

transportation agencies and other human service providers increased the efficiency of the transportation system, helped control costs, and can provide better service to Medicaid and non-Medicaid users of the transportation system. The commenter noted that it is in the interest of the community, State, and the health care and transportation industries to develop coordinated networks of transportation. Further, according to the commenter, States should have the ability to operate their non-emergency transportation services with Federal matching funding comparable to the optional medical service match to improve the States' capacity to coordinate transportation services, thereby saving Medicaid related costs while supporting the existing public transportation network.

Response: The issue of non-emergency transportation services is not an issue that is unique to managed care. This regulation only pertains to the Medicaid managed care provisions in the BBA, and thus, non-emergency transportation is beyond the scope of this regulation and the statute it implements.

Comment: One commenter disagreed with the deletion of the requirement that no more than 75 percent of enrollees in risk contracts be eligible for Medicare or Medicaid. Although it is not clear why this would be the case, the commenter apparently believed that this deletion would result in MCOs decreasing the numbers of Medicaid beneficiaries.

Response: First, the 75/25 enrollment requirement is a limit on the percentage of enrollees eligible for Medicaid, and therefore there is no reason to believe it would result in decreased Medicaid enrollment. Any changes that resulted from its elimination would presumably increase Medicaid enrollment. More importantly, this change was made by Congress in the BBA, and we thus had no discretion in this rulemaking to retain it. We note that this requirement was previously used as a rough "proxy" to ensure quality services by requiring that an MCO attract commercial customers. This "proxy" has been replaced in the BBA with more direct quality requirements implemented in this final rule.

Comment: We received one comment urging that the proposed rule deal with the effects on Medicaid of the law prohibiting "public benefits" going to individuals who are not citizens or permanent residents.

Response: This subject is outside the scope of this rulemaking.

Comment: A few commenters suggested that HCFA require State

agencies to consult with beneficiaries and the physician community at all stages of the planning and implementation of new managed care initiatives. The commenters believed that physician organizations can offer significant input into the development of professional standards effecting patient care delivery, evaluating the adequacy of provider networks, and assessing quality of care delivered. Further, the commenters believed that we should continuously monitor and evaluate State experiences with physician participation and serve as a clearinghouse of information for States on successful strategies.

Response: We realize that public and physician consultation are important factors in the development of Medicaid managed care initiatives and encourage stakeholder input at all stages of managed care development. However, we are not requiring a specific requirement for stakeholder involvement since States, based on the uniqueness of their Medicaid managed care programs, are in the best position to determine how this involvement should be structured. Each State is required to have a Medical Care Advisory Committee (MCAC) established for the purpose of advising the Medicaid agency about health and medical services. This committee, by regulatory definition, is required to include physicians and beneficiaries. We encourage States to continue to use the MCAC as a mechanism for obtaining input on managed care issues. Likewise, under § 438.302, we are requiring public consultation in development of the State's quality strategy, though we are not specifying the structure of this consultation.

Comment: One commenter expressed concern with the lack of discussion in the preamble and proposed regulation text of requirements or directions to States regarding long term care services and support delivered by MCOs. The commenter believed that this was of particular concern since the elderly and people with disabilities account for the majority of Medicaid spending.

Response: While long-term care services were not explicitly addressed in the regulation, we believe the regulation was written in such a manner to encompass all the types of services delivered under managed care including long-term care. Long-term care issues were considered in discussions during the development of the final regulation.

Comment: Several commenters were concerned with what they believed to be a lack of clarity and specificity in the proposed rule concerning children and children with special health care needs.

These commenters believed that the final rule should be more specific on child health requirements separate from adult health requirements, since children have distinct medical and developmental health care needs. The commenters also stated that the proposed rule offered no special protection for children with special health care needs. One commenter stated that when Congress enacted section 1932(a)(2)(A) of the Act, it intended that HCFA develop standards and protections for special needs children above and beyond the managed care standards and protections provided to all beneficiaries. The commenter further indicated that because children with special health care needs are the most vulnerable, it was essential that HCFA provide specific regulations that protect these children in managed care environments.

Response: We agree that children, and particularly children with special health care needs, have unique needs that differ from the adult population. While this final rule establishes a general framework for States to use when developing managed care programs to serve all of its enrolled populations, as discussed in section II. D. above, it also takes into account and implements recommendations set forth in HCFA's report to Congress on special needs beneficiaries required under section 4705(c)(2) of the BBA. We note that section 1932(a)(2)(A) specifically exempts special needs children from being mandatorily enrolled in the State Plan Option for Medicaid managed care. In addition, under 1915(b) waivers HCFA has established new interim criteria that States must meet when establishing programs for children with special health care needs. These criteria require additional reporting and monitoring for children with special health care needs. And finally, the terms and conditions for 1115 waiver programs also contain specific areas that address the needs of these types of children.

Comment: One commenter was concerned about the impact of Medicaid managed care on the nation's dental schools and other hospital-based or allied dental education programs. The commenter urged HCFA to recognize the special role of dental education institutions in serving the Medicaid population and to use the regulations to strengthen the Medicaid program by improving access to dental prevention and treatment services. Finally, this commenter recommended that the proposed regulations be revised to amplify the specific requirements of law related to the access of diagnostic,

preventive and treatment services for children under Medicaid's EPSDT program. The commenter was specifically concerned about the impact of managed care on the utilization rate for children's dental services.

Response: We recognize the importance of the nation's dental schools and other hospital-based dental education programs in serving the dental needs of the Medicaid population. At this time, we do not believe it is necessary to develop a separate regulation to address access to dental prevention and treatment services. This final rule is designed to address access issues related to all Medicaid managed care services. For example, an MCO that delivers dental services to Medicaid beneficiaries must comply with the access requirements in the regulation. The MCO must ensure that it offers an appropriate range of services and that it maintains a network of providers that is sufficient to meet the needs of its enrollees. Further, according to § 438.206(a), each State must ensure, through its contract with an MCO, that all of the covered services are accessible for all the beneficiaries enrolled with the MCO. We are also optimistic that managed care will facilitate increased utilization in the area of dental services.

Comment: Several commenters recommended that HCFA develop a final rule which ensures that States, MCOs and PCCMs will develop Medicaid managed care programs that protect the rights of enrollees who are homeless, promote their access to an appropriate range of services, and improve the quality of care available to them.

Response: We believe this final rule protects the rights of all beneficiaries, including persons who are homeless. For example, § 438.206 requires that the delivery network meet the needs of the population served and that access to services be guaranteed, while under § 438.100 all beneficiaries must be treated with dignity and respect. We recognize that persons who are homeless face unique difficulties in receiving information needed to make appropriate choices among MCO or PCCM options due to transience, lack of mailing address, and other circumstances. Under § 438.56(d)(2)(i), persons who are homeless, and who have been automatically assigned at their initial enrollment into an MCO or PCCM, may disenroll and re-enroll with a different MCO or PCCM at any time. We believe this will give persons who are homeless the opportunity to learn more about managed care when they need medical services and make the

most effective choice of MCOs or PCCMs at that time.

Comment: One commenter recommended that there should be some form of consumer assistance programs to help enrollees navigate the managed care system.

Response: We agree that there must be adequate and appropriate consumer assistance programs available to enable beneficiaries to navigate the managed care system. We also agree that it is a State's responsibility to ensure that consumer assistance is available to its beneficiaries. However, because consumer assistance can be accomplished in many different ways, and should be designed by each State to meet the unique characteristics of its managed care population and program, we are not imposing a Federal requirement for this. Some States already use toll free hotlines for consumer assistance, while others have developed ombudsman programs. We do require that MCOs must give enrollees reasonable assistance they need in completing forms or other procedural steps in the grievance process.

Comment: Several commenters believed that the regulation should clearly respond to the special needs of medically vulnerable beneficiaries with acute, chronic and disabling conditions and contain specific definitions of these diagnoses, as well as clear definitions of "mental illness" and "addictive disorders" so that coverage for these conditions are included under the service plan. One commenter recommended the inclusion within all Medicaid mental health managed care benefit packages of psychosocial rehabilitative services, self-help services and peer supports, and other non-medical services designed to help consumers improve their level of functioning, increase their ability to live independently and cope with ongoing symptoms and side effects of medications. Further, the commenter contended that States should be required to establish the methodology necessary to measure the prevalence of chronic mental illness, acute mental illness, or substance abuse per county, taking into account the predicted health care needs of the population to be enrolled. Another commenter believed that the regulation should incorporate a requirement that each Medicaid managed care behavioral health plan name and provide a full continuum of addiction treatment services in the network including: hospital and non-hospital detoxification, hospital and non-hospital rehabilitation, short and long term rehabilitation, outpatient,

partial hospitalization services and treatment for the family. This commenter also recommended that a particular university be given a strong role in review of these provisions, and that this role should be written into regulation.

Response: The regulation was intended to address needs and protections for all Medicaid beneficiaries in managed care. The information requirements at § 438.10 require that the State must, directly, or through the MCO, PHP, or PCCM, provide information on any benefits to which the beneficiary is entitled under the Medicaid program, but that are not covered under the MCO, PHP, or PCCM contract, and specific instructions on where and how to obtain those benefits, including how transportation is provided. Further, we are not identifying specific types of treatment and services in the regulation for one type of service category. Each State has the flexibility to determine the services that will be covered under their own State Medicaid program. This regulation pertains only to the delivery of services, not the benefits provided under the State's Medicaid program. With respect to the last comment on the role of a specified university, we do not believe it would be appropriate to grant an outside private body government oversight authority.

Comment: One commenter suggested that MCO, PHP, and PCCM contracts should specify the services that the entity is responsible to provide, and that the State should be required to make arrangements for providing other State plan services, and give beneficiaries written information on how to obtain them.

Response: As noted above in section II. C., § 438.210(a) requires that contracts specify the services the entity is required to provide, and § 438.206(c) requires that if an MCO contract does not cover all of the services covered under the State plan, the State must make available those services from other sources and instruct all enrollees on where and how to obtain them, including how transportation is provided. Further, the information requirements under § 438.10 require that the State must, directly or through the MCO, PHP, or PCCM, provide to Medicaid beneficiaries information on any services to which they may be entitled under the Medicaid program, but that are not covered under the MCO, PHP, or PCCM contract and specific instructions on where and how to obtain those services, including how transportation is provided.

Comment: One commenter recommended that a new paragraph should be included (titled "Americans with Disabilities Act") to require that each MCO must ensure that: (1) the physical and mental disabilities of enrollees and potential enrollees are reasonably accommodated, including flexible scheduling, extra assistance and specialized staff training; (2) enrollees with disabilities receive services in the most integrated setting appropriate to their needs, including community based services to enable them to live in community settings instead of institutions or residential treatment facilities; (3) no eligibility criteria, service authorization procedures, utilization review practices or other methods of administration are employed that defeat or substantially impair, with respect to individuals with disabilities, accomplishment of the objectives of the State's medical assistance program; and (4) qualified individuals with disabilities be provided services, benefits and aids that are as effective in affording equal opportunity to obtain the same result, to gain the same benefit or to reach the same level of achievement as that provided to others.

Response: We do not feel it is necessary to add a separate provision as other areas of the regulation respond to this issue. Section 438.100 requires that the State must ensure that each MCO and PHP comply with any and all Federal laws pertaining to enrollee rights, including the Americans with Disabilities Act. Further, § 438.6(f) requires that all contracts must comply with all applicable State and Federal laws and regulations, including Title VI of the Civil Rights Act of 1964; Title IX of the Education Amendments of 1972 (regarding education programs and activities); the Age Discrimination Act of 1975; the Rehabilitation Act of 1973; and the Americans with Disabilities Act.

Comment: One commenter was concerned with what will happen to people with mental retardation should an MCO, PHP, or PCCM withdraw from the Medicaid market. The commenter stated that if a Medicaid MCO or PHP leaves the Medicaid market, there must be protections in place to ensure continuing access to medically necessary services for individuals with mental retardation and other disabilities who critically need access to these health and health related services and supports to live in the community.

Response: It is the State's ultimate responsibility to ensure access to Medicaid covered services. In the event that an MCO or PHP withdraws from the Medicaid market, the State must ensure that services are delivered to all

Medicaid beneficiaries either through another Medicaid MCO or PHP, or through fee-for-service arrangements.

Comment: One commenter found it disturbing that managed care consumer protections and quality measures for the Medicare population have more "teeth" than those required for Medicaid. The commenter felt that this perceived distinction in the requirements of Medicare managed care and Medicaid managed care continues what the commenter believed to be ongoing discrimination against people who are poor and disabled.

Response: It was our intent to create consistency with the Medicare+Choice requirements to lessen the impact that multiple regulatory and administrative standards exert on the managed care industry. However, where there was a clear need for greater beneficiary protection or where consistency with the Medicare+Choice program was not appropriate for Medicaid managed care, we deviated from the Medicare+Choice policy. We believe that this final rule balances the need for flexibility and consistency, while providing States with the broad tools necessary to become better purchasers of health care. We believe that this final rule contains protections for enrollees that are equal to or exceed those in the Medicare+Choice final rule. This includes sanction and civil money penalty authority similar to that in the Medicare+Choice rule. We thus disagree with the commenter's premise about the Medicare+Choice rule having more "teeth."

Comment: Several commenters urged HCFA to provide special attention to the effect of these regulations on people with disabilities. The commenters believed that the regulations must provide specific protections for special needs populations, such as those with spinal cord injury or dysfunction when enrollment in Medicaid managed care is mandatory. One commenter believed a methodology should be developed which would allow States to inventory disabled populations on a per county basis in order to ensure that adequate numbers of providers, especially specialists, would be available to serve the enrolled special needs population.

Response: The regulation was intended to address the needs and protections for all Medicaid beneficiaries in managed care, including persons with disabilities. The regulation was written in a manner to establish a general framework for States to use when developing managed care programs to serve all of its enrolled populations. We believe the regulation allows greater access to quality health

care services delivered through managed care arrangements for persons with disabilities. As noted above in section II. C., § 438.206(d) requires that MCOs and PHPs take into account the anticipated enrollment of persons with special health care needs in establishing their provider network, and must have the appropriate numbers and "types" of providers in terms of training and experience to meet these needs. We believe these provisions directly address the commenters' concerns.

Comment: One commenter suggested that the final regulation make clear that all States are free to adopt more rigorous standards of consumer protections in Medicaid managed care.

Response: The consumer protections in this regulation were not designed to prevent States from developing more rigorous standards. States retain the flexibility to develop more restrictive consumer protection provisions that go beyond those contained in this regulation.

Comment: Several commenters noted that the issue of low physician participation in Medicaid does not appear to have been addressed in the proposed rule, and believed that this has always been a concern under the Medicaid program. Some of the commenters believed that because of inadequate funding and administrative requirements, physicians have minimized their participation in the Medicaid program. These commenters believed that financial incentives may be an appropriate mechanism to entice physician participation. On the other hand, a commenter felt that financial incentives that may prevent the delivery of medically necessary services may be partially controlled by prohibiting any financial incentives. Another commenter recommended that in addition to physician incentive plans that place physicians at substantial financial risk for services they do not provide, having to conduct enrollee surveys, and provide adequate and appropriate stop loss protection, HCFA should also state that financial risk will reside with the plan in instances where a plan decision results in a limit on the services provided. Finally, one commenter felt that there was a need to develop financial incentives for managed care plans to compete on the basis of quality rather than the basis of price. This commenter believed that it is important for Medicaid managed care regulations to establish rewards for MCOs based on quality, not merely cost reductions.

Response: The general issue of relatively low levels of physician participation in the Medicaid program is

outside the scope of this rulemaking. We note, however, that levels of participation in managed care settings have been higher than under fee-for-service Medicaid, and that a managed care enrollee is ensured access to a primary care provider under this final rule. Thus, to the extent managed care is involved, physician participation is guaranteed under this final rule to the extent necessary to meet access requirements. Specifically, § 438.207 requires that each MCO and PHP must ensure that it maintains a network of providers that is sufficient in number, mix and geographic distribution to meet the needs of the anticipated number of enrollees in the MCO's or PHP's service area. Further, under § 438.214, the State must ensure that each MCO and PHP have a process for formal selection and retention of providers that does not discriminate against those that serve high risk populations or specialize in conditions that require costly treatment. With respect to financial incentives for MCOs and PHPs, these are addressed in § 422.6(c)(5) as part of the discussion of actuarially sound rates. See section II. A. above. Beyond these limits, we believe States should have flexibility in this area. With respect to financial incentives for individual physicians, § 438.6(h) requires that MCO and PHP contracts provide for compliance with the physician incentive plan requirements.

Comment: One commenter wrote to express concerns regarding the quality of care delivered by a particular managed care program. The commenter was concerned about the introduction of managed care for persons with disabilities and persons with chronic conditions. The commenter contended that they were misled by their health plan, and the organization denied and reduced care when not appropriate.

Response: We anticipate that the new consumer protections, quality provisions and grievance system requirements in this final rule will work to alleviate problems in the areas addressed by the commenter.

Comment: One commenter believed that the final rule should maintain an adequate safety net to guarantee the continued viability of Medicaid managed care and to allow for reasonable alternatives. The commenter cautioned States moving towards mandatory managed care that they must avoid the tendency to make the area fit MCOs rather than the MCOs address the area. The commenter felt that "cookie cutter" approaches will not work in large rural States, and it might be difficult to develop health plan networks in rural areas.

Response: We recognize that States are unique and have different needs for their enrolled populations. This final rule was designed to maintain State flexibility as much as possible, so that States can implement managed care programs that meet the needs of their beneficiaries.

VI. Collection of Information Requirements

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

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

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

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

The following information collection requirements and associated burdens are subject to the PRA. For purposes of this requirement, we incorporated pertinent managed care data from the 1999 Medicaid enrollment report. As of June, 1999, there were 375 managed care organizations (MCOs) (this includes 2 HIOs that must adhere to the MCO requirements of this regulation), 37 primary care case management systems (PCCMs), 412 managed care entities (MCOs and PCCMs combined), and 129 prepaid health plans (PHPs). There were a total of 24,470,583 beneficiaries enrolled in these plans (some beneficiaries are enrolled in more than one plan) in forty-eight States and the District of Columbia (Wyoming and Alaska do not currently enroll beneficiaries in any type of managed care).

A. Section 438.6 Contract Requirements

1. Section 438.6(c) Payments Under the Contracts

a. Requirement

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

b. Burden

We believe that the burden of providing additional information to support the actuarial soundness of a State's capitation rates will be offset by the elimination of the UPL requirement. States will no longer be required to extract fee-for-service (FFP) data and manipulate that data by trending and other adjustments in order to establish a FFP equivalent for purposes of comparison to capitation rates.

2. Section 438.6(i)(2) Advance Directives

a. Requirement

This paragraph requires that MCOs and PHPs (States may determine that it is inappropriate to require this of some PHPs) provide adult enrollees with written information on advance directives policies and include a description of applicable State law.

b. Burden

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

B. Section 438.8 Provisions That Apply to PHPs

Section 438.8(a) Contract Requirements

a. Requirement

This section imposes most of the contract requirements contained in § 438.6 on PHPs, including advance

directives (in most instances) and physician incentive plan requirements.

2. Burden

PHPs have not previously been required to maintain written policies and procedures with respect to advance directives. This requires the PHP to provide written information to enrollees of their rights under this provision and the PHP's policies with respect to the implementation of those rights. We project 8 hours for each of the 129 PHPs to establish this policy and 2 minutes per enrollee for provision of this information, and acceptance of this right to each of approximately 8.1 million individuals enrolled in PHPs. The total time for this would be 271,032 hours.

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

We are basing our projections of burden upon information published in the **Federal Register** on March 27, 1996 and December 31, 1996 (61 FR 13445 and 61 FR 69049) which contained the original regulatory provisions on physician incentive plans for Medicare and Medicaid HMOs. Based on those assumptions, we believe no more than one third of the approximately 130 PHPs use incentive or risk payment arrangements with their subcontracting providers. Affected PHPs would be required to provide detailed responses to State surveys regarding their payment mechanisms and amounts. At the projected 100 hours per response for approximately 43 PHPs the total burden would be 4300 hours. For those PHPs with substantial financial risk, there are other requirements such as stop loss insurance and beneficiary surveys. We believe there would be minimal additional burden as a result of these requirements (because many already comply with these requirements) and that this would apply to no more than one fourth of those PHPs with risk or incentive payments, or a total of 11. We estimate an additional 10 hours per plan for a total of 110 hours. Altogether, we estimate 4,410 hours of burden through imposition of this requirement on PHPs.

C. Section 438.10 Information Requirements

1. Section 438.10(b), (d), (e), and (f)

a. Requirement

In summary, § 438.10(b), (d) and (e) state that each State, MCO, PHP, and PCCM must furnish information to enrollees and potential enrollees, to meet the requirements of this section. Paragraph (b) requires that the State notify enrollees and potential enrollees, and require each MCO, PHP, and PCCM to notify its enrollees and potential enrollees that oral interpretation and written information are available in languages other than English and how to access those services. The basic information listed in paragraph (d) and (e) of this section must be provided to each enrollee or to any potential enrollee upon request, by the MCO or PHP (unless the State chooses to furnish it directly), within a reasonable time after it receives from the State notice of the beneficiary's enrollment. This information must be provided on an annual basis thereafter, the MCO or PHP must notify enrollees of their right to obtain this information upon request. The information that must be provided includes the following:

Information for potential enrollees

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

Information specific to each MCO and PHP serving an area that encompasses the potential enrollee's service area must be provided. This includes information on benefits covered; cost sharing if any; service area; names, locations, and telephone numbers of current network providers, including at a minimum information on primary care physicians, specialists, and hospitals, and identification of providers that are not accepting new patients; and benefits that are available under the State plan but are not covered under the contract, including how and where the enrollee may obtain those benefits, any cost sharing, and how transportation is provided.

Information for enrollees

The State must give each enrollee written notice of any change (that the State defines as "significant") in the information specified at least 30 days before the intended effective date of the change and make a good faith effort to

give written notice of termination of a contracted provider, within 15 days after receipt or issuance of the termination notice, to each enrollee who received his or her primary care from, or was seen on a regular basis by, the terminated provider.

Required information:

- Kinds of benefits, and amount, duration, and scope of benefits available under the contract; enrollee rights as specified in § 438.100.

- Procedures for obtaining benefits, including authorization requirements.

- Names, locations, and telephone numbers of current network providers, including information at least on primary care physicians, specialists, and hospitals, and identification of providers that are not accepting new patients.

- Any restrictions on the enrollee's freedom of choice among network providers.

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

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

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

- Cost sharing, if any.

- Grievance, appeal, and fair hearing procedures for enrollees, including time-frames, required under § 438.414(b).

- Any appeal rights that the State chooses to make available to providers to challenge the failure of the organization to cover a service.

- Any benefits that are available under the State plan but are not covered under the contract, including how and where the enrollee may obtain those benefits, any cost sharing, and how transportation is provided. The State must furnish information about how and where to obtain the service.

- Information on how to obtain continued services during a transition, as provided in § 438.62.

- The rules for emergency and post-stabilization services, as set forth in § 438.114.

- Additional information that is available upon request, and how to request that information.

At least once a year, the MCO or PHP, or the State or its contracted representative, must notify enrollees of their right to request and obtain the information listed above.

In addition, § 438.10(f) requires that information related to the licensure, certification, and accreditation status of MCOs, PHPs, and their providers be

furnished to each enrollee and each potential enrollee.

b. Burden

We believe the burden placed on States, MCOs, PHPs, and enrollment brokers as a result of this requirement is the time associated with modifying the content of existing information materials, as well as the time associated with distributing the materials to enrollees as specified by the regulation. We estimate that it will initially take 12 hours for each MCO or PHP to modify existing information materials to conform with the requirement above. We further estimate that there are approximately 375 MCOs and 129 PHPs, equating to an initial modification burden of approximately 6,048 hours. After the initial modification, we estimate that it will take MCOs and PHPs approximately 4 hours each to annually update the information materials, equating to an annual total burden of approximately 2,016 hours.

We expect that it will take MCOs, PHPs, or States approximately 5 minutes per enrollee to mail the initial packet, for an estimated 20.2 million enrollees. The total burden associated with this requirement is approximately 1,683,000 hours, approximately 3,340 hours per MCO or PHP, or 34,000 hours per State.

We similarly estimate that it annually will take MCOs, PHPs, or States 5 minutes per enrollee to mail information materials upon request. We estimate that 10 percent of enrollees and potential enrollees will request information annually, equating to approximately 2,020,000 enrollees and potential enrollees. The annual mailing burden associated with this requirement is estimated to be 2,020,000 individuals multiplied by 5 minutes per person, for a total burden of approximately 168,300 hours (approximately 330 hours per MCO or PHP, or 3,400 hours per State).

Finally, we estimate that it will annually take MCOs, PHPs, or States 5 minutes per enrollee to notify enrollees of their right to receive information. Five minutes multiplied by an estimated total enrollee population of 20,200,000 individuals equates to an annual burden of approximately 16,830,000 hours or approximately 3,300 hours per MCO or PHP or 33,400 hours per State.

2. *Section 438.10(g)*

a. Requirement

Section 438.10(g) requires that each primary care case manager (PCCM) (and PHPs that operate like PCCMs) provide similar types information to potential enrollees including information on

provider names and locations, benefits, grievance procedures, and procedures for obtaining services during the appeals process.

b. Burden

The burden associated with this requirement is the amount of time required by States or their contracted representative to mail the required information to potential enrollees. We believe that it will take the 30 States approximately 5 minutes per enrollee to mail this information. We estimate that there are a total of approximately 4,274,000 PCCM enrollees, and that 10 percent of those enrollees will request this information. This equates to an annual burden of 5 minutes multiplied by 427,400 enrollees, or approximately 35,600 hours (approximately 962 hours per primary care case manager).

3. *Section 438.10(h)*

a. Requirement

In summary, § 438.10(h) states that if a State plan provides for mandatory MCO, PHP, or PCCM enrollment under section 1932(a)(1)(A) of the Act, the State or its contracted representative must provide information in a comparative, chart-like format, to potential enrollees and at least once a year thereafter. The information must include the MCO's, PHP's or PCCM's service area, the benefits covered under the contract, any cost sharing imposed by the MCO, PHP, or PCCM and, to the extent available, quality and performance indicators, including but not limited to disenrollment rates and enrollee satisfaction.

b. Burden

We believe that the additional burden on States (for example those not yet captured in the above provisions) is the length of time associated with creating the comparative chart. We estimate that it will take States approximately 4 hours each to create the comparative chart. We further estimate that approximately 8 States per year will avail themselves of the State Plan Option, for a total annual burden of approximately 32 hours.

D. Section 438.12 Provider Discrimination Prohibited

a. Requirement

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

b. Burden

The burden associated with this requirement is the time it takes the MCO

or PHP to draft and furnish the providers with the requisite notice. We estimate that it will take an hour to draft and furnish any given notice. We estimate that on average each MCO and PHP will need to produce 10 notices per year for a total of 5,040 hours.

E. Section 438.50(b) State Plan Information

a. Requirements

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

b. Burden

The burden associated with this section includes the time associated with developing the process for public involvement, including annual updates. We estimate that it will take 40 hours per State to develop the process for, and involving, the public for a total burden of 1960 hours (48 States and D.C.). We estimate that ensuring ongoing public involvement will take another 20 hours per State annually for a total annual burden of 980 hours.

F. Section 438.56z Disenrollment: Requirements and Limitations

1. *Section 438.56(b)*

a. Requirement

All MCO, PHP, and PCCM contracts must—

- (1) Specify the reasons for which the MCO, PHP, or PCCM may request disenrollment of an enrollee;
- (2) Provide that the MCO, PHP, or PCCM may not request disenrollment because of a change in the enrollee's health status, or because of the enrollee's utilization of medical services, diminished mental capacity, or uncooperative or disruptive behavior resulting from his or her special needs; and
- (3) Specify the methods by which the MCO, PHP, or PCCM ensures the agency that it does not request disenrollment for reasons other than those permitted under the contract.

b. Burden

The burden of submitting this supporting documentation when MCOs, PHPs, or PCCMs request disenrollment of beneficiaries would be two hours per request. We calculate that approximately one-tenth of one percent of enrollees (24,470) would be affected, or 43 per MCO, PHP, or PCCM annually. The total burden would be 48,940 hours, or 87 hours per MCO, PHP, or PCCM.

2. Section 438.56(d)(1)

a. Requirement

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

b. Burden

We believe that the burden associated with this requirement is the length of time it would take enrollees to submit in writing a disenrollment request, if they choose to use the written format. We estimate that it will take approximately 10 minutes per enrollee to generate a written disenrollment request. We estimate that approximately 5 percent of MCO, PHP, and PCCM enrollees will request that they be disenrolled from an MCO, PHP, or PCCM. Approximately one-fourth of the enrollees will choose a written rather than an oral request. This equates to an annual burden of approximately 10 minutes multiplied by 306,000 affected enrollees (one-fourth of the 1,221,000 enrollees requesting disenrollment), or approximately 51,000 hours.

3. Section 438.56(d)(3)

a. Requirement

When MCOs, PHPs, or PCCMs are processing disenrollment requests and do not act to approve them, they must submit written notice to the State and then the State takes action. When a State is acting on a for-cause disenrollment request, they may request written information from the MCO, PHP, or PCCM to determine the outcome. In addition, if the MCO, PHP, or PCCM approves the disenrollment for cause, it must give the enrollee and the State agency written notice of its determination.

b. Burden

We believe that the burden associated with this requirement is the time taken for MCOs, PHPs, or PCCMs to submit written notice to the State and beneficiaries.

Of the 1,221,000 affected enrollees, we calculate that one-fifth (244,000) will not be approved. If each notice takes 15 minutes to produce, the total burden would be 61,000 hours. Of the 244,000 enrollees not approved, we calculate that three-fourths (183,000) will involve the State requesting information from the MCO, PHP, or PCCM justifying the denial. At one hour per request, the total burden on MCOs, PHPs, or PCCMs would be 183,000 hours.

We estimate that the MCOs, PHPs, and PCCMs will need to produce notices for the remaining four-fifths of

enrollees requesting disenrollment (977,000) and the States to approve the request for disenrollment. As this notice will probably be a short form letter, with attachments as necessary, we believe that it will take ten minutes per request to send out the notices, or an annual burden of 163,000 hours.

G. Section 438.102 Enrollee-Provider Communications

a. Requirement

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

b. Burden

The above information collection requirement is subject to the PRA. However, we believe the burden associated with these requirements is captured in the general information requirements in § 438.10.

H. Section 438.114 Emergency Services

a. Requirement

Section 438.114(b) states that at the time of enrollment and at least annually thereafter, each MCO, PHP, and State (for PCCMs) must provide, in clear, accurate, and standardized form, information that, at a minimum, describes or explains (1) What constitutes an emergency, with reference to the definitions in paragraph (a) of this section, (2) the appropriate use of emergency services, (3) the process and procedures for obtaining emergency services, including use of the 911 telephone system or its local equivalent, (4) the locations of emergency settings and other locations at which MCO physicians and hospitals provide emergency services and post-stabilization care covered under the contract, and (5) the fact that prior authorization is not required.

a. Burden

The following information collection requirement is subject to the PRA. However, we believe the burden associated with these requirements is captured in the general information requirements in § 438.10.

I. Section 438.202 State Responsibilities

a. Requirement

Each State contracting with an MCO or PHP must have a strategy for assessing and improving the quality of managed care services offered by the MCO or PHP, document the strategy in writing and make it available for public comment before adopting it in final, and conduct periodic reviews to evaluate the effectiveness of the strategy at least every three years. Each State must also submit to HCFA a copy of the initial strategy and a copy of the revised strategy whenever significant changes are made. In addition, States are required to submit to HCFA regular reports on the implementation and effectiveness of the strategy, consistent with the State's own periodic review of its strategy's effectiveness, but at least every three years.

b. Burden

The burden associated with this section is limited to those States offering managed care through MCOs or PHPs (49) and includes the time associated with developing the proposed strategy, publicizing the proposed strategy, incorporating public comments, submitting an initial copy of the strategy to HCFA prior to its implementation and whenever significant changes are made, and submitting regular reports on the implementation and effectiveness of the strategy at least every three years. We estimate that it will take 40 hours per State to develop the proposed strategy for a total burden of 1960 hours. We estimate that publicizing the proposed strategy will take 2 hours per State for a total burden of 98 hours. We estimate that incorporating public comments for the final strategy will take another 40 hours per State for a total burden of 1960 hours. We estimate it will take one hour per State to submit an initial copy of the strategy to HCFA and whenever significant changes are made for a total of 49 hours. We estimate it will take 40 hours per State to create and submit a report on the implementation and effectiveness of the strategy. We assume that these reports will be submitted at least every three years for a total annual burden of 653 hours.

K. Section 438.204 Elements of State Quality Strategies

a. Requirement

In this final rule we have added a new requirement at § 438.204(b)(1)(iii) that a State identify the race, ethnicity, and primary language spoken by each MCO

and PHP enrollee and report this information to each MCO and PHP in which each beneficiary enrolls at the time of their enrollment.

b. Burden

We believe that most States currently track race and ethnicity data in their eligibility systems. If States do not, minor changes in their software will be needed. With respect to primary language of enrollees, there will likely be additional programming needed for all States. We estimate that this would require 2 hours of programming for each of the 49 jurisdictions for a total of 98 hours.

L. Section 438.206 Availability of Services

a. Requirement

Paragraph (c) of this section requires that if an MCO, PHP, or PCCM contract does not cover all of the services under the State plan, the State must make those services available from other sources and provide to enrollees information on where and how to obtain them, including how transportation is provided.

b. Burden

The burden associated with this requirement is the time it takes to provide the information. This burden of this requirement is included in the general disclosure requirements in § 438.10.

M. Section 438.207 Assurances of Adequate Capacity and Services

a. Requirement

Section 438.207 requires that each MCO and PHP must submit documentation to the State, in a format specified by the State and acceptable to HCFA, that it has the capacity to serve the expected enrollment in its service area in accordance with the States' standards for access to care and meets specified requirements.

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

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

b. Burden

We believe that MCOs and PHPs already collect and provide this information to State agencies as part of their customary and usual business practices and that the only additional burden on MCOs and PHPs is the length of time required for MCOs and PHPs to compile this information in the format specified by the State agency, and the length of time for the MCOs and PHPs to mail the information to the State and the HCFA. We estimate that it will take each MCO and PHP approximately 20 hours to compile the information necessary to meet this requirement, for a total of 20 hours multiplied by 504 MCOs and PHPs, or approximately 10,000 hours. In addition, we estimate that it will take MCOs and PHPs approximately 5 minutes each to mail the materials associated with this burden to the State for an annual burden of approximately 5 minutes multiplied by 502 MCOs and PHPs, or approximately 42 hours.

In this final rule we have added requirements to the types of assurances that MCOs and PHPs must provide (for example assurances that the MCO or PHP has policies and practices to address situations where there are: (1) unanticipated needs for providers with particular types of experience; and (2) unanticipated limitations on the availability of such providers. In addition, we have added new requirements under § 438.206(d) that when establishing and maintaining provider networks, each MCO and PHP must consider the anticipated enrollment with respect to persons with special health care needs and the experience of providers required to furnish contracted services.

Documentation to support assurances by each MCO and PHP that they have considered the anticipated enrollment of persons with special health care needs and have recruited or are in the process of recruiting experienced providers is part of the assurances that must be provided to the State. We do not believe that it is customary, or part of the usual business practice of MCOs and PHPs to collect data that includes totals for projected enrollment of persons with special health care needs and their specialized provider requirements. We estimate that obtaining information on: (1) the numbers and types of persons with special health care needs that could be anticipated to enroll in the MCO or PHP; (2) the types of experienced providers they would require; (3) the experience of the existing providers in the MCO's or PHP's network; and (4) the

numbers and types of additional experienced providers needed, would require an estimated 40 hours of work for each of the 504 MCOs and PHPs for a total estimated burden of 20,160 hours.

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

a. Requirement

Section 438.240(c) states that each MCO and PHP must annually measure its performance using standard measures required by the State and report its performance to the State. In this final rule we have added a requirement that the State must include any minimum performance measures and levels specified by HCFA. In addition to using and reporting on measures of its performance, in § 438.240(d)(3) States are to ensure that each MCO and PHP initiates each year one or more performance improvement projects. In § 438.240(d)(10) each MCO and PHP is required to report the status and results of each such project to the State as requested.

B. Burden

This regulation would require States to require each MCO and PHP to annually produce at least two performance measures. Based on discussions with the 17 States with the largest Medicaid managed care enrollments, all 17 States are already doing so. Because the use of performance measures in managed care has become commonplace in commercial, Medicare and Medicaid managed care, we do not believe that this regulatory provision imposes any new burden on MCOs, PHPs, or States.

With respect to the requirements for performance improvement projects in § 438.240(d), we expect that, in any given year, each MCO and PHP will complete two projects, and will have four others underway. We further expect that States will request the status and results of each MCO's and PHP's projects annually. Accordingly, we estimate that it will take each MCO and PHP 5 hours to prepare its report for each project, for an annual total burden of 30 hours per MCO and PHP. In aggregate, this burden equates to 30 hours multiplied by an estimated 504 MCOs and PHPs, or approximately 15,120 hours.

O. Section 438.242 Health Information Systems**a. Requirement**

Section 438.242(b)(2) requires the State to require each MCO and PHP to collect data on enrollee and provider characteristics as specified by the State, and on services furnished to enrollees, through an encounter data system or other such methods as may be specified by the State. Section 438.242(b)(3) states that each MCO and PHP must make all collected data available to the State and to HCFA, as required in this subpart, or upon request.

b. Burden

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

P. Section 438.402 General Requirements**a. Requirement**

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

b. Burden

We estimate that approximately 1 percent of 20.2 million MCO and PHP enrollees (202,000) annually will file a grievance with their MCO or PHP and that approximately .5 percent (101,000) annually will file an appeal. For these cases, we estimate that the burden on the enrollee filing a grievance or appeal is approximately 20 minutes per case. The total annual burden on enrollees is 101,000 hours.

Q. Section 438.404 Notice of Action**a. Requirement**

In summary, § 438.404 states that if an MCO or PHP intends to deny, limit, reduce, or terminate a service; deny payment; deny the request of an enrollee in a rural area with one MCO or PHP to go out of network to obtain a service; or fails to furnish, arrange, provide, or pay for a service in a timely

manner, the MCO or PHP must give the enrollee timely written notice and sets forth the requirements of that notice.

b. Burden

We estimate that the burden associated with this requirement is the length of time it would take an MCO or PHP to provide written notice of an intended action. We estimate that it will take MCOs and PHPs 30 seconds per action to make this notification. We estimate that approximately 5 percent (1,010,000) of the approximately 20.2 million MCO and PHP enrollees will receive one notice of intended action per year from their MCO or PHP (2,004 hours per MCO or PHP) for a total burden of approximately 8417 hours.

R. Section 438.406 Handling of Grievances and Appeals**a. Requirement**

In summary, § 438.406 states that each MCO and PHP must acknowledge receipt of each grievance and appeal.

b. Burden

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

S. Section 438.408 Resolution and Notification: Grievances and Appeals**a. Requirement**

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

This section also provides, for expedited appeals, that MCOs and PHPs must submit delayed and adverse appeal decisions to the State fair hearing office along with all supporting documentation.

b. Burden

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

T. Section 438.410 Expedited Resolution of Grievances**1. Paragraph (c)****a. Requirement**

Paragraph (c), Requirements for appeals, requires each MCO and PHP to document all oral requests in writing and maintain the documentation in the case file.

b. Burden

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

2. Paragraph (d)**a. Requirement**

Section 438.410(d) states that if an MCO denies a request for expedited grievance, it must automatically transfer the request to the standard time frame process and give the enrollee prompt oral notice of the denial and follow up, within 2 working days, with a written letter.

b. Burden

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

U. Section 438.414 Information About the Grievance System**a. Requirement**

Sections 438.414(a) and (b) state that each MCO and PHP must provide information about the grievance system, as specified in § 438.10 and this subpart to: (1) Enrollees, (2) potential enrollees (as permitted by the State), and (3) all providers and contractors, at the time of subcontracting. The information must explain the grievance system through a State-developed or State-approved description and must include the information set forth in § 438.414 (b)(1) through (6).

In addition, § 438.414(c) states that upon request, the MCO or PHP must provide enrollees and potential enrollees with aggregate information derived from the collected information in § 438.416(e), regarding the nature of enrollee grievances and their resolution.

(c) Requirements for appeals. Each MCO and PHP must meet the following requirements with respect to appeals:

(1) Establish a convenient and efficient means for an enrollee or a provider to request expedited resolution of an appeal;

(2) Provide expedited resolution of an appeal in response to an oral or written request if the MCO or PHP determines (with respect to a request from the enrollee) or the provider indicates (in making the request on the enrollee's behalf or supporting the enrollee's request) that taking the time for a standard resolution could seriously jeopardize the enrollee's life or health or ability to attain, maintain, or regain maximum function.

(3) Document all oral requests in writing; and

(4) Maintain the documentation in the case file.

b. Burden

These information collection requirements are subject to the PRA. However, we believe the burden associated with these requirements is captured in the general information requirements in § 438.10.

V. Section 438.416 Recordkeeping and Reporting Requirements

a. Requirement

Sections 438.416 (a) and (c) state that each MCO and PHP must maintain a log of all complaints and grievances and their resolution, and retain the records of complaints, grievances (including their resolution) and disenrollments for three years, in a central location, and make them accessible to the State.

In addition, § 438.416(d) states that each MCO and PHP must, at least once a year, send to the State a summary that includes the following information, (1) the number and nature of all grievances and appeals, (2) the time frames within which they were acknowledged and resolved, and (3) the nature of the decisions. This material is available to the public upon request under § 438.10.

b. Burden

We estimate that approximately .5 percent of the approximately 20.2 million MCO and PHP enrollees will file a grievance with their MCO or PHP (200 per MCO or PHP). The recording and tracking burden associated with each grievance is estimated to be 1 minute per request (3.4 hours per MCO or PHP), for a total burden of 1,680 hours (1 minute multiplied by an estimated 101,000 enrollees who would file a grievance).

This section also contains the applicable requirements that MCOs and

PHPs must follow to submit the annual summary of complaints and grievances. Every MCO and PHP (approximately 504 organizations) must submit an annual report. We estimate that the burden on the MCO or PHP for collecting information and preparing this summary will be approximately 4 hours per MCO/PHP or approximately 2,016 hours total.

W. Section 438.604 Data That Must Be Certified

a. Requirement

When payments from States to MCOs and PHPs are based on data submitted by the MCO or PHP that include, but are not limited to, enrollment information, encounter data, or other information required by the State, the MCO or PHP must attest to such data's accuracy, completeness, and truthfulness as a condition of receiving such payment. Each MCO and PHP must certify that it is in substantial compliance with its contract. Certification is required, as provided in § 438.606, for all documents specified by the State.

b. Burden

While the requirement for MCOs and PHPs (and their contractors) to attest to the accuracy of enrollment information encounter data or other information required by the State is subject to the PRA, as is the requirement for MCOs and PHPs to certify the accuracy, completeness, and truthfulness of all information provided in contracts, requests for proposals, or other related documents specified by the State, the burden associated with these requirements is captured during the submission of such information. Therefore, we are assigning one token hour of burden for this requirement.

X. Section 438.710 Due Process: Notice of Sanction and Pre-termination Hearing

1. (a) Due Process: Notice of Sanction and Pre-Termination Hearing

a. Requirement

Section 438.710(a) states that before imposing any of the sanctions specified in this subpart, the State must give the affected MCO or PCCM written notice that explains the basis and nature of the sanction. Section 438.724 also requires all intermediate sanctions to be published in a newspaper in order to notify the public.

b. Burden

The above information collection requirements are not subject to the P.A. They are exempt under 5 CFR 1320.4(a)

because they occur as part of an administrative action.

2. (b)(1) Due Process: Notice of Sanction and Pre-Termination Hearing

a. Requirement

Section 438.710(b)(1) states that before terminating an MCO's or PCCM's contract, the State must give the MCO or PCCM written notice of its intent to terminate, the reason for termination, and the time and place of the hearing.

b. Burden

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

Y. Section 438.722 Disenrollment During Termination Hearing Process

a. Requirement

Section 438.722(a) states that after a State has notified an MCO or PCCM of its intention to terminate the MCO or PCCM's contract, the State may give the MCO's or PCCM's enrollees written notice of the State's intent to terminate the MCO's or PCCM's contract.

b. Burden

States already have the authority to terminate MCO or PCCM contracts according to State law and have been providing written notice to the MCOs or PCCMs. States are now given, at their discretion, the option of notifying the MCO's or PCCM's enrollees of the State's intent to terminate the MCO's or PCCM's contract. While it is not possible to gather an exact figure, we estimate that 12 States may terminate 1 contract per year. We estimate that it will take States 1 hour to prepare the notice to enrollees, for a total burden of 12 hours. In addition, we estimate that it will take States approximately 5 minutes per beneficiary to notify them of the termination, equating to a burden of 5 minutes multiplied by 12 States multiplied by 40,080 beneficiaries per MCO or PCCM, for a burden of approximately 40,080 hours. The total burden of preparing the notice and notifying enrollees is 40,096.

Z. Section 438.810 Expenditures for Enrollment Broker Services

a. Requirement

Section 438.810(c) requires that a State contracting with an enrollment broker must submit the contract or memorandum of agreement (MOA) for services performed by the broker to HCFA for review and approval prior to the effective date of services required by the contract or MOA.

b. Burden

The burden associated with this requirement is the length of time for a State to mail each contract to HCFA for review. We estimate that the burden associated with this requirement is 5 minutes per enrollment broker contract, for a total annual burden of approximately 3 hours per year (5 minutes multiplied by an estimated 35 enrollment broker contracts in the States using brokers).

We have submitted a copy of this proposed rule to OMB for its review of the information collection requirements described above. These requirements are not effective until they have been approved by OMB.

If you comment on these information collection requirements, please mail copies directly to the following: Health Care Financing Administration, Office of Information Services, DHES, SSG, Attn: Julie Brown, HCFA-2001-F, Room N2-14-26, 7500 Security Boulevard, Baltimore, MD 21244-1850; and Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Brenda Aguilar, Desk Officer.

VII. Provisions of the Final Rule

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

Part 400—Introduction; Definitions*Section 400.203*

We have revised this section to include three new provisions. First, we specify that *PCCM* stands for primary care case manager. Second, we specify that *PCP* stands for primary care physician. Third, we have revised the definition of *provider* to clarify that, for the fee-for-service program, it means any individual or entity furnishing Medicaid services under an agreement with the Medicaid agency and for the managed care program, it means any individual or entity that is engaged in the delivery of health care services and is legally authorized to do so by the State in which it delivers the services.

Part 430—Grants to States for Medical Assistance*Section 430.5*

We have revised this section by removing the definition of *clinical laboratory*, moving the definition of *authorized representative* to this section from § 438.2, and moving the definitions of *capitation payment*, *federally qualified HMO*, *health insuring organization*, *nonrisk contract*, *prepaid health plan*, and *risk contract* from this

section to § 438.2. We have revised the definition of *authorized representative* to provide that the term will be defined by each State consistent with its laws, regulations, and policies.

Part 431—State Organization and General Administration*Section 431.200*

We have revised paragraph (c) to include a reference to section 1819(f)(3) of the Act.

Section 431.201

We have defined service authorization request to mean a managed care enrollee's request for the provision of a Medicaid-covered service.

Section 431.244

We have revised paragraph (f) regarding time frames for State fair hearings to include a requirement for an expedited hearing for certain service authorization requests. We have redesignated paragraph (g) as (h) and included a new paragraph (g) which permits States to allow a hearing officer to grant an extension of the time frames under certain circumstances.

Part 434—Contracts*Section 435.212*

We revised this section to replace "HMO," wherever it appears, with "MCO and PCCM" rather than "MCO."

Section 435.1002

We revised paragraph a to include a reference to § 438.814.

Part 438—Managed Care Provisions**Subpart A—General Provisions***Section 438.2*

We have revised this section by moving the definition of *authorized representative* to § 430.5 and moving the definitions of *capitation payment*, *federally qualified HMO*, *health insuring organization*, *nonrisk contract*, *prepaid health plan*, and *risk contract* from § 430.5 to this section. We have revised the definition of *capitation payment* to clarify that the State agency makes the payment regardless of whether the particular recipient receives services during the period covered by the *payment*, rather than a *fee*. We have clarified the definition of health insuring organization (HIO) so that it does not appear to require that an HIO's subcontractors be capitated. Since we have decided to specify within each regulatory provision, whether it applies to MCOs, PHPs, and/or PCCMs, we no longer use the term managed care entity, and have deleted that definition. We

have revised the definition of *nonrisk contract* to clarify that the term refers to a contract under which the contractor is not at financial risk for changes in utilization or for costs incurred under the contract that do not exceed the upper payment limits specified in § 447.362 of this chapter. In addition, under a nonrisk contract, the contractor may be reimbursed by the State at the end of the contract period on the basis of the incurred costs, subject to the specified limits. Finally, we have clarified the definition of PHP to indicate that PHPs may be reimbursed by any non-state plan methodology, not just capitation.

Section 438.6

We have revised this section to include a new paragraph (a) that provides for regional office review of all MCO and PHP contracts including those that are not subject to the prior approval requirements in § 438.806. We are making significant revisions to paragraph (c). We have extended the rate setting requirements to all risk contracts. We are removing the requirement that rates not exceed the upper payment limit (UPL) set forth in § 447.361 and substituting an expanded requirement for actuarial soundness including certification of capitation rates by an actuary. We specify data elements to be included in the methodology used to set capitation rates and require States to consider the costs for individuals with chronic illness, disability, ongoing health care needs, or catastrophic claims in developing rates. We also require States to provide explanations of risk-sharing or incentive methodologies and impose special rules, including a limitation on FFP, in contracts utilizing some of these arrangements. These changes are being made as a Final Rule with a 60-day period for submission of comments.

We have revised paragraph (d) to clarify that the provision applies to MCOs and PHPs, not MCEs. Paragraph (i)(2) is revised to clarify that MCOs and PHPs are not required to provide adult enrollees with oral information on advance directives.

Section 438.8

We have revised paragraph (a) to provide that the requirements for advance directives specified in § 438.6 apply to all PHPs except where the State believes that they are not appropriate, for example, if the PHP contract only covers dental services or non-clinical services such as transportation. We have also expanded the PHP requirements to include compliance with the physician incentive plan rules and all of the State

responsibility provisions of Subpart B (except for the State plan provisions in § 438.50).

Section 438.10

We have revised this section to include the substantive requirements from § 438.318. We have also made several minor wording and organizational changes that served to clarify the requirements of this section. We have clarified how these rules apply to PHPs, whereby PHPs that have PCCM contracts are subject to the rules governing PCCMs, but all other PHPs are subject to the rules governing MCOs.

In paragraph (c), we have clarified that informational material must be available in alternative formats and in a manner that takes into consideration special needs, such as visual impairment or limited reading proficiency. In addition, paragraph (c) provides that the State and MCE must provide instructions to enrollees and potential enrollees regarding how they may obtain information in an appropriate format.

We have revised paragraph (d) to require the State or its contracted representative to provide information to potential enrollees regarding which populations are excluded from enrollment, subject to mandatory enrollment, or free to enroll voluntarily.

We have included a new provision in paragraph (e)(1)(ii), which requires an MCO to inform enrollees regarding any significant changes in any of the information that was furnished to them. The MCO must furnish the information within 90 days after the effective date of the change. We have included regulatory language in paragraph (e)(2) requiring the information provided to enrollees to include names and locations of current network providers, including information at least on primary care physicians, specialists, and hospitals, and identification of providers that are not accepting new patients. In paragraph (e)(3), we have revised the annual notice requirement to provide that at least once each year, the MCO, the State or its contracted representative must notify enrollees of their right to request and obtain specified information.

In paragraph (g), we have clarified that the time frames for furnishing information are the same for both PCCMs and MCOs.

We have revised paragraph (f) to provide that enrollees and potential enrollees may request and receive information on requirements for accessing services, including factors such as physical accessibility.

Section 438.12

We have revised paragraph (b) to permit different reimbursement amounts for the different specialties or for the same specialty.

Subpart B—State Responsibilities

Section 438.50

We have revised this section by including paragraph (b)(4), which requires the State plan to specify the process that the State uses to involve the public in both the design and the initial implementation of the program and the methods it uses to ensure ongoing public involvement once the State plan has been implemented. We have also revised the language in paragraph (a) to clarify that the provisions of this section do not apply to programs that have mandatory managed care enrollment pursuant to a waiver under either section 1115 or section 1915(b) of the Act. We have moved the requirements regarding limitations on enrollment and default enrollment from § 438.56 to this section so that they are only applicable in State plan managed care programs.

Section 438.52

We have revised the definition of “rural” area in paragraph (a) to eliminate the State’s option to use definitions other than any area outside an “urban area” as defined in § 412.62(f)(1)(ii). We have revised the exception for rural area residents in paragraph (c) to clarify that an enrollee must be permitted to obtain services from an out of network provider if the provider is the main source of a service to that individual. We also require that, in rural areas, an enrollee must be permitted to obtain services from an out of network provider if he or she needs related services, not all related services are available within the network, and the enrollee’s primary care provider or another provider determines that receiving the services separately would subject the enrollee to unnecessary risk.

Section 438.56

We have moved the requirements regarding limitations on enrollment and default enrollment from this section to § 438.50. We have revised paragraph (a) to provide that the provisions of this section apply to all managed care arrangements whether enrollment is mandatory or voluntary and whether the contract is with an MCO, a PHP, or a PCCM provider.

We have revised paragraph (b) to require that all MCE contracts must specify the reasons for which the MCO, PHP, or PCCM may request disenrollment of an enrollee. The

contracts must also provide that the MCO, PHP, or PCCM may not request disenrollment because of a change in the enrollee’s health status, or because of the enrollee’s utilization of medical services, diminished mental capacity, or uncooperative or disruptive behavior resulting from his or her special needs except where the behavior impairs the ability of the MCO, PHP, or PCCM to furnish services to this enrollee or others.

In paragraph (c), we have clarified that an enrollee may request disenrollment without cause in four instances:

- During the 90 days following the date of the recipient’s initial enrollment, or the date the State sends the recipient notice of the enrollment, whichever is later.
- At least once every 12 months thereafter.
- Upon automatic reenrollment, if the temporary loss of Medicaid eligibility has caused the recipient to miss the annual disenrollment opportunity.
- When the State imposes an intermediate sanction, as specified in § 438.702(a)(3)

We have revised paragraph (d) to permit an enrollee to submit either an oral or a written request for disenrollment. In subparagraph (d)(2), we have significantly revised the provisions relating to “for cause” disenrollment. We identify three circumstances that would constitute cause under the final rule:

- The enrollee was homeless (as defined by the State) or a migrant worker at the time of enrollment and was enrolled in the MCO, PHP, or PCCM by default.
- The plan does not, because of moral or religious objects, cover the service the enrollee seeks.
- The enrollee needs related services to be performed at the same time, not all related services are available within the network, and the enrollee’s primary care provider or another provider determines that receiving the services separately would subject the enrollee to unnecessary risk.

In subparagraph (d)(iv), we recognize that the enrollee may cite other reasons for requesting disenrollment that could constitute “cause” under the rule, including poor quality of care, lack of access to services covered under the contract, or lack of access to providers experienced in dealing with an enrollee’s special health care needs.

In paragraph (e), we clarify the time frames for disenrollments to provide that regardless of the procedures followed, the effective date of an approved disenrollment must be no

later than the first day of the second month following the month in which the enrollee or the MCO, PHP, or PCCM files a request.

We have revised paragraph (f) to clarify that if a State restricts disenrollment under this section, it must provide that enrollees are furnished a written notice of their disenrollment rights at least 60 days before the start of each enrollment period. In addition, if a State denies a disenrollment request, it must provide notice to the enrollee of their right to file a request for a State Fair Hearing.

Section 438.60

We have deleted an exception for emergency and post stabilization services from this provision, which had been erroneously included in the NPRM, since duplicate payments are prohibited for these services.

Section 438.62

We have added a new paragraph (b) that requires the State agency to have in effect a mechanism to ensure continued access to services when an enrollee with ongoing health care needs is transitioned from fee-for-service to an MCO, PHP, or PCCM, from one MCO, PHP, or PCCM to another, or from an MCO, PHP, or PCCM to fee-for-service. We require that this mechanism apply at least to the following groups:

- Children and adults receiving SSI benefits.
- Children in Title IV–E foster care.
- Recipients aged 65 or older.
- Any other recipients whose care is paid for under State-established, risk-adjusted, high-cost payment categories.
- Any other category of recipients identified by HCFA.

In addition, we require the State to notify the enrollee that a transition mechanism exists, and provide instructions on how to access the mechanism. We also require the State to ensure that an enrollee's ongoing health care needs are met during the transition period, by establishing procedures to ensure that, at a minimum—

- The enrollee has access to services consistent with the State plan and is referred to appropriate health care providers.
- Consistent with Federal and State law, new providers are able to obtain copies of appropriate medical records.
- Any other necessary procedures are in effect.

Section 438.64

We have deleted this section which required that capitation payments be computed on an actuarially sound basis, and incorporated it into the new § 438.6(c) provisions.

Section 438.68

We have added this new section which requires the State agency to have in effect procedures for educating MCOs, PHPs, or PCCMs and their providers about the clinical and other needs of enrollees with special health care needs.

Subpart C—Enrollee Rights and Protections

Section 438.100

We removed the language relating to benefits and moved the provisions relating to “Enrollee Rights” from § 438.320 to this section. We revised the enrollee rights in paragraph (b) to include the following two rights:

- To obtain a second opinion from an appropriately qualified health care professional in accordance with § 438.3206(d)(3).
- To be free from any form of restraint or seclusion used as a means of coercion, discipline, convenience, or retaliation, as specified in other Federal regulations on the use of restraints.

In addition, we have revised three of the enrollee rights to provide that the State must ensure that the enrollee has the right—

- To receive information on available treatment options and alternatives, presented in a manner appropriate to the enrollee's condition and ability to understand. We clarify that if the MCO does not cover a service because of moral or religious objections, then the MCO need not furnish information on where and how to obtain the service, but only on where and how to obtain information about the service.
- To participate in decisions regarding his or her health care, including the right to refuse treatment.
- To request and receive a copy of his or her medical records and to request that they be amended or corrected, in accordance with § 438.3224.

We have included a new requirement in paragraph (c) that provides that the State must ensure that an enrollee's free exercise of his or her rights does not adversely affect the way the MCO, PCCM, or PHP, the MCO, PCCM, or PHP's providers, or the State agency treat the enrollee. In paragraph (d), we have revised the list of examples of applicable Federal and State laws for which States must ensure MCO, PCCM, or PHP compliance.

Section 438.102

We have replaced the term “practitioner” with “health care professional” and revised the definition to mirror the statutory language. We have reorganized the substantive

provisions of the section to clarify the requirements. We revised paragraph (c) to include all of the information requirements that apply if an MCO does not provide a counseling or referral service based on moral or religious objections. We have clarified that, if the MCO does not cover a service under this section, then it is not required to inform enrollees and potential enrollees about how and where to obtain the service, but rather how and where to obtain information about a service. In paragraph (d), we require the State to provide information to enrollees on how and where to obtain a service that the MCO does not cover based on moral or religious objections.

Section 438.104

In paragraph (a) we moved the definitions of *choice counseling*, *enrollment activities*, and *enrollment broker* from this section to § 438.810. We revised the definition of *marketing materials* to mean materials that are produced in any medium, by or on behalf of an MCO, PCCM, or PHP and can reasonably be interpreted as intended to market to enrollees or potential enrollees. We also defined *marketing* to mean any communication from an MCO, PCCM, or PHP, any of its agents or independent contractors, with an enrollee or potential enrollee that can reasonably be interpreted as intended to influence that individual to enroll or reenroll in that particular MCO, PCCM, or PHP's Medicaid product or disenroll from another MCO, PCCM, or PHP's Medicaid product.

In paragraph (b), we have clarified that inaccurate, false, or misleading statements include, but are not limited to, any assertion or statement (whether oral or written) that the beneficiary must enroll in the MCO, PCCM, or PHP in order to obtain benefits or in order to not lose benefits or that the MCO, PCCM, or PHP is endorsed by HCFA, the Federal or the State government, or similar entity. We have also revised two of the provisions in subparagraph (b)(2) in order to clarify that the MCO, PCCM, or PHP contract must provide that the MCO, PCCM, or PHP distributes their marketing materials to its entire service area, as indicated in the contract and that the MCO, PCCM, or PHP does not seek to influence enrollment in conjunction with the sale or offering of any other insurance.

Section 438.108

In § 447.53(e), we now prohibit providers from denying care or services to an individual eligible for the care or services on account of the individual's inability to pay the cost sharing.

Section 438.110

We have moved the provisions related to assurances of adequate capacity and services to § 438.207.

Section 438.114

We have removed the definitions of *emergency medical condition*, *emergency services*, and *post-stabilization services* and included cross references to the definitions of the same terms in the regulations governing the Medicare+Choice program. We have revised paragraph (c) to provide that the following entities are responsible for coverage and payment of emergency services and post-stabilization services:

- The MCO
- The primary care case manager that has a risk contract
- The State, in the case of a primary care case manager that has a fee-for-service contract.

In paragraph (d), we clarify the specific rules governing coverage and payment for emergency services. We revised paragraph (e) to provide for additional rules that govern emergency services. First, the entity responsible for payment may not limit what constitutes an emergency medical condition based on lists of particular diagnoses or symptoms and it may not refuse to process a claim because it does not contain the primary care provider's authorization number. Second, once a qualified provider determines that an enrollee has an emergency medical condition, the enrollee may not be held liable for subsequent screening and treatment needed to diagnose the specific condition, or stabilize the patient. Third, the attending emergency physician or the provider actually treating the enrollee is responsible for determining when the enrollee is sufficiently stabilized, and that determination is binding on the entities responsible for payment.

We have also revised paragraph (f) to require post-stabilization services to be covered and paid for as provided in the regulations governing the Medicare+Choice program (§ 422.113). We explain that, in applying the Medicare+Choice provisions, reference to "M+C" organization" must be read as reference to the entity responsible for Medicaid payment, as specified in paragraph (c) of this section.

Subpart D—Quality Assessment and Performance Improvement

Note: In the proposed rule, this subpart was subpart E, and the sections were numbered as §§ 438.300 to 438.342. In this final rule, this subpart has been relocated as Subpart D and the sections are numbered as §§ 438.200 to 438.242. Sections referenced

herein use the §§ 438.200 to 438.242 numbering of the final rule.

Section 438.202 State responsibilities

In paragraph (b) we require each State contracting with an MCO or PHP to document its quality strategy in writing. In paragraph (c) we require each State to provide for the input of recipients and other stakeholders in the development of the quality strategy, including making the strategy available for public comment before adopting it in final. In paragraph (e) we require the State to update the strategy. In paragraph (f) we require each State to submit to HCFA a copy of the initial strategy and a copy of the revised strategy whenever significant changes are made. In addition, we require the State to submit to HCFA regular reports on the implementation and effectiveness of the strategy.

Section 438.204 Elements of State Strategies

We have revised paragraph (b) to require that the State quality strategy must include procedures for identifying enrollees with special health care needs and assessing the quality and appropriateness of care furnished to those enrollees. We included a new paragraph (c) to require the State quality strategy to incorporate performance measures and levels prescribed by HCFA.

Section 438.206 Availability of Services

We have revised paragraph (d) to clarify that the State must ensure that when each MCO and PHP establishes and maintains its network of providers, each MCO and PHP considers the anticipated enrollment, with particular attention to pregnant women, children, and persons with special health care needs. We have also clarified that each MCO and PHP must consider the training and experience of providers when establishing and maintaining its provider network. In subparagraph (d)(3), we have included a new requirement for MCO and PHP networks (consistent with the scope of the PHP's contracted services) to provide for a second opinion from a qualified health care professional within the network or otherwise arrange for the enrollee to obtain one outside the network at no cost to the enrollee if an additional professional is not currently available within the network. In subparagraph (d)(5) we have added a new requirement that the MCO or PHP must permit an enrollee to access out-of-network providers to receive medical services, if the MCO's or PHP's network is unable

to provide the necessary medical services, for as long as the MCO or PHP is unable to provide the services. We have added a new requirement at subparagraph (d)(7) requiring an MCO or PHP to ensure that its providers do not discriminate against Medicaid enrollees. At subparagraph (d)(8) we have added a new requirement that requires the MCO or PHP to require out-of-network providers to coordinate with the MCO or PHP with respect to payment and ensure that the cost to the enrollee is no greater than it would be if the services were furnished within the network. We have moved requirements that MCOs and PHPs must ensure that provider hours of operation are convenient for the enrollees from subparagraph (d)(6) to subparagraph (e)(1)(ii), and have added a requirement that convenience be determined by a State-established methodology, and at least comparable to Medicaid fee-for-service. We have also moved the requirement that services must be available 24 hours a day, 7 days a week, when medically necessary from subparagraph (d)(5) to (e)(1)(iii).

We have moved the requirements relating to initial assessment from this section to § 438.208.

Section 438.207 Assurances of Adequate Capacity and Services

We have created this new section which relocates and adds to the requirements regarding assurances of adequate capacity and services previously located at § 438.110. We have revised paragraph (a) to provide that each MCO and PHP must give assurances to the State (in the NPRM the MCO was to also give assurance to HCFA) that it has the capacity to serve the expected enrollment in its service area in accordance with the State's standards for access to care under this subpart. In paragraph (b), we have required that each MCO and PHP must submit specific documentation that must be in a format specified by the State and acceptable to the HCFA. In subparagraph (b)(4), we have added requirements that each MCO and PHP must document that it has policies and practices in place to address situations in which there is unanticipated need for providers with particular types of experience or unanticipated limitation of the availability of such providers. We revised paragraph (c) to require the submission of the assurance documentation at least once a year as opposed to every two years as stated in the proposed rule. We also added in paragraph (c) circumstances which we believe constitute a significant change in the MCO's or PHP's operation and

which would require the MCO or PHP to resubmit assurances documenting adequate capacity and services. These are: (1) A significant change in the MCO's or PHP's services or benefits; (2) an expansion or reduction of the MCO's or PHP's geographic service area; (3) the enrollment of a new population in the MCO or PHP; and (4) a significant change in the MCO or PHP rates. We also revised paragraph (d) to provide that after the State reviews the documentation submitted by the MCO or PHP, the State must certify to HCFA that the MCO or PHP has complied with the State's requirements for availability of services, as set forth in § 438.206. We have added a new paragraph (e) to provide that the State must make available to HCFA, upon request, all documentation collected by the State from the MCO or PHP.

Section 438.208 Coordination and Continuity of Care

We have made significant changes to the content and organization of this section. As a part of those changes, we have moved section 438.306(e)(2) and (3) pertaining to initial assessment, and pregnancy and complex and serious medical conditions, to this section. We have clarified that the words "initial assessment" used in the proposed rule are actually two different functions: screening and assessment. We have also replaced the words "persons with serious and complex medical conditions" with the words "persons with special health care needs." In new paragraph (a) we have clarified that the State needs to determine the extent to which requirements pertaining to initial and ongoing screenings and assessments, and primary care are appropriate requirements for PHPs based on the scope of the PHP's services, and the way the State has organized the delivery of managed care services. New paragraph (b) requires the State to implement mechanisms to identify to the MCO and PHP upon enrollment, the following groups:

- Enrollees at risk of having special health care needs, including —
 - ++Children and adults who are receiving SSI benefits;
 - ++Children in Title IV-E foster care;
 - ++Enrollees over the age of 65;
 - ++Enrollees in relevant, State-established, risk-adjusted, higher-cost payment categories; and
 - ++Any other category of recipients identified by HCFA
- Other enrollees known to be pregnant or to have special health care needs
- Children under the age of 2

We have revised paragraph (d) to clarify and expand upon MCO and PHP responsibilities for screening and assessment. In subparagraph (d)(1)(i), we require that for enrollees identified by the State as being at risk of having special health care needs, the MCO (and PHP as determined appropriate by the State) must make a best effort attempt to perform a screening within 30 days of receiving the identification from the State. For any enrollee that the screening identifies as being pregnant or having special health care needs, the MCO (and PHP as determined appropriate by the State) must perform a comprehensive assessment as expeditiously as the enrollee's health requires, but no later than 30 days from the date of identification.

In subparagraph(d)(2), we require that for enrollees under the age of two or other enrollees known by the State to be pregnant or to have special health care needs, each MCO (and PHP as determined appropriate by the State) must perform a comprehensive assessment as expeditiously as the enrollee's health requires, but no later than 30 days from the date of identification.

In subparagraph (d)(3), we require that for all other enrollees, each MCO (and PHP as determined appropriate by the State) must screen them within 90 days from the date of enrollment. For any enrollee that the screening identifies as being pregnant or having special health care needs, each MCO (and PHP as determined appropriate by the State) must perform a comprehensive assessment as expeditiously as the enrollee's health requires, but no later than 30 days from the date of identification.

We have also added a requirement in subparagraph (e) for MCOs (and PHPs as determined appropriate by the State) to implement mechanisms to identify enrollees who develop special health care needs after enrollment in the MCO or PHP and perform comprehensive assessments as expeditiously as the enrollee's health requires, but no later than 30 days from the date of identification.

In subparagraph (f), we have revised the requirements relating to treatment plans. We require that each MCO and PHP must implement a treatment plan for pregnant women and for enrollees determined to have special health care needs. The treatment plan must —

- Be appropriate to the conditions and needs identified and assessed;
- Be for a specific period of time and periodically updated;

- Specify a standing referral or an adequate number of direct access visits to specialists;

- Ensure adequate coordination of care among providers;
- Be developed with enrollee participation; and
- Ensure periodic reassessment of each enrollee as his or her health requires.

In subparagraph (g), we clarify that MCOs and PHPs must use appropriate health care professionals to perform any comprehensive assessments required by this section and develop and implement any treatment plans required by this section. In paragraph (h) and subparagraph (h)(1), we have revised the requirements relating to primary care and over-all coordination to clarify that the MCO (and PHP as determined appropriate by the State) must have a coordination program that meets State requirements and ensures that each enrollee has an ongoing source of primary care appropriate to his or her needs and a person or entity formally designated as primarily responsible for coordinating the health care furnished to the enrollee. In subparagraph (h)(2) we require the MCO or PHP to coordinate the services it furnishes to the enrollee with the services the enrollee receives from any other MCOs or PHPs. In addition, subparagraph (h)(3) requires the MCO's or PHP's coordination program to ensure that the results of its screening and assessment of an enrollee is shared with the other entities serving the enrollee, so that those entities need not duplicate the screening or assessment. Subparagraph (h)(4) requires that in the process of coordinating care, the MCO or PHP ensures that each enrollee's privacy is protected consistent with confidentiality requirements at § 438.224. Subparagraph (h)(5) requires MCOs and PHPs to ensure that each provider maintains health records that meet professional standards and that there is appropriate and confidential sharing of information among providers.

In subparagraph (h)(6), we require each MCO and PHP to have in effect procedures to address factors that hinder enrollee adherence to prescribed treatments or regimens. In subparagraph (h)(7), we require the MCO to ensure that its providers have the information necessary for effective and continuous patient care and quality improvement, consistent with the confidentiality requirements in § 438.224 and the information system requirements of § 438.242.

Section 438.210 Coverage and Authorization of Services

We have revised paragraph (a) to clarify the contract requirements relating to coverage of services. In subparagraph (a)(1), we require that each contract identify, define and specify each service that the MCO or PHP is required to offer. In subparagraph (a)(2), we require that the MCO or PHP make available the services it is required to offer at least in the amount, duration, and scope that are specified in the State plan and can reasonably be expected to achieve the purpose for which the services are furnished. Subparagraph (a)(3) specifies that the MCO or PHP may not arbitrarily deny or reduce the amount, duration, or scope of a required services solely because of the diagnosis, type of illness, or condition and that the MCO or PHP may place appropriate limits on a service on the basis of criteria such as medical necessity or for the purposes of utilization control (provided the services furnished can reasonably be expected to achieve their purpose).

In subparagraph (a)(4), we require the contract to specify what constitutes medically necessary services in a manner that is no more restrictive than the State Medicaid program as indicated in State statutes and regulations, the State plan, and other State policy and procedures. The contract must specify the extent to which "medically necessary services" includes services to prevent, diagnose, treat, or cure health impairments, enable the enrollee to achieve age-appropriate growth and development, and enable the enrollee to attain, maintain, or regain functional capacity. Subparagraph (a)(5) requires the MCO or PHP to furnish services in accordance with their contract specifications.

We have revised paragraph (b) to specify that with respect to the processing of requests for initial and continuing authorization of services, each contract must not have information requirements that are unnecessary or unduly burdensome for the provider or the enrollee. We have also included a requirement that any decision to deny a service authorization request or to authorize service in an amount, duration, or scope that is less than requested, be made by an individual who has appropriate expertise in the field of medicine that encompasses the enrollee's condition or disease.

We have revised paragraph (c) to clarify that each contract must provide for the MCO or PHP to notify the requesting provider and give the enrollee written notice of any decision

to deny a service authorization request, or to authorize a service in an amount, duration, or scope that is less than requested. We also clarify that the notice must meet the requirements of § 438.404, except that the notice to the provider need not be in writing.

We have revised the time frames for expedited service authorization decisions. In paragraph (e), we require that under specific circumstances, the contract must provide for the MCO or PHP to make a decision as expeditiously as the enrollee's health condition requires but not later than 72 hours after receipt of the request for service.

Section 438.214 Provider Selection

We have changed the name of this section from "establishment of provider networks" to "provider selection." We have reorganized this section to clarify the requirements that apply to licensed independent providers (for example, physicians) and other providers. In subparagraph (b)(3), we have created an exception that applies to providers who are permitted to furnish services only under the direct supervision of a physician or other provider and hospital-based providers who provide services only incident to hospital services. The latter exception does not apply if the provider contracts independently with the MCO or PHP or is promoted by the MCO or PHP as part of the provider network. In subparagraph (b)(4) we have added requirements that the initial credentialing application be dated and signed and that applications, updates, and supporting information submitted by the applicant include an attestation of the correctness and completeness of the information. We have added a new requirement in paragraph (d) that specifies that MCOs and PHPs may not employ or contract with providers excluded from participation in Federal health care programs. In addition, we state in paragraph (e) that each MCO and PHP must comply with any additional requirements established by the State.

Section 438.218 Enrollee Information

We have moved the provisions from this section to § 438.10 and clarified that the information requirements that States must meet under § 438.10 constitute part of the State's quality strategy.

Section 438.320 Enrollee Rights

We have moved the requirements regarding enrollee rights to § 438.100.

Section 438.224 Confidentiality and Accuracy of Enrollee Records

We have changed the name of this section from "confidentiality" to "confidentiality and accuracy of enrollee records." We have also reorganized this section to clarify the requirements that apply to MCOs and PHPs. We clarify that this section applies to medical records and any other health and enrollment information maintained with respect to enrollees. In paragraph (c) we require MCOs and PHPs to establish and implement procedures that specify for what purposes the MCO or PHP uses the information and to which entities outside the MCO or PHP (and for what purposes) it discloses the information. In paragraph (d), we clarify that MCO and PHP procedures must safeguard the confidentiality of any information (in any form) that identifies a particular enrollee. We have revised the requirements of paragraph (e) to provide that MCO and PHP procedures must ensure that originals of medical records are released only in accordance with Federal and State law. We have also revised the requirements for access in paragraph (f) to require that, consistent with applicable Federal and State law, MCO and PHP procedures must ensure that each enrollee may request and receive a copy of his or her records and information and added a requirement that the enrollee may request that they be amended or corrected.

Section 438.228 Grievance Systems

We have added to this section two new paragraphs. Paragraph (b) requires that if the State delegates to the MCO or PHP responsibility for notice of action under subpart E of part 431 of this chapter, the State must conduct random reviews of each MCO and PHP and its providers and subcontractors to ensure that they are notifying enrollees in a timely manner. Paragraph (c) requires the State to establish a process to review, upon request by the enrollee, quality of care grievances not resolved by the MCO or PHP to the satisfaction of the enrollee.

Section 438.230 Subcontractual Relationships and Delegations

We have revised subparagraph (b)(3) to require each MCO and PHP to formally review its subcontractors' performances according to a periodic schedule established by the State, consistent with industry standards or State MCO laws and regulations. In the proposed rule this formal review was to be carried out at least once a year. We have included a new requirement in

subparagraph (b)(5) that, consistent with the requirements in §§ 438.604 and 438.606 pertaining to submission of certain data by the MCO and PHP that must be certified, each MCO and PHP must require subcontractors to provide certifications with respect to the performance of their duties under the contract and submissions that may be related to State payments.

Section 438.236 Practice Guidelines

We have revised the requirements in paragraph (b) to clarify that each MCO and PHP must adopt (as opposed to develop) practice guidelines. We have further revised the regulation to require that the guidelines—

- Are based, in part, on valid and reliable clinical evidence as opposed to “reasonable medical evidence”; and
- Are reviewed and updated periodically as appropriate.

We include an example of practice guidelines that satisfy the requirements of this section (The Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents and the Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection).

In paragraph (c), we clarify the dissemination requirements by specifying that each MCO and PHP must disseminate the guidelines to affected providers, and upon request to enrollees and potential enrollees.

Section 438.240 Quality Assessment and Performance Improvement Program

We have added additional provisions and made clarifications to this section. We have added in paragraph (a) a provision that HCFA may specify standardized quality measures and topics for performance improvement projects to be required by States in their contracts with MCOs and PHPs. We have added as subparagraph (b)(4) a provision that the State must require each MCO and PHP to have in effect mechanisms to assess the quality and appropriateness of care furnished to enrollees with special health care needs. We have revised subparagraph (c)(1) to clarify that each MCO and PHP must measure its performance annually. We have added in subparagraph (c)(2) a new requirement that the State must, in establishing minimum performance levels for MCOs and PHPs, include any minimum performance levels specified by HCFA.

In subparagraph (d)(2) we clarified that each performance improvement project must represent the entire Medicaid enrolled population to which the measurement specified in paragraph (d)(1)(i) of this section is relevant. In

subparagraph (d)(3), we have clarified that the State is to ensure that each MCO and PHP initiates each year one or more performance improvement projects. In subparagraph (d)(4), we have added “cultural competence” as a required non-clinical area for MCO and PHP performance improvement projects.

Section 438.242 Health Information Systems

In paragraph (a) we have deleted the requirement that MCO and PHP health information systems should provide information on MCO or PHP solvency. In paragraph (a) we also have clarified that information on Medicaid enrollee disenrollments pertains to disenrollments for other than loss of Medicaid eligibility.

Subpart F—Grievance System

Section 438.400

We have revised the terms used in this section, using “grievance and appeal” to replace “complaint and grievance”. We have added a definition of “action” and of “quality of care grievance”. We have also defined what constitutes an action.

Section 438.402

We have revised this section to include filing requirements as well as general requirements. In the general requirements in paragraph (b), we add that grievances and appeals must be accepted from the representative of the enrollee as well as from the enrollee; that the enrollee or his or her representative is to receive required notices and information; that the MCO or PHP must ensure that punitive action is neither threatened nor taken against a provider who requests an expedited resolution, or supports an enrollee’s grievance or appeal; that at the enrollee’s request, the MCO or PHP must refer to the State quality of care grievances not resolved to the satisfaction of the enrollee, and the MCO or PHP must require providers to give notice to enrollees of actions. Under the filing requirements in paragraph (c) we add that a provider may file an appeal on behalf of an enrollee with the enrollee’s written consent. We clarify that an enrollee has a reasonable time specified by the State, not to exceed 90 days, to file an appeal after the date of an action. We also provide that a appeal may be filed either orally or in writing but that an oral request for standard resolution of the appeal must be followed by a written request. We specify that notice of action for failure to furnish or arrange for a service or provide payment in a timely

manner must be provided whenever the entity has delayed access to the service to the point when there is substantial risk that further delay will adversely affect the enrollee’s heart condition.

Section 438.404

We have revised paragraph (a) to provide that the notice of action must be in writing and must meet the language and format requirements of § 438.10. In paragraph (b), we specify what must be contained in the notice of action. In this paragraph we have added that the notice must include information on the circumstances under which the enrollee may be required to pay for the costs of services furnished while the appeal is pending and how the enrollees may decline amortization of benefits; that the enrollee has the right to represent himself or herself, to use legal counsel, or to use a relative, or friend or other individual as spokesperson; and that filing an appeal or requesting a State fair hearing will not negatively affect or impact the way the MCO and the PHP and their providers, or the State agency, treat the enrollee. In paragraph (c), we refer to § 438.210 for the time frames that apply to mailing the notice. In paragraph (d), we specify certain notice requirements for subcontractors or providers who are not employees to furnish a notice of action. We also moved to § 438.406 the provision on the right of the enrollee to appear before the MCO or PHP in person and removed the provision that the appearance must be before the person assigned to resolve the grievance.

Section 438.406

We have revised paragraph (a) to clarify that each MCO or PHP must give enrollees any reasonable assistance in completing forms and taking other procedural steps, including providing interpreter services and toll-free numbers that have adequate TTY/TTD and interpreter capability. We also require the MCO or PHP to ensure that the enrollee’s communication is correctly classified as a “grievance” or an “appeal”, that each communication is transmitted timely to staff who have the authority to act upon it, and that it is investigated and disposed of or resolved as required. We expanded the provision in the proposed rule concerning the types of appeals that must be decided by a health care professional to include, in addition to denials based on lack of medical necessity, all grievances and appeals that involve clinical issues and grievances regarding a denial to expedite resolution of an appeal. We also clarify that a health care

professional with appropriate clinical expertise, not only a physician, can serve as the decision maker. In paragraph (b), we have included several additional requirements that apply only to appeals, including that the timeframes for resolution of appeals must take account of the enrollee's health condition, that the enrollee and his or her representative have the opportunity to examine the enrollee's case file, and that the enrollee and his or her representative are parties to the appeal.

Section 438.408

In paragraph (a), we added a basic rule that an MCO or PHP must dispose of grievances and resolve appeals as expeditiously as the enrollee's health condition requires within State-established timeframes not exceeding the timeframes specified in this section. We have included in paragraph (b) the provision in paragraph (a)(4) of the proposed rule regarding the basis for decisions. In paragraph (c) we specify the timeframes for disposing of grievances and resolving appeals. We have added timeframes for disposing of grievances, specifying that grievances of a denial of a request to expedite resolution of an appeal must be disposed of within 72 hours of receipt of the grievance. We also added a provision that all other grievances must be disposed of within 90 days. We continue to provide for a 30-day timeframe for resolving appeals that are not expedited. In paragraph (d) we address extensions of timeframes for decisions. In the final rule we eliminated the authority of the MCO or PHP to grant itself an extension when an appeal is expedited. In the final rule we have added a provision that when an MCO or PHP grants itself an extension of the timeframe for decision of an appeal that is not expedited, the enrollee must be given written notice of the reason for the delay and of the enrollee's right to file a grievance with the decision. We added in the final rule the provision in paragraph (e) that the enrollee must be given written notice of the disposition of all grievances filed in writing and of all quality of care grievances. Oral notices can be provided to enrollees who file oral grievances not related to quality of care, unless the enrollee requests a written notice. In paragraph (f) we have added to the final rule that the notice on disposition of a quality of care grievance must include information that the enrollee has the right to seek further review by the State, and how to request it. In paragraph (h) we have revised the requirement of the proposed regulation that the notice of an

appeal resolution must include the name of the MCO or PHP contact and now specify that the title of the contact, not the name, must be included. In paragraph (h) we add a requirement that the MCO or PHP must work with the State to dispose of the grievance if the State considers that the MCO or PHP response was insufficient. In paragraph (i) of the final rule we specify that expedited appeals not wholly favorable to the enrollee must be submitted to the State. In paragraph (j) we provide that the timeframe for fair hearing decision is 90 days minus the number of days taken by the MCO or PHP to resolve the internal appeal. The time used by the beneficiary to file for a State fair hearing does not count toward the 90 days. We have added a provision stating that the parties to a State fair hearing are the enrollee and his or her representative, or the representative of the deceased enrollee's estate. Finally, we add that for appeals of service authorization denials that meet the criteria for expedited resolution, the State fair hearing decision must be within 72 hours of receipt of the file.

Section 438.410

In paragraph (a), we retain the requirement from the proposed rule that each MCO and PHP must establish and maintain an expedited review process for grievances and appeals. In paragraph (b), we add to the final rule a requirement for expedited review of certain grievances. In paragraph (c), we describe the requirements that apply to appeals. In the proposed rule we provided for expedited resolution of appeal if non-expedited resolution would jeopardize the enrollee's life or health or the enrollee's ability to regain maximum function. In the final rule we add "attain and maintain" maximum function. In paragraph (d), we specify the steps that the MCO or PHP must take if it denies a request for expedited resolution of an appeal. In the final rule we require that the enrollee be notified of the decision within two calendar days. The proposed rule specified the timeframe as two working days. We also specify in the final rule that if the enroll resubmits the request for expedited resolution with a provider's letter of support, the resolution of the appeal will be expedited.

Section 438.414

In this section on information about the grievance system, in the final rule we differentiate between information that must be available with respect to fair hearings from that with respect to grievances and appeals. We added to the required items information about the

right of the enrollee to represent himself or herself or to be represented by legal counsel, a friend or relative, or other spokesperson. We also added that information be provided on the fact that benefits will be continued if requested by an enrollee who files an appeal or requests for fair hearing and that the enrollee may be required to pay the cost of services while an appeal is pending if the final decision is adverse to the enrollee. In the proposed rule we provided that benefits would continue only if requested by the enrollee.

Section 438.416

We have added to the reporting requirements that grievances and appeals be tracked according to whether the disposition and resolution was standard or expedited and that a record must be maintained of when grievances and appeals were acknowledged and provide that . We have deleted the requirement to record disenrollments and that the summary submitted to the State include trends by particular providers or services.

Section 438.420

We have revised the provision that for services to be continued they must have been ordered by the MCO or PHP treating physician or another MCO or PHP physician and that the physician is authorized to order services under the MCO or PHP contract. The new requirement is that the services must have been ordered by an authorized provider. The final rule adds in paragraph (d) specifications for the duration of continued or reinstated benefits.

Section 438.421

We have removed this section and moved the provisions relating to effectuation of reversed appeal resolutions from this section to § 438.424.

Section 438.422

We have removed this section and moved the provisions relating to monitoring of the grievance and appeal system from this section to § 438.426.

Section 438.424

We have removed the 30-calendar day and 60-calendar day time periods for providing services originally denied but authorized through an appeal or fair hearing, respectively. We retain as the sole time determinate that the service must be provided as expeditiously as the enrollee's health condition requires. We also add to the final rule a provision that services denied during appeal that were received and are subsequently

authorized must be paid for by the MCO, PHP, or the State, to State policy and regulations.

Section 438.426

We have added this new section and moved the requirements relating to monitoring of the grievance and appeal system from § 438.422 to this section. We also provide in this section that if the summaries of grievances and appeals reveal a need for changing the system, the MCO or PHP must conduct an in-depth review and take corrective action.

Subpart H—Certifications and Program Integrity Protections

Section 438.602

We have revised the name and content of this section to address the basic rule that as a condition for contracting and for receiving payment under the Medicaid managed care program, an MCO and its subcontractors must comply with the certification and program integrity requirements of this subpart.

Section 438.604

We have added this new section to identify the types of data that must be certified. In paragraph (a), we require that when State payments to the MCO is based on data submitted by the MCO, including, but not limited to, enrollment information, encounter data, and other information required by the State, including data in contracts, proposals and other related documents, the State must require certification of the data as provided in § 438.606. In paragraph (b), we require that the certification must ensure that the MCO is in substantial compliance with the terms of the contract, and must be as provided in § 438.606, regardless of whether or not payment is based on data. In paragraph (c), we provide that certification is required for all documents specified by the State.

Section 438.606

We have revised the name and content of this section to address the source, content and timing of certification. In paragraph (a), we provide that subcontractors must certify data that they submit to the MCO and that the MCO certify the data that it submits to the State. One of the following individuals must certify the MCOs data:

- The MCO's Chief Executive Officer (CEO)
- The MCO's Chief Financial Officer (CFO)

- An individual who has delegated authority to sign for, and who reports directly to, the MCO's CEO or CFO.

In paragraph (b), in the case of data and/or other documents specified by the State, we require that the certification must attest to the accuracy, completeness, and truthfulness of the data/documents, based on best knowledge, information, and belief. In paragraph (b), in the case of certification of contract compliance, we require that the MCO attest based on best knowledge, information, and belief that they are in substantial compliance with their contract. In paragraph (c), we require the MCO to submit the certification concurrently with the certified data. In paragraph (c), we require that the MCO submit the certification of substantial compliance when requesting payment.

Section 438.608

We have revised the name and content of this section to include the program integrity requirements. In paragraph (a), we specify that the general rule is that the MCO must have administrative and management arrangements or procedures, including a mandatory compliance plan, that are designed to guard against fraud and abuse. In paragraph (b), we describe the specific requirements that apply to the administrative and management arrangements or procedures, which include:

- Written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable Federal and State standards.
- The designation of a compliance officer and a compliance committee that are accountable to senior management.
- Effective training and education for the compliance officer and the organization's employees.
- Effective lines of communication between the compliance officer and the organization's employees.
- Enforcement of standards through well-publicized disciplinary guidelines.
- Provision of internal monitoring and auditing.
- Provision for prompt response to detected offenses and development of corrective action initiatives relating to the MCO's contract, including specific reporting requirements.

Subpart I—Sanctions

Section 438.700

We have revised paragraph (a) to clarify that States that contract with either MCOs or PHPs must establish intermediate sanctions. We have added

a sentence to paragraph (a) specifying that a State's determination may be based on findings from onsite surveys, enrollee or other complaints, financial audits, or any other means. In paragraph (c) we clarify that the intermediate sanctions may be imposed if the State determines that the MCO or PHP distributes directly, or indirectly through any agent or independent contract, marketing materials that have not been approved by the State or that contain false or materially misleading information.

We have moved the requirements that were previously in § 438.702(b) to this section for clarity. In the new paragraph (d) we provide that the intermediate sanctions described in § 438.702(a)(4) and (a)(5) may be imposed if the State determines that an MCO or PHP violates any of the requirements in section 1903(m) of the Act or an MCO or PHP violates any of the requirements of section 1932 of the Act.

Section 438.702

We have revised subparagraph (a)(4) to provide that the State may impose an intermediate sanction that suspends all new enrollment, including default enrollment, after the effective date of the sanction. We have revised subparagraph (a)(5) to provide that the State may suspend payment for recipients enrolled after the effective date of the sanction. We have revised paragraph (b) to specify that State agencies retain authority to impose additional sanctions under State statutes or State regulations that address areas of noncompliance.

Section 438.704

We have revised subparagraph (b)(3) to clarify that the penalty is subject to the overall limit of \$100,000 under subparagraph (b)(2). We have also revised subparagraph (b)(4) to clarify that the limit on the penalty is greater of double the amount of the excess charge or \$25,000.

Section 438.706

We have revised paragraph (a) to clarify that the State may impose the sanction of temporary management under certain circumstances. We also removed a reference to § 434.67. We have moved the requirements that were previously in § 438.708 to paragraph (b) of this section. That paragraph provides that the State must impose the sanction of temporary management if it finds that an MCO or PHP has repeatedly failed to meet substantive requirements in section 1903(m) or 1932 of the Act, or this subpart. In addition, the State must also grant enrollees the right to terminate enrollment without cause. In

paragraph (c) we specify that the State may not delay imposition of temporary management to carry out due process procedures and may not provide a hearing before imposing this sanction.

Section 438.708

We have revised the name and content of this section to include the requirements relating to termination of an MCO or PHP contract that were previously in § 438.718. We have moved the requirements relating to mandatory imposition of the sanction of temporary management from this section to § 438.706. We have revised terminology in paragraph (a) from “substantially” to “substantive.”

Section 438.710

We have revised the name and content of this section to include the requirements relating pre-termination hearing that were previously in § 438.720. We have revised paragraph (b) by removing the required time frames. Paragraph (b)(2) provides that prior to a pre-termination hearing, the State must give the MCO or PHP written notice of its intent to terminate, the reason for termination, and the time and place of the hearing. In addition, after the hearing, the State must give the MCO or PHP written notice of the decision affirming or reversing the proposed termination and, for an affirming decision, the effective date of termination. We have added a statement at paragraph (b)(2)(iii) that for an affirming decision, the State must give enrollees of the MCO or PHP notice of the termination along with information on their options for receiving care following the effective date of termination.

Section 438.718

We have removed this section and moved the requirements relating to termination of an MCE contract to § 438.708.

Section 438.720

We have removed this section and moved the requirements relating to pre-termination hearing to § 438.710.

Section 438.724

We have revised the name and content of this section to by removing the requirements for providing notice to HCFA of sanctions and by including new requirements for providing public notice of sanctions. In paragraph (a), we provide that the State must publish a notice that describes the intermediate sanction imposed, explains the reasons for the sanction and specifies the amount of any civil money penalty. In

paragraph (b), we require the State to publish the notice no later than 30 days after it imposes the sanction. The notice must be a public announcement in either the newspaper of widest circulation in each city within the MCO's or PHP's service area that has a population of 50,000 or more or the newspaper of widest circulation in the MCO's or PHP's service area, if there is no city with a population of 50,000 or more in that area.

Section 438.726

We have added this new section to include the requirement that was previously in § 438.730(g). We require that the State plan must provide for the State to monitor for violation that involve the actions and failures to act specified in this section and to implement the provisions of this section.

Section 438.730

We have revised paragraph (a) to provide that a State agency may recommend that HCFA impose the denial of payment sanction on an MCO with a comprehensive risk contract if the MCO acts or fails to act as specified in § 438.700(b)(1) through (b)(6). Under paragraph (b), we have clarified that if HCFA accepts a State's recommendation, HCFA must convey the determination to the OIG for consideration of possible imposition of civil money penalties under section 1902(m)(5)(A) of the Act and part 1003 of this title. We also explain that, in accordance with the provisions of part 10003, the OIG may impose civil money penalties in addition to, or in place of, the sanctions that may be imposed under this section.

Subpart J—Conditions for Federal Financial Participation

Section 438.802

We have revised paragraph (b) to provide that FFP is available under an MCO or PHP contract only for periods during which the MCO or PHP and its subcontractors are in substantial compliance with the physician incentive plan requirements and the MCO or PHP and the State are in substantial compliance with the requirements of the MCO or PHP contract and of this part.

Section 438.810

We moved the definitions of *choice counseling*, *enrollment activities*, and *enrollment broker* from § 438.104 to paragraph (a) of this section. We have also included a new definition of *enrollment services*, which means choice counseling, enrollment activities,

or both. We have revised paragraph (b) to include the conditions that enrollment brokers must meet so that State expenditures for their use qualify for FFP. In subparagraph (b)(1), we require that the broker and its subcontractors are independent of any managed care entity or health care provider in the State in which they provide enrollment services. We clarify that a broker or subcontractor is not considered “independent” if it is, owned by, or owns any MCO, PHP, PCCM or other health care provider in the State in which it provides enrollment services. In subparagraph (b)(2), we require that the broker and its subcontractors be free from conflict of interest.

Section 438.814

We have added this new section to prohibit FFP for payments in accordance with risk corridors or incentive arrangements to the extent that these arrangements result in payments that exceed 105% of the approved capitation rates, for the services or enrollees covered by the risk corridor or incentive arrangement.

Part 447—Payments for Services

Section 447.53

We have revised paragraph (e) to specify that no provider may deny care or services to an individual eligible for the care or services on account of the individual's inability to pay the cost sharing.

Section 447.361

This section, which contained the upper payment limit for risk contracts, has been deleted and replaced by expanded requirements for actuarial soundness of capitation rates in new § 438.6(c).

Part 447—Payments for Services

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Part 447—Payments for Services*Section 447.53*

We have revised paragraph (e) to specify that no provider may deny care or services to an individual eligible for the care or services on account of the individual's inability to pay the cost sharing.

VIII. Regulatory Impact Analysis*A. Introduction*

We have examined the impacts of this final rule as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits, including potential economic, environmental, public health and safety effects, distributive impacts, and equity. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This rule meets the criteria of being economically significant because the impact will be over \$100 million.

The RFA requires agencies to analyze options for regulatory relief of small entities. This rule implements Medicaid managed care provisions as directed by BBA. The statute does not permit significant alternatives to regulation; however, we have considered ways to reduce burden on small entities.

This final rule with comment period primarily impacts beneficiaries, State Medicaid agencies, enrollment brokers, MCOs, PHPs, and PCCMs. Small entities include small businesses, nonprofit organizations, and other entities that have annual revenues of \$5 million or less. Individuals and State governments are not included in this definition. Thus, most of the entities impacted by this regulation do not qualify as small entities. Individual PCCMs and a limited number of small PHPs would be considered small entities for purposes of this regulation.

In publishing this final rule with comment period, we considered regulatory alternatives that would reduce the burden on small entities. Thus, we have decided against imposing additional requirements on PCCMs beyond those specified in the BBA. We also have not applied all MCO requirements to all PHPs. For example, the advance directives requirements do not apply to PHPs that only cover dental or nonclinical services. In addition, PHPs are only required to comply with quality assessment and performance

improvement provisions to the extent that they apply services actually provided by the PHP.

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a Metropolitan Statistical Area and has fewer than 50 beds.

We do not anticipate that the provisions in this final rule with comment period will have a substantial economic impact on most hospitals, including small rural hospitals. The BBA provisions include some new requirements on States, MCOs, and PHPs, but no new direct requirements on individual hospitals. The impact on individual hospitals will vary according to each hospital's current and future contractual relationships with MCOs and PHPs. Furthermore, the impact will also vary according to each hospital's current procedures and level of compliance with existing law and regulation pertaining to Medicaid managed care. For these reasons, this final rule is not expected to have a significant impact on the operations of a substantial number of hospitals.

The Unfunded Mandates Reform Act of 1995 requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an expenditure in any 1 year by State, local and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation). This rule does not impose any mandates on State, local, or tribal governments, or the private sector that will result in an annual expenditure of \$100 million or more.

B. Summary of the Final Rule

This rule implements the Medicaid provisions as directed by the BBA. The primary objectives of these provisions are to allow for greater flexibility for State agencies to participate in Medicaid managed care programs and provide greater beneficiary protections and quality assurance standards. The regulation addresses pertinent areas of concern between States and MCOs, PHPs, and PCCMs, including enrollment, access to care, provider network adequacy, and grievance and appeal procedures for beneficiaries.

Specific provisions of the regulation include the following:

- Permitting States to require in their State plan that Medicaid beneficiaries be enrolled in managed care.
- Eliminating the requirement that no more than 75 percent of enrollees in an MCO or PHP be Medicaid or Medicare enrollees.
- Specifying a grievance and appeal procedure for MCO and PHP enrollees.
- Providing for the types of information that must be given to enrollees and potential enrollees, including language and format requirements.
- Requiring that MCOs and PHPs document for the States that they have adequate capacity to serve their enrollees and that States certify this to HCFA.
- Specifying quality standards for States and MCOs and PHPs.
- Increasing program integrity protections and requiring certification of data by MCOs and PHPs.
- Increasing the threshold for prior approval of MCO and PHP contracts from \$100,000 to \$1 million.
- Permitting cost sharing for managed care enrollees under the same circumstances as permitted in fee-for-service.
- Expanding the managed care population for which States can provide 6 months of guaranteed eligibility.
- Revising the rules for setting capitation rates.

It would be extremely difficult to accurately quantify the overall impact of this regulation on States, MCOs, PHPs, and PCCMs because there is enormous variation among States and these entities regarding their current regulatory and contract requirements, as well as organizational structure and capacity. Any generalization would mask important variations in the impact by State or managed care program type. The Lewin Group, under a contract with the Center for Health Care Strategies, recently completed a study to measure the cost impact of the proposed regulation. The study is the best information we currently have available on the potential incremental impact of the proposed regulation. Further, the study does not include an analysis of the proposed regulation in total, as it only focused on four areas within the proposed regulation: individual treatment plans, initial health assessments, quality improvement programs and grievance systems/State fair hearings. While the study's focus is on some of the proposed regulation provisions, of which many have changed, we believe that the overall cost conclusions are relevant to this final rule. In addition to examining the four regulatory requirements, they cited the

need to evaluate the incremental and aggregate effects of the rule; different managed care models (for example, overall enrollment; the Medicare, commercial, and Medicaid mix; geographic location); and State regulatory requirements (for example, State patient rights laws, regulation of noninsurance entities). The Lewin report also points out that many of the BBA provisions were implemented through previous guidance to the States, so the regulatory impact only captures a subset of the actual impact of the totality of BBA requirements.

According to the MCOs included in Lewin's study, many of the proposed provisions are not expected to have large incremental costs. The study mainly focused on the assessment and treatment management components of the regulation, as well as the quality improvement projects. For example, they estimate the incremental cost of an initial assessment (called screening in the final regulation) as ranging from \$0.17 to \$0.26 per member per month (PMPM), but for an MCO that currently performs an initial assessment, the incremental cost is estimated as \$0.03 to \$0.06 PMPM. Similarly, the costs of quality improvement projects can vary from \$60,000 to \$100,000 in the first year (start-up), \$80,000 to \$100,000 in the second and third years (the intervention and improvement measurement cycle), and \$40,000 to \$50,000 for the fourth and subsequent years (ongoing performance measurement).

In summary, according to the Lewin Study, States and their contracting managed care plans have already implemented many provisions of the BBA. While there are incremental costs associated with the proposed and final regulatory requirements, they will vary widely based on characteristics of individual managed care plans and States. Finally, the BBA requirements are being implemented in an increasingly regulatory environment. Therefore, States, MCOs, and PHPs will likely face additional costs not related to these regulatory requirements. Thus, the incremental impact of these requirements on costs to be incurred would be difficult if not impossible to project.

We believe that the overall impact of this final rule will be beneficial to Medicaid beneficiaries, MCOs, PHPs, States, and HCFA. Many of the BBA Medicaid managed care requirements merely codify in Federal law standards widely in place in State law or in the managed care industry. Some of the BBA provisions represent new requirements for States, MCOs, PHPs,

and PCCMs but also provide expanded opportunities for participation in Medicaid managed care.

It is clear that all State agencies will be affected by this Medicaid regulation but in varying degrees. Much of the burden will be on MCOs, PHPs, and PCCMs contracting with States, but this will also vary by existing and continuing relationships between State agencies and MCOs, PHPs, and PCCMs. This regulation is intended to maximize State flexibility and minimize the compliance cost to States, MCOs, and PHPs to the extent possible consistent with the detailed BBA requirements. We believe the final rule will result in improved patient care outcomes and satisfaction over the long term.

Recognizing that a large number of entities, such as hospitals, State agencies, and MCOs will be affected by the implementation of these statutory provisions, and a substantial number of these entities may be required to make changes in their operations, we have prepared the following analysis. This analysis, in combination with the rest of the preamble, is consistent with the standards for analysis set forth by both the RFA and RIA.

C. State Options to Use Managed Care

1. Managed Care Organizations

Under this provision, a State agency may amend its State plan to require all Medicaid beneficiaries in the State to enroll in either an MCO or PCCM without the need to apply for a waiver of "freedom of choice" requirements under either section 1915(b) or 1115 of the Act. However, waivers would still be required to include certain exempted populations in mandatory managed care programs, notably SSI populations, American Indians, and other groups of children with special needs. Federal review would be limited to a one-time State Plan Amendment (SPA) approval, while States would no longer need to request waiver renewals every 2 years for section 1915(b) of the Act and 5 years for section 1115 of the Act waivers. State agencies may include "exempted" populations as voluntary enrollees in State plan managed care programs to maintain parallel waiver programs. Currently, four States use SPAs to require beneficiary enrollment in capitated managed care organizations. In short, the new State plan option provides State agencies with a new choice of method to require participation in managed care. MCOs, PHPs, and providers would continue to provide care in a manner consistent with current and future standards, regardless of SPAs, and consequently

Medicaid beneficiaries would receive the same level of health care in compliance with current and future standards.

Pursuing the SPA option rather than a section 1915(b) or 1115 of the Act waiver may reduce State administrative procedures because it would eliminate the need for States to go through the waiver renewal process. Likewise, we will benefit from a reduced administrative burden if fewer waiver applications and renewals are requested. However, we believe the overall reduction in burden to both States and to us would be small in relation to the overall administrative requirements of the Medicaid program.

2. Primary Care Case Management

Prior to the BBA, many State agencies elected to implement a PCCM system through a freedom of choice waiver under section 1915(b)(1) of the Act. Under the BBA, States may now require beneficiaries to use a PCCM provider under their State plans without the need for a waiver. As of December 2000, five States have chosen this option. Most State agencies, however, have continued to use waiver authority to require enrollment in PCCMs. Therefore, while the BBA provision provides potential for more PCCM programs to come into being, we do not expect expansion of PCCMs to be substantial due to the State plan option. To the extent that the use of PCCMs increases, patients of these providers will benefit from greater continuity of care and patient protections deriving from new and existing standards.

D. Elimination of 75/5 Rule

Prior to the passage of the BBA, nearly all MCOs and PHPs contracting with Medicaid were required to limit combined Medicare and Medicaid participation to 75 percent of their enrollment, and State agencies had to verify enrollment composition as a contract requirement. Elimination of this rule allows MCOs and PHPs to participate without meeting this requirement and eliminates the need for States to monitor enrollment composition in contracting MCOs and PHPs. This will broaden the number of MCOs and PHPs available to States for contracting, leading to more choice for beneficiaries.

With greater flexibility for State and MCO or PHP participation in managed care, providers can serve more Medicaid beneficiaries under managed care programs. Medicaid managed care enrollees will have better access to care and improved satisfaction.

E. Increased Beneficiary Protection—Grievance Procedures

The BBA requires MCOs to establish internal grievance procedures that permit an eligible enrollee, or a provider on behalf of an enrollee, to challenge the denials of coverage of medical assistance or denials of payment. While these requirements were not previously required by statute, we believe, based on recent State surveys, such as the National Academy for State Health Policy survey of 10 States in 1999, and the American Public Human Services Association survey of 13 States in 1997, that they reflect widespread current practice and, therefore, do not impose significant incremental costs on MCOs, PHPs, or State agencies.

F. Provision of Information

In mandatory managed care programs, we have required that beneficiaries be fully informed of the choices available to them in enrolling with MCOs and PHPs. Section 1932(a)(5) of the Act, enacted in section 4701(a)(5) of the BBA, describes the kind of information that must be made available to Medicaid enrollees and potential enrollees. It also requires that this information, and all enrollment notices and instructional materials related to enrollment in MCOs and PHPs, be in a format that can be easily understood by the individuals to which it is directed. We do not believe that these requirements deviate substantially from current practice. Furthermore, there is no way to quantify the degree of burden on State agencies, MCOs, and PHPs for several reasons. We do not have State-specific data on what information States currently provide, or the manner in which they provide it. Variability among States indicates that implementing or continuing enrollee information requirements will represent different degrees of difficulty and expense.

As a requirement under the provision of information section, State agencies opting to implement mandatory managed care programs under the SPA option are required to provide comparative information on MCOs and PCCMs to potential enrollees. Currently only eight States have exercised the option to use an SPA to require beneficiary enrollment in managed care. However, for States that do select this option, we do not believe that providing the comparative data in itself represents a burden, as these are elements of information that most States currently provide. The regulation specifies that the information must be presented in a comparative or chart-like form that facilitates comparison among MCOs,

PHPs, and PCCMs. This may be perceived as a burden to States that have previously provided this information in some other manner; however, it is our belief that even in the absence of the regulation, the trend is for States, and many accreditation bodies such as the National Committee for Quality Assurance (NCQA), to use chart-like formats. Consequently, enrollees will benefit from having better information for selecting MCOs, PHPs, and PCCMs. Only a few States have opted for SPAs so far, but it is anticipated that more States will participate over the long term. States that participate in the future will benefit from any comparative tools developed by other States.

G. Demonstration of Adequate Capacity and Services

The BBA requires Medicaid MCOs to provide the State and the Secretary of HHS with assurances of adequate capacity and services, including service coverage within reasonable time frames. States currently require assurances of adequate capacity and services as part of their existing contractual arrangements with MCOs and PHPs. However, certification of adequacy has not been routinely provided to HCFA in the past. Under this rule, each State retains its authority to establish standards for adequate capacity and services within MCO and PHP contracts. This may be perceived as a burden to MCOs and PHPs, and for States which have to date not been required to formally certify that an MCO or PHP meets the State's capacity and service requirements. However, certification to HCFA will ensure an important beneficiary protection while imposing only a minor burden on States to issue a certification to HCFA.

Quantifying the additional burden on States, MCOs, or PHPs as a result of implementing this regulation is not feasible for several reasons. First, HCFA does not have State-specific data on the types of detailed information States currently require of their MCOs and PHPs to assure adequate capacity and services. Second, we do not have State-specific information on the manner in which State agencies collect and evaluate documentation in this area. Rather, each State agency has its own documentation requirements and its own procedures to assure adequate capacity and services. This regulation contemplates that States continue to have that flexibility.

Under this regulation, State agencies will determine and specify both the detail and type of documentation to be submitted by the MCO or PHP to assure

adequate capacity and services and the type of certification to be submitted to us. Accordingly, variability among State agencies implementing this regulation represents different degrees of detail and expense. Regardless of the level of additional burden on MCOs, PHPs, State agencies, and us, Medicaid beneficiaries will receive continued protections in access to health care under both State and Federal law.

H. New Quality Standards

The BBA requires that each State agency have an ongoing quality assessment and improvement strategy for its Medicaid managed care contracting program. The strategy, among other things, must include: (1) standards for access to care so that covered services are available within reasonable time frames and in a manner that ensures continuity of care and adequate capacity of primary care and specialized services providers; (2) examination of other aspects of care and service directly related to quality of care, including grievance procedures, marketing, and information standards; (3) procedures for monitoring and evaluating the quality and appropriateness of care and service to enrollees; and (4) regular and periodic examinations of the scope and content of the State's quality strategy.

The provisions of this regulation establish requirements for State quality strategies and requirements for MCOs and PHPs that States are to incorporate as part of their quality strategy. These MCO and PHP requirements address: (1) MCO and PHP structure and operations; (2) Medicaid enrollees' access to care; and (3) MCO and PHP responsibilities for measuring and improving quality. While these new Medicaid requirements are a significant increase in Medicaid regulatory requirements in comparison to the regulatory requirements that existed before the BBA, we believe the increases are appropriate because many of the requirements are either identical to or consistent with quality requirements placed on MCOs and PHPs by private sector purchasers, the Medicare program, State licensing agencies, and private sector accreditation organizations. While these new requirements also will have implications for State Medicaid agencies that will be responsible for monitoring for compliance with the new requirements, we believe that a number of recent statutory, regulatory, and private sector developments will enable State Medicaid agencies to more easily monitor for compliance than in the past at potentially less cost to the State. First, the BBA also included provisions

addressing how States are to fulfill the statutory requirement for an annual, external quality review (EQR) of each Medicaid-contracting MCO and PHP. (These provisions are addressed in a separate rulemaking). Prior to the BBA, 75 percent Federal financial participation in the cost of these activities was available to States only if the State used a narrowly defined list of entities to perform the quality review. The BBA opened up the possibility for use of a much wider array of entities to perform this function. Further, in HCFA's proposed rule to implement these EQR provisions published on December 1, 1999, we specified that the 75 percent Federal match would also be available to EQR organizations that performed activities necessary for monitoring compliance with these BBA quality requirements for MCOs and PHPs. The BBA also provided that States could exercise an option whereby MCOs that were accredited by a private accrediting organization under certain conditions could be determined to meet certain of the quality requirements specified in this rule, thereby avoiding costs to the State of directly monitoring for compliance with these requirements. In response to this, private accrediting organizations such as the National Committee for Quality Assurance have developed Medicaid accreditation product lines.

In addition, prior to issuance of the proposed rule, we worked closely with State Technical Advisory Groups (TAGs) in developing the managed care quality regulations and standards. Requirements under this regulation build on a variety of initiatives of State Medicaid agencies and HCFA to promote the assessment and improvement of quality in plans contracting with Medicaid, including:

- The Quality Improvement System for Managed Care (QISMC), an initiative with State and Federal officials, beneficiary advocates, and the managed care industry to develop a coordinated quality oversight system for Medicare and Medicaid that reduces duplicate or conflicting efforts and emphasizes demonstrable and measurable improvement.
- QARI, serving as a foundation to the development of QISMC, highlights the key elements in the Health Care Quality Improvement System (HCQIS), including internal quality assurance programs, State agency monitoring, and Federal oversight. This guidance emphasizes quality standards developed in conjunction with all system participants, such as managed care contractors, State regulators, Medicaid

beneficiaries or their representatives, and external review organizations.

Further, we have built on efforts in other sectors in developing these quality requirements in order to capitalize on current activities and trends in the health care industry. For example, many employers and cooperative purchasing groups and some State agencies already require that organizations be accredited by the National Committee on Quality Assurance (NCQA), the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the American Accreditation Healthcare Commission (AAHC), or other independent bodies. Many also require that organizations report their performance using Health Plan Employer Data & Information Set (HEDIS), Foundation for Accountability (FACCT), or other measures and conduct enrollee surveys using the Consumer Assessment of Health Plans Study (CAHPS) or other instruments. NCQA estimates that more than 90 percent of plans are collecting some or all of HEDIS data for their commercial population. Also, States have heightened their regulatory efforts through insurance or licensing requirements, and the National Association of Insurance Commissioners (NAIC) has developed model acts on network adequacy, quality assessment and improvement, and utilization review.

While we anticipate that many organizations will need to invest in new staff and information systems in order to perform these new quality improvement activities, it is difficult to quantify these financial and operational "investments," as State agencies, MCOs, and PHPs across the country exhibit varying capabilities in meeting these standards. These new quality requirements will present administrative challenges for some State agencies and MCOs; however, PHPs and States have significant latitude in how these requirements will be implemented. Acknowledging that there likely will be some degree of burden on States, MCOs, and PHPs, we also believe that the long-term benefits of greater accountability and improved quality in care delivery will outweigh the costs of implementing and maintaining these processes over time.

I. Administration

1. Certifications and Program Integrity Protections

BBA sections 1902(a)(4) and (19) require that States conduct appropriate processes and methods to ensure the efficient operation of the health plans.

This includes mechanisms to not only safeguard against fraud and abuse but also to ensure accurate reporting of data among health plans, States, and HCFA.

Section 438.602 of the regulation addresses the importance of reliable data that are submitted to States and requires MCOs and PHPs to certify the accuracy of these data to the State. These data include enrollment information, encounter data, or other information that is used for payment determination. For the most part, States reimburse MCOs and PHPs on a capitated basis and do not use claims or encounter data as a basis for payment. However, the collection of encounter, provider, and enrollment data will be most useful for States in measuring quality performance and addressing various methodologies of rate-setting and risk adjustment. The Medicaid provision of attesting to the validity of data presents an additional step in the process of data submission. MCOs and PHPs have historically worked closely with States when reporting Medicaid data in order to affirm that the data are accurate and complete. Submitting a certification of validity could take place in a variety of ways and will represent a varying degree of burden for health plans.

Section 438.606 requires MCOs and PHPs to have effective operational capabilities to guard against fraud and abuse. This will result in reporting violations of law by MCOs and PHPs to the State. Providers and health plans have traditionally ensured compliance with Federal and State laws when providing and delivering health care to members. For example, many health plans comply with standards set by the National Association of Insurance Commissioners (NAIC). However, additional resources and procedures will be necessary to have a systematic process for documenting violations and formally notifying the State of these instances.

The requirement for MCOs and PHPs to certify the accuracy and completeness of provider contracts or other documents is consistent with current practices. These demonstrations are evident in NCQA accreditation procedures, Medicaid waiver reviews, and audits that are necessary for compliance with other relevant State and Federal laws. Depending on the MCO or PHP, new processes may be necessary to comply with this standard. This requirement may not necessarily result in new mechanisms or resources for MCOs and PHPs but may create the need for more coordination with additional State Medicaid Agency

representatives in the review of provider contracts.

2. Change in Threshold from \$100,000 to \$1 Million

Before the passage of the BBA, the Secretary's prior approval was required for all HMO contracts involving expenditures in excess of \$100,000. Under the BBA, the threshold amount is increased to \$1 million. This change in threshold will have minimal impact on plans currently contracting with State agencies for Medicaid managed care. Currently, only one or two plans in the country have annual Medicaid expenditures of under \$1 million. Therefore, this new provision will not affect a significant number of plans or States.

J. Permitting Same Copayments in Managed Care as in FFP

Under section 4708(c) of the BBA, States may now allow copayments for services provided by MCOs and PHPs to the same extent that they allow copayments under fee-for-service. Imposition of copayments in commercial markets typically results in

lower utilization of medical services, depending on the magnitude of payments required of the enrollee. Thus, we would normally expect State agencies that implement copayments for MCO or PHP enrollees to realize some savings as a result. However, applying copayments in Medicaid populations may cause States, MCOs, and PHPs to incur overhead costs related to administering these fees that more than offset these savings. This is due to several factors including that copayments are significantly lower for Medicaid beneficiaries than typical commercial copayments, that it is difficult to ensure compliance with these payments, and that collection efforts would be necessary for MCOs or PHPs to obtain all fees due to them. Also, if State agencies take advantage of this option, Medicaid managed care enrollees may defer receipt of health care services and find their health conditions deteriorate such that costs of medical treatment may be greater over the long term. As a result of these variables, it is difficult to predict how many States will take advantage of this

new option of permitting copayments for MCO or PHP enrollees.

K. Six-Month Guaranteed Eligibility

The legislation has expanded the States' option to guarantee up to 6 months eligibility in two ways. First, it expands the types of MCOs whose members may have guaranteed eligibility, in that it now includes anyone who is enrolled with a Medicaid managed care organization as defined in section 1903(m)(1)(A) of the Act. Second, it expands the option to include those enrolled with a PCCM as defined in section 1905(t) of the Act. These changes are effective October 1, 1997. To the extent that State agencies choose this option, we expect MCOs, PHPs, and PCCMs in those States to support the use of this provision since it affords health plans with assurance of membership for a specified period of time. Likewise, beneficiaries will gain from this coverage expansion, and continuity of care will be enhanced. The table below displays our estimates of the impact of the expanded option for 6 months of guaranteed eligibility under section 4709 of the BBA.

COST OF 6-MONTH GUARANTEED ELIGIBILITY OPTION

[Dollars in millions rounded to the nearest \$5 million]

| | FY 2000 | FY 2001 | FY 2002 | FY 2003 | FY 2004 | FY 2005 |
|---------------|---------|---------|---------|---------|---------|---------|
| Federal | 40 | 55 | 80 | 115 | 165 | 230 |
| State | 30 | 45 | 60 | 905 | 125 | 175 |
| Total | 70 | 100 | 140 | 205 | 290 | 405 |

The estimates of Federal costs are reflected in the current budget baseline. The estimates assume that half of the current Medicaid population is enrolled in managed care and that this proportion will increase to about two-thirds by 2003. We also assume that 15 percent of managed care enrollees are currently covered by guaranteed eligibility under rules in effect prior to enactment of the BBA and that the effect of the expanded option under section 4709 of the BBA will be to increase this rate to 20 percent initially and to 30 percent by 2003. The guaranteed eligibility provision is assumed to increase average enrollment by 3 percent in populations covered by the option. This assumption is based on computer simulations of enrollment and turnover in the Medicaid program. Per capita costs used for the estimate were taken from the President's FY 1999 budget projections and the costs for children take into account the interaction of this provision with the State option for 12 months of

continuous eligibility under section 4731 of the BBA. The distribution between Federal and State costs is based on the average Federal share representing 57 percent of the total costs.

In States electing the 6-month guaranteed eligibility option, Medicaid beneficiaries will have access to increased continuity of care, which should result in better health care management and improved clinical outcomes.

L. Financial Impact of Revised Rules for Setting Capitation Payments

This rule replaces the current upper payment limit (UPL) requirement at § 447.361 with new rate-setting rules incorporating an expanded requirement for actuarial soundness of capitation rates as described in detail in § 438.6(c) below. In general, we do not expect a major budget impact from the use of these new rate setting rules. While the new rate setting rules may provide some States additional flexibility in setting

higher capitation rates than what would have been allowed under current rules, we believe that the requirements for actuarial certification of rates, along with budgetary considerations by State policy makers, would serve to limit increases to within reasonable amounts. Moreover, the Secretary would retain the authority to look behind rates that appear questionable and disapprove any that did not comply with the new rate setting requirements.

M. Administrative Costs

This regulation requires States to include certain specifications in their contracts with MCOs, PHPs, and PCCMs and to monitor compliance with those contract provisions. It also requires States to take a proactive role in monitoring the quality of their managed care program. These requirements will add some administrative burden and costs to States. The amount of additional administrative cost will vary by State depending on how inclusive current practice is of the new

requirements. In addition, for those States not using like requirements at present, we believe that most would be adopting similar requirements on their own in the future absent this regulation.

The regulation will also increase Federal responsibilities for monitoring State performance in managing their managed care programs. However, no new Federal costs are expected as HCFA plans to use existing staff to monitor these new requirements.

N. Conclusion

This BBA managed care regulation will affect HCFA, States, MCOs, PHPs, PCCMs, providers, and beneficiaries in different ways. The initial investments that are needed by State agencies and MCOs, PHPs, and PCCMs will result in improved and more consistent standards for the delivery of health care to Medicaid beneficiaries. Greater consumer safeguards will result from new quality improvement and protection provisions. Consequently, long term savings will derive from more consistent standards across States, MCOs, PHPs, and PCCMs and increased opportunities for provider and beneficiary involvement in improved access, outcomes, and satisfaction.

O. Federalism

Under Executive Order 13132, we are required to adhere to certain criteria regarding Federalism in developing regulations. We have determined that this final regulation will not significantly affect States rights, roles, and responsibilities. The BBA requires States that contract with section 1903(m) of the Act organizations to have certain beneficiary protections in place when mandating managed care enrollment. This final rule implements those BBA provisions in accordance with the Administrative Procedure Act. This rule also eliminates certain requirements viewed by States as impediments to the growth of managed care programs, such as disenrollment without cause at any time and the inability to amend the State plan without a waiver for mandatory managed care enrollment. We apply many of these requirements to prepaid health plans as set forth in our September 29, 1998 proposed rule. We believe this is consistent with the intent of the Congress in enacting the quality and beneficiary protection provisions of the BBA.

We worked closely with States in developing this regulation. We met with State officials and other stakeholders to discuss opportunities and concerns before the end of the comment period. Throughout the development of the

regulation, we consulted with State Medicaid agency representatives in order to gain more understanding of potential impacts. At the November 1997 meeting of the Executive Board of the National Association of State Medicaid Directors (NASMD), we discussed the process for providing initial guidance to States about the Medicaid provisions of the BBA. We provided this guidance through issuance of a series of letters to State Medicaid Directors. From October 1997 through April 2000, over 50 of these letters were issued. Much of the policy included in this regulation relating to the State plan option provision was included in these letters. In May 1998, the Executive Committee of NASMD was briefed on the general content of the regulation. More specific State input was obtained through discussions throughout the Spring of 1998 with the Medicaid Technical Advisory Groups (TAGs) on Managed Care and Quality. These groups are comprised of Medicaid agency staff with notable expertise in the subject area and our regional office staff and are staffed by the American Public Human Services Association. The Managed Care TAG devoted much of its agenda for several monthly meetings to BBA issues. The Quality TAG participated in two conference calls exclusively devoted to discussion of BBA quality issues. Through these contacts, HCFA explored with State agencies their preferences regarding policy issues and the feasibility and practicality of implementing policy under consideration. We also invited public comments as part of the rulemaking process and received comments from over 300 individuals and organizations. Most of the commenters had substantial comments that addressed many provisions of the regulation.

We also received hundreds of comments on every subpart of the final rule, including comments for many States and membership organizations representing States. Many of the recommendations made by commenters have been incorporated into this final rule. For recommendations not accepted, a response has been included in this preamble. Moreover, we discussed technical issues with State experts through technical advisory groups to make certain that the final rule could be practically applied.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

For the reasons set forth in the preamble, the Health Care Financing

Administration is amending 42 CFR Chapter IV as set forth below:

PART 400—INTRODUCTION; DEFINITIONS

1. The authority citation for part 400 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 400.203 [Amended]

2. In § 400.203, the following statements are added, in alphabetical order, and the definition of “provider” is revised to read as set forth below.

PCCM stands for primary care case manager.

PCP stands for primary care physician.

Provider means either of the following:

(1) For the fee-for-service program, it means any individual or entity furnishing Medicaid services under an agreement with the Medicaid agency.

(2) For the managed care program, it means any individual or entity that is engaged in the delivery of health care services and is legally authorized to do so by the State in which it delivers the services.

PART 430—GRANTS TO STATES FOR MEDICAL ASSISTANCE PROGRAMS

1. The authority citation for part 430 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. In part 430 a new § 430.5 is added, to read as follows:

§ 430.5 Definitions.

As used in this subchapter, unless the context indicates otherwise—

Contractor means any entity that contracts with the State agency, under the State plan and in return for a payment, to process claims, to provide or pay for medical services, or to enhance the State agency’s capability for effective administration of the program.

Representative has the meaning given the term by each State consistent with its laws, regulations, and policies.

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

1. The authority citation for part 431 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. In § 431.51, the following changes are made:

a. In paragraph (a) introductory text, “and 1915(a) and (b) of the Act.” is

revised to read “1915(a) and (b) and 1932(a)(3) of the Act.”

b. Paragraphs (a)(4) and (a)(5) are revised and a new paragraph (a)(6) is added, as set forth below.

c. In paragraph (b)(1) introductory text, “and part 438 of this chapter” is added immediately before the comma that follows “this section”.

d. In paragraph (b)(2), “an HMO” is revised to read “a Medicaid MCO”.

The additions and revisions read as follows:

§ 431.51 Free choice of providers.

(a) *Statutory basis.* * * *

(4) Section 1902(a)(23) of the Act provides that a recipient enrolled in a primary care case management system or Medicaid managed care organization (MCO) may not be denied freedom of choice of qualified providers of family planning services.

(5) Section 1902(e)(2) of the Act provides that an enrollee who, while completing a minimum enrollment period, is deemed eligible only for services furnished by or through the MCO or PCCM, may, as an exception to the deemed limitation, seek family planning services from any qualified provider.

(6) Section 1932(a) of the Act permits a State to restrict the freedom of choice required by section 1902(a)(23), under specified circumstances, for all services except family planning services.

* * * * *

3. In § 431.55, a sentence is added at the end of paragraph (c)(1)(i) to read as follows:

§ 431.55 Waiver of other Medicaid requirements.

* * * * *

(c) * * *

(1) * * *

(i) * * * The person or agency must comply with the requirements set forth in part 438 of this chapter for primary care case management contracts and systems.

4. Section 431.200 is revised to read as follows:

§ 431.200 Basis and scope.

This subpart—

(a) Implements section 1902(a)(3) of the Act, which requires that a State plan provide an opportunity for a fair hearing to any person whose claim for assistance is denied or not acted upon promptly;

(b) Prescribes procedures for an opportunity for hearing if the State agency takes action to suspend, terminate, or reduce services, or an MCO or PHP takes action under subpart F of part 438 of this chapter; and

(c) Implements sections 1919(f)(3) and 1919(e)(7)(F) of the Act by providing an appeals process for any person who—

(1) Is subject to a proposed transfer or discharge from a nursing facility; or

(2) Is adversely affected by the pre-admission screening or the annual resident review that are required by section 1919(e)(7) of the Act.

§ 431.201 [Amended]

5. In § 431.201, the following definition is added in alphabetical order:

* * * * *

Service authorization request means a managed care enrollee's request for the provision of a service.

6. In § 431.220, the introductory text of paragraph (a) is revised, the semicolons after paragraphs (a)(1), (a)(2), and (a)(3) and the “and” after the third semicolon are removed and periods are inserted in their place, and a new paragraph (a)(5) is added, to read as follows:

§ 431.220 When a hearing is required.

(a) The State agency must grant an opportunity for a hearing to the following:

* * * * *

(5) Any MCO or PHP enrollee who is entitled to a hearing under subpart F of part 438 of this chapter.

* * * * *

§ 431.244 [Amended]

7. In § 431.244, paragraph (f) is revised to read as follows:

* * * * *

(f) The agency must take final administrative action as follows:

(1) Ordinarily, within 90 days from the earlier of the following:

(i) The date the enrollee files an MCO or PHP appeal.

(ii) The date the enrollee files a request for State fair hearing.

(2) As expeditiously as the enrollee's health condition requires, but no later than 72 hours after the agency receives, from the MCO or PHP, the case file and information for any appeal of a denial of a service that, as indicated by the MCO or PHP—

(i) Meets the criteria for expedited resolution as set forth in § 438.410(c)(2) of this chapter, but was not resolved within the timeframe for expedited resolution; or

(ii) Was resolved within the timeframe for expedited resolution, but reached a decision wholly or partially adverse to the enrollee.

(3) As expeditiously as the enrollee's health condition requires, but no later than 72 hours after the agency receives,

directly from an MCO or PHP enrollee, a fair hearing request on a decision to deny a service that it determines meets the criteria for expedited resolution, as set forth in § 438.410(c)(2) of this chapter.

PART 434—CONTRACTS

1. The authority citation for part 434 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. In § 434.1, paragraph (a) is revised to read as follows:

§ 434.1 Basis and scope.

(a) *Statutory basis.* This part is based on section 1902(a)(4) of the Act, which requires that the State plan provide for methods of administration that the Secretary finds necessary for the proper and efficient operation of the plan.

* * * * *

§ 434.2 [Amended]

3. In § 434.2, the definitions of “Capitation fee”, “Clinical laboratory”, “Contractor”, “Enrolled recipient”, “Federally qualified HMO”, “Health insuring organization (HIO)”, “Health maintenance organization (HMO)”, “Nonrisk”, “Prepaid health plan (PHP)”, “provisional status HMO”, and “risk or underwriting risk” are removed.

§§ 434.6 [Amended]

4. In paragraph (a)(1), “Appendix G” is removed.

§ 434.20 through 434.38 [Removed]

5. Subpart C, consisting of §§ 434.20 through 434.38, is removed and reserved.

§§ 434.42 and 434.44 [Removed]

6. In subpart D, §§ 434.42 and 434.44 are removed.

§§ 434.50 and 434.67 [Removed]

7. Subpart E, consisting of §§ 434.50 through 434.67, is removed and reserved.

8. Section 434.70 is revised to read as follows:

§ 434.70 Conditions for Federal financial participation (FFP).

(a) *Basic requirements.* FFP is available only for periods during which the contract—

(1) Meets the requirements of this part;

(2) Meets the applicable requirements of 45 CFR part 74; and

(3) Is in effect.

(b) *Basis for withholding.* HCFA may withhold FFP for any period during which—

(1) The State fails to meet the State plan requirements of this part; or
 (2) Either party substantially fails to carry out the terms of the contract.

§§ 434.71 through 434.75 and 434.80 [Removed]

9. Sections 434.71 through 434.75, and 434.80 are removed.

PART 435—ELIGIBILITY IN THE STATES, THE DISTRICT OF COLUMBIA, THE NORTHERN MARIANA ISLANDS, AND AMERICAN SAMOA

1. The authority citation for part 435 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. In § 435.212, the following changes are made:

a. Throughout the section, “HMO”, wherever it appears, is revised to read “MCO”.

b. The section heading and the introductory text are revised to read as follows:

§ 435.212 Individuals who would be ineligible if they were not enrolled in an MCO or PCCM.

The State agency may provide that a recipient who is enrolled in an MCO or PCCM and who becomes ineligible for Medicaid is considered to continue to be eligible—

* * * * *

3. Section 435.326 is revised to read as follows:

§ 435.326 Individuals who would be ineligible if they were not enrolled in an MCO or PCCM.

If the agency provides Medicaid to the categorically needy under § 435.212, it may provide it under the same rules to medically needy recipients who are enrolled in MCOs or PCCMs.

§ 435.1002 [Amended]

4. In § 435.1002, in paragraph (a), “§§ 435.1007 and 435.1008” is revised to read §§ 435.1007, 435.1008, and 438.814 of this chapter.”

5. A new part 438 is added to chapter IV to read as follows:

PART 438—MANAGED CARE PROVISIONS

Subpart A—General Provisions

Sec.

- 438.1 Basis and scope.
- 438.2 Definitions.
- 438.6 Contract requirements.
- 438.8 Provisions that apply to PHPs.
- 438.10 Information requirements.
- 438.12 Provider discrimination prohibited.

Subpart B—State Responsibilities

- 438.50 State Plan requirements.
- 438.52 Choice of MCOs, PHPs, and PCCMs.
- 438.56 Disenrollment: Requirements and limitations.
- 438.58 Conflict of interest safeguards.
- 438.60 Limit on payment to other providers.
- 438.62 Continued services to recipients.
- 438.66 Monitoring procedures.
- 438.68 Education of MCOs, PHPs, and PCCMs and subcontracting providers.

Subpart C—Enrollee Rights and Protections

- 438.100 Enrollee rights.
- 438.102 Provider-enrollee communications.
- 438.104 Marketing activities.
- 438.106 Liability for payment.
- 438.108 Cost sharing.
- 438.114 Emergency and post-stabilization services.
- 438.116 Solvency standards.

Subpart D—Quality Assessment and Performance Improvement

- 438.200 Scope.
- 438.202 State responsibilities.
- 438.204 Elements of State quality strategies.

Access Standards

- 438.206 Availability of services.
- 438.207 Assurances of adequate capacity and services.
- 438.208 Coordination and continuity of care.
- 438.210 Coverage and authorization of services.

Structure and Operation Standards

- 438.214 Provider selection.
- 438.218 Enrollee information.
- 438.224 Confidentiality and accuracy of enrollee records.
- 438.226 Enrollment and disenrollment.
- 438.228 Grievance systems.
- 438.230 Subcontractual relationships and delegation.

Measurement and Improvement Standards

- 438.236 Practice guidelines.
- 438.240 Quality assessment and performance improvement program.
- 438.242 Health information systems.

Subpart E—[Reserved]

Subpart F—Grievance System

- 438.400 Statutory basis and definitions.
- 438.402 General requirements.
- 438.404 Notice of action.
- 438.406 Handling of grievances and appeals.
- 438.408 Resolution and notification: Grievances and appeals.
- 438.410 Expedited resolution of grievances and appeals.
- 438.414 Information about the grievance system.
- 438.416 Recordkeeping and reporting requirements.
- 438.420 Continuation of benefits while the MCO or PHP appeal and the State Fair Hearing are pending.
- 438.424 Effectuation of reversed appeal resolutions.
- 438.426 Monitoring of the grievance system.

Subpart G—[Reserved]

Subpart H—Certifications and Program Integrity Provisions

- 438.600 Statutory basis.
- 438.602 Basic rule.
- 438.604 Data that must be certified.
- 438.606 Source, content, and timing of certification.
- 438.608 Program integrity requirements.

Subpart I—Sanctions

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Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

Subpart A—General Provisions

§ 438.1 Basis and scope.

(a) *Statutory basis.* This part is based on sections 1902(a)(4), 1903(m), 1905(t), and 1932 of the Act.

(1) Section 1902(a)(4) requires that States provide for methods of administration that the Secretary finds necessary for proper and efficient operation of the State Medicaid plan. The application of the requirements of this part to PHPs that do not meet the statutory definition of MCO or to a PCCM is under the authority in section 1902(a)(4).

(2) Section 1903(m) contains requirements that apply to comprehensive risk contracts.

(3) Section 1903(m)(2)(H) provides that an enrollee who loses Medicaid eligibility for not more than 2 months may be enrolled in the succeeding month in the same MCO or PCCM if that MCO or PCCM still has a contract with the State.

(4) Section 1905(t) contains requirements that apply to PCCMs.

(5) Section 1932—

(i) Provides that, with specified exceptions, a State may require

Medicaid recipients to enroll in MCOs or PCCMs;

(ii) Establishes the rules that MCOs, PCCMs, the State, and the contracts between the State and those entities must meet, including compliance with requirements in sections 1903(m) and 1905(t) of the Act that are implemented in this part;

(iii) Establishes protections for enrollees of MCOs and PCCMs;

(iv) Requires States to develop a quality assessment and performance improvement strategy;

(v) Specifies certain prohibitions aimed at the prevention of fraud and abuse;

(vi) Provides that a State may not enter into contracts with MCOs unless it has established intermediate sanctions that it may impose on an MCO that fails to comply with specified requirements; and

(vii) Makes other minor changes in the Medicaid program.

(b) *Scope.* This part sets forth requirements, prohibitions, and procedures for the provision of Medicaid services through MCOs, PHPs, and PCCMs. Requirements vary depending on the type of entity and on the authority under which the State contracts with the entity. Provisions that apply only when the contract is under a mandatory managed care program authorized by section 1932(a)(1)(A) of the Act are identified as such.

§ 438.2 Definitions.

As used in this part—

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

Comprehensive risk contract means a risk contract that covers comprehensive services, that is, inpatient hospital services and any of the following services, or any three or more of the following services:

- (1) Outpatient hospital services.
- (2) Rural health clinic services.
- (3) FQHC services.
- (4) Other laboratory and X-ray services.
- (5) Nursing facility (NF) services.
- (6) Early and periodic screening diagnostic, and treatment (EPSDT) services.
- (7) Family planning services.
- (8) Physician services.
- (9) Home health services.

Federally qualified HMO means an HMO that HCFA has determined to be

a qualified HMO under section 1310(d) of the PHS Act.

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

- (1) Through payments to, or arrangements with, providers; and
- (2) Under a risk contract with the State.

Managed care organization (MCO) means an entity that has, or is seeking to qualify for, a comprehensive risk contract under this part, and that is —

- (1) A Federally qualified HMO that meets the advance directives requirements of subpart I of part 489 of this chapter; or
- (2) Any public or private entity that meets the advance directives requirements and is determined to also meet the following conditions:
 - (i) Makes the services it provides to its Medicaid enrollees as accessible (in terms of timeliness, amount, duration, and scope) as those services are to other Medicaid recipients within the area served by the entity.
 - (ii) Meets the solvency standards of § 438.116.

Nonrisk contract means a contract under which the contractor—

- (1) Is not at financial risk for changes in utilization or for costs incurred under the contract that do not exceed the upper payment limits specified in § 447.362 of this chapter; and
- (2) May be reimbursed by the State at the end of the contract period on the basis of the incurred costs, subject to the specified limits.

Prepaid health plan (PHP) means an entity that—

- (1) Provides medical services to enrollees under contract with the State agency, and on the basis of prepaid capitation payments, or other payment arrangements that do not use State plan payment rates; and
- (2) Does not have a comprehensive risk contract.

Primary care means all health care services and laboratory services customarily furnished by or through a general practitioner, family physician, internal medicine physician, obstetrician/gynecologist, or pediatrician, to the extent the furnishing of those services is legally authorized in the State in which the practitioner furnishes them.

Primary care case management means a system under which a PCCM contracts with the State to furnish case management services (which include the location, coordination and monitoring of primary health care services) to Medicaid recipients.

Primary care case manager (PCCM) means a physician, a physician group

practice, an entity that employs or arranges with physicians to furnish primary care case management services or, at State option, any of the following:

- (1) A physician assistant.
- (2) A nurse practitioner.
- (3) A certified nurse-midwife.

Risk contract means a contract under which the contractor—

- (1) Assumes risk for the cost of the services covered under the contract; and
- (2) Incurs loss if the cost of furnishing the services exceeds the payments under the contract.

§ 438.6 Contract requirements.

(a) *Regional office review.* The HCFA Regional Office must review and approve all MCO and PHP contracts, including those risk and nonrisk contracts that, on the basis of their value, are not subject to the prior approval requirement in § 438.806.

(b) *Entities eligible for comprehensive risk contracts.* A State agency may enter into a comprehensive risk contract only with one of the following:

- (1) An MCO.
- (2) The entities identified in section 1903(m)(2)(B)(i), (ii), and (iii) of the Act.
- (3) Community, Migrant, and Appalachian Health Centers identified in section 1903(m)(2)(G) of the Act. Unless they qualify for a total exemption under section 1903(m)(2)(B) of the Act, these entities are subject to the regulations governing MCOs under this part.
- (4) An HIO that arranges for services and became operational before January 1986.
- (5) An HIO described in section 9517(c)(3) of the Omnibus Budget Reconciliation Act of 1985 (as added by section 4734(2) of the Omnibus Budget Reconciliation Act of 1990).

(c) *Payments under risk contracts.*—

(1) *Terminology.* As used in this paragraph, the following terms have the indicated meanings:

- (i) *Actuarially sound capitation rates* means capitation rates that—
 - (A) Have been developed in accordance with generally accepted actuarial principles and practices;
 - (B) Are appropriate for the populations to be covered, and the services to be furnished under the contract; and
 - (C) Have been certified, as meeting the requirements of this paragraph (c), by actuaries who meet the qualification standards established by the American Academy of Actuaries and follow the practice standards established by the Actuarial Standards Board.
- (ii) *Adjustments to smooth data* means adjustments made, by cost-neutral methods, across rate cells, to

compensate for distortions in costs, utilization, or the number of eligibles.

(2) *Basic requirements.* (i) All capitation rates paid under risk contracts and all risk-sharing mechanisms in contracts must be actuarially sound.

(ii) The contract must specify the payment rates and any risk-sharing mechanisms, and the actuarial basis for computation of those rates and mechanisms.

(3) *Requirements for actuarially sound rates.* In setting actuarially sound capitation rates, the State must apply the following elements, or explain why they are not applicable:

(i) Base utilization and cost data that are derived from the Medicaid population, or if not, are adjusted to make them comparable to the Medicaid population.

(ii) Adjustments made to smooth data and adjustments to account for factors such as inflation, MCO or PHP administration (subject to the limits in § 438.6(c)(4)(ii) of this section), and utilization;

(iii) Rate cells specific to the enrolled population, by:

(A) Eligibility category;

(B) Age;

(C) Gender;

(D) Locality/region; and

(E) Risk adjustments based on diagnosis or health status (if used).

(iv) Other payment mechanisms and utilization and cost assumptions that are appropriate for individuals with chronic illness, disability, ongoing health care needs, or catastrophic claims, using risk adjustment, risk sharing, or other appropriate cost-neutral methods.

(4) *Documentation.* The State must provide the following documentation:

(i) The actuarial certification of the capitation rates.

(ii) An assurance (in accordance with paragraph (c)(3) of this section) that all payment rates are based only upon services covered under the State plan and to be provided under the contract to Medicaid-eligible individuals.

(iii) Its projection of expenditures under its previous year's contract (or under its FFS program if it did not have a contract in the previous year) compared to those projected under the proposed contract.

(iv) An explanation of any incentive arrangements, or stop-loss, reinsurance, or any other risk-sharing methodologies under the contract.

(5) *Special contract provisions.* (i) Contract provisions for reinsurance, stop-loss limits or other risk-sharing methodologies (other than risk corridors) must be computed on an actuarially sound basis.

(ii) If risk corridors or incentive arrangements result in payments that exceed the approved capitation rates, the FFP limitation of § 438.814 applies.

(iii) For all incentive arrangements, the contract must provide that the arrangement is —

(A) For a fixed period of time;

(B) Not to be renewed automatically;

(C) Designed to include withholds or other payment penalties if the contractor does not perform the specified activities or does not meet the specified targets;

(D) Made available to both public and private contractors;

(E) Not conditioned on intergovernmental transfer agreements; and

(F) Necessary for the specified activities and targets.

(d) *Enrollment discrimination prohibited.* Contracts with MCOs, PHPs, and PCCMs must provide as follows:

(1) The MCO, PHP or PCCM accepts individuals eligible for enrollment in the order in which they apply without restriction (unless authorized by the Regional Administrator), up to the limits set under the contract.

(2) Enrollment is voluntary, except in the case of mandatory enrollment programs that meet the conditions set forth in § 438.50(a).

(3) The MCO, PHP or PCCM will not, on the basis of health status or need for health care services, discriminate against individuals eligible to enroll.

(4) The MCO, PHP or PCCM will not discriminate against individuals eligible to enroll on the basis of race, color, or national origin, and will not use any policy or practice that has the effect of discriminating on the basis of race, color, or national origin.

(e) *Services that may be covered.* An MCO or PHP contract may cover, for enrollees, services that are in addition to those covered under the State plan.

(f) *Compliance with contracting rules.* All contracts under this subpart must:

(1) Comply with all applicable State and Federal laws and regulations including Title VI of the Civil Rights Act of 1964; Title IX of the Education Amendments of 1972 (regarding education programs and activities); the Age Discrimination Act of 1975; the Rehabilitation Act of 1973; and the Americans with Disabilities Act; and

(2) Meet all the requirements of this section.

(g) *Inspection and audit of financial records.* Risk contracts must provide that the State agency and the Department may inspect and audit any financial records of the entity or its subcontractors.

(h) *Physician incentive plans.* (1) MCO and PHP contracts must provide

for compliance with the requirements set forth in §§ 422.208 and 422.210 of this chapter.

(2) In applying the provisions of §§ 422.208 and 422.210, references to "M+C organization", "HCFA", and "Medicare beneficiaries" must be read as references to "MCO or PHP", "State agency" and "Medicaid recipients", respectively.

(i) *Advance directives.* (1) All MCO and most PHP contracts must provide for compliance with the requirements of § 422.128 of this chapter for maintaining written policies and procedures with respect to advance directives. This requirement does not apply to PHP contracts where the State has determined such application would be inappropriate, as described in § 438.8(a)(2).

(2) The MCO or PHP must provide adult enrollees with written information on advance directives policies, and include a description of applicable State law.

(3) The information must reflect changes in State law as soon as possible, but no later than 90 days after the effective date of the change.

(j) *Special rules for certain HIOs.*

Contracts with HIOs that began operating on or after January 1, 1986, and that the statute does not explicitly exempt from requirements in section 1903(m) of the Act are subject to all the requirements of this part that apply to MCOs and contracts with MCOs. These HIOs may enter into comprehensive risk contracts only if they meet the criteria of paragraph (a) of this section.

(k) *Additional rules for contracts with PCCMs.* A PCCM contract must meet the following requirements:

(1) Provide for reasonable and adequate hours of operation, including 24-hour availability of information, referral, and treatment for emergency medical conditions.

(2) Restrict enrollment to recipients who reside sufficiently near one of the manager's delivery sites to reach that site within a reasonable time using available and affordable modes of transportation.

(3) Provide for arrangements with, or referrals to, sufficient numbers of physicians and other practitioners to ensure that services under the contract can be furnished to enrollees promptly and without compromise to quality of care.

(4) Prohibit discrimination in enrollment, disenrollment, and re-enrollment, based on the recipient's health status or need for health care services.

(5) Provide that enrollees have the right to disenroll from their PCCM in accordance with § 438.56.

(l) *Subcontracts.* All subcontracts must fulfill the requirements of this part that are appropriate to the service or activity delegated under the subcontract.

(m) *Choice of health professional.* The contract must allow each enrollee to choose his or her health professional in the MCO to the extent possible and appropriate.

§ 438.8 Provisions that apply to PHPs.

The following requirements and options apply to PHPs, PHP contracts, and States with respect to PHPs, to the same extent that they apply to MCOs, MCO contracts, and States with respect to MCOs.

(a) The contract requirements of § 438.6, except for the following:

(1) Requirements that pertain to HIOs.
(2) Requirements for advance directives, if the State believes that they are not appropriate, for example, for a PHP contract that covers only dental services or non-clinical services such as transportation services.

(b) The information requirements in § 438.10.

(c) The provision against provider discrimination in § 438.12.

(d) The State responsibility provisions of subpart B except § 438.50.

(e) The enrollee rights and protection provisions in subpart C of this part.

(f) The quality assessment and performance improvement provisions in subpart D of this part to the extent that they are applicable to services furnished by the PHP.

(g) The grievance system provisions in subpart F of this part.

(h) The certification and program integrity protection provisions set forth in subpart H of this part.

§ 438.10 Information requirements.

(a) *Basic rules.* (1) Each State or its contracted representative, and each MCO, PHP, or PCCM must, in furnishing information to enrollees and potential enrollees, meet the requirements that are applicable to it under this section.

(2) The information required for all potential enrollees must be furnished by the State or its contracted representative or, at State option, by the MCO or PHP.

(3) The information required for all enrollees must be furnished by each MCO or PHP, unless the State chooses to furnish it directly or through its contracted representative.

(4) PHPs must comply with the requirements of this section, as appropriate. PHPs that contract as

PCCMs must meet all of the requirements applicable to PCCMs. All other PHPs must meet all of the requirements applicable to MCOs.

(5) The language and format requirements of paragraphs (b) and (c) of this section apply to all information furnished to enrollees and potential enrollees, such as enrollment notices and instructions, as well as the information specified in this section.

(6) The State must have in place a mechanism to help enrollees and potential enrollees understand the State's managed care program.

(7) Each MCO and PHP must have in place a mechanism to help enrollees and potential enrollees understand the requirements and benefits of the plan.

(8) If the State plan provides for mandatory enrollment under section 1932(a)(1)(A) of the Act (that is, as a State plan option), the additional requirements of paragraph (h) of this section apply.

(b) *Language.* The State must meet the following requirements:

(1) Establish a methodology for identifying the non-English languages spoken by enrollees and potential enrollees throughout the State.

(2) Provide written information in each non-English language that is necessary for effective communication with a significant number or percentage of enrollees and potential enrollees.

(3) Require each MCO, PHP, and PCCM to make its written information available in the languages that are prevalent in its particular service area.

(4) Make oral interpretation services available and require each MCO, PHP, and PCCM to make those services available free of charge to the recipient to meet the needs of each enrollee and potential enrollee.

(5) Notify enrollees and potential enrollees, and require each MCO, PHP, and PCCM to notify its enrollees and potential enrollees—

(i) That oral interpretation and written information are available in languages other than English; and

(ii) Of how to access those services.

(c) *Format.* (1) The material must—

(i) Use easily understood language and format; and

(ii) Be available in alternative formats and in an appropriate manner that takes into consideration the special needs of those who, for example, are visually limited or have limited reading proficiency.

(2) The State must provide instructions to enrollees and potential enrollees and require each MCO, PHP, and PCCM to provide instructions to its enrollees and potential enrollees on how to obtain information in the appropriate format.

(d) *Information for potential enrollees.*—(1) *To whom and when the information must be furnished.* The State or its contracted representative must provide the information specified in paragraph (d)(2) of this section as follows:

(i) To each potential enrollee residing in the MCO's or PHP's service area;

(ii) At the time the potential enrollee first becomes eligible for Medicaid, is considering choice of MCOs or PHPs under a voluntary program, or is first required to choose an MCO or PHP under a mandatory enrollment program; and

(iii) Within a timeframe that enables the potential enrollee to use the information in choosing among available MCOs or PHPs.

(2) *Required information.* The information for potential enrollees must include the following:

(i) General information about—

(A) The basic features of managed care;

(B) Which populations are excluded from enrollment, subject to mandatory enrollment, or free to enroll voluntarily in an MCO or PHP; and

(C) MCO and PHP responsibilities for coordination of enrollee care;

(ii) Information specific to each MCO and PHP serving an area that encompasses the potential enrollee's service area:

(A) Benefits covered;

(B) Cost sharing, if any;

(C) Service area;

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

(E) Benefits that are available under the State plan but are not covered under the contract, including how and where the enrollee may obtain those benefits, any cost sharing, and how transportation is provided. For a counseling or referral service that the MCO or PHP does not cover because of moral or religious objections, the MCO or PHP need not furnish information about how and where to obtain the service, but only about how and where to obtain information about the service. The State must furnish information about where and how to obtain the service.

(e) *Information for enrollees.*—(1) *To whom and when the information must be furnished.* The MCO or PHP must—

(i) Furnish to each of its enrollees the information specified in paragraph (e)(2) of this section within a reasonable time

after the MCO or PHP receives, from the State or its contracted representative, notice of the recipient's enrollment, and once a year thereafter.

(ii) Give each enrollee written notice of any change (that the State defines as "significant") in the information specified in paragraph (e)(2) of this section, at least 30 days before the intended effective date of the change.

(iii) Make a good faith effort to give written notice of termination of a contracted provider, within 15 days after receipt or issuance of the termination notice, to each enrollee who received his or her primary care from, or was seen on a regular basis by, the terminated provider.

(2) *Required information.* The information for enrollees must include the following:

(i) Kinds of benefits, and amount, duration, and scope of benefits available under the contract. There must be sufficient detail to ensure that enrollees understand the benefits to which they are entitled, including pharmaceuticals, and mental health and substance abuse benefits.

(ii) Enrollee rights as specified in § 438.100.

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

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

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

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

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

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

(ix) Cost sharing, if any.

(x) Grievance, appeal, and fair hearing procedures for enrollees, including timeframes, required under § 438.414(b).

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

(xii) Any benefits that are available under the State plan but are not covered under the contract, including how and where the enrollee may obtain those benefits, any cost sharing, and how transportation is provided. For a counseling or referral service that the

MCO or PHP does not cover because of moral or religious objections, the MCO or PHP need not furnish information on how and where to obtain the service, but only on how and where to obtain information about the service. The State must furnish information about how and where to obtain the service.

(xiii) Information on how to obtain continued services during a transition, as provided in § 438.62.

(xiv) The rules for emergency and post-stabilization services, as set forth in § 438.114.

(xv) Additional information that is available upon request, and how to request that information.

(3) *Annual notice.* At least once a year, the MCO or PHP, or the State or its contracted representative, must notify enrollees of their right to request and obtain the information listed in paragraphs (e)(2) and (f) of this section.

(f) *MCO or PHP information available upon request.* The following information must be furnished to enrollees and potential enrollees upon request, by the MCO or PHP, or by the State or its contracted representative if the State prohibits the MCO or PHP from providing it:

(1) With respect to MCOs and health care facilities, their licensure, certification, and accreditation status.

(2) With respect to health care professionals, information that includes, but is not limited to, education, licensure, and Board certification and recertification.

(3) Other information on requirements for accessing services to which they are entitled under the contract, including factors such as physical accessibility and non-English languages spoken.

(4) A description of the procedures the MCO or PHP uses to control utilization of services and expenditures.

(5) A summary description of the methods of compensation for physicians.

(6) Information on the financial condition of the MCO or PHP, including the most recently audited information.

(7) Any element of information specified in paragraphs (d) and (e) of this section.

(g) *Information on PCCMs and PHPs.*—(1) *To whom and when the information must be furnished.* The State or its contracted representative must furnish information on PCCMs and PHPs to potential enrollees—

(i) When potential enrollees first become eligible for Medicaid or are first required to choose a PCCM or PHP under a mandatory enrollment program; and

(ii) Within a timeframe that enables them to use the information in choosing among available PCCMs or PHPs.

(2) *Required information.*—(i) *General rule.* The information must include the following:

(A) The names of and non-English languages spoken by PCCMs and PHPs and the locations at which they furnish services.

(B) Any restrictions on the enrollee's choice of the listed PCCMs and PHPs.

(C) Except as provided in paragraph (g)(2)(ii) of this section, any benefits that are available under the State plan but not under the PCCM or PHP contract, including how and where the enrollee may obtain those benefits, any cost-sharing, and how transportation is provided.

(ii) *Exception.* For counseling and referral services that are not covered under the PCCM or PHP contract because of moral or religious objections, the PCCM or PHP need not furnish information about how and where to obtain the service but only about how and where to obtain information about the service. The State must furnish the information on how and where to obtain the service.

(3) *Additional information available upon request.* Each PCCM and PHP must, upon request, furnish information on the grievance procedures available to enrollees, including how to obtain benefits during the appeals process.

(h) *Special rules: States with mandatory enrollment.*—(1) *Basic rule.* If the State plan provides for mandatory enrollment under section 1932(a)(1)(A) of the Act, the State or its contracted representative must furnish information on MCOs, PHPs, and PCCMs (as specified in paragraph (h)(3) of this section), either directly or through the MCO, PHP, or PCCM.

(2) *When and how the information must be furnished.* The information must be furnished to all potential enrollees—

(i) At least once a year; and
(ii) In a comparative, chart-like format.

(3) *Required information.* Some of the information is the same as the information required for potential enrollees under paragraph (d) of this section. However, all of the information in this paragraph is subject to the timeframe and format requirements of paragraph (h)(2) of this section, and includes the following for each contracting MCO, PHP, or PCCM:

(i) The MCO's, PHP's, or PCCM's service area.

(ii) The benefits covered under the contract.

(iii) Any cost sharing imposed by the MCO, PHP, or PCCM.

(iv) To the extent available, quality and performance indicators, including, but not limited to, disenrollment rates as defined by the State, and enrollee satisfaction.

§ 438.12 Provider discrimination prohibited.

(a) *General rules.* (1) An MCO or PHP may not discriminate with respect to the participation, reimbursement, or indemnification of any provider who is acting within the scope of his or her license or certification under applicable State law, solely on the basis of that license or certification. If an MCO or PHP declines to include individual or groups of providers in its network, it must give the affected providers written notice of the reason for its decision.

(2) In all contracts with health care professionals an MCO or PHP must comply with the requirements specified in § 438.214.

(b) *Construction.* Paragraph (a) of this section may not be construed to—

(1) Require the MCO or PHP to contract with providers beyond the number necessary to meet the needs of its enrollees;

(2) Preclude the MCO or PHP from using different reimbursement amounts for different specialties or for different practitioners in the same specialty; or

(3) Preclude the MCO or PHP from establishing measures that are designed to maintain quality of services and control costs and are consistent with its responsibilities to enrollees.

Subpart B—State Responsibilities

§ 438.50 State plan requirements.

(a) *General rule.* A State plan that provides for requiring Medicaid recipients to enroll in managed care entities must comply with the provisions of this section, except when the State imposes the requirement—

(1) As part of a demonstration project under section 1115 of the Act; or

(2) Under a waiver granted under section 1915(b) of the Act.

(b) *State plan information.* The plan must specify—(1) The types of entities with which the State contracts;

(2) The payment method it uses (for example, whether fee-for-service or capitation);

(3) Whether it contracts on a comprehensive risk basis; and

(4) The process the State uses to involve the public in both design and initial implementation of the program and the methods it uses to ensure ongoing public involvement once the State plan has been implemented.

(c) *State plan assurances.* The plan must provide assurances that the State meets applicable requirements of the following laws and regulations:

(1) Section 1903(m) of the Act, with respect to MCOs and MCO contracts.

(2) Section 1905(t) of the Act, with respect to PCCMs and PCCM contracts.

(3) Section 1932(a)(1)(A) of the Act, with respect to the State's option to limit freedom of choice by requiring recipients to receive their benefits through managed care entities.

(4) This part, with respect to MCOs and PCCMs.

(5) Part 434 of this chapter, with respect to all contracts.

(6) Section 438.6(c), with respect to payments under any risk contracts, and § 447.362 with respect to payments under any nonrisk contracts.

(d) *Limitations on enrollment.* The State must provide assurances that, in implementing the State plan managed care option, it will not require the following groups to enroll in an MCO or PCCM:

(1) Recipients who are also eligible for Medicare.

(2) Indians who are members of Federally recognized tribes, except when the MCO or PCCM is—

(i) The Indian Health Service; or

(ii) An Indian health program or Urban Indian program operated by a tribe or tribal organization under a contract, grant, cooperative agreement or compact with the Indian Health Service.

(3) Children under 19 years of age who are—

(i) Eligible for SSI under title XVI;

(ii) Eligible under section 1902(e)(3)

of the Act;

(iii) In foster care or other out-of-home placement;

(iv) Receiving foster care or adoption assistance; or

(v) Receiving services through a family-centered, community-based, coordinated care system that receives grant funds under section 501(a)(1)(D) of title V, and is defined by the State in terms of either program participation or special health care needs.

(e) *Priority for enrollment.* The State must have an enrollment system under which recipients already enrolled in an MCO or PCCM are given priority to continue that enrollment if the MCO or PCCM does not have the capacity to accept all those seeking enrollment under the program.

(f) *Enrollment by default.* (1) For recipients who do not choose an MCO or PCCM during their enrollment period, the State must have a default enrollment process for assigning those recipients to contracting MCOs and PCCMs.

(2) The process must seek to preserve existing provider-recipient relationships and relationships with providers that have traditionally served Medicaid recipients. If that is not possible, the State must distribute the recipients equitably among qualified MCOs and PCCMs available to enroll them, excluding those that are subject to the intermediate sanction described in § 438.702(a)(4).

(3) An "existing provider-recipient relationship" is one in which the provider was the main source of Medicaid services for the recipient during the previous year. This may be established through State records of previous managed care enrollment or fee-for-service experience, or through contact with the recipient.

(4) A provider is considered to have "traditionally served" Medicaid recipients if it has experience in serving the Medicaid population.

§ 438.52 Choice of MCOs, PHPs, and PCCMs.

(a) *General rule.* Except as specified in paragraphs (b) and (c) of this section, a State that requires Medicaid recipients to enroll in an MCO, PHP, or PCCM must give those recipients a choice of at least two entities.

(b) *Exception for rural area residents.*

(1) Under any of the following programs, and subject to the requirements of paragraph (b)(2) of this section, a State may limit a rural area resident to a single MCO, PHP, or PCCM system:

(i) A program authorized by a plan amendment under section 1932(a) of the Act.

(ii) A waiver under section 1115 of the Act.

(iii) A waiver under section 1915(b) of the Act.

(2) A State that elects the option provided under paragraph (b)(1) of this section, must permit the recipient—

(i) To choose from at least two physicians or case managers; and

(ii) To obtain services from any other provider under any of the following circumstances:

(A) The service or type of provider is not available within the MCO, PHP, or PCCM network.

(B) The provider is not part of the network, but is the main source of a service to the recipient. (This provision applies as long as the provider continues to be the main source of the service).

(C) The only plan or provider available to the recipient does not, because of moral or religious objections, provide the service the enrollee seeks.

(D) The recipient's primary care provider or other provider determines

that the recipient needs related services that would subject the recipient to unnecessary risk if received separately (for example, a cesarean section and a tubal ligation) and not all of the related services are available within the network.

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

(3) As used in this paragraph, "rural area" is any area other than an "urban area" as defined in § 412.62(f)(1)(ii) of this chapter.

(c) *Exception for certain health insuring organizations (HIOs).* The State may limit recipients to a single HIO if—

(1) The HIO is one of those described in section 1932(a)(3)(C) of the Act;

(2) The recipient who enrolls in the HIO has a choice of at least two primary care providers within the entity.

(d) *Limitations on changes between primary care providers.* For an enrollee of a single MCO, PHP, or HIO under paragraph (b)(2) or (b)(3) of this section, any limitation the State imposes on his or her freedom to change between primary care providers may be no more restrictive than the limitations on disenrollment under § 438.56(c).

§ 438.56 Disenrollment: Requirements and limitations.

(a) *Applicability.* The provisions of this section apply to all managed care arrangements whether enrollment is mandatory or voluntary and whether the contract is with an MCO, a PHP, or a PCCM.

(b) *Disenrollment requested by the MCO, PHP or PCCM.* All MCO, PHP, and PCCM contracts must—(1) Specify the reasons for which the MCO, PHP or PCCM may request disenrollment of an enrollee;

(2) Provide that the MCO, PHP or PCCM may not request disenrollment because of a change in the enrollee's health status, or because of the enrollee's utilization of medical services, diminished mental capacity, or uncooperative or disruptive behavior resulting from his or her special needs (except where his or her continued enrollment in the MCO, PHP or PCCM seriously impairs the entity's ability to furnish services to either this particular enrollee or other enrollees); and

(3) Specify the methods by which the MCO, PHP or PCCM assures the agency that it does not request disenrollment for reasons other than those permitted under the contract.

(c) *Disenrollment requested by the enrollee.* If the State chooses to limit disenrollment, its MCO, PHP, and PCCM contracts must provide that a

recipient may request disenrollment as follows:

(1) For cause, at any time.

(2) Without cause, at the following times:

(i) During the 90 days following the date of the recipient's initial enrollment with the MCO, PHP or PCCM, or the date the State sends the recipient notice of the enrollment, whichever is later.

(ii) At least once every 12 months thereafter.

(iii) Upon automatic reenrollment under paragraph (g) of this section, if the temporary loss of Medicaid eligibility has caused the recipient to miss the annual disenrollment opportunity.

(iv) When the State imposes the intermediate sanction specified in § 438.702(a)(3).

(d) *Procedures for disenrollment.* (1) *Request for disenrollment.* The recipient (or his or her representative) must submit an oral or written request—

(i) To the State agency (or its agent); or

(ii) To the MCO, PHP or PCCM, if the State permits MCOs, PHPs, and PCCMs to process disenrollment requests.

(2) *Cause for disenrollment.* The following are cause for disenrollment:

(i) The enrollee was homeless (as defined by the State) or a migrant worker at the time of enrollment and was enrolled in the MCO, PHP or PCCM by default.

(ii) The plan does not, because of moral or religious objections, cover the service the enrollee seeks.

(iii) The enrollee needs related services (for example a cesarean section and a tubal ligation) to be performed at the same time; not all related services are available within the network; and the enrollee's primary care provider or another provider determines that receiving the services separately would subject the enrollee to unnecessary risk.

(iv) Other reasons, including but not limited to, poor quality of care, lack of access to services covered under the contract, or lack of access to providers experienced in dealing with the enrollee's health care needs.

(3) *MCO, PHP or PCCM action on request.* (i) An MCO, PHP or PCCM may either approve a request for disenrollment or refer the request to the State.

(ii) If the MCO, PHP, PCCM, or State agency (whichever is responsible) fails to make a disenrollment determination so that the recipient can be disenrolled within the timeframes specified in paragraphs (e)(1) of this section, the disenrollment is considered approved.

(4) *State agency action on request.* For a request received directly from the

recipient, or one referred by the MCO, PHP or PCCM, the State agency must take action to approve or disapprove the request based on the following:

(i) Reasons cited in the request.

(ii) Information provided by the MCO, PHP or the PCCM at the agency's request.

(iii) Any of the reasons specified in paragraph (d)(2) of this section.

(5) *Use of the MCO, PHP, or PCCM grievance procedures.* (i) The State agency may require that the enrollee seek redress through the MCO, PHP, or PCCM's grievance system before making a determination on the enrollee's request.

(ii) The grievance process, if used, must be completed in time to permit the disenrollment (if approved) to be effective in accordance with the timeframe specified in § 438.56(e)(1).

(iii) If, as a result of the grievance process, the MCO, PHP, or PCCM approves the disenrollment, the State agency is not required to make a determination.

(e) *Timeframe for disenrollment determinations.* (1) Regardless of the procedures followed, the effective date of an approved disenrollment must be no later than the first day of the second month following the month in which the enrollee or the MCO, PHP or PCCM files the request.

(2) If the MCO, PHP or PCCM or the State agency (whichever is responsible) fails to make the determination within the timeframes specified in paragraphs (e)(1) and (e)(2) of this section, the disenrollment is considered approved.

(f) *Notice and appeals.* A State that restricts disenrollment under this section must take the following actions:

(1) Provide that enrollees and their representatives are given written notice of disenrollment rights at least 60 days before the start of each enrollment period.

(2) Ensure access to State fair hearing for any enrollee dissatisfied with a State agency determination that there is not good cause for disenrollment.

(g) *Automatic reenrollment: Contract requirement.* If the State plan so specifies, the contract must provide for automatic reenrollment of a recipient who is disenrolled solely because he or she loses Medicaid eligibility for a period of 2 months or less.

§ 438.58 Conflict of interest safeguards.

(a) As a condition for contracting with MCOs or PHPs, a State must have in effect safeguards against conflict of interest on the part of State and local officers and employees and agents of the State who have responsibilities relating to MCO or PHP contracts or the default

enrollment process specified in § 438.50(f).

(b) These safeguards must be at least as effective as the safeguards specified in section 27 of the Office of Federal Procurement Policy Act (41 U.S.C. 423).

§ 438.60 Limit on payment to other providers.

The State agency must ensure that no payment is made to a provider other than the MCO or PHP for services available under the contract between the State and the MCO or PHP, except where such payments are provided for in title XIX of the Act or 42 CFR.

§ 438.62 Continued services to recipients.

(a) The State agency must arrange for Medicaid services to be provided without delay to any Medicaid enrollee of an MCO, PHP or PCCM whose contract is terminated and for any Medicaid enrollee who is disenrolled from an MCO, PHP or PCCM for any reason other than ineligibility for Medicaid.

(b) The State agency must have in effect a mechanism to ensure continued access to services when an enrollee with ongoing health care needs is transitioned from fee-for-service to an MCO, PHP or PCCM, from one MCO, PHP or PCCM to another, or from an MCO, PHP or PCCM to fee-for-service.

(1) The mechanism must apply at least to the following:

(i) Children and adults receiving SSI benefits.

(ii) Children in title IV–E foster care.

(iii) Recipients aged 65 or older.

(iv) Pregnant women.

(v) Any other recipients whose care is paid for under State-established, risk-adjusted, high-cost payment categories.

(vi) Any other category of recipients identified by HCFA.

(2) The State must notify the enrollee that a transition mechanism exists, and provide instructions on how to access the mechanism.

(3) The State must ensure that an enrollee's ongoing health care needs are met during the transition period, by establishing procedures to ensure that, at a minimum—

(i) The enrollee has access to services consistent with the State plan, and is referred to appropriate health care providers;

(ii) Consistent with Federal and State law, new providers are able to obtain copies of appropriate medical records; and

(iii) Any other necessary procedures are in effect.

§ 438.66 Monitoring procedures.

The State agency must have in effect procedures for monitoring the MCO's or

PHP's operations, including, at a minimum, operations related to:

(a) Recipient enrollment and disenrollment.

(b) Processing of grievances and appeals.

(c) Violations subject to intermediate sanctions, as set forth in subpart I of this part.

(d) Violations of the conditions for FFP, as set forth in subpart J of this part.

(e) All other provisions of the contract, as appropriate.

§ 438.68 Education of MCOs, PHPs, and PCCMs and subcontracting providers.

The State agency must have in effect procedures for educating MCOs, PHPs, PCCMs and any subcontracting providers about the clinical and other needs of enrollees with special health care needs.

Subpart C—Enrollee Rights and Protections

§ 438.100 Enrollee rights.

(a) *General rule.* The State must ensure that—

(1) Each MCO and each PHP has written policies regarding the enrollee rights specified in this section; and

(2) Each MCO, PHP, and PCCM complies with any applicable Federal and State laws that pertain to enrollee rights, and ensures that its staff and affiliated providers take those rights into account when furnishing services to enrollees.

(b) *Specific rights*—(1) *Basic requirement.* The State must ensure that each managed care enrollee is guaranteed the rights as specified in paragraphs (b)(2) and (b)(3) of this section.

(2) An enrollee of an MCO, PHP, or PCCM has the following rights: The right

(i) To receive information in accordance with § 438.10.

(ii) To be treated with respect and with due consideration for his or her dignity and privacy.

(iii) To receive information on available treatment options and alternatives, presented in a manner appropriate to the enrollee's condition and ability to understand. (The information requirements for services that are not covered under the contract because of moral or religious objections are set forth in § 438.10(e).)

(iv) To participate in decisions regarding his or her health care, including the right to refuse treatment.

(v) To be free from any form of restraint or seclusion used as a means of coercion, discipline, convenience or retaliation, as specified in other Federal

regulations on the use of restraints and seclusion.

(3) An enrollee of an MCO or a PHP also has the following rights—The right

(i) To be furnished health care services in accordance with §§ 438.206 through 438.210.

(ii) To obtain a second opinion from an appropriately qualified health care professional in accordance with § 438.206(d)(3).

(iii) To request and receive a copy of his or her medical records, and to request that they be amended or corrected, as specified in § 438.224.

(c) *Free exercise of rights.* The State must ensure that each enrollee is free to exercise his or her rights, and that the exercise of those rights does not adversely affect the way the MCO, PHP or PCCM and its providers or the State agency treat the enrollee.

(d) *Compliance with other Federal and State laws.* The State must ensure that each MCO, PHP, and PCCM complies with any other applicable Federal and State laws (such as: Title VI of the Civil Rights Act of 1964 as implemented by regulations at 45 CFR part 484; the Age Discrimination Act of 1975 as implemented by regulations at 45 CFR part 91; the Rehabilitation Act of 1973; and Titles II and III of the Americans with Disabilities Act and other laws regarding privacy and confidentiality).

§ 438.102 Provider-enrollee communications.

(a) *Health care professional defined.* As used in this subpart, “health care professional” means a physician or any of the following: a podiatrist, optometrist, chiropractor, psychologist, dentist, physician assistant, physical or occupational therapist, therapist assistant, speech-language pathologist, audiologist, registered or practical nurse (including nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, and certified nurse midwife), licensed certified social worker, registered respiratory therapist, and certified respiratory therapy technician.

(b) *General rules.* (1) An MCO or PHP may not prohibit, or otherwise restrict a health care professional acting within the lawful scope of practice, from advising or advocating on behalf of an enrollee who is his or her patient, with respect to the following:

(i) The enrollee's health status, medical care, or treatment options, including any alternative treatment that may be self-administered.

(ii) Any information the enrollee needs in order to decide among all relevant treatment options.

(iii) The risks, benefits, and consequences of treatment or non-treatment.

(iv) The enrollee's right to participate in decisions regarding his or her health care, including the right to refuse treatment, and to express preferences about future treatment decisions.

(2) MCOs and PHPs must take steps to ensure that health care professionals—

(i) Furnish information about treatment options (including the option of no treatment) in a culturally competent manner; and

(ii) Ensure that enrollees with disabilities have effective communication with all health system participants in making decisions with respect to treatment options.

(3) Subject to the information requirements of paragraph (c) of this section, an MCO or PHP that would otherwise be required to provide, reimburse for, or provide coverage of, a counseling or referral service because of the requirement in paragraph (b)(1) of this section is not required to do so if the MCO or PHP objects to the service on moral or religious grounds.

(c) *Information requirements: MCO and PHP responsibility.* (1) An MCO or PHP that elects the option provided in paragraph (b) (3) of this section must furnish information about the services it does not cover as follows:

(i) To the State—

(A) With its application for a Medicaid contract; and

(B) Whenever it adopts the policy during the term of the contract.

(ii) Consistent with the provisions of § 438.10—

(A) To potential enrollees, before and during enrollment; and

(B) To enrollees, within 90 days after adopting the policy with respect to any particular service. (Although this timeframe would be sufficient to entitle the MCO or PHP to the option provided in paragraph (b)(3) of this section, the overriding rule in § 438.10(e)(1)(ii) requires the MCO or the PHP to furnish the information at least 30 days before the effective date of the policy.)

(2) As specified in § 438.10(d) and (e), the information that MCOs and PHPs must furnish to enrollees and potential enrollees does not include how and where to obtain the service excluded under paragraph (b)(3) of this section, but only how and where to obtain information about the service.

(d) *Information requirements: State responsibility.* For each service excluded by an MCO or PHP under paragraph (b)(2) of this section, the State must furnish information on how and

where to obtain the service, as specified in §§ 438.10(e)(2)(xii) and 438.206(c).

(e) *Sanction.* An MCO or PHP that violates the prohibition of paragraph (b)(1) of this section is subject to intermediate sanctions under subpart I of this part.

§ 438.104 Marketing activities.

(a) *Terminology.* As used in this section, the following terms have the indicated meanings:

Cold-call marketing means any unsolicited personal contact by the MCO, PHP, or PCCM with a potential enrollee for the purpose of marketing as defined in this paragraph.

Marketing means any communication, from an MCO, PHP, or PCCM to an enrollee or potential enrollee, that can reasonably be interpreted as intended to influence the recipient to enroll or reenroll in that particular MCO's, PHP's, or PCCM's Medicaid product, or either to not enroll in, or to disenroll from, another MCO's, PHP's, or PCCM's Medicaid product.

Marketing materials means materials that—

(1) Are produced in any medium, by or on behalf of an MCO, PHP, or PCCM; and

(2) Can reasonably be interpreted as intended to market to enrollees or potential enrollees.

MCO, PHP, PCCM, and entity include any of the entity's employees, affiliated providers, agents, or contractors.

(b) *Contract requirements.* Each contract with an MCO, PHP, or PCCM must comply with the following requirements:

(1) Provide that the entity—

(i) Does not distribute any marketing materials without first obtaining State approval;

(ii) Distributes the materials to its entire service area as indicated in the contract;

(iii) Complies with the information requirements of § 438.10 to ensure that, before enrolling, the recipient receives, from the entity or the State, the accurate oral and written information he or she needs to make an informed decision on whether to enroll;

(iv) Does not seek to influence enrollment in conjunction with the sale or offering of any other insurance; and

(v) Does not, directly or indirectly, engage in door-to-door, telephone, or other cold-call marketing activities.

(2) Specify the methods by which the entity assures the State agency that marketing, including plans and materials, is accurate and does not mislead, confuse, or defraud the recipients or the State agency. Statements that would be considered

inaccurate, false, or misleading include, but are not limited to, any assertion or statement (whether written or oral) that—

(i) The recipient must enroll in the MCO, PHP, or PCCM in order to obtain benefits or in order to not lose benefits; or

(ii) The MCO, PHP, or PCCM is endorsed by HCFA, the Federal or State government, or similar entity.

(c) *State agency review.* In reviewing the marketing materials submitted by the entity, the State must consult with the Medical Care Advisory Committee established under § 431.12 of this chapter or an advisory committee with similar membership.

§ 438.106 Liability for payment.

Each MCO and PHP must provide that its Medicaid enrollees are not held liable for any of the following:

(a) The MCO's or PHP's debts, in the event of the entity's insolvency.

(b) Covered services provided to the enrollee, for which—

(1) The State does not pay the MCO or the PHP; or

(2) The State, or the MCO or PHP does not pay the individual or health care provider that furnishes the services under a contractual, referral, or other arrangement.

(c) Payments for covered services furnished under a contract, referral, or other arrangement, to the extent that those payments are in excess of the amount that the enrollee would owe if the MCO or PHP provided the services directly.

§ 438.108 Cost sharing.

The contract must provide that any cost sharing imposed on Medicaid enrollees is in accordance with §§ 447.50 through 447.60 of this chapter.

§ 438.114 Emergency and post-stabilization services.

(a) *Definitions.* As used in this section—

Emergency medical condition has the meaning given the term in § 422.113(b) of this chapter.

Emergency services has the meaning given the term in § 422.113(b) of this chapter.

Post-stabilization care services has the meaning given the term in § 422.113(c) of this chapter.

(b) *Information requirements.* To enrollees and potential enrollees upon request, and to enrollees during enrollment and at least annually thereafter, each State (or at State option, each MCO, PHP, and PCCM) must provide, in clear, accurate, and

standardized form, information that describes or explains at least the following:

(1) What constitutes emergency medical condition, emergency services, and post-stabilization services, with reference to the definitions in paragraph (a) of this section.

(2) The fact that prior authorization is not required for emergency services.

(3) The process and procedures for obtaining emergency services, including use of the 911 telephone system or its local equivalent.

(4) The locations of any emergency settings and other locations at which MCO, PHP, and PCCM providers and hospitals furnish emergency services and post-stabilization services covered under the contract.

(5) The fact that, subject to the provisions of this section, the enrollee has a right to use any hospital or other setting for emergency care.

(6) The post-stabilization care services rules set forth at § 422.113(c) of this chapter.

(c) *Coverage and payment: General rule.* The following entities are responsible for coverage and payment of emergency services and post-stabilization care services.

(1) The MCO or PHP.

(2) The PCCM that has a risk contract that covers such services.

(3) The State, in the case of a PCCM that has a fee-for-service contract.

(d) *Coverage and payment: Emergency services.* (1) The entities identified in paragraph (c) of this section—

(i) Must cover and pay for emergency services regardless of whether the entity that furnishes the services has a contract with the MCO, PHP, or PCCM; and

(ii) May not deny payment for treatment obtained under either of the following circumstances:

(A) An enrollee had an emergency medical condition, including cases in which the absence of immediate medical attention would not have had the outcomes specified in paragraphs (b)(1)(A), (B), and (C) of the definition of emergency medical condition in § 422.113 of this chapter.

(B) A representative of the MCO, PHP, or PCCM instructs the enrollee to seek emergency services.

(2) A PCCM must—

(i) Allow enrollees to obtain emergency services outside the primary care case management system regardless of whether the case manager referred the enrollee to the provider that furnishes the services; and

(ii) Pay for the services if the manager's contract is a risk contract that covers those services.

(e) *Additional rules for emergency services.* (1) The entities specified in paragraph (c) of this section—

(i) May not limit what constitutes an emergency medical condition with reference to paragraph (a) of this section, on the basis of lists of diagnoses or symptoms; and

(ii) May not refuse to process any claim because it does not contain the primary care provider's authorization number.

(2) An enrollee who has an emergency medical condition may not be held liable for payment of subsequent screening and treatment needed to diagnose the specific condition or stabilize the patient.

(3) The attending emergency physician, or the provider actually treating the enrollee, is responsible for determining when the enrollee is sufficiently stabilized for transfer or discharge, and that determination is binding on the entities identified in paragraph (c) of this section as responsible for coverage and payment.

(f) *Coverage and payment: Post-stabilization services.* Post-stabilization care services are covered and paid for in accordance with provisions set forth at § 422.113(c) of this chapter. In applying those provisions, reference to "M+C organization" must be read as reference to the entities responsible for Medicaid payment, as specified in paragraph (c) of this section.

§ 438.116 Solvency standards.

(a) *Requirement for assurances.* (1) Each MCO and PHP that is not a Federally qualified HMO (as defined in section 1310 of the Public Health Service Act) must provide assurances satisfactory to the State showing that its provision against the risk of insolvency is adequate to ensure that its Medicaid enrollees will not be liable for the MCO's or PHP's debts if the entity becomes insolvent.

(2) Federally qualified HMOs, as defined in section 1310 of the Public Health Service Act, are exempt from this requirement.

(b) *Other requirements.*—(1) *General rule.* Except as provided in paragraph (b)(2) of this section, a MCO and a PHP must meet the solvency standards established by the State for private health maintenance organizations, or be licensed or certified by the State as a risk-bearing entity.

(2) *Exception.* Paragraph (b)(1) of this section does not apply to an MCO or PHP that meets any of the following conditions:

(i) Does not provide both inpatient hospital services and physician services.

(ii) Is a public entity.

(iii) Is (or is controlled by) one or more Federally qualified health centers and meets the solvency standards established by the State for those centers.

(iv) Has its solvency guaranteed by the State.

Subpart D—Quality Assessment and Performance Improvement

§ 438.200 Scope.

This subpart implements section 1932(c)(1) of the Act and sets forth specifications for quality assessment and performance improvement strategies that States must implement to ensure the delivery of quality health care by all MCOs and PHPs. It also establishes standards that States, MCOs and PHPs must meet.

§ 438.202 State responsibilities.

Each State contracting with an MCO or PHP must—

(a) Have a strategy for assessing and improving the quality of managed care services offered by all MCOs and PHPs:

(b) Document the strategy in writing.

(c) Provide for the input of recipients and other stake-holders in the development of the strategy, including making the strategy available for public comment before adopting it in final;

(d) Ensure compliance with standards established by the State, consistent with this subpart; and

(e) Conduct periodic reviews to evaluate the effectiveness of the strategy, and update the strategy as often as the State considers appropriate, but at least every 3 years.

(f) Submit to HCFA the following:

(1) A copy of the initial strategy, and a copy of the revised strategy, whenever significant changes are made.

(2) Regular reports on the implementation and effectiveness of the strategy, consistent with paragraph (e), at least every 3 years.

§ 438.204 Elements of State quality strategies.

At a minimum, State strategies must include the following—

(a) MCO and PHP contract provisions that incorporate the standards specified in this subpart.

(b) Procedures for assessing the quality and appropriateness of care and services furnished to all Medicaid enrollees under the MCO and PHP contracts. These include, but are not limited to—

(1) Procedures that—

(i) Identify enrollees with special health-care needs; and

(ii) Assess the quality and appropriateness of care furnished to

enrollees with special health-care needs; and

(iii) Identify the race, ethnicity, and primary language spoken of each Medicaid enrollee. States must provide this information to the MCO and PHP for each Medicaid enrollee at the time of enrollment.

(2) Continuous monitoring and evaluation of MCO and PHP compliance with the standards.

(c) Performance measures and levels prescribed by HCFA consistent with section 1932(c)(1) of the Act.

(d) Arranging for annual, external independent reviews of the quality outcomes and timeliness of, and access to the services covered under each MCO and PHP contract.

(e) Appropriate use of intermediate sanctions that, at a minimum, meet the requirements of Subpart I of this part.

(f) An information system that supports initial and ongoing operation and review of the State's quality strategy.

(g) Standards, at least as stringent as those in the following sections of this subpart, for access to care, structure and operations, and quality measurement and improvement.

Access Standards

§ 438.206 Availability of services.

(a) *Basic rule.* Each State must ensure that all covered services are available and accessible to enrollees.

(b) *Choice of entities.* If a State limits freedom of choice, it must comply with the requirements of § 438.52, which specifies the choices that the State must make available.

(c) *Services not covered by an MCO, PHP, or PCCM contract.* If an MCO, PHP, or PCCM contract does not cover all of the services under the State plan, the State must make those services available from other sources and provide to enrollees information on where and how to obtain them, including how transportation is provided.

(d) *Delivery network.* The State must ensure that each MCO, and each PHP consistent with the scope of PHP's contracted services, meets the following requirements:

(1) Maintains and monitors a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to all services covered under the contract. In establishing and maintaining the network, each MCO and PHP must consider the following:

(i) The anticipated Medicaid enrollment, with particular attention to pregnant women, children, and persons with special health-care needs.

(ii) The expected utilization of services, considering Medicaid enrollee characteristics and health care needs.

(iii) The numbers and types (in terms of training, experience, and specialization) of providers required to furnish the contracted Medicaid services.

(iv) The numbers of network providers who are not accepting new Medicaid patients.

(v) The geographic location of providers and Medicaid enrollees, considering distance, travel time, the means of transportation ordinarily used by Medicaid enrollees, and whether the location provides physical access for Medicaid enrollees with disabilities.

(2) Provides female enrollees with direct access to a women's health specialist within the network for covered care necessary to provide women's routine and preventive health care services. This is in addition to the enrollee's designated source of primary care if that source is not a women's health specialist.

(3) Provides for a second opinion from a qualified health care professional within the network, or arranges for the enrollee to obtain one outside the network, at no cost to the enrollee, if an additional qualified professional is not currently available within the network.

(4) When seeking an expansion of its service area, demonstrates that it has sufficient numbers and types (in terms of training, experience, and specialization) of providers to meet the anticipated additional volume and types of services the added Medicaid enrollee population may require.

(5) If the network is unable to provide necessary medical services, covered under the contract, to a particular enrollee, the MCO or PHP must adequately and timely cover these services out of network for the enrollee, for as long as the MCO or PHP is unable to provide them.

(6) Demonstrates that its providers are credentialed as required by § 438.214.

(7) Ensures that its providers do not discriminate against Medicaid enrollees.

(8) Requires out-of-network providers to coordinate with the MCO or PHP with respect to payment and ensures that cost to the enrollee is no greater than it would be if the services were furnished within the network.

(e) *Furnishing of services.* The State must ensure that each MCO and PHP complies with the requirements of this paragraph.

(1) *Timely access.* Each MCO and each PHP must —

(i) Meet and require its providers to meet State standards for timely access to

care and services, taking into account the urgency of need for services;

(ii) Ensure that its network's provider hours of operation are convenient for the enrollees, as determined by a State-established methodology, and at least comparable to Medicaid fee-for-service.

(iii) Make services available 24 hours a day, 7 days a week, when medically necessary.

(iv) Establish mechanisms to ensure compliance;

(v) Monitor continuously to determine compliance; and

(vi) Take corrective action if there is a failure to comply.

(2) *Cultural considerations.* Each MCO and each PHP ensures that services are provided in a culturally competent manner to all enrollees, including those with limited English proficiency and diverse cultural and ethnic backgrounds.

§ 438.207 Assurances of adequate capacity and services.

(a) *Basic rule.* Each MCO and each PHP must give assurances to the State that it has the capacity to serve the expected enrollment in its service area in accordance with the State's standards for access to care under this subpart.

(b) *Nature of assurances.* Each MCO and each PHP must submit documentation to the State, in a format specified by the State and acceptable to HCFA, to demonstrate that it complies with the following requirements:

(1) Offers an appropriate range of services, including preventive services, primary care services and specialty services that is adequate for the anticipated number of enrollees for the service area.

(2) Maintains a network of providers that is sufficient in number, mix, and geographic distribution to meet the needs of the anticipated number of enrollees in the service area.

(3) Meets the availability of services requirements in § 438.206.

(4) Has in place policies and practices to deal with situations in which there is—

(i) Unanticipated need for providers with particular types of experience; or

(ii) Unanticipated limitation of the availability of such providers.

(c) *Timing of documentation.* Each MCO and each PHP must submit the documentation described in paragraph (b) of this section at least once a year, and specifically—

(1) At the time it enters into a contract with the State; and

(2) At any time there has been a significant change (as defined by the State) in the MCO's or PHP's operations that would affect adequate capacity and services, including—

(i) A significant change in the MCO's or PHP's services or benefits;

(ii) An expansion or reduction of the MCO's or PHP's geographic service area;

(iii) The enrollment of a new population in the MCO or PHP; and

(iv) A significant change in the MCO or PHP rates.

(d) *State review and submission to HCFA.* After the State reviews the documentation submitted by the MCO or PHP, the State must certify to HCFA that the MCO or PHP has complied with the State's requirements for availability of services, as set forth in § 438.206.

(e) *HCFA's right to inspect documentation.* The State must make available to HCFA, upon request, all documentation collected by the State from the MCO or PHP.

§ 438.208 Coordination and continuity of care.

(a) *Basic requirement.*—(1) *General rule.* Except as specified in paragraphs (a)(2) and (a)(3) of this section, the State must ensure that MCOs and PHPs comply with the requirements of this section.

(2) *PHP exception.* For PHPs, the State determines, based on the scope of the entity's services, and on the way the State has organized the delivery of managed care services, whether a particular PHP is required—

(i) To perform the initial and ongoing screenings and assessments specified in paragraphs (d) and (e) of this section; and

(ii) To meet the primary care requirement of paragraph (h)(1) of this section.

(3) *Exception for MCOs that serve dually eligible enrollees.* (i) For an MCO that serves enrollees who are also enrolled in a Medicare+Choice plan and also receive Medicare benefits, the State determines to what extent that MCO must meet the initial screening, assessment, and treatment planning provisions of paragraphs (d), (e), and (f) of this section.

(ii) The State bases its determination on the services it requires the MCO to furnish to dually eligible enrollees.

(b) *State responsibility to identify enrollees with special health care needs.* The State must implement mechanisms to identify to the MCO and PHP, upon enrollment, the following groups:

(1) Enrollees at risk of having special health care needs, including—

(i) Children and adults who are receiving SSI benefits;

(ii) Children in Title IV–E foster care;

(iii) Enrollees over the age of 65; and

(iv) Enrollees in relevant, State-established, risk-adjusted, higher-cost payment categories.

(v) Any other category of recipients identified by HCFA.

(2) Children under the age of 2.

(3) Other enrollees known by the State to be pregnant or to have special health care needs.

(c) *Requirements for MCOs and PHPs.* The State must ensure—

(1) That each MCO, and each PHP for which the State determines it is appropriate in accordance with paragraphs (a)(2) and (a)(3) of this section, meets the requirements of paragraphs (d), (e), and (h)(1) of this section; and

(2) That each MCO and each PHP meets the requirements of paragraphs (f), (g), and (h)(2) through (h)(6) of this section.

(d) *Initial screening and assessment.* Each MCO and each PHP must make a best effort attempt to meet the following standards:

(1) For enrollees identified under paragraph (b)(1) of this section,

(i) Performs enrollee screening within 30 days of receiving the identification; and

(ii) For any enrollee the screening identifies as being pregnant or having special health care needs, performs a comprehensive health assessment as expeditiously as the enrollee's health requires, but no later than 30 days from the date of identification.

(2) For enrollees identified under paragraphs (b)(2) and (b)(3) of this section, or who identify themselves as being pregnant or having special health care needs, performs a comprehensive health assessment as expeditiously as the enrollee's health requires, but no later than 30 days from the date of identification.

(3) For all other enrollees—

(i) Performs screening within 90 days from the date of enrollment; and

(ii) For any enrollee the screening identifies as being pregnant or having special health care needs, performs the comprehensive health assessment as expeditiously as the enrollee's health requires but no later than 30 days from the date of identification.

(e) *On-going screening and assessment.* Each MCO and each PHP must implement mechanisms to—

(1) Identify enrollees who develop special health care needs after they enroll in the MCO or PHP; and

(2) Perform comprehensive health assessments as expeditiously as the enrollee's health requires, but no later than 30 days from the date of identification.

(f) *Treatment plans.* For pregnant women and for enrollees determined to have special health care needs, each MCO and each PHP implements a treatment plan that—

(1) Is appropriate to the conditions and needs identified and assessed under paragraphs (d) and (e) of this section;

(2) Is for a specific period of time and is updated periodically;

(3) Specifies a standing referral or an adequate number of direct access visits to specialists;

(4) Ensures adequate coordination of care among providers;

(5) Is developed with enrollee participation; and

(6) Ensures periodic reassessment of each enrollee as his or her health condition requires.

(g) *Use of health care professionals.*

Each MCO and each PHP uses appropriate health care professionals to—

(1) Perform any comprehensive health assessments required by this section; and

(2) Develop, implement, and update any treatment plans required by this section.

(h) *Primary care and coordination program.* Each MCO and each PHP must implement a coordination program that meets State requirements and achieves the following:

(1) Ensures that each enrollee has an ongoing source of primary care appropriate to his or her needs and a person or entity formally designated as primarily responsible for coordinating the health care services furnished to the enrollee.

(2) Coordinates the services the MCO or PHP furnishes to the enrollee with the services the enrollee receives from any other MCOs and PHPs;

(3) Shares with other MCOs and PHPs serving the enrollee the results of its screenings and assessments of the enrollee so that those activities need not be duplicated.

(4) Ensures that in the process of coordinating care, each enrollee's privacy is protected consistent with the confidentiality requirements in § 438.224.

(5) Ensures that each provider maintains health records that meet professional standards and that there is appropriate and confidential sharing of information among providers.

(6) Has in effect procedures to address factors (such as a lack of transportation) that may hinder enrollee adherence to prescribed treatments or regimens.

(7) Ensures that its providers have the information necessary for effective and continuous patient care and quality improvement, consistent with the confidentiality and accuracy requirements of § 438.224 and the information system requirements of § 438.242.

§ 438.210 Coverage and authorization of services.

(a) *Coverage.* Each contract with an MCO, PHP, or PCCM must identify, define, and specify each service that the MCO, PHP, or PCCM is required to offer, and each contract with an MCO or PHP must meet the following requirements:

(1) Require that the MCO or PHP make available the services it is required to offer at least in the amount, duration, and scope that—

(i) Are specified in the State plan; and
(ii) Are sufficient to reasonably be expected to achieve the purpose for which the services are furnished.

(2) Provide that the MCO or PHP—

(i) May not arbitrarily deny or reduce the amount, duration, or scope of a required service solely because of the diagnosis, type of illness, or condition; and
(ii) May place appropriate limits on a service—

(A) On the basis of criteria such as medical necessity; or
(B) For the purpose of utilization control, provided the services furnished can reasonably be expected to achieve their purpose, as required in paragraph (a)(1)(ii) of this section.

(3) Specify what constitutes “medically necessary services” in a manner that—

(i) Is no more restrictive than the State Medicaid program as indicated in State statutes and regulations, the State Plan, and other State policy and procedures; and
(ii) Addresses the extent to which the MCO or PHP is responsible for covering services related to the following:

(A) The prevention, diagnosis, and treatment of health impairments.
(B) The ability to achieve age-appropriate growth and development.
(C) The ability to attain, maintain, or regain functional capacity.

(4) Provide that the MCO or PHP furnishes the services in accordance with the specifications of paragraph (a)(3) of this section.

(b) *Processing of requests.* With respect to the processing of requests for initial and continuing authorizations of services, each contract must require—

(1) That the MCO or PHP and its subcontractors have in place, and follow, written policies and procedures that reflect current standards of medical practice;

(2) That the MCO or PHP—
(i) Not have information requirements that are unnecessary, or unduly burdensome for the provider or the enrollee;

(ii) Have in effect mechanisms to ensure consistent application of review criteria for authorization decisions; and

(iii) Consult with the requesting provider when appropriate.

(3) That any decision to deny a service authorization request or to authorize a service in an amount, duration, or scope that is less than requested, be made by a health care professional who has appropriate clinical expertise in treating the enrollee's condition or disease.

(c) *Notice of adverse action.* Each contract must provide for the MCO or PHP to notify the requesting provider, and give the enrollee written notice of any decision by the MCO or PHP to deny a service authorization request, or to authorize a service in an amount, duration, or scope that is less than requested. The notice must meet the requirements of § 438.404, except that the notice to the provider need not be in writing.

(d) *Timeframe for standard authorization decisions.* Each contract must provide for the MCO or PHP to make a standard authorization decision and provide notice—

(1) As expeditiously as the enrollee's health condition requires and within State-established timeframes that may not exceed 14 calendar days following receipt of the request for service, with a possible extension of up to 14 additional calendar days, if—

(i) The enrollee, or the provider, requests extension; or

(ii) The MCO or the PHP justifies (to the State agency upon request) a need for additional information and how the extension is in the enrollee's interest.

(e) *Timeframe for expedited authorization decisions.* (1) For cases in which a provider indicates, or the MCO or PHP determines, that following the standard timeframe could seriously jeopardize the enrollee's life or health or ability to attain, maintain, or regain maximum function, each contract must provide for the MCO or PHP to make an expedited authorization decision and provide notice as expeditiously as the enrollee's health condition requires and no later than 72 hours after receipt of the request for service.

(2) The MCO or PHP may extend the 72-hour time period by up to 14 calendar days if the enrollee requests extension.

(f) *Compensation for utilization management activities.* Each contract must provide that, consistent with § 438.6(g), and § 422.208 of this chapter, compensation to individuals or entities that conduct utilization management activities is not structured so as to provide incentives for the individual or entity to deny, limit, or discontinue medically necessary services to any enrollee.

Structure and Operation Standards**§ 438.214 Provider selection.**

(a) *General rules.* The State must ensure that each contracted MCO and PHP implements written policies and procedures for selection and retention of providers and that those policies and procedures include, at a minimum, the requirements of this section.

(b) *Credentialing and recredentialing requirements.* Each MCO and each PHP must follow a documented credentialing process for providers who have signed contracts or participation agreements with the MCO or the PHP.

(1) *Physicians and other licensed independent providers.* The process for physicians, including members of physician groups, and other licensed independent providers, includes—

(i) Initial credentialing when a physician or other provider enters the MCO or PHP network or a physician enters a physician group; and

(ii) Recredentialing within timeframes set by the State, which may be no less than the State requires for private MCOs.

(2) *Other providers.* The process for other providers must include an initial determination, and redetermination at specified intervals. The redetermination cycles must be the same as Federal or State credentialing cycles. The purpose is to ensure that, at a minimum, the provider—

(i) Is licensed (if required by the State); and

(ii) Has met any other applicable Federal or State requirements.

(3) *Exception.* The requirements of paragraphs (b)(1) and (b)(2) of this section do not apply to either of the following:

(i) Providers who are permitted to furnish services only under the direct supervision of a physician or other provider.

(ii) Hospital-based providers (such as emergency room physicians, anesthesiologists, or certified nurse anesthetists) who provide services only incident to hospital services. This exception does not apply if the provider contracts independently with the MCO or PHP or is promoted by the MCO or PHP as part of the provider network.

(4) *Initial credentialing.* Initial credentialing—

(i) Requires a written, dated and signed application that is updated in writing at recredentialing;

(ii) Requires that applications, updates, and supporting information submitted by the applicant include an attestation of the correctness and completeness of the information; and

(iii) Is based on primary source verification of licensure, disciplinary status, and a site visit as appropriate.

(5) *Recredentialing*. Recredentialing includes updating of information obtained during initial credentialing and an assessment of provider performance indicators obtained through the following:

(i) Quality Assessment and Performance Improvement Programs.

(ii) The utilization management system.

(iii) The grievance system.

(iv) Enrollee satisfaction surveys.

(v) Other MCO or PHP activities specified by the State.

(c) *Nondiscrimination*. MCO and PHP provider selection policies and procedures, consistent with § 438.12, do not discriminate against particular providers that serve high risk populations or specialize in conditions that require costly treatment.

(d) *Excluded providers*. MCOs or PHPs may not employ or contract with providers excluded from participation in Federal health care programs under either section 1128 or section 1128A of the Act.

(e) *State requirements*. Each MCO and PHP must comply with any additional requirements established by the State.

§ 438.218 Enrollee information.

The requirements that States must meet under § 438.10 constitute part of the State's quality strategy at § 438.204.

§ 438.224 Confidentiality and accuracy of enrollee records.

The State must ensure that (consistent with subpart F of part 431 of this chapter), for medical records and any other health and enrollment information that identifies a particular enrollee, each MCO and PHP establishes and implements procedures to do the following:

(a) Maintain the records and information in a timely and accurate manner.

(b) Abide by all Federal and State laws regarding confidentiality and disclosure.

(c) Specify—

(1) For what purposes the MCO or PHP uses the information; and

(2) To which entities outside the MCO or PHP, and for what purposes, it discloses the information.

(d) Except as provided in applicable Federal and State law, ensure that each enrollee may request and receive a copy of records and information pertaining to him or her and request that they be amended or corrected.

(e) Ensure that each enrollee may request and receive information on how

the MCO or PHP uses and discloses information that identifies the enrollee.

§ 438.226 Enrollment and disenrollment.

The State must ensure that each MCO and PHP complies with the enrollment and disenrollment requirements and limitations set forth in § 438.56.

§ 438.228 Grievance systems.

(a) The State must ensure that each MCO and PHP has in effect a grievance system that meets the requirements of subpart F of this part.

(b) If the State delegates to the MCO or PHP responsibility for notice of action under subpart E of part 431 of this chapter, the State must conduct random reviews of each delegated MCO or PHP and its providers and subcontractors to ensure that they are notifying enrollees in a timely manner.

(c) The State must establish a process to review, upon request by the enrollee, any quality of care grievance that the MCO or the PHP does not resolve to the enrollee's satisfaction.

§ 438.230 Subcontractual relationships and delegation.

(a) *General rule*. The State must ensure that each MCO and PHP—

(1) Oversees and is accountable for any functions and responsibilities that it delegates to any subcontractor; and

(2) Meets the conditions of paragraph (b) of this section.

(b) *Specific conditions*. (1) Before any delegation, each MCO and PHP evaluates the prospective subcontractor's ability to perform the activities to be delegated.

(2) There is a written agreement that—

(i) Specifies the activities and report responsibilities delegated to the subcontractor; and

(ii) Provides for revoking delegation or imposing other sanctions if the subcontractor's performance is inadequate.

(3) The MCO or PHP monitors the subcontractor's performance on an ongoing basis and subjects it to formal review according to a periodic schedule established by the State, consistent with industry standards or State MCO laws and regulations.

(4) If any MCO or PHP identifies deficiencies or areas for improvement, the MCO and the subcontractor take corrective action.

(5) Consistent with §§ 438.604 and 438.606, each MCO and PHP requires from subcontractors certifications with respect to—

(i) Submissions that may be related to State payments; and

(ii) The performance of their duties under the contract.

Measurement and Improvement Standards

§ 438.236 Practice guidelines.

(a) *Basic rule*. The State must ensure that each MCO and PHP meets the requirements of this section.

(b) *Adoption of practice guidelines*. Each MCO and PHP adopts practice guidelines (for example, The Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents and the Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection) that meet the following requirements:

(1) Are based on valid and reliable clinical evidence or a consensus of health care professionals in the particular field;

(2) Consider the needs of the MCO's or PHP's enrollees;

(3) Are adopted in consultation with contracting health care professionals; and

(4) Are reviewed and updated periodically as appropriate.

(c) *Dissemination of guidelines*. Each MCO and PHP disseminates the guidelines to all affected providers and, upon request, to enrollees and potential enrollees.

(d) *Application of guidelines*. Decisions with respect to utilization management, enrollee education, coverage of services, and other areas to which the guidelines apply are consistent with the guidelines.

§ 438.240 Quality assessment and performance improvement program.

(a) *General rules*. (1) The State must require, through its contracts, that each MCO and PHP have an ongoing quality assessment and performance improvement program for the services it furnishes to its enrollees.

(2) Paragraphs (b) through (d) of this section set forth the basic elements, minimum performance levels, and performance improvement projects required for MCOs and PHPs.

(3) HCFA may specify standardized quality measures, and topics for performance improvement projects to be required by States in their contracts with MCOs and PHPs.

(b) *Basic elements of MCO and PHP quality assessment and performance improvement programs*. At a minimum, the State must require that each MCO and PHP comply with the following requirements:

(1) Achieve required minimum performance levels on standardized quality measures, in accordance with paragraph (c) of this section;

(2) Conduct performance improvement projects as described in

paragraph (d) of this section. These projects must achieve, through ongoing measurements and intervention, demonstrable and sustained improvement in significant aspects of clinical care and non-clinical care areas that can be expected to have a favorable effect on health outcomes and enrollee satisfaction; and

(3) Have in effect mechanisms to detect both underutilization and overutilization of services.

(4) Have in effect mechanisms to assess the quality and appropriateness of care furnished to enrollees with special health care needs.

(c) *Minimum performance levels.* (1) Each MCO and PHP must meet the following requirements:

(i) Annually measure its performance, using standard measures required by the State, consistent with the requirements of § 438.204(c), and report its performance to the State.

(ii) Achieve all minimum performance levels that the State establishes with respect to the standard measures.

(2) The State—

(i) May specify the standard measures in uniform data collection and reporting instruments; and

(ii) Must, in establishing minimum performance levels for the MCOs and PHPs—

(A) Include any minimum performance measures and levels specified by HCFA;

(B) Consider data and trends for both the MCOs and PHPs and fee-for-service Medicaid in that State; and

(C) Establish the minimum performance levels prospectively, each time a contract is initiated or renewed.

(d) *Performance improvement projects.* (1) Performance improvement projects are MCO and PHP initiatives that focus on clinical and non-clinical areas, and that involve the following:

(i) Measurement of performance using objective quality indicators.

(ii) Implementation of system interventions to achieve improvement in quality.

(iii) Evaluation of the effectiveness of the interventions.

(iv) Planning and initiation of activities for increasing or sustaining improvement.

(2) Each project must represent the entire Medicaid enrollee population to which the measurement specified in paragraph (d)(1)(i) of this section is relevant.

(3) The State must ensure that each MCO and PHP initiates each year one or more projects among the required clinical and non-clinical areas specified in paragraphs (d)(4) and (d)(5) of this

section. To ensure that the projects are representative of the entire spectrum of clinical and non-clinical areas associated with MCOs and PHPs, the State must specify the appropriate distribution of projects.

(4) Clinical areas include—

(i) Prevention and care of acute and chronic conditions;

(ii) High-volume services;

(iii) High-risk services; and

(iv) Continuity and coordination of care.

(5) Non-clinical areas include—

(i) Grievances and appeals;

(ii) Access to, and availability of, services; and

(iii) Cultural competence.

(6) In addition to requiring each MCO and PHP to initiate its own performance improvement projects, the State may require that an MCO or PHP—

(i) Conduct particular performance improvement projects on a topic specified by the State; and

(ii) Participate annually in at least one Statewide performance improvement project.

(7) For each project, each MCO and PHP must assess its performance using quality indicators that are—

(i) Objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research; and

(ii) Capable of measuring outcomes such as changes in health status, functional status, and enrollee satisfaction, or valid proxies of these outcomes.

(8) Performance assessment on the selected indicators must be based on systematic ongoing collection and analysis of valid and reliable data.

(9) Each MCO's and PHP's interventions must achieve improvement that is significant and sustained over time.

(10) Each MCO and PHP must report the status and results of each project to the State as requested.

(e) *Program review by the State.* (1) The State must review, at least annually, the impact and effectiveness of each MCO's and PHP's quality assessment and performance improvement program. The review must include—

(i) The Each MCO's and PHP's performance on the standard measures on which it is required to report; and

(ii) The results of the each MCO's and PHP's performance improvement projects.

(2) The State may require that an MCO or PHP have in effect a process for its own evaluation of the impact and effectiveness of its quality assessment and performance improvement program.

§ 438.242 Health information systems.

(a) *General rule.* The State must ensure that each MCO and PHP maintains a health information system that collects, analyzes, integrates, and reports data and can achieve the objectives of this subpart. The system should provide information on areas including, but not limited to, utilization, grievances, and disenrollments for other than loss of Medicaid eligibility.

(b) *Basic elements of a health information system.* The State must require, at a minimum, that each MCO and PHP comply with the following:

(1) Collect data on enrollee and provider characteristics as specified by the State, and on services furnished to enrollees through an encounter data system or such other methods as may be specified by the State.

(2) Ensure that data received from providers is accurate and complete by—

(i) Verifying the accuracy and timeliness of reported data;

(ii) Screening the data for completeness, logic, and consistency; and

(iii) Collecting service information in standardized formats to the extent feasible and appropriate.

(3) Make all collected data available to the State and upon request to HCFA, as required in this subpart.

Subpart E [Reserved]

Subpart F—Grievance System

§ 438.400 Statutory basis and definitions.

(a) *Statutory basis.* This subpart is based on sections 1902(a)(3), 1902(a)(4), and 1932(b)(4) of the Act.

(1) Section 1902(a)(3) requires that a State plan provide an opportunity for a fair hearing to any person whose claim for assistance is denied or not acted upon promptly.

(2) Section 1902(a)(4) requires that the State plan provide for methods of administration that the Secretary finds necessary for the proper and efficient operation of the plan.

(3) Section 1932(b)(4) requires Medicaid managed care organizations to establish internal grievance procedures under which Medicaid enrollees, or providers acting on their behalf, may challenge the denial of coverage of, or payment for, medical assistance.

(b) *Definitions.* As used in this subpart, the following terms have the indicated meanings:

Action means—

(1) In the case of an MCO or PHP or any of its providers—

(i) The denial or limited authorization of a requested service, including the type or level of service;

(ii) The reduction, suspension, or termination of a previously authorized service;

(iii) The denial, in whole or in part, of payment for a service;

(iv) For a resident of a rural area with only one MCO or PHP, the denial of a Medicaid enrollee's request to exercise his or her right to obtain services outside the network; or

(v) The failure to furnish or arrange for a service or provide payment for a service in a timely manner.

(vi) The failure, of an MCO or PHP, to resolve an appeal within the timeframes provided in § 408(i)(2).

(2) In the case of a State agency, the denial of a Medicaid enrollee's request for disenrollment. An appeal of this type is to the State Fair Hearing Office.

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

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

Grievance means an expression of dissatisfaction about any matter other than an action, as "action" is defined in this section. The term is also used to refer to the overall system that includes grievances and appeals handled at the MCO or PHP level and access to the State Fair Hearing process. (Possible subjects for grievances include, but are not limited to, the quality of care or services provided, and aspects of interpersonal relationships such as rudeness of a provider or employee, or failure to respect the enrollee's rights.)

Quality of care grievance means a grievance filed because the enrollee believes that any aspect of the care or treatment that he or she received failed to meet accepted standards of health care and caused or could have caused harm to the enrollee.

§ 438.402 General requirements.

(a) *The grievance system.* Each MCO and PHP must have a system that includes a grievance process, an appeal process, and access to the State's fair hearing system.

(b) *General requirements for the grievance system.* The MCO or PHP must—

(1) Base its grievance and appeal processes on written policies and procedures that, at a minimum, meet the conditions set forth in this subpart;

(2) Obtain the State's written approval of the policies and procedures before implementing them;

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

(4) Provide for its governing body to review and dispose of grievances and

resolve appeals, or make written delegation of this responsibility to a grievance committee;

(5) Ensure that punitive action is neither threatened nor taken against a provider who requests an expedited resolution, or supports an enrollee's grievance or appeal;

(6) Accept grievances and appeals, and requests for expedited disposition or resolution or extension of timeframes from the enrollee, from his or her representative, or from the provider acting on the enrollee's behalf and with the enrollee's written consent.

(7) Provide to the enrollee and to his or her representative the notices and information required under this subpart; and

(8) At the enrollee's request, refer for State review any quality of care grievance resolution with which the enrollee is dissatisfied.

(9) Require providers to give notice in accordance with § 438.404(d).

(c) *Filing requirements.*—(1) *Authority to file.* (i) An enrollee may file a grievance and an MCO or PHP level appeal, and may request a State fair hearing.

(ii) A provider, acting on behalf of the enrollee and with the enrollee's written consent, may file an appeal. A provider may not file a grievance or request a State fair hearing.

(2) *Timing.* (i) For an action as defined in § 438.400 (b)(1)(v), the enrollee or the provider may file an appeal whenever the entity has delayed access to the service to the point where there is a substantial risk that further delay will adversely affect the enrollee's health condition.

(ii) For all other actions, the State specifies a reasonable timeframe that may be no less than 20 days and not to exceed 90 days from the date on the MCO's or PHP's notice of action.

Within that timeframe—

(A) The enrollee or the provider may file an appeal; and

(B) In a State that does not require exhaustion of MCO and PHP level appeals, the enrollee may request a State fair hearing.

(3) *Procedures.* (i) The enrollee may file a grievance either orally or in writing and, as determined by the State, either with the State or with the MCO or the PHP.

(ii) The enrollee or the provider may file an appeal either orally or in writing, and unless he or she requests expedited resolution, must follow an oral filing with a written, signed, appeal.

§ 438.404 Notice of action.

(a) *Language and format requirements.* The notice must be in

writing and must meet the language and format requirements of § 438.10(b) and (c) of this chapter to ensure ease of understanding.

(b) *Content of notice.* The notice must explain the following:

(1) The action the MCO or PHP or its contractor has taken or intends to take.

(2) The reasons for the action.

(3) Any laws and rules that require or permit the action.

(4) The enrollee's or the provider's right to file an MCO or PHP appeal.

(5) The enrollee's right to request a State fair hearing.

(6) The enrollee's right to present evidence in person if he or she chooses.

(7) The procedures for exercising the rights specified in this paragraph.

(8) The circumstances under which expedited resolution is available and how to request it.

(9) The enrollee's right to have benefits continue pending resolution of the appeal or issuance of a fair hearing decision, if the enrollee or the provider timely files the appeal or the enrollee timely requests a State fair hearing.

(10) The circumstances under which the enrollee may be required to pay the costs of any services furnished while the appeal is pending if the final outcome is an adverse decision.

(11) How the enrollee may request continuation of benefits.

(12) How to contact the MCO or PHP to receive assistance in filing an appeal or requesting a State fair hearing.

(13) How to obtain copies of enrollee records, including records other than medical records.

(14) That the enrollee has the right to represent himself or herself, to use legal counsel, or to use a relative, or friend or other individual as spokesperson.

(15) That filing an appeal or requesting a State fair hearing will not negatively affect or impact the way the MCO and the PHP and their providers, or the State agency, treat the enrollee.

(c) *Timing of notice.* Except as provided in paragraph (d) of this section, the MCO or PHP must mail the notice within the following timeframes:

(1) For termination, suspension, or reduction of previously authorized Medicaid-covered services, within the timeframes specified in §§ 431.211, 431.213, and 431.214 of this chapter.

(2) For denial of payment, at the time of any action affecting the claim.

(3) For standard service authorization decisions that deny or limit services, within the timeframe specified in § 438.210(d)

(4) If the MCO or PHP extends the timeframe in accordance with § 438.210(d), it must—

(i) Give the enrollee written notice of the reason for the decision to extend the

timeframe and inform the enrollee of the right to file a grievance if he or she disagrees with that decision; and

(ii) Issue and carry out its determination as expeditiously as the enrollee's health condition requires and no later than the date the extension expires.

(5) For service authorization decisions not reached within the timeframes specified in § 438.210(d) (which constitutes a denial and is thus an adverse action), on the date that the timeframes expire.

(6) For expedited service authorization decisions, within the timeframes specified in § 438.210(e).

(d) *Special rule for subcontractors and providers who are not employees.*

(1) An MCO or PHP may permit its subcontractors and providers who are not employees to give enrollees notice that includes only the information specified in paragraphs (b)(4) through (b)(15) of this section.

(2) If the MCO or PHP elects the option provided in paragraph (d)(1) of this section, and receives an appeal on any action by the subcontractor or provider who is not an employee, the MCO or PHP must, in acknowledging the appeal, include the information required under paragraphs (b)(1) through (b)(3) of this section.

§ 438.406 Handling of grievances and appeals.

(a) *General requirements.* In handling grievances and appeals, each MCO and each PHP must meet the following requirements:

(1) Have an adequately staffed office that is designated as the central point for enrollee issues, including grievances and appeals.

(2) Establish an appeals process that meets the requirements of paragraph (b) of this section.

(3) Give enrollees any reasonable assistance in completing forms and taking other procedural steps. This includes providing interpreter services and toll-free numbers that have adequate TTY/TTD and interpreter capability.

(4) Ensure that the enrollee's communication is correctly classified as a "grievance" or an "appeal".

(5) Acknowledge receipt of each grievance and appeal.

(6) Ensure that each grievance and appeal—

(i) Is transmitted timely to staff who have authority to act upon it; and

(ii) Is investigated and disposed of or resolved in accordance with § 438.408.

(7) Ensure that the individuals who make decisions on grievances and appeals are individuals—

(i) Who were not involved in any previous level of review or decision-making; and

(ii) Who, if deciding any of the following, are health care professionals who have the appropriate clinical expertise in treating the enrollee's condition or disease.

(A) An appeal of a denial that is based on lack of medical necessity.

(B) A grievance regarding denial of expedited resolution of an appeal.

(C) A grievance or appeal that involves clinical issues.

(b) *Special requirements for appeals.* The process for appeals must consist of clearly explained steps that meet the following requirements:

(1) Include, for each step, timeframes that take account of the enrollee's health condition and provide for expedited resolution in accordance with § 438.410.

(2) Provide that oral inquiries about the opportunity to appeal are treated as appeals (to establish the earliest possible filing date for the appeal) and must be confirmed in writing, unless the enrollee or the provider requests expedited resolution.

(3) Ensure that the acknowledgment of an oral appeal specifies that, although the time allowed for the MCO or PHP to resolve the appeal has begun, unless the request is for expedited resolution, the MCO or PHP cannot complete the resolution until the enrollee or the provider submits the appeal in writing.

(4) Provide the enrollee a reasonable opportunity to present evidence, and allegations of fact or law, in person as well as in writing. (The MCO or PHP must inform the enrollee of the limited time available for this in the case of expedited resolution.)

(5) Provide the enrollee and his or her representative opportunity, before and during the appeals process, to examine the enrollee's case file, including medical records, and any other documents and records considered during the appeals process.

(6) Include, as parties to the appeal—

(i) The enrollee and his or her representative; or

(ii) The legal representative of a deceased enrollee's estate.

§ 438.408 Resolution and notification: Grievances and appeals.

(a) *Basic rule.* The MCO or PHP must dispose of each grievance and resolve each appeal, and provide notice, as expeditiously as the enrollee's health condition requires, within State-established timeframes that may not exceed the timeframes specified in this section.

(b) *Basis for decision.* The MCO or PHP must base the decision on the

record of the case, including all relevant Federal and State statutes, program regulations and policies, and any evidence presented under § 438.406(b)(4), in connection with the filing of the appeal.

(c) *Specific timeframes.*—(1) *Standard disposition of grievances.* For standard disposition of a grievance and notice to the affected parties, the timeframe is established by the State but may not exceed 90 days from the day the MCO or PHP receives the grievance.

(2) *Expedited disposition of grievances.* For a grievance on a denial of a request to expedite resolution of an appeal, the timeframe is 72 hours after receipt of the grievance.

(3) *Standard resolution of appeals.* For standard resolution of an appeal and notice to the affected parties, the timeframe is 30 days after the MCO or the PHP receives the appeal. This timeframe may be extended under paragraph (d) of this section.

(4) *Expedited resolution of appeals.* For expedited resolution of an appeal, the timeframe for resolution and notice to the enrollee is 72 hours after the MCO or PHP receives the appeal. This timeframe may be extended under paragraph (d) of this section.

(d) *Extension of timeframes.*—(1) *Limits on extension.* (i) For a grievance on denial of a request to expedite resolution of an appeal, the timeframe may not be extended.

(ii) For expedited resolution of an appeal, the MCO or PHP may extend the 72-hour timeframe by up to 14 calendar days only if the enrollee requests extension.

(iii) For standard resolution of an appeal or for a quality of care grievance, the MCO or PHP may extend the 30-day timeframe for up to 14 calendar days if—

(A) The enrollee requests extension; or

(B) The MCO or PHP shows (to the satisfaction of the State agency, upon its request) that there is need for additional information and how the delay is in the enrollee's interest.

(2) *Requirements following extension.* If the MCO or PHP extends the timeframes, it must—

(i) For any extension not requested by the enrollee, give the enrollee written notice of the reason for the delay and of the enrollee's right to file a grievance if he or she disagrees with the decision to extend the timeframe; and

(ii) For any extension, dispose of the grievance or resolve the appeal no later than the date on which the extension expires.

(e) *Format of notice.*—(1) *Grievances.* (i) For all written grievances and all

grievances that relate to quality of care, the MCO or PHP must provide a written notice of disposition.

(ii) For an oral grievance that does not relate to quality of care, the MCO may provide oral notice unless the enrollee requests that it be written.

(2) *Appeals.* (i) For all appeals, the MCO or PHP must provide written notice of disposition.

(ii) For notice of expedited resolution, the MCO or PHP must also provide oral notice.

(f) *Content of notice of MCO or PHP grievance disposition.* The written notice must explain the following:

(i) The disposition of the grievance.

(ii) The fact that, if dissatisfied with the disposition of a quality of care grievance, the enrollee has the right to seek further State review, and how to request it.

(g) *Content of notice of appeal resolution.* The written notice of the resolution must include the following:

(1) The title of the MCO or PHP contact for the appeal.

(2) The results of the resolution process and the date it was completed.

(3) A summary of the steps the MCO or the PHP has taken on the enrollee's behalf in resolving the issue.

(4) For appeals not resolved wholly in favor of the enrollees—

(i) The right to request a State Fair Hearing, and how to do so;

(ii) The right to request to receive benefits while the hearing is pending, and how to make the request; and

(iii) That the enrollee may be held liable for the cost of those benefits if the hearing decision upholds the MCO's or PHP's action.

(h) *Collaboration on State review of grievances.* The MCO or PHP must work with the State to dispose of the grievance if the State considers that the MCO or PHP response was insufficient.

(i) *Referral of adverse or delayed appeal decisions to the State Fair Hearing Office—(1) Basis for submission.* The MCO or PHP must submit to the State Fair Hearing Office the file and all supporting documentation—

(i) For any appeal that was subject to expedited resolution and for which the MCO or PHP—

(A) Reaches a decision that is wholly or partially adverse to the enrollee; or

(B) Fails to reach a decision within the timeframes specified in paragraph (i)(2) of this section.

(ii) For any appeal that was not expedited, at the request of the State.

(2) *Timeframes for decision—(i) Standard resolution.* For a standard resolution, the basic timeframe is 30 days from receipt of the appeal, and

may be extended for an additional 14 calendar days if the enrollee requests extension or the MCO or PHP justifies (to the State agency upon request) a need for additional information and how the extension is in the enrollee's interest.

(ii) *Expedited resolution.* For an expedited resolution, the basic timeframe is 72 hours from receipt of the appeal and may be extended for up to 14 calendar days, but only if the enrollee requests extension.

(3) *Timeframes for submission.* The timeframes for submission to the State Fair Hearing Office are as follows:

(i) For a standard resolution: 72 hours after the MCO or PHP receives the State's request.

(ii) For an expedited resolution: 24 hours after the MCO or PHP reaches an adverse decision, or the basic or extended timeframe for decision expires.

(j) *Requirements for State fair hearings—(1) Availability.* The State must permit the enrollee to request a State fair hearing within a reasonable time period specified by the State, but not less than 20 or in excess of 90 days if—

(i) The State requires exhaustion of the MCO or PHP level appeal procedures, from the date of the MCO's or PHP's notice of resolution; and

(ii) The State does not require exhaustion of the MCO or PHP level appeal procedures and the enrollee appeals directly to the State for a fair hearing, from the date on the MCO's or PHP's notice of action.

(2) *Parties.* The parties to the State fair hearing include the MCO or PHP as well as the enrollee and his or her representative or the representative of a deceased enrollee's estate.

(3) *Timeframes for decision.* The State agency must take final administrative action as follows:

(i) Other than as specified in paragraph (j)(3)(ii) of this section, within a period of time not to exceed 90 days minus the number of days taken by the MCO or PHP to resolve the internal appeal. This timeframe begins on the date the State receives the beneficiaries' request for a State Fair Hearing.

(ii) For service authorization appeals that meet the criteria for expedited resolution as set forth in § 438.410, as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of a fair hearing request from the enrollee, or the file from the MCO or PHP.

§ 438.410 Expedited resolution of grievances and appeals.

(a) *General rule.* Each MCO and PHP must establish and maintain an

expedited review process for grievances and appeals.

(b) *Requirements for grievances.* (1) The MCO or PHP must expedite disposition of grievances that pertain to denial of a request for expedited resolution of an appeal.

(2) The MCO or PHP may expedite disposition of other grievances, consistent with State guidelines.

(c) *Requirements for appeals.* Each MCO and PHP must meet the following requirements with respect to appeals:

(1) Establish a convenient and efficient means for an enrollee or a provider to request expedited resolution of an appeal;

(2) Provide expedited resolution of an appeal in response to an oral or written request if the MCO or PHP determines (with respect to a request from the enrollee) or the provider indicates (in making the request on the enrollee's behalf or supporting the enrollee's request) that taking the time for a standard resolution could seriously jeopardize the enrollee's life or health or ability to attain, maintain, or regain maximum function.

(3) Document all oral requests in writing; and

(4) Maintain the documentation in the case file.

(d) *Action following denial of a request for expedited resolution.* If the MCO or PHP denies a request for expedited resolution of an appeal, it must—

(1) Transfer the appeal to the timeframe for standard resolution, beginning the 30-day period as of the day it received the request for expedited resolution;

(2) Give the enrollee prompt oral notice of the denial, and follow up within two calendar days with a written notice that includes the following:

(i) Informs the enrollee of the right to—

(A) File a grievance if he or she is dissatisfied with the MCO's or PHP's decision not to expedite resolution of the appeal; or

(B) Resubmit the request with a provider's letter of support.

(ii) Explains that—

(A) If the enrollee files a grievance, the MCO or PHP will process the appeal using the 30-day timeframe for standard resolution; and

(B) If the enrollee resubmits the request with a provider's letter of support, the MCO or PHP will expedite resolution of the appeal.

(iii) Provides instructions about grievance procedures, including timeframes.

§ 438.414 Information about the grievance system.

(a) *To whom information must be furnished.* (1) Each MCO and PHP must provide the information specified in paragraph (b) of this section to enrollees and to all providers and subcontractors at the time they enter into a contract.

(2) Each MCO or PHP or, at State option, the State or its contracted representative must provide the information specified in paragraph (b) to all potential enrollees.

(b) *Required information.* The information that is provided under paragraph (a) of this section must explain the grievance system through a State-developed or State-approved description, in the format required under § 438.10(c), and must include the following:

(1) With respect to State fair hearing—

- (i) The right to hearing;
- (ii) The method for obtaining a hearing; and
- (iii) The rules that govern representation at the hearing.

(2) The right to file grievances and appeals.

(3) The requirements and timeframes for filing a grievance or appeal.

(4) The availability of assistance in the filing process.

(5) The right to represent himself or herself or to be represented by legal counsel or a relative or friend or other spokesperson.

(6) The toll-free numbers that the enrollee can use to file a grievance or an appeal by phone.

(7) The fact that filing a grievance or appeal or requesting a State fair hearing will not adversely affect or impact the way the MCO or the PHP and their providers or the State agency treat the enrollee.

(8) The fact that, when requested by the enrollee

(i) Benefits will continue if the enrollee files an appeal or a request for State fair hearing within the timeframes specified for filing; and

(ii) The enrollee may be required to pay the cost of services furnished while the appeal is pending, if the final decision is adverse to the enrollee.

(c) *Language, format, and timing requirements.* The information furnished under this section must meet the language and format requirements of § 438.10(b) and (c), and must be furnished to enrollees and potential enrollees at the times specified in § 438.10(e) through (h).

(d) *Aggregate information.* Upon request, the MCO or PHP must provide to enrollees, potential enrollees, and the general public, aggregate information based on the information required under § 438.416(d).

§ 438.416 Record keeping and reporting requirements.

Each MCO and PHP must comply with the following requirements, and in so doing must also comply with the confidentiality requirements of § 438.224.

(a) *Log.* Maintain a log of all grievances and appeals, showing the date of acknowledgment, the MCO's or PHP's decision, and the date of disposition or resolution.

(b) *Tracking.* Track each grievance and appeal until its final disposition or resolution, and classify them in terms of whether the disposition or resolution was standard or expedited.

(c) *Retention of records.* (1) Retain the record of each grievance and appeal, and its disposition or resolution in a central location, and accessible to the State, for at least 3 years.

(2) If any litigation, claim negotiation, audit, or other activity involving these records is initiated before the end of the 3-year period, retain the record until the later of the following:

- (i) The date the activity is completed and any issues arising from it are resolved.
- (ii) The end of the 3-year period.

(d) *Reporting.* As often as the State requests, but at least once a year, each MCO and PHP must analyze the records maintained under this paragraph and submit to the State a summary that includes the following information:

- (1) The number and nature of all grievances and appeals.
- (2) The timeframes within which they were acknowledged and disposed of or resolved.
- (3) The nature of the decisions.

§ 438.420 Continuation of benefits while the MCO or PHP appeal and the State Fair Hearing are pending.

(a) *Terminology.* As used in this section, "timely" filing means filing on or before the later of the following:

(1) The expiration of the timeframe specified by the State (in accordance with § 438.404(c)(3)) and communicated in the notice of action.

(2) The intended effective date of the MCO's or PHP's proposed action.

(b) *Continuation of benefits.* The MCO or PHP must continue the enrollee's benefits if—

- (1) The enrollee or the provider files the appeal timely;
- (2) The appeal involves the termination, suspension, or reduction of a previously authorized course of treatment;
- (3) The services were ordered by an authorized provider;
- (4) The period covered by the authorization has not expired; and

(5) The enrollee requests extension of benefits.

(c) *Reinstatement of benefits.* The MCO or PHP must reinstate the enrollee's benefits under any of the circumstances specified in § 431.231 of this chapter.

(d) *Duration of continued or reinstated benefits.* If the MCO or PHP continues or reinstates the enrollee's benefits while the appeal is pending, the following rules apply:

(1) The MCO or PHP must continue the benefits until one of the following occurs:

- (i) The enrollee withdraws the appeal.
- (ii) The MCO or PHP resolves the appeal in the enrollee's favor.

(iii) The State Fair Hearing Office issues a hearing decision on a request received directly from the enrollee or referred by the MCO or PHP.

(2) If the MCO or PHP appeals the decision or the State fair hearing decision is favorable to the enrollee, the MCO or PHP must restore regular benefits.

(e) *Enrollee responsibility for services furnished while the appeal is pending.* If the final resolution of the appeal is adverse to the enrollee, that is, upholds the MCO's or PHP's action, the MCO or PHP may recover the cost of the services furnished to the enrollee while the appeal is pending, to the extent that they were furnished solely because of the requirements of this section, and in accordance with the policy set forth in § 431.230(b) of this chapter.

§ 438.424 Effectuation of reversed appeal resolutions.

(a) *Services not furnished while the appeal is pending.* If the MCO or PHP, or the State fair hearing officer reverses a decision to deny, limit, or delay services that were not furnished while the appeal was pending, the MCO or PHP must authorize or provide the disputed services promptly, and as expeditiously as the enrollee's health condition requires.

(b) *Services furnished while the appeal is pending.* If the MCO or PHP, or the State fair hearing officer reverses a decision to deny authorization of services, and the enrollee received the disputed services while the appeal was pending, the MCO or the PHP or the State must pay for those services, in accordance with State policy and regulations.

§ 438.426 Monitoring of the grievance system.

(a) *Basis for monitoring.* The records that the MCOs and PHPs are required to maintain and summarize under § 438.416 provide the basis for

monitoring by the MCO or PHP, and by the State.

(b) *Responsibility for corrective action.* If the summaries required under paragraph (d) of § 438.416 reveal a need for changing the system, the MCO or the PHP must conduct an in-depth review, and take corrective action.

Subpart G—[Reserved]

Subpart H—Certifications and Program Integrity Provisions

§ 438.600 Statutory basis.

This subpart is based on sections 1902(a)(4) and 1902(a)(19) of the Act.

(a) Section 1902(a)(4) requires that the State plan provide for methods of administration that the Secretary finds necessary for the proper and efficient operation of the plan.

(b) Section 1902(a)(19) requires that the State plan provide the safeguards necessary to ensure that eligibility is determined and services are provided in a manner consistent with simplicity of administration and the best interests of the recipients.

§ 438.602 Basic rule.

As a condition for contracting and for receiving payment under the Medicaid managed care program, an MCO or PHP and its subcontractors must comply with the certification and program integrity requirements of this section.

§ 438.604 Data that must be certified.

(a) *Data certifications.* When State payments to the MCO or PHP are based on data submitted by the MCO or PHP, the State must require certification of the data as provided in § 438.606. The data that must be certified includes, but is not limited to, enrollment information, encounter data, and other information required by the State and contained in contracts, proposals, and related documents.

(b) *Certification of substantial compliance with contract.* Regardless of whether payment is based on data, each MCO and PHP must certify that it is in substantial compliance with its contract.

(c) *Additional certifications.* Certification is required, as provided in § 438.606, for all documents specified by the State.

§ 438.606 Source, content, and timing of certification.

(a) *Source of certification.* With respect to the data specified in § 438.604, the MCO or PHP must require—

(1) That subcontractors certify the data they submit to the MCO or PHP; and

(2) That one of the following certify the data the MCO or PHP submits to the State:

(i) The MCO's or PHP's Chief Executive Officer.

(ii) The MCO's or PHP's Chief Financial Officer.

(iii) An individual who has delegated authority to sign for, and who reports directly to, the MCO's or PHP's Chief Executive Officer or Chief Financial Officer.

(b) *Content of certification.* The certification must attest, based on best knowledge, information, and belief, as follows:

(1) To the accuracy, completeness and truthfulness of data.

(2) That the MCO or PHP is in substantial compliance with its contract.

(3) To the accuracy, completeness and truthfulness of documents specified by the State.

(c) *Timing of certification.* The MCO or PHP must submit the certification concurrently with the certified data or, in the case of compliance with the terms of the contract, when requesting payment.

§ 438.608 Program integrity requirements.

(a) *General requirement.* The MCO or PHP must have administrative and management arrangements or procedures, including a mandatory compliance plan, that are designed to guard against fraud and abuse.

(b) *Specific requirements.* The arrangements or procedures must include the following:

(1) Written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable Federal and State standards.

(2) The designation of a compliance officer and a compliance committee that are accountable to senior management.

(3) Effective training and education for the compliance officer and the organization's employees.

(4) Effective lines of communication between the compliance officer and the organization's employees.

(5) Enforcement of standards through well-publicized disciplinary guidelines.

(6) Provision of internal monitoring and auditing.

(7) Provision for prompt response to detected offenses, and for development of corrective action initiatives relating to the MCO's or PHP's contract.

Subpart I—Sanctions

§ 438.700 Basis for imposition of sanctions.

(a) Each State that contracts with an MCO must, and each State that contracts

with a PCCM may, establish intermediate sanctions, as specified in § 438.702, that it may impose if it makes any of the determinations specified in paragraphs (b) through (d) of this section. The State's determination may be based on findings from onsite survey, enrollee or other complaints, financial status, or any other source.

(b) An MCO acts or fails to act as follows:

(1) Fails substantially to provide medically necessary services that the MCO is required to provide, under law or under its contract with the State, to an enrollee covered under the contract.

(2) Imposes on enrollees premiums or charges that are in excess of the premiums or charges permitted under the Medicaid program.

(3) Acts to discriminate among enrollees on the basis of their health status or need for health care services. This includes termination of enrollment or refusal to reenroll a recipient, except as permitted under the Medicaid program, or any practice that would reasonably be expected to discourage enrollment by recipients whose medical condition or history indicates probable need for substantial future medical services.

(4) Misrepresents or falsifies information that it furnishes to HCFA or to the State.

(5) Misrepresents or falsifies information that it furnishes to an enrollee, potential enrollee, or health care provider.

(6) Fails to comply with the requirements for physician incentive plans, as set forth (for Medicare) in §§ 422.208 and 422.210 of this chapter.

(c) An MCO or a PCCM distributes directly, or indirectly through any agent or independent contractor, marketing materials that have not been approved by the State or that contain false or materially misleading information.

(d) An MCO violates any of the requirements in section 1903(m) of the Act and implementing regulations, or an MCO or a PCCM violates any of the requirements of section 1932 of the Act and implementing regulations. (For these violations, only the sanctions specified in § 438.702(a)(4) and (a)(5) may be imposed.)

§ 438.702 Types of intermediate sanctions.

(a) The types of intermediate sanctions that a State may impose under this subpart include the following:

(1) Civil money penalties in the amounts specified in § 438.704.

(2) Appointment of temporary management as provided in § 438.706. (The State may not impose this sanction on a PCCM.)

(3) Granting enrollees the right to terminate enrollment without cause. (The State must notify the affected enrollees of their right to disenroll.)

(4) Suspension of all new enrollment, including default enrollment, after the effective date of the sanction.

(5) Suspension of payment for recipients enrolled after the effective date of the sanction and until HCFA or the State is satisfied that the reason for imposition of the sanction no longer exists and is not likely to recur.

(b) State agencies retain authority to impose additional sanctions under State statutes or State regulations that address areas of noncompliance specified in § 438.700, as well as additional areas of noncompliance. Nothing in this subpart prevents State agencies from exercising that authority.

§ 438.704 Amounts of civil money penalties

(a) *General rule.* The limit on, or specific amount of, a civil money penalty the State may impose varies depending on the nature of the MCO's or PCCM's action or failure to act, as provided in this section.

(b) *Specific limits.* (1) The limit is \$25,000 for each determination under the following paragraphs of § 438.700:

(i) Paragraph (b)(1) (Failure to provide services).

(ii) Paragraph (b)(5) (Misrepresentation or false statements to enrollees, potential enrollees, or health care providers).

(iii) Paragraph (b)(6) (failure to comply with physician incentive plan requirements).

(iv) Paragraph (c) (Marketing violations).

(2) The limit is \$100,000 for each determination under paragraph (b)(3) (discrimination) or (b)(4) (Misrepresentation or false statements to HCFA or the State) of § 438.700.

(3) The limit is \$15,000 for each recipient the State determines was not enrolled because of a discriminatory practice under paragraph (b)(3) of § 438.700. (This is subject to the overall limit of \$100,000 under paragraph (b)(2) of this section).

(c) *Specific amount.* For premiums or charges in excess of the amounts permitted under the Medicaid program, the amount of the penalty is \$25,000 or double the amount of the excess charges, whichever is greater. The State must deduct from the penalty the amount of overcharge and return it to the affected enrollees.

§ 438.706 Special rules for temporary management.

(a) *Optional imposition of sanction.* The State may impose temporary

management if it finds (through onsite survey, enrollee complaints, financial audits, or any other means) that —

(1) There is continued egregious behavior by the MCO, including but not limited to behavior that is described in § 438.700, or that is contrary to any requirements of sections 1903(m) and 1932 of the Act;

(2) There is substantial risk to enrollees' health; or

(3) The sanction is necessary to ensure the health of the MCO's enrollees—

(i) While improvements are made to remedy violations under § 438.700; or

(ii) Until there is an orderly termination or reorganization of the MCO.

(b) *Required imposition of sanction.*

(1) The State must impose temporary management (regardless of any other sanction that may be imposed) if it finds that an MCO has repeatedly failed to meet substantive requirements in section 1903(m) or 1932 of the Act, or this subpart. The State must also grant enrollees the right to terminate enrollment without cause, as described in § 438.702(a)(3).

(c) *Hearing.* The State may not delay imposition of temporary management to provide a hearing before imposing this sanction.

(d) *Duration of sanction.* The State may not terminate temporary management until it determines that the MCO can ensure that the sanctioned behavior will not recur.

§ 438.708 Termination of an MCO or PCCM contract.

A State has the authority to terminate an MCO or PCCM contract and enroll that entity's enrollees in other MCOs or PCCMs, or provide their Medicaid benefits through other options included in the State plan, if the State determines that the MCO or PCCM—

(a) Has failed to carry out the substantive terms of its contract; or

(b) Has failed to meet applicable requirements in sections 1932, 1903(m), and 1905(t) of the Act.

§ 438.710 Due process: Notice of sanction and pre-termination hearing.

(a) *Notice of sanction.* Before imposing any of the alternative sanctions specified in this subpart, the State must give the affected entity timely written notice that explains—

(1) The basis and nature of the sanction; and

(2) Any other due process protections that the State elects to provide.

(b) *Pre-termination hearing.*—(1) *General rule.* Before terminating an MCO or PCCM contract under § 438.708,

the State must provide the entity a pretermination hearing.

(2) *Procedures.* The State must—

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

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

(iii) For an affirming decision, give enrollees of the MCO or PCCM notice of the termination and information, consistent with § 438.10, on their options for receiving Medicaid services following the effective date of termination.

§ 438.722 Disenrollment during termination hearing process.

After a State notifies an MCO or PCCM that it intends to terminate the contract, the State may—

(a) Give the entity's enrollees written notice of the State's intent to terminate the contract; and

(b) Allow enrollees to disenroll immediately without cause.

§ 438.724 Public notice of sanction.

(a) *Content of notice.* The State must publish a notice that describes the intermediate sanction imposed, explains the reasons for the sanction and specifies the amount of any civil money penalty.

(b) *Publication of notice.* The State must publish the notice—

(1) No later than 30 days after it imposes the sanction; and

(2) As a public announcement in—

(i) The newspaper of widest circulation in each city within the MCO's service area that has a population of 50,000 or more; or

(ii) The newspaper of widest circulation in the MCO's service area, if there is no city with a population of 50,000 or more in that area.

§ 438.726 State plan requirement.

The State plan must provide for the State to monitor for violations that involve the actions and failures to act specified in this section and to implement the provisions of this section.

§ 438.730 Sanction by HCFA: Special rules for MCOs with risk contracts.

(a) *Basis for sanction.* (1) A State agency may recommend that HCFA impose the denial of payment sanction on an MCO with a comprehensive risk contract if the MCO acts or fails to act as specified in § 438.700(b)(1) through (b)(6).

(2) The State agency's recommendation becomes HCFA's recommendation unless HCFA rejects it within 15 days of receipt.

(b) *Notice of sanction.* If HCFA accepts the recommendation, the State agency and HCFA take the following actions:

(1) The State agency—

(i) Gives the MCO written notice of the proposed sanction;

(ii) Allows the MCO 15 days from date of receipt of the notice to provide evidence that it has not acted or failed to act in the manner that is the basis for the recommended sanction;

(iii) May extend the initial 15-day period for an additional 15 days if, before the end of the initial period, the MCO submits a written request that includes a credible explanation of why it needs additional time; and

(iv) May not grant an extension if HCFA determines that the MCO's conduct poses a threat to an enrollee's health or safety.

(2) HCFA conveys the determination to the OIG for consideration of possible imposition of civil money penalties under section 1903(m)(5)(A) of the Act and part 1003 of this title. In accordance with the provisions of part 1003, the OIG may impose civil money penalties in addition to, or in place of, the sanctions that may be imposed under this section.

(c) *Informal reconsideration.* (1) If the MCO submits a timely response to the notice of sanction, the State agency—

(i) Conducts an informal reconsideration that includes review of the evidence by a State agency official who did not participate in the original recommendation; and

(ii) Gives the MCO a concise written decision setting forth the factual and legal basis for the decision.

(2) The State agency decision under paragraph (c)(1) of this section, forwarded to HCFA, becomes HCFA's decision unless HCFA reverses or modifies the decision within 15 days from date of receipt.

(3) If HCFA reverses or modifies the State agency decision, the agency sends the MCO a copy of HCFA's decision.

(d) *Effective date of sanction.* (1) If the MCO does not seek reconsideration, a sanction is effective 15 days after the date of the notice of sanction under paragraph (b) of this section.

(2) If the MCO seeks reconsideration, the following rules apply:

(i) Except as specified in paragraph (d)(2)(ii) of this section, the sanction is effective on the date specified in HCFA's reconsideration notice.

(ii) If HCFA, in consultation with the State agency, determines that the MCO's

conduct poses a serious threat to an enrollee's health or safety, HCFA may make the sanction effective earlier than the date of HCFA's reconsideration decision under paragraph (c) of this section.

(e) *HCFA's role.* HCFA retains the right to independently perform the functions assigned to the State agency under this section.

Subpart J—Conditions for Federal Financial Participation

§ 438.802 Basic requirements.

FFP is available in expenditures for payments under an MCO contract only for the periods during which the following conditions are met:

(a) The contract—

(1) Meets the requirements of this part; and

(2) Is in effect.

(b) The MCO and its subcontractors are in substantial compliance with the physician incentive plan requirements set forth in §§ 422.208 and 422.210 of this chapter.

(c) The MCO and the State are in substantial compliance with the requirements of the MCO contract and of this part.

§ 438.806 Prior approval.

(a) *Comprehensive risk contracts.* FFP is available under a comprehensive risk contract only if—

(1) The Regional Office has confirmed that the contractor meets the definition of MCO or is one of the entities described in paragraphs (a)(2) through (a)(5) of § 438.6; and

(2) The contract meets all the requirements of section 1903(m)(2)(A) of the Act, the applicable requirements of section 1932 of the Act, and the implementing regulations in this part.

(b) *MCO contracts.* Prior approval by HCFA is a condition for FFP under any MCO contract that extends for less than one full year or that has a value equal to, or greater than, the following threshold amounts:

(1) For 1998, the threshold is \$1,000,000.

(2) For subsequent years, the amount is increased by the percentage increase in the consumer price index for all urban consumers.

(c) FFP is not available in an MCO contract that does not have prior approval from HCFA under paragraph (b) of this section.

§ 438.808 Exclusion of entities.

(a) *General rule.* FFP is available in payments under MCO contracts only if the State excludes from such contracts any entities described in paragraph (b) of this section.

(b) *Entities that must be excluded.* (1) An entity that could be excluded under section 1128(b)(8) of the Act as being controlled by a sanctioned individual.

(2) An entity that has a substantial contractual relationship as defined in § 431.55(h)(3), either directly or indirectly, with an individual convicted of certain crimes as described in section 1128(b)(8)(B) of the Act.

(3) An entity that employs or contracts, directly or indirectly, for the furnishing of health care, utilization review, medical social work, or administrative services, with one of the following:

(i) Any individual or entity excluded from participation in Federal health care programs under either section 1128 or section 1128A of the Act.

(ii) Any entity that would provide those services through an excluded individual or entity.

§ 438.810 Expenditures for enrollment broker services.

(a) *Terminology.* As used in this section—

Choice counseling means activities such as answering questions and providing information (in an unbiased manner) on available MCO, PHP, or PCCM delivery system options, and advising on what factors to consider when choosing among them and in selecting a primary care provider;

Enrollment activities means activities such as distributing, collecting, and processing enrollment materials and taking enrollments by phone or in person; and

Enrollment broker means an individual or entity that performs choice counseling or enrollment activities, or both.

Enrollment services means choice counseling, or enrollment activities, or both.

(b) *Conditions that enrollment brokers must meet.* State expenditures for the use of enrollment brokers are considered necessary for the proper and efficient operation of the State plan and thus eligible for FFP only if the broker and its subcontractors meet the following conditions:

(1) *Independence.* The broker and its subcontractors are independent of any MCO, PHP, PCCM, or other health care provider in the State in which they provide enrollment services. A broker or subcontractor is not considered "independent" if it—

(i) Is an MCO, PHP, PCCM or other health care provider in the State

(ii) Is owned or controlled by an MCO, PHP, PCCM, or other health care provider in the State; or

(iii) Owns or controls an MCO, PHP, PCCM or other health care provider in the State.

(2) *Freedom from conflict of interest.* The broker and its subcontractor are free from conflict of interest. A broker or subcontractor is not considered free from conflict of interest if any person who is the owner, employee, or consultant of the broker or subcontractor or has any contract with them—

(i) Has any direct or indirect financial interest in any entity or health care provider that furnishes services in the State in which the broker or subcontractor provides enrollment services;

(ii) Has been excluded from participation under title XVIII or XIX of the Act;

(iii) Has been debarred by any Federal agency; or

(iv) Has been, or is now, subject to civil money penalties under the Act.

(c) *Prior approval.* The initial contract or memorandum of agreement (MOA) for services performed by the broker has been reviewed and approved by HCFA before the effective date of the contract or MOA.

§ 438.812 Costs under risk and nonrisk contracts.

(a) Under a risk contract, the total amount the State agency pays for carrying out the contract provisions is a medical assistance cost.

(b) Under a nonrisk contract—

(1) The amount the State agency pays for the furnishing of medical services to eligible recipients is a medical assistance cost; and

(2) The amount the State agency pays for the contractor's performance of other functions is an administrative cost.

§ 438.814 Limit on payments in excess of capitation rates.

FFP is not available for payments pursuant to risk corridors or incentive arrangements that exceed 105 percent of that portion of the aggregate amount approved capitation payments attributable to the enrollees or services covered by the risk corridor or incentive management.

PART 440—SERVICES: GENERAL PROVISIONS

1. The statutory citation for part 440 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. In subpart A, a new § 440.168 is added, to read as follows:

§ 440.168 Primary care case management services.

(a) Primary care case management services means case management related services that—

(1) Include location, coordination, and monitoring of primary health care services; and

(2) Are provided under a contract between the State and either of the following:

(i) A PCCM who is a physician or may, at State option, be a physician assistant, nurse practitioner, or certified nurse-midwife.

(ii) A physician group practice, or an entity that employs or arranges with physicians to furnish the services.

(b) Primary care case management services may be offered by the State—

(1) As a voluntary option under the regular State plan program; or

(2) On a mandatory basis under section 1932 (a)(1) of the Act or under section 1915(b) or section 1115 waiver authority.

PART 447—PAYMENTS FOR SERVICES

1. The authority citation for part 447 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. A new § 447.46 is added, to read as follows:

§ 447.46 Timely claims payment by MCOs.

(a) *Basis and scope.* This section implements section 1932(f) of the Act by specifying the rules and exceptions for prompt payment of claims by MCOs.

(b) *Definitions.* “Claim” and “clean claim” have the meaning given those terms in § 447.45.

(c) *Contract requirements.*—(1) *Basic rule.* A contract with an MCO must provide that the organization will meet

the requirements of paragraphs (d)(2), (d)(3) of § 447.45, and abide by the specifications of paragraphs (d)(5) and (d)(6) of that section..

(2) *Exception.* The MCO and its providers may, by mutual agreement, establish an alternative payment schedule.

(3) Any alternative schedule must be stipulated in the contract.

§ 447.53 [Amended]

3. In § 447.53(b), the following changes are made:

A. In paragraph (b) introductory text, the parenthetical phrase is removed.

B. Paragraph (b)(6) is removed.

4. A new paragraph (e) is added to read as follows:

(e) No provider may deny services, to an individual who is eligible for the services, on account of the individual's inability to pay the cost sharing.

§ 447.58 [Amended]

5. In § 447.58, “Except for HMO services subject to the copayment exclusion in § 447.53(b)(6), if “ is removed and “If” is inserted in its place.

6. A new § 447.60 is added to subpart A to read as follows:

§ 447.60 Cost-sharing requirements for services furnished by MCOs.

Contracts with MCOs must provide that any cost-sharing charges the MCO imposes on Medicaid enrollees are in accordance with the requirements set forth in §§ 447.50 and 447.53 through 447.58 for cost-sharing charges imposed by the State agency.

§ 447.361 [Removed]

Section 447.361 is removed.

(Catalog of Federal Domestic Assistance Program No. 93778, Medical Assistance)

Dated: December 21, 2000.

Robert A. Berenson,

Acting Deputy Administrator, Health Care Financing Administration.

Dated: December 20, 2000.

Donna E. Shalala,

Secretary.

[FR Doc. 01-1447 Filed 1-18-01; 8:45 am]

BILLING CODE 4120-01-P