the commenters stated that it is unclear whether the regulations allow States to broaden the parameters for imposing sanctions on MCOs or limit the States to the basis set forth in the Act and the regulations. States have made progress in developing their own protections and responses to hold MCOs accountable and should not be preempted by Federal law from using them. They stated that we recognized this concept in the preamble of the proposed rule and suggested that we incorporate this concept into the actual regulations text. They believe that the six offenses outlined in the regulation should not be the only offenses that would permit imposition of sanctions. There are numerous offenses that MCOs could commit that could affect both the integrity of the Medicaid program and the quality of care that Medicaid enrollees receive, for example, failure by the plan to submit accurate data or failure to achieve State defined quality improvement standards. The commenters believe that we should not limit a State's ability to enforce its contract and should instead give States the explicit authority to impose sanctions if an MCO performs unsatisfactorily as found during an annual medical review or audit or if an MCO does not provide complete data to a State or Federal regulator. Recommended solutions provided by the commenters included the following:

- Add a paragraph (a)(7) to § 438.700 stating that sanctions can be used for violations of 1903(m) and 1932 of the Act;
- Add a new paragraph (c) to § 438.700 that specifies: "State agencies retain authority to provide for additional sanctions under State law or regulation that address both these specified areas of noncompliance as well as additional areas of noncompliance. Nothing in this regulation prevents State agencies from exercising that authority;"
- Add a new paragraph (a)(7) § 438.700 that allows States to impose sanctions for any breach of contract not mentioned in paragraphs (a)(1) through (a)(6);
- Amend § 438.700(a) to specify that the sanctionable violations include, but are not limited to, the specified violations;
- Add to § 438.700(a), after the word "determination," "based on findings from onsite survey, enrollee, or other

complaints, financial audits, or any other means." This language clarifies that the State is authorized to act based on findings it has made, regardless of the source of the original information. Broad authority for the State to sanction on the basis of complaints provides enrollees with assurances that the State can hold the entity accountable for specific acts of noncompliance that enrollees or their advocates bring to the State's attention but that might not be evident on an onsite survey.

Response: We agree with the commenters that the sanctions in subpart I do not prevent States from imposing any other sanction they wish under State law, and that the regulations should clearly state that this is the case. We are adopting the commenter's suggested regulations text in a new paragraph (b) in § 438.702. We also agree that it would be useful to clarify that these sanctions may be imposed based on information obtained through enrollee complaints, audits, onsite surveys, or any other means and have added the commenter's suggested language to § 438.700(a).

We disagree with the commenters' suggestions that the list of sanctions in proposed § 438.700(a) be broadened or that the regulations provide for imposing the full range of possible sanctions in the case of any violation of section 1932 or 1903(m) of the Act. To the extent that a State is relying not on any State law, but solely on the affirmative authority enacted by the Congress in section 1932(e) of the Act, this authority is necessarily limited to that provided by the Congress. While we have broadly interpreted paragraphs (D) and (E) of section 1932(e)(2) of the Act to permit suspension of enrollment or payment for any violations of 1903(m) and 1932 of the Act (see § 438.700(d)) and the above discussion of proposed § 438.702(b), section 1932(e) of the Act does not contain authority to impose any of the other sanctions in section 1932(e)(2) of the Act for violations other than those enumerated in section 1932(e)(1)(A)(i) through (v) of the Act.

Comment: One commenter argued that we should amend § 438.700(a) to apply to PCCMs as well as to MCOs. This commenter does not believe there was a compelling argument for applying most sanctions only to MCOs. The commenter argued that PCCMs that fail to provide medically necessary services, misrepresent information provided to HCFA, the State, an enrollee, potential enrollee, or health care provider, or impose excessive premiums or charges on enrollees should be subject to sanctions. Another commenter strongly advised HCFA against drawing a

distinction between MCOs and PCCMs in granting the States authority to impose sanctions for inappropriate behavior. Other commenters also believe that the final rule should provide additional authority to impose sanctions on all MCOs and PCCMs and specifically suggested that the final rule gives States the authority to—

- Require noncompliant MCOs or PCCMs to submit a corrective action plan;
- Temporarily and permanently withhold capitation payments and shared savings in response to unsatisfactory MCO or PCCM performance during an annual medical review or an audited review;
- Make adjustments in MCO or PCCM payments;
- Mandate payment for medically necessary treatment;
- Recoup the cost of State payment for out-of-plan care from a noncompliant MCO or PCCM; and
- Arrange for the provision of health care services by third parties at the cost and expense of the delinquent MCO or PCCM.

These commenters believe that Medicaid beneficiaries in both delivery systems should receive equal protection under the law and that denying States equal authority for imposing sanctions under both delivery systems is not judicious. Conversely, one commenter found applying sanctions to PCCMs problematic because this would hold these entities to a higher standard. California PCCMs currently are not Knox-Keene licensed. This commenter was concerned that this section of the proposed rule may require PCCMs to become Knox-Keene licensed and/or their contracts may have to be amended to reflect the new higher standard.

Response: To the extent a State is relying solely on the Federal authority provided by the Congress as its authority to impose a sanction, this authority is limited to that which the Congress provided. With respect to the violations enumerated in paragraphs (i) through (v) of section 1932(e)(1)(A) of the Act, all but the marketing violations are limited to MCOs. We have already interpreted paragraphs (D) and (E) of section 1932(e)(2) of the Act broadly to permit the sanctions in those paragraphs to be imposed on PCCMs in the case of any violation of section 1932 of the Act. We do not believe that section 1932(e) of the Act can reasonably be interpreted to provide authority for the types of sanctions suggested by the commenter. Because most PCCMs are paid on a fee-for-service basis, they do not have the same incentives to deny medically necessary services that MCOs do. States

may provide for sanctions against PCCMs under their own State sanction laws. With respect to the commenter concerned about applying sanctions to PCCMs, the Congress provided for this in section 1932(e) of the Act, and we do not believe that this application is inappropriate or would subject PCCMs to the Knox-Keene Act.

While States are free to adopt the specific additional enforcement strategies suggested by the commenter in the bullet points above, these strategies cannot be included in regulations implementing section 1932(e) of the Act, since there is no reasonable reading of the provisions of section 1932(e) of the Act that would authorize those remedies.

Comment: One commenter believes that HCFA should specify additional grounds for imposing intermediate sanctions and suggested that the final regulations explicitly state that States may impose sanctions when an MCO fails to comply with the grievance regulations of this part. States would be more likely to impose these intermediate sanctions rather than the options provided for in § 438.424.

Response: The sanction authority provided for by the Congress in section 1932(e) of the Act is limited. Section 1932(e) of the Act sets forth the minimum set of violations that must be subject to sanction and provides Federal authority to impose sanctions for these violations. We cannot expand on this authority by regulation. We have clarified in the preamble, and now in § 438.702(b), that States are free to impose sanctions under State law that go beyond those authorized by the Congress in section 1932(e) of the Act, including sanctions for failing to comply with grievance requirements. To the extent that an MCO violates the grievance requirements or regulations implementing section 1932(b)(4) of the Act, States could impose the limited sanctions provided for under paragraph (D) and (E) of section 1932(e)(2) of the Act and § 438.700(b).

Comment: One commenter believes that we should amend § 438.700(a)(1) to refer expressly to the failure to provide medically necessary “items” as well as services, since this term is included in section 1932(e)(1)(A)(i) of the Act. Alternatively, the commenter suggested that we use the term “benefits” rather than “services,” since the commenter believes that the former term would include services and items. For example, prescription drugs and durable medical equipment may not be considered “services.”

Response: We do not use the term “items” in our regulations because the

term “services” as used in the regulations includes covered “items” as well. While only the Medicare regulations expressly specify that “services” includes “items” (§ 400.202), section 1905(a) of the Act uses the term “care and services” to encompass all services or items for which Medicaid payment may be made. References in the regulations to “services” include covered “items” as well.

Comment: A few commenters were confused regarding our role in the sanction area. These commenters are unclear as to whether HCFA would be making sanction determinations, either at the request of the State or independently. The commenters are opposed to HCFA making sanction determinations without the involvement of the State.

Response: Under § 438.730 of the final rule, previously codified at § 434.67, we may impose sanctions on an MCO based on the recommendation of the State. Under paragraph (e) of § 438.730, we also retain the right to act independently with respect to sanctions. This is consistent with section 1903(m)(5) of the Act, which grants us the authority to impose sanctions against an MCO. This Federal authority was not affected by the new BBA sanction provisions in section 1932(e) of the Act. While we would not expect to impose sanctions without the involvement of the State, we believe that the regulations should reflect the fact that the Congress has authorized us to do so.

Comment: One commenter believes that additional consumer protections were needed with regard to the right to disenroll without cause when sanctions are imposed and that States should be required to educate enrollees on the circumstances that allow them to disenroll automatically. Another commenter requested that HCFA clarify that a State is free to suspend default enrollment, leaving beneficiaries to make an affirmative decision whether to enroll. Several other commenters suggested that HCFA further clarify this provision and give States the option of suspending all enrollment, not just default enrollment. According to the commenters, this clarification would not only provide States with greater flexibility but would also permit greater choice for Medicaid beneficiaries.

Response: Under § 438.702(a)(4) of the final rule, the State may suspend all new enrollment, including default enrollment, as an intermediate sanction. The State is not precluded from establishing other types of intermediate sanctions that are not included in the

regulation. With respect to the suggestion concerning information provided to enrollees, § 438.56(c) requires that information on an enrollee's disenrollment rights be provided annually, including the circumstances under which a beneficiary can disenroll "for cause."

Comment: Several commenters requested clarification that States still have the flexibility to establish civil money penalties beyond those listed in the regulation. One commenter specifically mentioned that the amounts of the civil money penalties seemed high but that they would not be problematic so long as the amounts were not mandatory. Another commenter mentioned that if PCCMs could be sanctioned, there should be a regulatory ceiling on the amount of the penalty.

Response: The amounts specified in this provision only apply to the extent the State is relying upon Federal law, under section 1932(e) of the Act, as its authority to act. States may, under State law, establish additional civil money penalties that may be more severe than those authorized under section 1932(e)(2)(A) of the Act or § 438.704. With respect to PCCMs, to the extent the State is relying on Federal law as its authority for the establishment of sanctions, the civil money penalties under § 438.704 would be maximum amounts. A State is not precluded from developing additional intermediate sanctions against PCCMs or MCOs, as explicitly noted in § 438.702(b).

Comment: One commenter believes that HCFA should provide additional guidance as to how the amount of the civil money penalty elected, in cases in which States have discretion to choose an amount below a specified maximum, should be related to the purported harm. The commenter believes that HCFA should provide some rationale for assessing money penalties and should discuss this section with the commenter to develop this rationale.

Response: Section 1932(e)(2)(A) of the Act establishes a relationship between the amount of the civil money penalty (as described in § 438.704 of the final rule) and the specific violations to which these penalties apply. In clauses (i) and (ii), "maximum" amounts are specified. We believe that by establishing a "maximum" amount for these violations, the Congress intended that States have the discretion to decide what amount to impose below these maximum amounts. We are allowing the States to decide the amount they wish to impose in penalties and to establish criteria for cases when particular

amounts at or below the specified maximums will be imposed.

Comment: One commenter expressed confusion regarding the maximum penalty that can be imposed under section 1932(e)(2)(A)(iii) of the Act for imposing premiums or charges in excess of those permitted. Under section 1932(e)(2)(A)(iii) of the Act, for this type of violation, the penalty that can be imposed is double the amount of any excess amount charged to an enrollee with half this amount refunded to the overcharged enrollee or enrollees. The commenter asked whether this would be for the one enrollee who reported a \$5 overcharge (that is, one \$10 amount) or \$10 per each enrollee in the plan. Another commenter suggested that the regulation should be changed to provide that it is the MCO's responsibility, not the State's, to return the amount of the overcharge to affected enrollees and that the authority to collect double the amount of the excess charge provides authority to collect more than the \$25,000 limit stated in paragraph (a).

Response: Section 438.704(b)(4) of the final rule specifies that for premiums or charges in excess of the amounts permitted under the Medicaid program, civil money penalties may be imposed at an amount representing double the amount of the excess charges. This would be imposed for each instance of the violation and not necessarily calculated using the total number of enrollees in the plan. If all enrollees were charged the excess amount, this amount would be doubled for all enrollees. Since the State imposes and collects the entire fine, we believe that the State ordinarily would reimburse enrollees by distributing half the amount specified in section 1932(e)(2)(A)(iii) of the Act. We would leave it to the State's discretion, however, whether it wishes to reimburse enrollees through the MCO.

With respect to the commenter's last point about the applicability of the authority to impose \$25,000 in penalties in cases of overcharges to enrollees, section 1932(e)(2)(A)(i) of the Act permits a civil money penalty of "not more than" \$25,000 for "each determination" under section 1932(a)(1)(A) of the Act, "except as provided in clause (ii), (iii), or (iv)." We believe that this language could reasonably be interpreted in two ways. Under one reading, "except as provided in clause (ii), (iii), or (iv)" would be interpreted to mean that clause (i) has applicability only when the other three clauses do not apply. Under this interpretation, one would look solely to clause (ii), (iii), or (iv) to determine the amount that could be imposed in civil

money penalties when those clauses apply. If the amount under section 1932(e)(2)(A)(iii) of the Act was \$10,000, only this amount could be imposed in penalties. The commenter has suggested an alternative reading, under which the "except as provided" clause is read as an exception to the \$25,000 limit in clause (i). Under this interpretation, civil money penalties of up to \$25,000 could be imposed for any determination under section 1932(e)(1)(A) of the Act "except" to the extent that an even higher amount is permitted in the cited clauses. The \$25,000 amount would, under this reading, constitute a "floor" authorized penalty with potentially higher "ceilings" under the other clauses. The \$100,000 amount provided for under clause (ii) is higher than \$25,000 and would constitute an exception to the \$25,000 limit. The amount determined under clause (iv) would similarly be higher than \$25,000, as long as just two individuals were denied enrollment based on health status (which would result in a penalty of \$30,000). Under clause (iii), "double the excess amount charged" also could easily exceed \$25,000, and thus also constitute an "exception" to the \$25,000 limit in clause (i). We agree with the commenter that this latter interpretation is the best interpretation of the statute, in that a substantial penalty could be imposed for overcharging enrollees, even if the amount of the overcharge is not substantial. We are providing in § 438.704(b)(4) that States may impose civil money penalties of the "higher of" \$25,000 or the amount under section 1932(e)(2)(A)(iii) of the Act.

Comment: Several commenters requested that HCFA reconcile the numerous variations between proposed § 438.704 and 42 U.S.C. 1396u2(e)(2)(A). The commenters suggested that the term "either" in proposed § 438.704(a) should be eliminated and replaced with the term "any" and that the words "a failure to act" in proposed § 438.704(a)(1) should be replaced with "an act or failure to act." These changes would make it clear that the State is not being directed to respond to one circumstance at the expense of another and that noncompliance can be applied in both actions and failures to act.

Response: We agree with the commenter's points, and the revised version of § 438.704 does not contain the reference to "failure to act" without "action," or the word "either" as referenced by the commenter.

Comment: Numerous commenters believe that we were too restrictive in our interpretation of the \$100,000 cap for some of the civil money penalties

outlined in the proposed regulation. In the view of these commenters, the MCO should be fined \$15,000 for each beneficiary not enrolled as a result of discrimination, plus \$100,000. One commenter believes that there should not be a \$100,000 cap at all, because in large areas that threshold is quickly met and enforcement could not proceed.

Response: Under section 1932(e)(2)(A)(iv) of the Act, the provision for a \$15,000 penalty for each individual denied enrollment under “a practice” described in section 1932(e)(1)(A)(iii) of the Act is “subject to” section 1932(e)(2)(A)(ii) of the Act. Section 1932(e)(2)(A)(ii) of the Act limits the amount of any penalty for “a determination under [section 1932(e)](1)(A) to \$100,000.” If section 1932(e)(2)(A)(iv) of the Act were intended to permit penalties in excess of \$100,000 for a finding of discrimination under section 1932(e)(1)(A)(iii) of the Act, it would have said “in addition to” the amount in clause (ii) of section 1932(e)(2)(A)(ii). Instead, it says that the amount under section 1932(e)(2)(A)(iv) of the Act is “subject to” clause (ii). We believe this can only be read to mean that the total amount under clause (iv) is “subject to” the limit in clause (ii) and cannot exceed \$100,000 per determination of a discriminatory practice. If there is more than one finding of a discriminatory “practice described in” section 1932(e)(1)(A)(iii) of the Act, a penalty of up to \$100,000 could be imposed for each such finding.

Comment: All of the commenters oppose the required imposition of temporary management in the case of repeated violations. They believe that we should take a flexible approach to this provision, as it is unlikely that States would choose to impose this requirement, and in many instances this requirement would be overly burdensome. Most commenters indicated that States will be more likely to terminate an MCO’s contract under these egregious circumstances in which our regulation requires the imposition of temporary management. Commenters stated that, putting aside the practical problems associated with such a remedy, they believe that a plan that is incapable of managing itself would be equally poorly run by temporary management. In the view of these commenters, this plan should have its contract terminated and should not be subject to the imposition of outside management in a probably futile attempt to salvage the operation. Another commenter stated that this provision is of great concern because the State should always have the authority to terminate the MCO’s contract if the

MCO meets any specified contract termination threshold. Forcing the State to continue a contractual arrangement and payment when the State has determined that termination is the most appropriate course of action strikes this commenter as imprudent. The imposition of temporary management may be very administratively complex if the State MCO licensing agency does not concur with this course of action, particularly when the MCO has lines of non-Medicaid business that would be affected. Requiring the State to work through the complexities of imposing temporary management when this does not appear to be the appropriate response would be very problematic to the State and have potentially negative ramifications for both enrollees and providers. One commenter believes that if it is appropriate for a State government agency to take over the management of a managed care plan, the appropriate agency would be the State Department of Insurance. That agency generally has far more experience in managing troubled insurers and managed care plans. The commenter recommended that HCFA convey these points to State agencies. Another commenter stated that temporary management requires extensive knowledge and should only be used sparingly. The commenter believes that the State should defer to the State insurance commissioner as temporary management should fall under his or her purview. One commenter would favor a change in the regulation to allow temporary management as an option rather than a mandate. Implementing this sanction would place a heavy administrative burden on the State. Although States would have the discretion to impose this sanction on an MCO, it is doubtful this sanction would ever be used. Authorizing the State to take over management of a commercial enterprise seems to go beyond the scope of authority available to the State, while allowing immediate disenrollment of enrollees is quite justified. The commenter also stated that it is not necessary to assume management of the MCO when other sanctions are available, including termination of the MCO’s contract. This sanction is overreaching and invades the State’s right to determine appropriate sanctions for its plans. Another commenter stated that in the event of continued egregious behavior by an MCO, the State would certainly terminate the contract and reassign enrollees but would not want to be put in the position of managing an MCO. Although this provision is based on statutory language, the commenter

urged HCFA to recognize and to minimize the potential conflict with existing State insurance regulations, policies, and processes for monitoring and taking action against financially insecure plans. One commenter recommended that the regulations reflect the decision reached in the preamble, stating that States set the thresholds for egregious actions requiring temporary management and that the contract can be terminated rather than imposing temporary management.

Response: Section 1932(e)(3) of the Act provides that the State shall (regardless of what other sanctions are provided) impose the sanction of temporary management in cases in which an MCO has “repeatedly” violated section 1903(m) of the Act. To the extent that the commenters believe that the requirement in § 438.706(b) is inappropriate, their arguments are properly directed at the Congress, since this regulatory provision merely reflects the statutory requirement in section 1932(e)(3) of the Act and has no independent legal effect. We have no authority to alter or delete this requirement. We agree with some of the sentiments reflected in the above comments and intend to give States the maximum flexibility permitted by statute. The regulations permit the State to terminate a contract at any time and to do so rather than imposing temporary management. States are also free to establish a threshold in their State plan or otherwise that would have to be met before an MCO is considered to have “repeatedly” committed violations of section 1903(m) of the Act for purposes of the mandatory temporary management requirement in section 1932(e)(3) of the Act. Since the circumstances for each population and MCO vary greatly, we believe it is prudent to work with each State to determine a reasonable threshold. All States will have ample ability to terminate a contract, if they choose, rather than imposing the temporary management requirement.

Comment: Two commenters were concerned over the effect imposition of temporary management would have on the MCO’s commercial enrollment. Another noted that, based upon the regulatory language, this provision could apply to an MCO that also has Medicare and/or commercial business. These commenters believe that this sanction provision raises serious practical concerns, especially with the lack of any due process protections other than written notice. One commenter recommended adding a new paragraph (c) to § 438.706 that says the

State shall develop criteria for who can serve as a temporary manager and shall maintain a list of individuals and entities meeting the criteria who are able and willing to serve in that capacity.

Response: We have no authority to change the requirement in § 438.706(b), since it reflects the statutory requirement in section 1932(e)(3) of the Act. States are free to develop the criteria suggested by the commenter or to maintain the list suggested. Since States are free to terminate a contract before it gets to the stage of a mandatory temporary management, and in keeping with our decision to grant States maximum flexibility in complying with section 1932(e)(3) of the Act, we do not accept the commenter's suggestion that these specific approaches be mandated. We note that for those situations in which temporary management would be mandated under whatever criteria the State develops, MCOs would have had ample warning through other intermediate sanctions and corrective action plans. Since States have the authority to terminate a contract instead of imposing temporary management, termination is more likely to be a State's sanction of choice, with MCOs receiving hearings prior to termination. Except for repeated section 1903(m) of the Act violations, the rest of this section is for use entirely at a State's option. Because we believe that States will be unlikely to exercise temporary management under § 438.706, we believe there should be no effect on an MCO's commercial or Medicare enrollment. In the unlikely event that a State takeover of management were to occur, we would expect States to take measures to limit the scope of their control to the parameters necessary to administer the Medicaid contract.

Comment: One commenter encouraged States to take into consideration the unique needs of children when determining the identification of egregious behavior and threats to enrollees and the number of offenses that would require imposition of temporary management.

Response: We encourage States to take the unique needs of children into consideration when determining when temporary management of an MCO is appropriate. We will take this into consideration when working with States that wish to develop thresholds of section 1903(m) of the Act violations.

Comment: One commenter appreciated being given the clear authority to impose temporary management on an MCO. Another group of commenters supported HCFA's guidance in § 438.706(a) regarding when

the voluntary imposition of temporary management is appropriate. Voluntary imposition of temporary management is appropriate when the State finds through onsite survey, enrollee complaints, financial audits, or any other means that there is egregious behavior on the part of the MCO, substantial risk to enrollees' health, or the need to impose the sanctions to ensure the health of the MCO's enrollees.

Response: We appreciate the commenters' support and approval.

Comment: Numerous commenters were concerned over their perception of a lack of an adequate opportunity for MCOs to contest a State decision to impose a sanction. The commenters noted that while § 438.710(b) requires that a hearing be provided before a contract is terminated, § 438.710(a) requires in the case of other sanctions only that written notice be provided of the sanction and of any due process requirements that the State elects to provide. One commenter was concerned about a perceived lack of minimum procedures before the State can impose sanctions such as civil money penalties or suspension of new enrollment or payments. Another commenter had serious concerns about the absence of Federal procedural process requirements before the imposition of sanctions on MCOs. Based on the terms of the proposed rule, the State agency would have discretion to impose civil money penalties suspend new enrollment, and suspend payment without giving the MCO and PCCM an opportunity to present its views before the decision maker. One commenter believes that rather than denying the right to a hearing relative to the imposition of temporary management, as provided in section 1932(e)(5) of the Act, the entire concept should be reconsidered. One commenter suggested that minimum procedural safeguards should be included in these regulations but did not specify what these minimum safeguards should be. Another commenter recommended that HCFA require State agencies to ensure some form of procedural due process to be used prior to imposition of sanctions. Two commenters recommended that, at a minimum, MCOs be granted procedural safeguards that are the same or very similar to the procedural safeguards that HCFA has given Medicare+Choice organizations.

Response: We do not prohibit States from establishing the "due process protections" that they consider appropriate. As noted earlier, section 1932(e)(5) of the Act provides States with the discretion to make this

decision, stating that " * * * the State shall provide the entity with notice and such other due process protections as the State may provide, * * * " (Emphasis added.) We believe it would be inconsistent with this provision to dictate that specific procedures be employed. We find one area in which our proposed rule goes beyond the requirements of the statute in potentially denying an MCO an opportunity to contest a sanction. Proposed § 438.710(b) of the Act provides that the State could not delay imposition of temporary management "during the time required for due process procedures, and may not provide a hearing before the imposition of temporary management." (Emphasis added.) Section 1932(e)(5) of the Act provides for the State to afford "due process protections," but precludes a State only from providing a "hearing" before imposing temporary management. In response to the above concerns, we have revised what is now § 438.706(c) to eliminate the reference to due process protections and to reflect the statute by prohibiting the State only from providing a hearing before imposing temporary management.

Comment: One commenter believes that when a contractor is terminated, adequate notice needs to be given to beneficiaries. The commenter recommended that we require timely notice to beneficiaries when States terminate an MCO or when an MCO withdraws from the program. This notice should include accurate information on options to enable beneficiaries to make informed choices among other available MCOs and PCCMs.

Response: We agree that Medicaid beneficiaries enrolled in an MCO or PCCM that is being terminated should receive timely notice of the termination with information on the options available to the beneficiary once the termination is effective. While the Congress provided in section 1932(e)(4)(C)(i) of the Act for notice to enrollees of a decision to terminate a contract, this notice is provided only when the State exercises its discretion to permit enrollees to disenroll immediately without cause before the termination hearing is completed. Section 1932(e)(4)(C)(i) of the Act clearly provides that States "may" provide such notice. We agree with the commenter that if a decision to terminate an MCO is upheld, and a termination is about to take effect, beneficiaries should be notified. Under section 1902(a)(19) of the Act, which requires that States provide safeguards necessary to assure that care and

services are provided in a manner “consistent with * * * the best interests of recipients,” we are adding § 438.710(b)(2)(iii) to require that notice of the termination be provided to enrollees of the terminated MCO or PCCM, with information on their options following the effective date of the termination.

Comment: We received one comment that stated that in order to avoid conferring an unintended defense to MCOs that meet the contractual standard for termination of the contract, we should specify that failure of a State to impose intermediate sanctions is no basis for objection or affirmative defense against a contract termination.

Response: States have the authority to terminate an MCO’s or PCCM’s contract without first having to impose intermediate sanctions, such as civil money penalties. If a State chooses not to impose intermediate sanctions before it terminates an MCO’s or PCCM’s contract, this action should not be used as an affirmative defense on the part of the MCO or PCCM against contract termination. We do not believe it is necessary or appropriate to make this statement in the regulation text itself.

Comment: Several commenters disagreed with the language in proposed § 438.718(a) that allows a State to terminate an MCO’s or PCCM’s contract if the MCO or PCCM failed “substantially” to carry out the terms of its contract. These commenters argued that the term substantially does not appear in section 1932(e)(4) of the Act, which is implemented in revised § 438.708, and severely restricts State flexibility in protecting Medicaid beneficiaries and the integrity of the Medicaid program. In the commenters’ view, the added burden of proving substantial failure to comply is unnecessary and will add layers of litigation when a State seeks to terminate an MCO or PCCM. These commenters recommended removing the word “substantially.”

Other commenters made the same point about our inclusion of the word “substantially” in proposed § 438.708, which implements the obligation in section 1932(e)(3) of the Act to impose temporary management in the case of repeated violations. Although the preamble indicates that we introduced the word “substantially” in order to allow States greater flexibility, there is no indication that the Congress intended for there to be greater flexibility in the application of this statutory requirement. These commenters argued that if the Congress had intended flexibility, it would not have made this provision “mandatory”

in the first place, noted that this provision is the only mandatory requirement that sanctions be imposed, and noted that this provision is triggered only in instances in which the MCO repeatedly failed to meet requirements. These commenters found it difficult to understand why we would take what they considered the only mandatory sanction in the statute and attempt to give States greater flexibility.

Response: We agree that the word “substantially” is not used in section 1932(e)(4) or section 1932(e)(3) of the Act, is potentially ambiguous, and could create misunderstanding and enforcement problems. We included this term in proposed §§ 438.718(a) and 438.708 because we did not believe that termination or temporary management would be warranted for violations that are not substantive in nature, such as clerical or non-quality related reporting violations. In response to the above comments, in the final rule, we have changed “substantially” to “substantive” in both § 438.708(a) and § 438.706(b) as codified at § 438.708 in the proposed rule.

Comment: One commenter believes that the 30-to 60-day time frame for the termination hearing was insufficient and imposed an undue administrative burden. Another commenter recommended that the regulation provide notice of the intent to terminate 60 days before the effective date of the termination. The commenter also believes that the final regulation should establish criteria for when termination should be imposed and notice of when a termination decision has been made. A third commenter argued that this proposed requirement would impose a hardship on States because they are required to set the date and time for a hearing that the provider may not wish to have or be willing to attend. One commenter suggested that the termination notification should inform the MCO of its right to request a hearing and the procedures for doing so by phone or by mail. Upon the receipt of a hearing request, the State would be required to schedule the hearing not fewer than 30 or more than 60 days thereafter, unless the State agency and MCO or PCCM agree in writing to a different date.

Response: Because of legitimate concerns from many different parties, and in light of the fact that the Congress chose to provide States with their own discretion to establish due process protections, we are removing the time frames that were in the proposed rule and allowing the State to develop its hearing process and its timing.

Comment: We received several comments requesting that we require the pre-termination hearings be open to the public, since public disclosure is an important step towards ensuring accountability. These commenters stated that the Supreme Court has recognized the public policy value of having program participants most affected by an enforcement decision participate in an enforcement hearing, citing the Supreme Court’s decision in *O’Bannon v. Town Court Nursing Center*, 447 U.S. 773 (1980). One commenter requested that we clarify who may participate in the hearing and the procedural rules that apply to the hearing. Another commenter recommended that States be required to provide potentially affected enrollees with the following: (1) written notice at least 15 days before the date of the pre-termination hearing and (2) information regarding how enrollees may testify at that hearing. Commenters stated that we should require that this notice be (1) written at no higher than a fourth grade level, (2) translated into the prevalent languages spoken by the population in the service area, and (3) accessible to persons with hearing and sight impairments.

Response: We believe that the above suggestions represent good ideas. With respect to the period prior to a decision following a hearing, the Congress has suggested that States should have discretion whether to notify enrollees of the proposed termination. Under section 1932(e)(4)(C) of the Act, the State “may” notify “individuals enrolled with a managed care entity which is the subject of a hearing to terminate the entity’s contract with the State of the hearing.” We believe it would be inconsistent with Congressional intent to mandate notice at this time. We have required that notice to enrollees be provided if a decision to terminate is upheld in a hearing. Any notice the State sends to enrollees must meet the language and format requirements of § 438.10(b) and (c).

Comment: One commenter stated that sometimes it is necessary for the State to terminate a contract with a PCCM because, the PCCM has left the practice without notifying the State. In that situation, the proposed requirement for notice and hearing before termination would not allow the State to take immediate action and would cause hardship to enrollees whose access to medical care would be greatly hindered.

Response: While a State may not terminate a contract with an MCO or PCCM, unless the State provides a hearing before termination in the situation described by the commenter,

the statutory requirement for pre-termination hearing would not apply because the PCCM would have "terminated" the contract. Enrollees would not be adversely affected if the State gives them prompt notice and assists them to enroll in another MCO or PCCM or change to the fee-for-service program.

Comment: Several commenters recommended that we specify that States may inform enrollees of their right to disenroll any time after the State notifies the MCO or PCCM of its intent to terminate. Commenters stated that this section does not make clear at what point in the termination process States are required to notify enrollees. The commenters suggested that we explicitly require MCOs or PCCMs to provide both oral and written notification to enrollees and specify that this may be sent before completion of the hearing process. Steps should be taken to ensure that all people, including individuals with limited English proficiency, limited reading skills, visual impairments, or other disabilities are effectively notified. The final regulation should include adequate safeguards to ensure continuity of care during the time needed for enrollees to select another MCO or PCCM. Other commenters stated that this notification should be mandatory.

Response: Under § 438.722, the State may notify enrollees and authorize them to disenroll without cause at any time after it notifies the MCO or PCCM of its intent to terminate. The notice to enrollees must meet the language and format requirements of § 438.10(b) and (c). Section 438.62 requires the State agency to have a mechanism to ensure continuity of care during the transition from one MCO or PCCM to another or from an MCO or PCCM to fee-for-service. We have not required that notice be oral as well as written.

Comment: The State does not notify HCFA before imposing sanctions or once the sanction has been lifted. Why would HCFA need or want to be notified for each MCO infraction when it never has been in the past and has not needed the information? The commenter recommends that the requirement to notify HCFA of every sanction is not necessary and should be dropped.

Response: We agree that this would be burdensome. It is also unnecessary since we can access this information when needed. This requirement has been removed.

Comment: Many commenters recommended some level of public notification of imposition of sanctions. Some commenters stated that notice of

the sanctions should be required to be given to current enrollees, by all enrollment brokers to potential enrollees, and to a newspaper of wide circulation in the area served by the MCO. Public information about the imposition of sanctions will contribute another layer of accountability to the extent members of the public, specifically the Medicaid population, are able to exercise choice among health care providers. Others stated that, although this section is an important provision to assist Federal oversight, enrollees, health care providers, and potential enrollees should also receive timely information concerning the following issues: (1) whether a specific MCO has been sanctioned, (2) the type of sanction, (3) the reason the sanction was imposed, and (4) what steps the enrollee can take to protect himself or herself. The independent enrollment assistant should provide potential enrollees with this information in both oral and written form, and the sanctioned MCO should be required to provide to current enrollees and health care providers in its network timely written information on sanctions. This requirement will ensure public access to critical information on quality of services. The State should also provide this information, upon request, to the general public. These notices should also meet the literacy recommendations discussed previously. Commenters further suggested that we add the following, "prior to enrollment, the enrollment broker (or other entity conducting enrollment) shall provide each eligible recipient with information regarding which MCOs or primary care case managers have been sanctioned, the types of sanctions, and the reasons for the sanctions. In addition, this information will be publicly available, upon request, from the State."

Response: In response to this and the preceding comment, we have revised § 438.724 so that, instead of requiring notice to HCFA, it requires States to publish public notice describing the intermediate sanction imposed, the reasons for the sanction, and the amount of any civil money penalty. We specify that the notice must be published no later than 30 days after imposition of the sanction and must appear as a public announcement in either the newspaper of widest circulation in each city with a population of 50,000 or more within the MCO's service area, or the newspaper of widest circulation in the MCO's service area if there is not, within that area, any city with a population of 50,000 or more.

Comment: Section 438.730 authorizes HCFA to impose sanctions directly on

MCOs. Although this provision is authorized by the BBA, some commenters urged HCFA, except in extraordinary circumstances, to defer to States on the appropriateness of sanctions. They stated that such an approach is consistent with the roles performed by States and HCFA under the Medicaid program. The commenters were concerned about HCFA making sanction determinations without the involvement of the State and want clarification that sanctions will not be imposed by HCFA without involvement of the State.

Response: We already had sanctioning authority codified by § 434.67, which has been redesignated as § 438.730. We have no plans to deviate from our traditional role of deferring to States on the monitoring of day-to-day MCO or PCCM operations and their appropriateness. The regulation itself makes clear that our involvement would be based on the State's recommendation.

Comment: Several commenters suggested that HCFA should take a more proactive role in ensuring oversight and monitoring. The early implementation of mandatory Medicaid managed care has been plagued with problems. Neither the State nor HCFA has provided adequate oversight to protect beneficiaries. Managed care has clearly not lived up to its promise of providing quality care at lower costs. There is considerable doubt that it ever will. Unlike their wealthier counterparts, Medicaid beneficiaries cannot simply pay out-of-pocket if their managed care plan does not provide the care they need. Health care consumers across the nation are calling for greater accountability and oversight. This is extremely important to Medicaid beneficiaries. The commenters are deeply concerned that HCFA has placed too much of the oversight and enforcement responsibilities on the State Medicaid agencies. The Congress did not revoke HCFA's statutory authority to sanction MCOs or PCCMs. Although the regulations transfer much of this responsibility to the State, beneficiaries have little assurance that the State will adequately protect them, particularly since State Medicaid agencies do not have a good track record of oversight and enforcement. Reports by the GAO and OIG have called for greater Federal oversight and enforcement. This focus makes even less sense with the BBA changes than it did under preexisting authority. Why would a State interested in enforcing compliance recommend that HCFA impose a sanction that the State itself is authorized to impose? Why would a

State not interested in enforcing compliance recommend anything at all to HCFA? The proposed rule lacks any assurance that HCFA will act if the State fails to act. When will HCFA perform these functions, if they are not performed by the State? What would trigger HCFA action or will it be entirely at HCFA's discretion? Will HCFA monitor States' actions or failure to act? The commenters believe that this section should be rewritten to eliminate the State as a recommender of action to HCFA and to emphasize HCFA's independent authority to impose sanctions. As with States, the section should direct that sanctions can be imposed based on findings made through onsite surveys, enrollee complaints, financial audits, or any other means. The regulation should state that HCFA will automatically perform the functions articulated in § 438.730 if an MCO performs any of the following activities: (1) Fails to carry out the terms of its contract; (2) fails to substantially provide medically necessary services that it is required to provide; (3) imposes premiums or charges in excess of those permitted by law; (4) discriminates among enrollees on the basis of health status or requirements for health care services; (5) misrepresents information that is furnished to HCFA, the State, an enrollee, a potential enrollee, or managed care plan; (6) does not comply with physician incentive requirements; (7) distributes, either directly or indirectly, information that has not been approved by the State or that contains false or materially misleading information; (8) engages in any behavior that is contrary to any requirements of section 1903(m) or 1932 of the Act and implementing regulations; (9) places enrollee health at substantial risk; or (10) by virtue of its conduct, poses a serious threat to an enrollee's health or safety or both.

Response: We have always had independent authority to sanction MCOs but not the resources to monitor them individually. Our primary tools to influence State activities with its MCOs have been corrective action plans, specific performance actions, and denials of FFP.

Comment: Several commenters were concerned at the absence of guidelines or criteria that would be used by a State agency in determining the amount of sanctions and urge us to include these guidelines and criteria. There must be standards of reasonableness that would apply to ensure that MCOs are not arbitrarily subjected to sanctions that are excessive in comparison with the nature of the offense in question.

Response: We may not impose standards or criteria because the Federal sanctioning authority is completely a State option (other than temporary management) and we do not set criteria for States using State authority. Any extra requirements could have a chilling effect of discouraging the use of the Federal authority. The monetary amounts specified in § 438.704 are limits, giving MCOs protection against excessive fines. The only mandatory due process protections involve termination of the contract and are contained in the statute.

Comment: One commenter recommended deletion of § 438.730. The commenter stated that if the State believes that an MCO should be sanctioned, it is free to impose that sanction without HCFA involvement. The commenter also pointed out that the sanctions that HCFA may impose are the same sanctions available to the State.

Response: This section is a redesignation of § 434.67, which reflects authority granted through section 1903(m)(5) of the Act, part of the Social Security Act before enactment of the BBA. We have no authority to remove these provisions from the regulations.

Comment: Several commenters believe that HCFA should publicly report the number of times States have recommended that HCFA deny payment and the result of each of the recommendations. This information should then be updated regularly. Requiring that this information be made public and updated on a regular basis will help ensure the State's accountability to recipients and the public at large. Since a similar provision under § 434.67 has existed for several years, they would like HCFA to specify in the preamble the number of times States have recommended that HCFA deny payment and the result of each of the recommendations. They are concerned that this provision has not been implemented to the extent necessary to protect beneficiaries. They believe that information on the number of times States have recommended denial of payment is a critical element in determining how active States have been in monitoring compliance and protecting beneficiaries.

Response: We disagree that sanctions should be publicly reported. The existing longstanding sanction provision at § 434.67 does not require us to report to the public the number of recommendations by States for imposition of sanctions or actions resulting from the recommendations. We do not require regular reporting of sanctions that are imposed on MCOs

through provisions of this final regulation because we do not want to discourage State use of sanctions. The preamble to this final regulation is not the appropriate place to report on activity related to the existing regulation.

H. Conditions for Federal Financial Participation (Subpart J)

Subpart J of the proposed rule set forth largely recodified versions of the regulations in part 434, subpart F. These regulations contain rules regarding the availability of Federal financial participation (FFP) in MCO contracts.

1. Basic Requirements (§ 438.802)

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

Comment: One commenter noted that proposed § 438.802(c) represents a more stringent standard than the long-standing standard in § 434.70(b), arguing that the proposed standard is "much too onerous." The commenter noted that under § 434.70(b), FFP could be withheld if an MCO "substantially fails to carry out the terms of the contract," while under proposed § 438.802(c), FFP is based on the MCO and State being "in compliance" with the requirements of the contract. The commenter argued that States may hesitate to incorporate special quality initiatives into their contracts anticipating that FFP will be withheld if State or plan (or both) are not in complete compliance.

Response: Like proposed § 438.802, § 434.70(a) provided that FFP was available in contract payments "only" for periods that the contract "is in effect" and "[m]eets the requirements of this part," specifically including physician incentive plan requirements. Unlike proposed § 438.802, however, § 434.70(a) is also based on FFP on meeting "appropriate requirements of 45 CFR part 74." Proposed § 438.802 dropped this latter condition. Proposed § 438.802 was less stringent than § 434.70. The commenter is focusing not on the contract's compliance with requirements but on the MCO's compliance with the contract. We agree with the commenter that § 438.802(c) imposes a stricter standard than § 431.70(b) and it was not our intent to put States and plans at higher risk of FFP withholding than they were before. In this final rule with comment period,

we have substituted "substantial compliance" for "compliance" in the Basic Requirements section, both in § 438.802(c) and § 438.802(b), regarding compliance with physician incentive plan requirements.

Comment: Several commenters argued that compliance with ADA and Civil Rights Act requirements should be added to § 438.802.

Response: Entities that contract with Medicaid are required to comply with both the ADA and the Civil Rights Act as well as all other applicable law and Federal regulation. As discussed above, in § 438.6 of this final rule with comment period, we have added language requiring that contracts expressly prohibit MCOs from discrimination based on race, color, or national origin and require compliance with all applicable State and Federal laws.

Comment: A commenter argued that there is an inequity in a system that certain States pay extremely high capitation rates for disabled populations (in which FFP is awarded) but do not provide for a comparable level of FFP to cover equivalent populations in other States. This commenter found general reason for concern about which populations different States are covering and the method by which different States are providing that care (fee-for-service versus managed care).

Response: Section 1902 of the Act requires that States provide medical assistance to certain mandatory groups and provide them with a certain specified minimum level of benefits. However, States have considerable latitude in deciding which other groups to cover and what levels of payment to set for their contracting MCOs, within the parameters of actuarial soundness and the rate setting requirements in § 438.6(c). It is the nature of a State run program for benefits to vary from State to State. However, as discussed above in section II. A, § 438.6(c)(1)(i)(B) requires that payment rates be "appropriate for the populations to be covered," and § 438.6(c)(1)(i)(B)(3)(iv) requires that payment and cost assumptions be "appropriate for individuals with special health needs." We believe that these requirements should ensure that payments are sufficient for disabled enrollees when they are enrolled in managed care contracts.

2. Prior Approval (§ 438.806)

Proposed § 438.806 was based on § 434.71 and provided that FFP was not available in expenditures under contracts involving over a specified financial amount (\$1 million for 1998,

adjusted by the consumer price index for future years) "prior approved" by us.

Comment: Several commenters believe that the \$1 million figure for 1998 was too low, and one suggested raising it to a \$5 million minimum.

Response: We do not have the authority to raise the threshold amount for required prior approval of contracts, which is stipulated in section 1903(m)(2)(A)(iii) of the Act.

Comment: A commenter suggested that this final rule with comment period clarify (1) that State or county-level purchasers will not be at risk because the State has not obtained the approval required under § 438.806 by the time the contract needs to be implemented and (2) that FFP is available retroactively if approval from the HCFA Regional Office is not secured by the time of the effective date of the contract.

Response: This rule does not change our existing interpretation of the prior approval requirement. For any contract that is implemented without first obtaining approval from the HCFA Regional Office, the State is at risk for FFP in payment for those services should the contract not be approved. The risk facing county-level purchasers is a question of the degree to which a State puts its own counties at risk within the context of State law and regulations. With regard to the related question of FFP retroactive to the effective date of the contract, the revision of § 438.806(b)(1) does not expand the scope of the original regulation. It merely adjusts upward the threshold amount for prior approval, which was \$100,000 before the BBA raised the cost.

3. Exclusion of Entities (§ 438.808)

Proposed § 438.808 reflects the limitation on FFP in section 1902(p)(2) of the Act under which FFP in payments to MCOs is based. FFP payments are based on the State excluding from participation as an MCO any entity that could be excluded from Medicare and Medicaid under section 1128(b)(8) of the Act, that has a substantial contractual relationship with an entity described in section 1128(b)(8)(B) of the Act, or employs or contracts with individuals excluded from Medicaid. We received no comments on this section.

4. Expenditures for Enrollment Broker Services (§ 438.810)

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

enrollment brokers only if the following conditions are met:

- The broker is independent of any managed care entity or health care provider that furnishes services in the State in which the broker provides enrollment services.
- No person who is the owner, employee, or consultant of the broker or has any contract with the broker—
 - Has any direct or indirect financial interest in any entity or health care provider that furnishes services in the State in which the broker provides enrollment services;
 - Has been excluded from participation under title XVIII or XIX of the Act;
 - Has been debarred by any Federal agency; or
 - Has been, or is now, subject to civil monetary penalties under the Act.
- The initial contract or memorandum of agreement (MOA) or memorandum of understanding (MOU) for services performed by the broker has been reviewed and approved by HCFA before the effective date of the contract or MOA.

Comment: Several commenters expressed support for this provision and indicated that it is critical that the broker remain independent and unbiased.

Response: We appreciate the commenters support and agree that this provision is of great help in ensuring that beneficiaries are able to make informed choices.

Comment: One commenter suggested that we allow a "de minimis" exception for certain levels of stock ownership, especially in a publicly traded company. The commenter also suggested that HCFA rules preempt similar State rules to avoid excessive application of these rules.

Response: We believe that any degree of ownership, including any amount of stock in an MCO, PHP, or PCCM or other provider, by enrollment broker owners, staff, or contractors may create the potential for bias. That is why we are not providing for exceptions in § 438.810. Although section 1903(b)(4) of the Act and § 438.810 of the regulations set forth conditions that must be met to receive FFP, States have the prerogative to set rules more stringent than the Federal rules.

Comment: Some commenters believe that § 438.810 should include safeguards to protect Medicaid beneficiaries from false and deceptive advertising. A commenter recommended that, when brokers are used to enroll Medicaid beneficiaries into managed care, States should be required to assure that they have

accurate data about the Medicaid eligibles and the availability of MCOs, PHPs, or PCCMs and any subcontracting providers.

Response: We agree that it is important for States to provide enrollment staff with accurate information about Medicaid eligibles and about MCOs, PHPs, or PCCMs and their subcontracting providers. Sections 438.10(d) and (e) require that enrollees and potential enrollees be provided with names and locations of current network providers, including identification of those who are not accepting new patients. It also emphasizes that information must be sufficient to allow an informed decision. We believe that this addresses the expressed concerns. States or enrollment brokers must make efforts to provide the most accurate and current information available. State and broker data systems differ in their capabilities, and provider and eligibility information changes daily. We ordinarily address this issue during pre-implementation review and monitoring of mandatory programs.

Comment: One commenter believes that it is not necessary for us to approve initial enrollment broker contracts or memoranda of understanding because statutory limitations are straightforward, FFP is limited, and brokers must be independent. In this commenter's view, contract approval is not necessary to ensure compliance, since the threat of civil money penalties is sufficient.

Another commenter supported our decision to require prior approval of initial enrollment broker contracts but suggested that we provide additional guidance pointing to minimum qualifications of enrollment brokers.

One commenter acknowledged the need for contract review but suggested that we impose a 30 day time limit for review in order to avoid delaying contract implementation. Once this time had elapsed, the contract would be deemed approved.

Response: We have already reviewed some broker contracts and MOAs/MOUs on a voluntary basis. Much of the current review consists of technical assistance and advice about whether contracts contain legally required provisions, as well as assurances of quality and results of noncompliance. We intend to issue contract review guidelines for our staff.

We will not impose a time limit for review of contracts since it is impossible to assess workloads and the amount of time required for review. Once mandatory contract review is implemented, we will assess the length

of time required for review and recommend time frames if necessary.

Comment: One commenter believes that fiscal intermediaries for State Medicaid programs face an inherent conflict of interest, because they are paid to process claims for traditional fee-for-service Medicaid programs, and assisting Medicaid beneficiaries to enroll in a managed care entity poses a threat to these agents' primary source of revenue. In this commenter's view, the intermediaries have a strong incentive to maintain the status quo. The commenter recommended that HCFA's rules should prohibit entities from serving as enrollment brokers for States in which they serve as fiscal intermediaries.

Response: We are aware that some fiscal intermediaries have adapted to the managed care environment by performing enrollment broker functions in some States. This is often convenient for States that already have fiscal intermediary contracts in place. Since enrollment brokering has become an additional line of business for some of these agents, we believe that the incentives for bias toward fee-for-service are minimal. In addition, we anticipate that States desiring to use fiscal intermediaries in the role of enrollment brokers would consider any inherent bias during the selection process.

Comment: One commenter asked about the applicability of this provision to a public entity in which eligibility and enrollment functions might occur in one division and other divisions might be responsible for purchasing or providing some Medicaid covered services. The commenter asked whether State "conflict of interest" regulations, if approved by HCFA, would satisfy the intent of this section. The commenter noted that if county government employees conduct enrollment and education, and counties are also directly involved in arranging for or providing Medicaid services directly, FFP would not be payable for the county employee's enrollment services. The commenter suggested that we define "independent" in such a way as to allow a county employee to conduct enrollment activities as long as the county has in place adequate safeguards to protect against conflict of interest. For example, if an employee conducting enrollment is employed under a separate division or department and is not subject to supervision or discipline by a separate division or department that conducts purchasing or operates an MCO, the commenter recommended that this be considered acceptable.

Response: The managed care enrollment function is an administrative

function of the State. The State may choose to contract out this function, have it done by the State or local staff, or even allow MCO staff to perform this function. The example of a county eligibility employee performing enrollment activities when the county also provides services would violate § 438.810, thus precluding payment of FFP for the enrollment activities. The Medicaid eligibility function must always be performed by State or local staff. This function cannot be contracted out to other entities. If MCO, PHP, or PCCM enrollment is contracted out to an enrollment broker, defined as an entity or individual that performs choice counseling and/or enrollment activities, the broker may not have any connection to or interest in any entity or health care provider that provides coverage of services in the same State. An enrollment broker might be a public or quasi-public entity with a contract or MOA/MOU with the State or county. In this situation, this entity may not furnish health care services in the State. For example, a State may not contract with or have an MOU with a county health department to do managed care enrollment or choice counseling because the health department provides health services. A community organization that provides health services in the State, for example, an organization providing health care to homeless individuals, may contract or subcontract to perform outreach and education, but not enrollment and choice counseling functions. An MCO, PHP, PCCM, or other health care provider that provides services in a State may not also have an interest of any sort in an organization performing Medicaid enrollment or choice counseling. This restriction is based upon the statutory language contained in section 1903(b)(4) of the Act.

In § 438.810(b)(1) of this final rule with comment period, we have clarified that an enrollment broker would not meet the test for independence if it is an MCO, PHP, PCCM or other health care provider, or owns, or is owned by an MCO, PHP, PCCM, or other health care provider in the State in which the broker operates.

A State's conflict of interest regulations ordinarily address situations in which a State or local officer, employee, or agent has responsibilities related to the awarding of contracts. Conflicts of interest involving Medicaid officials have long been prohibited under sections 1902(a)(4)(C) and (D) of the Act. This language prohibits conflict of interest by current or former State and local officers, employees, or independent contractors responsible for

the expenditure of substantial amounts of funds under the State plan. The conflict of interest language in § 438.58 applies to State and local officers and employees and agents of the State who have responsibilities relating to MCO contracts or the default enrollment process. Conversely, it specifically prohibits conflict of interest in any Medicaid managed care contracting activities, including enrollment broker contracting. Section 438.810 specifically addresses situations in which a relationship between a health care provider and an individual or entity responsible for choice counseling or enrollment may be biased by that relationship. While conflict of interest provisions would be expected to be in place in the State, § 438.810 covers an additional situation in which potential conflict of interest might influence a Medicaid recipient's choice of plan.

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

Proposed § 438.812 was transferred in its entirety from previous §§ 434.74 and 434.75 and was unchanged in the proposed rule. Proposed § 438.812 provides that States receive Federal matching for all costs covered under a risk contract at the "medical assistance" rate, while under a nonrisk contract only the costs of medical services are matched as "medical assistance," and all other costs are matched at the administrative rate.

Comment: One commenter believes that we should provide additional guidance on what constitutes the "furnishing of medical services" as described in § 438.812(b)(1). The distinction between what is administrative and what is a medical service is becoming less clear in this commenter's view.

Response: We do not believe additional clarification in the regulations text is necessary. The costs of medical services are the payments made to providers for furnishing services covered under the contract. In the case of fee-for-service Medicaid, this would be the State plan payment amounts. These costs could either be in the form of payments to providers (fee-for-service, per diem, or capitation) or "salary" in the case of an employee. Administrative costs would include member services, claims processing, coverage decisions, and other activities that would be matched as administrative costs under fee-for-service Medicaid.

Comment: One commenter noted that the proposed rule discussion of § 438.812 did not address the Federal medical assistance percentage (FMAP)

that States receive for services provided to American Indians by the Indian Health Service (IHS) and tribally operated programs. The commenter believes that the regulation should specifically address how the special matching rate for eligible IHS services will be applied and the State role in assuring that standards are met.

Response: We agree that the FMAP rate for services provided to Indians by IHS or tribally operated programs applies whether the IHS or tribal facility operates in fee-for-service or managed care. There is no need to change this regulation since, when applicable, this special FMAP rate is the "medical assistance" rate in that case. The regulation differentiating FMAP rates for risk and nonrisk contracts would not prohibit or in any way modify the matching rate that is required for IHS or eligible tribal facilities. Section 438.812 simply recodifies longstanding regulations and does not involve or affect HCFA policy on the application of the FMAP for IHS services in the managed care context.

In response to this and other comments received, we want to reemphasize that tribal and IHS providers are not necessarily required to be licensed by a State as long as they meet the State's or MCO's qualifications. We believe that the definition of provider in § 400.203 will ensure that these providers are not inappropriately excluded from participation in Medicaid managed care programs.

6. Condition for Federal Financial Participation (FFP) in Certain Contract Arrangements (§ 438.814)

As discussed in detail in section II. A of this regulation, this new section reflects the condition for FFP in contracts that contain incentive arrangement or risk corridors. As described in new § 438.6(c)(5) on rate setting for risk contracts, FFP is only available in these contracts to the extent that payments do not exceed 105 percent of the payment rate determined to be actuarially sound.

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

In addition to the provisions set forth in the new part 438, and the fair hearing provisions in part 431 discussed in section II. E. above, the proposed rule contained amendments to Parts 435, 440, and 447 which we discuss below. These provisions included amendments to §§ 435.212 and 435.326 to reflect the new terminology adopted by the BBA (for example, "MCO" and "MCE"). We also proposed a new § 440.168 in part 440 to include a description of primary

care case management services. Amendments to part 447 not already addressed above include a new § 447.46(f) implementing the timely claims payment requirements in section 1932(f), and a new § 447.60 regulating MCO cost-sharing, which was made permissible under BBA amendments to section 1916 of the Act. In this section, we discuss the comments we received on the above regulations. We received no comments on the revisions to part 435, or on § 447.60. We also in this section address miscellaneous comments that did not relate to a specific section of the proposed regulations.

1. Guaranteed Eligibility

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

Comment: One commenter observed that the provision in the proposed rule is inconsistent, authorizing guaranteed eligibility for individuals enrolled in any MCE (MCO or PCCM) in the introductory text of the section, while limiting the authority to MCOs elsewhere.

Response: Using both terms in the proposed rule was an inadvertent error. We have clarified this issue by using the terms MCO and PCCM throughout the final rule, as intended by the BBA.

2. Definition of PCCM Services (Proposed § 440.168)

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

Proposed § 440.168(a) set forth the definition of primary care case management services, for case

management related services that include "location, coordination, and monitoring of primary health care services," that are provided under a contract between the State and either (1) an individual physician (or, at State option, a physician assistant, nurse practitioner, or certified nurse-midwife), or (2) a group practice or entity that employs or arranges with physicians to furnish services. Proposed § 438.168(b) provided that PCCM services may be offered as a voluntary option or on a mandatory basis under section 1932(a)(1) or a section 1115 or 1915(b) waiver.

Comment: One commenter expressed concerns about any form of required case management.

Response: Current law, through freedom of choice waivers under sections 1915(b) and 1115 of the Act, has for many years permitted States to require that Medicaid beneficiaries obtain their care through PCCM programs. Section 4702 of the BBA provided States additional flexibility by adding PCCM services to the list of optional Medicaid services. This allows States, at their option, to provide quality health care services and to enhance access to Medicaid beneficiaries through an arrangement that has proven to be cost effective to the Medicaid program. In addition, this section sets forth new requirements for contracts between primary care case managers and the State agency that provide important protections for beneficiaries and ensure access to quality health care. We believe that these protections, along with other beneficiary protections provided for in this final rule, adequately address the commenter's concerns.

3. Timeliness of Provider Payments (Proposed § 447.46)

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

requirements were included in proposed § 447.46.

Comment: One commenter objected generally to the requirements in proposed § 447.46, while another argued that the provision for developing a mutually agreed upon alternative payment schedule between an MCO and provider would not resolve the issue of timely payments. This commenter recommended that the timely payment provisions should provide that payments must be made in a manner consistent with State law, or, in the absence of a State requirement, in accordance with requirements in Federal regulation. This commenter did not believe that MCOs should be free to negotiate alternative arrangements. Another commenter contended that delayed payments for both managed care and fee-for-service programs have long been a problem in State Medicaid programs. This commenter felt that physicians, hospitals, and health systems should be paid for the covered services they provide to Medicaid beneficiaries in a timely manner, and that chronic payment delays by Medicaid programs and plans discourage physician and provider participation, are disruptive to the patient-physician relationship, and could adversely affect patient access. This commenter recommended that HCFA adopt a standard that would require payment to health care providers within 14 days for uncontested claims which are filed electronically and within 30 days for paper claims which are uncontested. In addition, the commenter recommended that for capitated payment systems, HCFA should require MCOs to make capitated payment to physicians and providers shortly after the beneficiary's enrollment, and also promulgate a standard time frame for payments by States to physicians and other providers of services under Medicaid fee-for-service programs.

Response: Congress was very specific in section 1932(f) to incorporate the standards set forth in section 1902(a)(37)(A), and provide that parties could also agree to an alternative payment schedule. We do not have the discretion to change the timeframes in section 1902(a)(37)(A), or to eliminate the right to negotiate an alternative schedule, as these are mandated by statute. We note that if an alternative payment schedule is established, it must be stipulated in the contract according to § 447.46(c)(3). The statute does not address the timing of capitation payments, which we believe should be negotiated between the parties.

4. Miscellaneous Preamble Comments

a. Effective Date of the Final Rule

In the proposed rule, we stated our intention to make the final rule effective 60 days following publication. However, those provisions which must be implemented through contracts would be effective for contracts entered into or revised on or after 60 days following the effective date, but no longer than 12 months from the effective date.

Comment: Several commenters asked us to clarify or revise the proposed effective date. In particular, the commenters were concerned that adequate time was not allowed for implementing the many changes proposed in the regulation. One commenter suggested that HCFA give States an additional year from final publication of the regulation to bring contracts into compliance. Another commenter recommended that HCFA consider allowing States at least 120 days to implement the final regulation.

Response: In recognition of the significant changes within this final rule, we have set the implementation date of this final rule to take effect 90 days following publication. Although we believe that it is important to provide BBA protections as soon as possible, we believe that changing the effective date will help to ease the State burden of implementing these provisions. Further, those provisions of the final rule that must be implemented through contracts with MCOs, PHPs, HIOs or enrollment brokers must be reflected in contracts entered into or revised on or after 90 days following the publication date, but no longer than 12 months from the effective date. Because a substantial number of the provisions of the final rule are implemented through contract revisions, the effective date for many provisions will be delayed in many States. Of course, some provisions in this final rule reflect statutory requirements that are already in effect. HCFA has provided State agencies with guidance on implementing these provisions through a series of letters to State Medicaid Directors. These letters appear on the HCFA Home Page and can be accessed at <http://www.hcfa.gov>.

b. Absence of FQHC and RHC Provisions in the Proposed Rule

Comment: Several commenters requested that HCFA address the new FQHC and RHC reimbursement requirements set forth in section 4712(b) of the BBA. One of the commenters was concerned that unless these provisions were included in the regulation there would be no mechanism to ensure State

and MCO compliance. The commenter acknowledged that HCFA had undergone a process to inform State Medicaid Directors of their new obligations under the BBA through a series of letters. However, without this requirement in the regulation, the commenter was concerned that both MCOs and States would disregard the Federal statutory protections intended to preserve FQHCs and RHCs as vital Medicaid providers. Moreover, the commenter argued that regulations have the force of law, whereas States have challenged in the past whether they are legally bound by guidance in letters to State Medicaid Directors. By placing these requirements in its regulations, the commenter believed that HCFA could ensure that States or MCOs that fail to comply with BBA's requirements would be subject to sanctions by HCFA. The remaining commenters questioned HCFA's interpretation of the FQHC/RHC statutory provision and believe that this area should be clarified in regulation and open to public comment.

Response: This rulemaking primarily implements Chapter 1 of Subtitle H of the BBA, titled "Managed Care." The provisions relating to FQHC/RHC payment are set forth in Chapter 2, "Flexibility in Payment of Providers," and thus arguably are outside the scope of this rulemaking. Even if this rule were the appropriate vehicle for regulations implementing these FQHC/RHC provisions, we do not believe that such regulations would be warranted. The rules in question are "transitional" in nature, as the 100 percent cost payments described will eventually be phased out over the next several years. We do not believe it appropriate to promulgate regulations that will be obsolete in a relatively short period of time.

Moreover, we do not believe regulations are necessary, as the statutory requirements are straightforward and self-implementing, and HCFA has provided guidance to all States, through State Medicaid Director Letters on April 21, 1998 and October 23, 1998, on FQHCs and RHCs. We disagree with the commenter that there is no "enforcement mechanism" for these requirements. The requirements in question, as interpreted by HCFA in State Medicaid Director Letters, are fully enforceable. A State that fails to fulfill its obligations under section 1902(a)(13)(C)(ii) to make required quarterly supplemental payments to FQHCs/RHCs that subcontract with MCOs would be subject to a compliance enforcement action under section 1904. If an MCO fails to comply with section 1903(m)(2)(A)(ix) by paying at least

what it pays other providers, HCFA would disallow Federal financial participation (FFP) in payments under the MCO's contract. Thus, the FQHC/RHC requirements in question are self-implementing and fully enforceable. HCFA's interpretations of these requirements are also enforceable, and entitled to deference from courts.

c. General Comments on the Proposed Rule

Comment: Several commenters supported HCFA in its implementation of the BBA, and were pleased to see the proposed rule reflect many of the recommendations from the Consumer's Bill of Rights and Responsibilities (CBRR). These commenters also believed that the proposed rule was a thoughtful implementation of the BBA provisions, which adequately reflected the intent and hope of the Congress and provides functional guidance to States without becoming overly burdensome or demanding. Other commenters believed that the regulation is a positive step toward improving quality for Medicaid beneficiaries in managed care and that the regulation is brief, simple and written at a readable level.

However, several other commenters criticized HCFA for creating regulations that they perceived as overly burdensome that did not allow sufficient State flexibility. These commenters also argued that the proposed regulations went beyond the statutory intent and authority of the BBA, and that the regulations would lead to increased administrative costs for Medicaid MCOs. These commenters believed that HCFA was micro-managing its approach to Medicaid managed care, and the proposed regulations, if finalized, would make it increasingly difficult for State Medicaid agencies to provide access to quality health care through MCOs, since MCOs would not be willing to participate. Another commenter believed that the proposed regulations did not reflect the approach of a purchaser, but the approach of a unilateral regulator particularly with respect to the CBRR and other beneficiary protections.

Response: The regulation was developed to provide States with an appropriate level of flexibility that we believe to be consistent with necessary beneficiary protections. Thus, State flexibility had to be balanced against statutory requirements of the BBA, and a Presidential directive that required Medicaid program compliance to the extent permitted by law, with the recommendations in the CBRR. In response to specific comments regarding the over-prescriptiveness or burden of certain provisions, we have made some

changes to promote even greater flexibility, and also added requirements in response to other commenters. Further, the regulation has been designed to provide a framework that allows HCFA and States to continue to incorporate further advances for oversight of managed care, particularly as it pertains to beneficiary protection and quality of care. With respect to HCFA's statutory authority, we summarize each provision of the effected regulations followed by our response.

Comment: In general, a few commenters were concerned that what they believe to be over-prescriptiveness of the regulation would result in MCOs leaving the Medicaid managed care market. These commenters believed that the prescriptive mandates of the regulation would limit and hinder negotiations with MCOs, because of the additional requirements that would have to be met for Medicaid members as opposed to commercial members. As a result, the commenters argued that these requirements would be administratively burdensome for MCOs. In addition, the commenters believed that the financing of these administrative requirements was so inadequate MCOs would be forced out of the Medicaid market due to financial reasons.

Response: We will be reviewing this issue as we are also concerned about the continued viability of MCOs in the Medicaid managed care market. However, we also recognize the importance of quality care and consumer protections for Medicaid beneficiaries enrolled in Medicaid managed care and are unwilling to sacrifice these very necessary protections. In this final rule we have also revised the upper payment limit requirement, which may result in increased levels of funding for MCOs.

d. Beneficiary Protections in FFP

Comment: Commenters expressed concern that the proposed rule did not extend its numerous beneficiary protections to the fee-for-service (FFP) delivery system, and that many of the protections within the regulation have no corollary protections in FFP. The commenters noted that in FFP Medicaid, there were no rights afforded to providers who will coordinate care, nor was there adequate quality assurance activities, information on participating providers, or detailed grievance procedures. The commenters believed that the proposed regulation makes it difficult to make meaningful comparisons between FFP and managed care. Another commenter felt that the proposed rule did not adequately

recognize that managed care is not the only system that States will be using to provide health services to beneficiaries, as many States will continue to operate a FFP system. The commenter believed that it is the clear intent of Federal legislation that all Medicaid beneficiaries should receive the same protections and advantages without respect to the type of provider that is under contract. Therefore, in the commenters opinion, the regulations that apply to MCOs should also apply to the State Medicaid agencies in their operation of FFP systems.

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

e. Use of Examples in the Preamble

Comment: Some commenters were concerned over the use of examples in the preamble to the September 29, 1998 Notice of Proposed Rule Making (NPRM) and the potential applicability of these examples in a court of law. These commenters requested that HCFA clarify that the examples in the preamble to the proposed rule would not be standards enforceable by law. They believed that the use of examples could lead to unintended interpretations of the final rule. One commenter suggested that HCFA make a clear statement "that the preamble that accompanied the proposed rule was intended to spark discussion, not provide guidance for further interpretations."

Response: The examples provided in the preamble to the NPRM were intended to be just that, examples. They were included in the preamble discussion to provide options for States when implementing the provisions within the proposed rule. We did not include these examples in the regulation text itself, as they were intended to be illustrative in nature and States always retain the flexibility to deviate from these examples.

f. Consistency with Medicare

Comment: Several commenters disagreed with our guiding principle that, where appropriate, we would promote consistency with the Medicare+Choice program in developing this regulation. One commenter argued that the Medicaid statute is not designed to promote consistency with Medicare. The commenter did not believe that consistency between Medicare and Medicaid is a valid reason to deviate from the principle of State flexibility. The commenter believed that Title XIX provides Federal funds for various State medical assistance programs that are to be administered by States within broad Federal rules, and noted that those Federal rules, as found in Title XIX, contain no general requirement for consistency with Medicare. The commenter further noted that the preamble to the proposed rule also states that "the regulations were written to support State agencies in their role as health care purchasers * * * and * * * to provide State agencies with the tools needed to become better purchasers." The commenter found this to be a "paternalistic" approach, which in the commenter's view was inconsistent with the nature of the Medicaid program as one administered by States within broad Federal rules. Portions of the proposed regulations intended to "support" States as health care purchasers, but which do not implement any requirement under Title XIX, should in the commenter's view be issued as guidance or advice to States, not as additional requirements in Federal regulations. Finally, the commenter found the "uniform national application" of "best practices," as defined by HCFA, to be inconsistent with the nature of the Medicaid program as one administered by States within broad Federal rules.

Several other commenters, however, supported the guiding principle of consistency with the Medicare+Choice program, and believed that it would help relieve the administrative burdens imposed on MCOs, because to the extent that the Medicare and Medicaid programs are consistent with each other, administrative efficiencies result. The commenters also felt that establishing uniform industry standards was beneficial not only to MCOs and primary care case managers, but also for consumers receiving services and providers who contract with those MCOs or primary care case managers to deliver health care services. The commenters commended HCFA for recognizing that while it is imperative

that there be consistency and uniform application of standards, some areas require a unique approach by States; as a result, the commenters support HCFA's efforts to allow States the flexibility in developing such programs.

Response: It was our intent to create consistency with Medicare+Choice program requirements in order to ensure that the managed care industry would not have to comply with multiple sets of standards. However, where there was a clear need for State flexibility or where consistency with the Medicare+Choice program was not appropriate for Medicaid managed care, we deviated from Medicare+Choice policy. We believe that this final rule effectively balances the need for flexibility and consistency, while providing States with the broad tools they need to become more efficient purchasers of health care. As we developed this final rule, we continued to work with our Medicare colleagues to coordinate changes to provisions in this final rule that had counterparts in the Medicare+Choice regulations. While we have promoted uniform national application of knowledge and best practices learned, the Medicaid statute has always given States the flexibility to design their own Medicaid programs.

g. Applicability of BBA Provisions to Waiver Programs

Section 4710(c) of the BBA provides that nothing in the managed care provisions of the BBA (Chapter 1 of subtitle H) shall be construed as affecting the terms and conditions of any waivers granted States under section 1915(b) or 1115 of the Act. The Conference Report on the BBA clarifies that this exemption is intended solely for waivers that are approved or in effect as of August 5, 1997 (the date of enactment). We indicated in the preamble to the proposed rule that we interpreted this exemption to apply to 1915(b) waivers only for the period of time for which a waiver has been approved as of August 5, 1997, at which time the State would be required to comply with the BBA provisions. In the case of waivers under section 1115 demonstration projects approved as of August 5, 1997, the terms and conditions are similarly "grandfathered" under section 4710(c) of the Act only for the period of time for which the waivers were approved as of August 5, 1997. However, unlike section 1915(b) waivers, these demonstration projects are subject to another BBA provision that affects the applicability of BBA managed care provisions. Section 4757 of the BBA added a new section 1115(e), providing for a three year

extension of demonstrations if certain conditions are met. If a section 1115 demonstration approved on or before August 5, 1997 is renewed under the terms of section 1115(e), the terms and conditions that applied on the last day approved under the original demonstration remain in effect during the three year extension period. Thus, if terms inconsistent with the BBA managed care provisions were still in effect by virtue of section 4710(c), these terms were extended for three years if there an extension was granted under section 1115(e).

Comment: Many commenters felt that HCFA's interpretation of section 4710(c) as applicable only for periods for which waivers were approved on August 5, 1997 was inconsistent with the commenters' view of the intent of this provision. These commenters felt that States had developed specific provisions of their waivers and demonstrations to address specific issues within the State, doing so in consultation with all appropriate stakeholders, and that to require changes in the programs now would result in confusion for enrollees and providers, disruptions in the delivery system, and increased administrative costs for both the States and health plans.

Response: We disagree with the commenters' view of this provision. Language in the Conference Report on the Balanced Budget Act of 1997 specifically states the intent of Congress as limiting the exemption contained in section 4710(c) to waivers "either approved or in effect" as of the date of enactment. Since section 1915(b) waivers are specifically limited by statute to no more than 2 years and section 1115 demonstration waivers are typically granted for periods of no more than 5 years, the waiver which is "approved" or "in effect" as of the date of enactment expires at some point thereafter. While States may request renewals of section 1915(b) waivers for up to 2 years, these additional waiver periods cannot be seen to have been "approved" or "in effect" on August 5, 1997. This is similarly the case with respect to standard extensions of a section 1115 demonstration approved after August 5, 1997. As explained above, however, in this latter case, a totally separate provision of the BBA created section 1115(e) of the Act, that requires the terms and conditions in effect on the date before a section 1115 demonstration would otherwise expire be extended for three years. Section 1115 demonstrations that do not qualify for an extension under the authority in section 1115(e)(1) do not maintain the

same exemption, and would be subject to all BBA provisions in effect at the time of the expiration of the 1115 authority approved as of August 5, 1997 (in the absence of new waiver or matching authority under section 1115(a) exempting a State from BBA requirements).

We have provided some flexibility to States in phasing in BBA requirements by permitting exemptions for any provisions addressed in the State's waiver proposal, statutory waivers, special terms and conditions, operational protocol, or other official State policy or procedures approved by HCFA, rather than limiting the exemption solely to specific "Special Terms and Conditions" negotiated between HCFA and the States. We believe that HCFA has balanced the need to implement important beneficiary protections contained within the BBA with the flexibility that States need to effectively phase-in these requirements in programs designed to meet specific needs within the State.

Comment: Some commenters felt that the terms and conditions agreed to by HCFA and the State should continue to be the applicable rules under which a waiver program is operated.

Response: As indicated above, not only the special terms and conditions, but any other policies, procedures or protocols approved by HCFA will remain in effect for the period the State is entitled to an exemption under this provision. With the exception of section 1115 demonstrations extended under section 1115(e) of the Act, we believe that Congress limited this exemption to the time period of the waiver approved or in effect as of August 5, 1998.

Comment: Several commenters argued that the BBA provisions were intended to apply to managed care programs established under State plan amendments authorized by section 1932(a) of the Act, and should not apply at all to waiver programs.

Response: The BBA provisions on managed care in sections 4701 through 4710 of the BBA that are limited in their application to mandatory managed care under the State plan contain a specific reference to that section of the Act. Both the definition of PCCM services in section 1905(t) (in section 1905(t)(3)(F)), and section 1903(m)(2)(A), in the case of MCOs, require compliance with applicable provisions in section 1932. Thus, when a provision in section 1932 applies to an MCO or MCE, and is not limited to a program under section 1932(a)(1), it applies regardless of the authority under which the managed care program in which they participate operates. Thus, these provisions apply

to all types of managed care—voluntary or mandatory, State plan or waiver.

Comment: Some commenters felt that HCFA inappropriately limited this exemption by applying it only to provisions that were "specifically addressed" in approved State documents, rather than to the entire waiver program.

Response: We believe that we have adopted a broad interpretation of the applicability of section 4710(c). Section 4710(c) states that the managed care provisions shall not be construed to affect the "terms and conditions" of waivers. As noted above, this could have been interpreted to apply only to provisions set forth in actual formal "terms and conditions." We have interpreted this to refer to anything addressed in the State's approved waiver materials. In such cases, no determination need be made as to whether the State's policy or procedures meet or exceed the BBA requirement during the duration of the waiver period approved as of August 5, 1997 (or an extension under section 1115(e) in the case of a section 1115 demonstration). We note that the BBA contains provisions such as fraud and abuse protections, some of the quality provisions, a prudent layperson's definition of emergency, and the extension of guaranteed eligibility to PCCMs, which would not usually be addressed in a State's waiver materials. We believe it is important to implement these provisions which can provide beneficiary protections beyond that already provided for in a State's waiver.

Comment: One commenter questioned the impact of this exemption on a State which is phasing-in a waiver on a county-by-county basis, where parts of the State would be exempt from BBA requirements, while other parts of the State would be subject to them.

Response: A State that is phasing-in a waiver which was approved prior to August 5, 1997 maintains exemptions from the BBA for the whole service area of its waiver program as it is implemented, not merely the areas which were implemented prior to that date. The language in the Conference Report provides the exemptions for any waiver which is "approved or in effect."

Comment: One commenter believed that HCFA should provide additional clarification as to how this exemption from BBA provisions applies to section 1115 demonstrations.

Response: HCFA Regional Offices have been working with section 1115 States to identify those areas that need to come into compliance with BBA provisions. These decisions will have to be on a State-by-State basis, determined

by the specific provisions in effect in each State's waiver program. Once HCFA has determined which BBA provisions apply and which do not apply, the exemptions will remain in place until the current approved period of the waiver expires, or if it is extended under section 1115(e), the end of the three year extension. At this time States will need to come into compliance with all BBA provisions that are currently in effect. The only exception is for a State that receives an extension of its section 1115 authority under section 1115(e)(1) which, as indicated above, requires the same terms and conditions to be in place when the waiver is extended for up to three years.

Comment: One commenter felt that the BBA provisions should be applied immediately to all new and existing waiver programs.

Response: Section 4710(c) provides that nothing in the BBA provisions on managed care "shall be construed as affecting the terms and conditions of any waiver . . . under section 1115 or 1915(b) of the Social Security Act." We believe that this language precluded us from applying these provisions in an inconsistent manner with such waiver terms and conditions.

h. Comments Relating to American Indians and Alaskan Native Populations

Comment: We received several comments that specifically addressed the relationship of the proposed regulation to the American Indian and Alaskan Native (AI/AN) populations. Most of the commenters were concerned that the tribal health care systems would be drastically impacted by the proposed regulation. Because of this impact, one commenter recommended that the Indian Health Service (IHS) and the tribal system be exempted from the proposed regulations, and that we consult with IHS and tribal organizations before including them in the proposed regulations. Another commenter indicated that States should recognize the inherent sovereignty of Indian Tribes and Nations and the special status of health programs for American Indians under Federal law. This commenter recommended that States implementing Federal programs need to develop a consultation policy that ensures tribal participation in developing health care programs. Another commenter stated that the proposed regulation showed concern for consumer protection in general, but gave little attention to the specific needs and circumstances of AI/AN consumers and Indian health providers. In the commenter's opinion, the best way to ensure that this happens is to require

States to engage in meaningful tribal consultation. Several other commenters specified that the proposed rule does not mention or discuss the special relationship that exists between the United States and its indigenous peoples, namely American Indians, Alaskan Natives, Aleuts, Eskimos and Native Hawaiians. These commenters believed that it is important to specifically include language that acknowledges this relationship and allows the Federal government to provide services for these groups. This would be done not on the basis of race or ethnicity, but rather upon the Federal government's historical relationship with native peoples and their governments who live in areas which are not portions of States of the United States but who have had affinities to these areas long before these States came to be part of the United States. The commenters also noted the importance of including language in the final rule that recognized the trust responsibilities of the Federal government to indigenous peoples and their respective tribes in developing program standards, including defining cultural competence, enrollment policies and procedures, marketing, access, grievances, quality assurance and sanctions for MCOs providing health services to their peoples and not the States.

Response: While we are aware of, and concerned about, the impact of this final rule on IHS and tribal health systems, we are not exempting them from its application when they operate as Medicaid managed care entities or subcontract with Medicaid managed care entities. First, there is no basis in the statute for such an exemption. We also believe that Medicaid beneficiaries who use such systems are entitled to the protections and safeguards embodied in this rule whether or not they use IHS and tribal systems. We do however understand that IHS and tribal health systems have unique circumstances, and we have consulted with IHS and tribal governments on many issues. These consultations have resulted in some adjustments to the rule. We will continue the consultation process as we interpret and implement this final rule to ensure that we address the concerns of IHS and tribal health systems. We do not believe, however, that this rulemaking is an appropriate vehicle to address the full range of Federal treaty relationships with tribal groups cited, since its scope is limited to the Medicaid managed care provisions in Chapter 1 of Subtitle H of the BBA.

Comment: One commenter strongly suggested that efforts be made by Tribal, Federal and State officials to implement

the IHS/HCFA Memorandum of Agreement (MOA). The commenter believed that MOA provisions for 100 percent FMAP for tribally operated facilities should be honored under any State managed care system in the views of this commenter. The commenter believed that States operating Medicaid managed care programs should carve out IHS and tribal programs as Medicaid providers eligible for the "pass-through" reimbursement. Another commenter stated that Indian health facilities should be paid by Medicaid for every visit in which Medicaid covered services are provided to a Medicaid beneficiary. This would apply to the Indian Health Service direct service facilities, tribally operated facilities, and urban Indian clinics, collectively known as the I/T/U. The commenter believed that the I/T/U should be paid by Medicaid at a rate that covers the cost of delivering services, considering that there is little opportunity to shift costs to other third party payers. The commenter further stated that barriers to participation should be eliminated for AI/AN populations for health care programs that receive any Federal funding. Recognizing the limitations in funding, the commenter believed that resources should be used to the maximum extent for direct patient care and prevention activities while keeping administrative functions as efficient as possible.

Response: As discussed above in the discussion of comments on Subpart J section II. H., issues of Federal matching funding levels are outside the scope of the proposed rule or this final rule, which has no effect on matching rates for services furnished by IHS or tribal facilities. We note that the commenter is mistaken in suggesting that the cited MOA requires any particular payment levels to IHS or tribal facilities (and further note that it does not address urban Indian facilities at all). We recognize, however, that IHS and tribal health systems and providers may have unique circumstances in contracting with such programs. We intend to continue to work with IHS and the tribes to minimize barriers to participation in Medicaid managed care programs, and to address the matching rate issues raised by the commenters.

i. Miscellaneous Comments

Comment: One commenter recommended that the final rule address the administration of non-emergency MCO transportation services. The commenter believed (based on recommendations made by HCFA's Transportation Technical Advisory Group) that coordination with