B. State Responsibilities (Subpart B)

Proposed subpart B set forth the State option to implement mandatory managed care through a State plan amendment, as well as other State responsibilities in connection with managed care, such as beneficiary choice, provisions for disenrollment, continuity of care, conflict of interest standards, limits on payment, and monitoring.

1. State Plan Requirements (Proposed §438.50)

Proposed §438.50 permits State agencies to enroll most Medicaid beneficiaries in MCOs or PCCMs on a mandatory basis without a waiver under sections 1915(b) or 1115 of the Act, and without being out of compliance with the provisions in section 1902 of the Act for Statewideness, comparability, or freedom of choice. Paragraphs (b) and (c) set forth the requirements for these programs and the assurances that States must provide. Paragraphs (d) and (e) identified populations that cannot be mandatorily enrolled in an MCO or PCCM and address the requirements for a default enrollment mechanism.

Comment: Two commenters viewed proposed §438.50(b)(2) as a first step in better understanding how managed care organizations pay physicians and recognize that payment to providers in managed care is controlled by the managed care organizations. The commenters recommended that CMS also require managed care plans to specify the manner in which increases in Medicaid payment for services will be passed through to intended physicians.

Response: Section 438.50(b)(2) is a general requirement that a State plan amendment under this authority specify the payment arrangement between the State and its managed care contractor. This section does not require the submission of any information

regarding payment mechanisms or amounts between MCOs and their subcontracting providers. CMS does not review these subcontracts. We do not believe that it is necessary to impose these requirements beyond requiring that payments to providers be sufficient to encourage sufficient provider participation.

Comment: Several commenters supported the provisions for public involvement in the design and implementation of the State plan amendment and on-going public participation after implementation of the State plan amendment as proposed in §438(b)(4). One commenter opposed the requirements for public involvement citing that this requirement is not applied to any other State plan amendment and requires additional State resources. The commenter suggested that latitude be given to States with history of public appearance.

Response: While not all State plan amendments require public involvement, this language is consistent with the public notice requirements of the State Children's Health Insurance Program and reflects the requirements under the section 1115 of the Act demonstration authority.

Comment: Several commenters suggested adding PIHPs and PAHPs, as well as MCOs and PCCMs, to the introductory clause in §438.50(d), which describes populations that cannot be mandatorily enrolled in an MCO or PCCM under the authority in section 1932(a) of the Act and §438.50(a).

Response: Section 1932(a)(1) prohibits States from mandatorily enrolling specified groups of beneficiaries in MCOs and PCCMs under the authority in that section, which is implemented in §438.50. This section of the statute and regulations only permit States to enroll beneficiaries in MCOs and PCCMs, even if the beneficiaries are not in an

exempted group. Since this provision is an exception to authority that only permits enrollments in MCOs or PCCMs, it is not appropriate to reference PIHPs or PAHPs in this provision. Unless the PAHP also qualifies as a PCCM, and thus, would already be covered by this latter term, enrollment in a PIHP or PAHP may only be mandated under waiver authority in sections 1915(b) or 1115(a) of the Act.

Comment: We received several comments on the enrollment by default in proposed §438.50(f) with one commenter applauding CMS' effort to maintain existing relations that recipients may have with providers. Another commenter recommended that CMS delete the specific requirements to take relationships with existing providers into account. Two commenters believe that the default enrollment process discourages health plans and providers who have not traditionally served Medicaid beneficiaries. Another commenter inquired as to how the default enrollment process should function if the individual's provider is part of more than one MCO network. One commenter recommended that the default enrollment process consider geographic location, family relations and special needs of the individual.

Response: Section 1932(a)(4)(D) of the Act clearly states that the default mechanism must consider existing relationships or "relationships with providers that have traditionally served beneficiaries under this title." We believe that the States should have the flexibility to consider other factors in the design of a default enrollment process that best meets the needs of the individual, including factors suggested by the commenter. Therefore, we have not added any new requirements to §438.50(f).

Comment: A few commenters requested clarification of the phrase in proposed §438.50(f)(2), "must distribute the recipients equitably." One commenter recommended

that the regulation be restated to explicitly grant States the right to determine what is an equitable distribution.

Response: This provision requires States to have a process whereby they can assign beneficiaries to MCOs or PCCMs, if the beneficiary does not exercise his or her right to choose. When the State is unable to make an assignment based on an existing provider-recipient relationship or a relationship with a provider that has traditionally serviced the Medicaid population, it must do so by distributing "the recipients equitably among qualified MCOs and PCCMs available to enroll them." The State is the only party that can determine when it is unable to make an assignment based on its records of an existing relationship or traditional service to the Medicaid population. Further, we agree with the commenter that the State is best suited to determine how to make an equitable distribution of default-assigned beneficiaries. This may be done through a specific assignment algorithm or as a simple distribution among all qualified providers up to any limits established. We have added language to the text of §438.50(f)(2) to clarify this.

Comment: To help ensure the best quality of care, one commenter recommended that the proposed requirement for "existing provider-recipient relations" in §438.50(f)(3) be based on the provider being the main source of Medicaid services for the recipient in the last 2 years.

Response: We believe that a 1-year period allowed in §438.50(f)(3) is sufficiently long to identify an existing provider-recipient relationship. This provision only applies to the default assignment of individuals who did not take the opportunity to choose their MCO or PCCM, and we would assume that most individuals would make this selection if their relationship with a particular provider is important to them.

Comment: One commenter expressed concerns that these provisions in §438.50 do not directly address the importance of ensuring that families are able to choose among health plans and health care providers when enrolling in mandatory managed care plan. The commenter believes that the process of auto-assigning can cause problems with the assignment of different family members of the same family to numerous providers and the assignment of certain individuals to providers many miles away and recommended that States be required to make every effort to ensure that families make their own selections.

Response: Through a mandatory assignment under §438.50(f), or any mandatory managed care arrangement under a waiver authority, it is possible that individuals in a family may be assigned to different providers. We do not believe that this should be prohibited, since the arrangement may be in the best interest of the individuals in the family based on their specific health care needs. If this assignment is problematic, all enrollees are free to disenroll without cause during the first 90 days of their enrollment period. Consequently, we do not believe any changes are warranted in this provision.

2. Choice of MCOs, PIHPs, PAHPs, and PCCMs (Proposed §438.52)

Proposed §438.52 implements the requirement in section 1932(a)(3) of the Act that States must permit an individual to choose from at least two MCOs or PCCMs, but would have permitted States to offer a single MCO in a rural area under certain conditions, and to offer a single HIO in certain counties.

Comment: Several commenters were concerned about the impact of these regulations on States with a single carve-out PIHP contract, such as a mental health carve-out in a non-rural area, because the requirement for choice in this section would appear to

prohibit this type of program.

Response: Although we are extending the choice requirement in §438.52 to PIHPs and PAHPs under the authority of this regulation, the Secretary will continue to have the discretionary authority to grant waivers for the operation of managed care programs contracting with single PIHPs or PAHPs on a case-by-case basis.

As under current provisions, these entities can operate under waivers of the freedom of choice requirement in section 1902(a)(23) of the Act, which permits a State to establish or continue a program. For the purposes of PIHPs and PAHPs, this waiver could extend to the requirement for choice in section 1932(a)(3) of the Act. All requirements that apply to PIHPs and PAHPs, including the choice requirement, are based only upon the regulatory authority for the existence of these entities, which is derived from section 1902(a)(4) of the Act, which can be waived under section 1915(b). The waiver would not be possible for MCOs or PCCMs since this section of the Act cannot be waived under section 1915(b).

Therefore, under these rules, as before, CMS can grant States a waiver to operate a program with a single PIHP or PAHP, in a rural or non-rural area.

Comment: One commenter pointed out that a State could not restrict enrollment in one plan as a sanction in non-rural areas where only two plans exist, because the State would not be in compliance with this requirement for choice.

Response: The commenter is correct that a State cannot impose a sanction that would leave only one plan available in a non-rural area unless the State then offers fee-for-service as an alternative.

Comment: A few commenters suggested there should be no exception to allow a

State to limit choice in rural areas. Another commenter felt that allowing a choice in a rural area of two primary care providers as opposed to two managed care systems, would limit choices that might in fact be otherwise available to an enrollee.

Response: The exception allowing a State agency to restrict choice of coverage to a single MCO or PCCM system in rural areas is specified in section 1932(a)(3)(B) of the Act and cannot be revoked by this regulation. Even without the rural exception to the choice requirement permitted by section 1932(a)(3)(B), a State may limit a beneficiary's freedom of choice of providers in a rural or any other area through a waiver under section 1115 or 1915(b) of the Act, or a State plan amendment under section 1932(a)(1) of the Act. Both these waivers and the exception permitted under this rule may have the impact of limiting beneficiary choices, which would otherwise be available, as suggested by the commenter. However, the limitation in this rule is specifically authorized by section 1932(a)(3) of the Act.

We have specified conditions that must be met in order for this exception to be implemented. These include the requirement in §438.52(b)(2) that a beneficiary in a rural area who has been receiving services from a provider that is not part of the managed care network can receive out-of-plan treatment from that provider on a limited basis, as specified in that paragraph. Thus, we believe that the statute and this final rule contain sufficient beneficiary protections when the choice of managed care entity is restricted in rural areas.

Comment: One commenter was concerned that rural area PIHPs and PAHPs that do not include primary care services would not qualify for a rural exception because of the requirement to permit beneficiaries to choose from at least two physicians or case

managers.

Response: If either of these entities operating in a rural area do not include primary care services, then the requirement would not apply to them. These primary care services would be available through another source.

Comment: One commenter was concerned about what the commenter saw as a contradiction in the preamble in the statement that, allowing beneficiaries in a single rural plan to choose another primary care provider in the network would make it unnecessary for a State agency to operate a parallel fee-for-service system for those individuals who disenroll for cause.

Response: The commenter is correct that this statement is misleading, and a State may not always be able to be relieved from operating a fee-for-service system in this situation. The State may be obligated to cover out-of-network services on a FFS basis in the situations described in §438.52(2)(b)(ii)(A) through (b)(ii)(D). Further, enrollees in a program operated under the rural exception to the choice requirement, have the right to disenroll from their primary care providers, but not necessarily from the single entity providing health care in the rural area (except for instances when the enrollee moves out of the entity's service area). When the enrollee no longer resides in the rural area served by the single entity, he or she may be required to re-enroll in a managed care entity serving his or her new area of residence.

However, the commenter is correct that there may always be individual instances when States must maintain the ability to make FFS payments to providers even if an entire parallel FFS system is no longer necessary.

Comment: There were several commenters who appreciated requiring MCOs to

solicit enrollment of providers who are the source of service to a new enrollee, and to transition the enrollee within 60 days to other providers in the MCO network if the provider chooses not to participate. These commenters were concerned that rural area enrollees would otherwise remain out-of-network indefinitely. One commenter suggested a transition period shorter than 60 days and a few suggested a longer period. Many commenters felt that it was not appropriate to require a rural provider to join an MCO in order to continue to serve a patient with whom there was a prior relationship, particularly for pregnant women. They indicated belief that rural providers would choose not to enroll and, therefore, enrollees' choices would be severely restricted. Some commenters questioned if this section meets the requirement of section1396u-2(a)(3)(B)(ii) U.S.C. to allow for consideration of when using an out-of-plan provider is "appropriate." Some commenters opposed requiring MCOs to offer contracts to "any willing provider" because it would prevent MCOs from building networks that are the correct composition for their enrollees and would undermine the financial viability of MCO networks.

Response: We believe that in establishing the "appropriate circumstances" for allowing an enrollee to go out of network when there is a rural exception to choice, we need to balance the needs of enrollees with supporting good managed care practices. By requiring an MCO to offer a contract to any qualified provider who is the main source of service to the recipient, we prohibit the MCO from barring the client's access to that provider. The 60-day period provides sufficient time to assure that a provider has the option to continue to serve an enrollee with whom they have an existing relationship. Allowing a recipient to continue indefinitely (that is, as long as an acute medical condition exists) to see a non-participating provider could encourage providers to not contract with

MCOs and not continue their participation in the Medicaid program. We especially want to encourage, rather than discourage, the continued participation of providers who treat pregnant women, and we believe that this provision helps to accomplish that goal.

We disagree with the commenter that this provision requires MCOs to offer contracts to "any willing provider." Section 438.52(b)(2)(ii)(*B*)(2) specifically recognizes that a provider "may not meet the qualification requirements to join" the managed care network. If this is the case, there is no requirement that the provider be offered a contract, and the beneficiary must be transitioned into the managed care network.

Comment: Two commenters were concerned that the definition of “rural” at §438.52(b)(3) does not recognize that a Metropolitan Statistical Area may be largely rural although it has a large city, and due to the rural nature outside the city it would be appropriate for an exemption to the choice of two MCOs requirement. They suggested that the State should apply its own definition of “rural” subject to approval of CMS.

Response: We initially proposed three possible definitions of rural, and asked for comments. There was no clear consensus among the comments we received at that time, and CMS decided to use the single definition of rural based on being outside of an MSA. We believe that this definition best assures that States can use the exemption when appropriate but it reasonably limits the extent to which an area is considered rural, and is consistent with the Medicare definition for the purpose of defining rural hospitals.

3. Enrollment and disenrollment (Proposed §438.56)

Proposed §438.56 implements the provision in section 1932(a)(4) of the Act, and sets forth a number of requirements relating to enrollment and disenrollment in Medicaid

managed care programs.

Comment: One commenter questioned the authority to apply the provisions of this section to voluntary managed care programs.

Response: Section 1932(a)(4) of the Act contains new requirements that apply to the enrollment and disenrollment of beneficiaries in MCOs and PCCMs. In addition to applying directly to the mandatory programs under section 1932(a)(1)(A) of the Act, these requirements are incorporated under section 1903(m)(2)(A) of the Act for MCOs and section 1905(t) of the Act for PCCMs. In addition, through this regulation we are extending these provisions to PIHPs and PAHPs.

Comment: Several commenters were pleased that the proposed §438.56(b) was consistent with the Medicare+Choice requirements restricting disenrollment by a plan. One commenter was concerned that there was no guidance as to what would constitute acceptable grounds for disenrollment.

Response: We believe that §438.56(b)(2) clearly identifies the reasons an MCO, PIHP, PAHP, or PCCM may not request disenrollment of a beneficiary. We have not provided other limits as long as beneficiaries are not disenrolled for these reasons. States may wish to establish specific instances in which entities may request disenrollment of a beneficiary in their contract provisions.

However, we note that §438.56(b)(2) as set forth in the proposed rule omitted the word "adverse," describing a change in an enrollee's health status, as contained in the prior section governing disenrollment by the plan in §434.27(a)(2). We inadvertently omitted this term, and we have inserted "adverse" in the final rule to clarify that the prohibition on requests for disenrollment under this section applies only to adverse changes in health

status, not where an enrollee's health status has improved.

Comment: Several commenters expressed concern that the ability to disenroll without cause during the 90 days following initial enrollment would disrupt continuity of care and was contrary to HEDIS reporting timeframes. Several other commenters were concerned that 90 days was not enough time and there should be more flexibility to change without cause.

Response: Under section 1932(a)(4)(A) of the Act, beneficiaries must be able to disenroll without cause from an MCO or PCCM within the first 90 days of initial enrollment. We have no authority to modify this requirement by this regulation, but we believe that represents a reasonable time period for enrollees to decide whether the managed care entity in which they are enrolled will best meet their needs.

Comment: One commenter suggested that all States with ongoing programs should be required to provide a right to disenroll without cause, immediately upon implementation of these regulations. The commenter also suggested that disenrollments for cause should be applied retroactively.

Response: Nearly every State (that is not operating under the authority of a section 1115 demonstration) has already implemented the BBA rules regarding enrollment and disenrollment in accordance with the guidance contained in the letter to all State Medicaid Directors letter dated January 21, 1998. As discussed elsewhere, provisions of this rule will become effective 60 days following publication of this final rule and must be implemented by 1 year from the effective of this final rule.

We believe that an automatic disenrollment without cause for all of the over 25 million Medicaid managed care enrollees upon implementation of the regulation would

create a chaotic situation disrupting current patterns of care, and is not justified by any evidence of problems in States' existing Medicaid managed care programs. We do not understand how the commenter envisions implementing retroactive disenrollments for cause, but we do not believe there is any justification for the suggested provision.

Comment: Many commenters suggested that homelessness or being a migrant worker should be added as a cause for disenrollment at any time.

Response: We do not believe it is necessary to add these conditions as a cause for disenrollment. A beneficiary in one of these circumstances, like all other Medicaid enrollees, is entitled to disenroll, without cause for the first 90 days of enrollment in an MCO, PIHP, PAHP, or PCCM. Further, he or she may still disenroll for cause after that date, if one of the conditions in §438.56(d)(2) listed is met. Section 438.56(d)(2)(i) specifies that an enrollee's movement out of an MCO, PIHP, PAHP, or PCCM service area is one of the required examples of cause for disenrollment. We believe that this option will often be available to migrant workers. In addition, a State may include additional reasons, such as homelessness as a cause for disenrollment under §438.56(d)(2)(iv).

Comment: One commenter was supportive of the reasons allowed for disenrollment with cause. Another commenter was concerned that the broad definition of cause for other reasons at §§ 438.56(d)(2)(iv) was too broad and could lead to disenrollment on demand, particularly if MCOs may approve disenrollment through the grievance process.

Response: CMS has specified three specific circumstances where cause for disenrollment exists and permitted States to develop other reasons, including but limited to, the examples in §438.56(d)(iv). It is not our intent in this provision to permit

disenrollment on demand. States will make determinations on request for disenrollment based on these requirements and any others they select, and beyond these limited requirements, have the flexibility to implement this provision as best serves their beneficiaries and the Medicaid program.

Comment: One commenter suggested that the timeframe for processing disenrollments should be more flexible to accommodate situations where more time is needed to make a determination.

Response: We believe that the fixed timeframe will assure that all information is properly collected and evaluated in a timely fashion. Making the timeframe flexible could create an incentive to delay in accumulating necessary information. This timeframe reflects the time permitted for the determinations previously, and we do not believe it was problematic.

Comment: One commenter suggested that the requirement in §§438.56(f)(1), that enrollees be given written notice of their disenrollment rights at least 60 days before the end of each enrollment period, would confuse enrollees and seem to encourage disenrollment. The commenter suggested that including disenrollment rights in enrollment materials, and providing information through the enrollment broker should be sufficient.

Response: Section 1932(a)(4) requires an annual notice at least 60 days before the beginning of an individual's annual opportunity to disenroll. We believe that this information will be provided to enrollees along with all other enrollment materials that must be provided in this time frame. The purpose of this requirement is to ensure that enrollees have sufficient information in order to make a decision whether or not to continue enrollment in their current MCO, PIHP, PAHP, or PCCM within the time allotted for a

change in enrollment.

Comment: One commenter applauded the requirement to automatically reenroll a recipient who was disenrolled solely because he or she lost Medicaid eligibility for a period of 2 months or less.

Response: We appreciate the commenters' support.

4. Conflict of Interest Safeguards (§438.58)

Proposed §438.58 requires as a condition for contracting with MCOs that States establish conflict of interest safeguards at least as effective as those specified in section 27 of the Office of Federal Procurement Policy Act. We received no comments on this section.

5. Limit on Payment to Other Providers (Proposed §438.60)

Proposed § 438.60 prohibits direct payments to providers for services available under a contract with an MCO, PIHP, or PAHP.

Comment: Many commenters asked what type of payments to providers are exempt from this prohibition on direct payments, based on exceptions in title XIX of the Act or Federal regulations, and whether this exemption applies to graduate medical education (GME) payments to teaching hospitals, requiring GME payments to be included in capitation rates.

Response: The exemption in proposed §438.60 applies to two types of providers--disproportionate share hospitals (DSH) and Federally qualified health centers (FQHCs). Section 1902(a)(13) of the Act specifically requires direct payments to these providers when they are part of an MCO provider network. The proposed provision

would prohibit States from making direct payments to teaching hospitals for GME when their Medicaid patients are enrolled in, and their services are provided under a contract between the State and an MCO or PIHP. Proposed §438.60 would require any GME payments to be included in the capitation rates paid the MCO or PIHP.

Comment: Numerous commenters opposed this limitation on GME payments in managed care arrangements, arguing that States should be permitted to maintain their current payment methodology for GME. A number of these commenters stated that this prohibition on GME is directly contradictory to the Medicare managed care requirements, for GME be carved out and paid directly to the teaching hospitals, and asked for CMS' rationale for this inconsistency.

Many commenters stated that this requirement would adversely impact teaching hospitals and discourage them from participating in managed care. Others indicated that including GME payments in capitation rates would not work since payments vary widely by provider and therefore by MCO network. They added that including GME in capitation rates would take away States' control over whether and to what extent teaching hospitals receive payments intended to go to them.

Most commenters suggested that approved GME payments should be made an exception to this provision, like DSH and FQHC payments.

Response: The intent of proposed §438.60 was to prevent duplicate and inappropriate supplemental payments to providers. Under the new rules governing payments under risk contracts in §438.6(c), States are expected to make actuarially sound payments to MCOs, PIHPs, and PAHPs that include amounts for all services covered under the contract. In most instances, we do not believe there should be a need for payments

directly from the State to providers who are delivering all of their services to Medicaid MCO enrollees. The Congress has made a statutory exception to require States to pay directly to the two types of providers identified above, when their services are delivered through a Medicaid-contracting MCO. As some commenters pointed out, the Congress also made an exception for Medicare GME, where amounts are required to be carved out of Medicare managed care payments and paid directly to teaching hospitals. A rationale for treating GME differently in Medicaid would be that the Medicare statute specifically authorizes payment of GME, while the Medicaid statute does not contain a similar provision.

However, we recognize that GME payments have become a common payment practice in State Medicaid programs. In response to the concerns raised, we are amending §438.60 to allow an exception to this prohibition on direct payment to providers, "where the State agency has adjusted the actuarially sound capitation rates paid under the contract in accordance with §438.6(c)(5)(v), to make payments for graduate medical education." The aggregate amount of allowable payments under this exception would be limited to the total amount that would have been paid under the approved state plan for FFS. We believe that this is an equitable approach that mirrors the requirements in Medicare managed care and addresses State concerns of preventing harm to teaching hospitals and Federal concerns of ensuring the fiscal accountability of these payments. As part of our larger strategy of improving the fiscal integrity of Medicaid payments, we also plan to study existing Medicaid GME payment arrangements and may issue additional policies in the future.

6. Continued Service to Recipients (Proposed §438.62)

Proposed §438.62 requires States to arrange for continued services to beneficiaries who were enrolled in an MCO, PIHP, PAHP, or PCCM whose contract was terminated, or for any enrollee who is disenrolled for any reason other than ineligibility for Medicaid.

Comment**:** Many commenters recommended adding provisions to require mechanisms to assure continued access for enrollees with ongoing health care needs who move from FFS to managed care, between one managed care entity and another, or from managed care to FFS. These commenters wanted the requirements to apply to all special needs children, beneficiaries over age 65, pregnant women, and other groups identified by the State and include procedures for notification regarding the State's transition mechanisms and assurances that enrollees' ongoing health care needs would be met.

These commenters felt that enrollees may not understand how to access continued services during transition and this could be dangerous for those with special health care needs for which continuity of care is necessary. For example, an enrollee who requires home health services may find himself unable to receive care while being transferred from one MCO to another.

Another commenter stated that it was important to have some type of mechanism to insure that individuals may be treated by their current provider for a reasonable period of time. One commenter also suggested requiring a period of up to 60 days for beneficiaries going though one of these transitions, during which they could continue an ongoing course of treatment with a nonparticipating health care provider.

Several commenters supported the proposed provision.

Response: The goal of our proposed rule is to ensure that there are adequate

protections for managed care enrollees, while providing flexibility to States to determine how to best implement these protections. Most States, in their waiver programs under sections 1115 or 1915(b) of the Act already have mechanisms in place to transition enrollees into managed care from fee-for-service (FFS) and from one MCO to another. Further, we are concerned that it would be very difficult to enforce the requirement when a recipient moves from managed care to FFS as there are few mechanisms in the FFS delivery system for care coordination and follow-up.

7. Monitoring Procedures (Proposed §438.66)

Proposed §438.66 is a redesignation of §434.63, with non-substantive revisions and appropriate changes in terminology, and requires States to have in place procedures for monitoring MCOs, PIHPs, and PAHPs

Comment: One commenter stated that since Medicaid provides care to many low income children, monitoring should include a focus on pediatric services. A recent General Accounting Office report (GAO-01-749, published July 2001) found that States have done a poor job in complying with EPSDT requirements, particularly in the area of managed care. The commenter urged CMS to implement the GAO recommendations to work with States to develop a timetable for improving their compliance, and for highlighting best practices.

Response: We have initiated a number of projects that address the GAO recommendations, and are working to improve our monitoring of States as well as identifying and providing needed technical assistance to them.