

C. Enrollee Rights and Protections (Subpart C)

Proposed subpart C set forth a variety of enrollee protections, including enrollee rights (proposed §438.100), protection of provider-enrollee communications (proposed §438.102), limits on marketing activities (proposed §438.104), limits on enrollee liability for payment (proposed §438.106) and cost-sharing (proposed §438.108), rights in connection with emergency and post-stabilization services (proposed §438.114), and solvency standards (proposed §438.116).

1. Enrollee Rights (Proposed §438.100)

As part of these standards, proposed §438.100, required that each MCO and PIHP have written policies with respect to enrollee rights, and that each MCO, PIHP, PAHP, and PCCM ensure compliance with Federal and State laws affecting the rights of enrollees, and ensure that its staff and affiliated providers take these rights into account when furnishing services. Under proposed §438.100(b), States were required to ensure that each enrollee of an MCO, PIHP, PAHP, or PCCM has the right to (1) receive information regarding his or her health care; (2) be treated with respect and with due consideration for enrollee dignity and privacy; (3) receive information on available treatment options and alternatives that is presented in a manner appropriate to the enrollee's condition and ability to understand; (4) participate in decisions regarding his or her health care, including the right to refuse treatment; and (5) be free from any form of restraint or seclusion used as a means of coercion, discipline, convenience, or retaliation. Further, enrollees of MCOs or PIHPs were given the right to (1) be furnished health care services in accordance with proposed §§438.206 through 438.210; (2) obtain a second

opinion from an appropriately qualified health care professional; (3) request and receive a copy of his or her medical records, and to request that they be amended or corrected. The State also had to 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, PIHP, PAHP, or PCCM and its providers or the State agency treat the enrollee. Proposed §438.100(d) required that States ensure compliance with various civil rights laws.

Comment: Several commenters provided support for the enrollee rights provisions as proposed. Several other commenters felt that all of the rights in this section should apply to PAHPs as well as PIHPs, or that the differences between these two types of plans should be narrower.

Response: In response to the latter comments, we have expanded the enrollee rights to be provided for PAHP enrollees. We have clarified that PAHP enrollees have the right to request and receive a copy of their medical records, and to request that they be amended, as specified in 45 CFR part 164. Further, we have revised §438.100(b)(3) to provide that PAHP enrollees, consistent with the scope of the PAHP's contracted services, have the right to be furnished health care services in accordance with §§438.206 through 438.210. We also removed from the regulation text the language referring to the right to obtain a second opinion from an appropriately qualified health care professional in accordance with §438.206(b)(3) to avoid duplication. Please note, this language was only removed to avoid duplication, we did not remove the right to a second opinion, as it is subsumed within §438.100(b)(3) as one of the health care services enrollees of MCOs, PIHPs and PAHPs have the right to be furnished under §438.206.

Comment: One commenter suggested that CMS should consider HIPAA privacy rules before finalizing this rule to ensure that there is no conflict.

Response: The Health Insurance Portability and Accountability Act of 1996 (HIPAA) included comprehensive health privacy legislation. HHS published the final privacy rule on December 28, 2000 (65 FR 82462). The final rule took effect on April 14, 2001 and applies to covered entities as that term is defined at 45 CFR §160.103. Most health plans and providers must comply with the new requirements by April 14, 2003. Enforcement of the privacy rule requirements will not occur until April 2003. The compliance date for small health plans is April 14, 2004. The privacy rule gives patients greater access to their own medical records and more control over how their personal health information is used. Specifically, the privacy rule gives patients the right to access their records, request a change or challenge a particular part of the medical record, and have that challenge be included in the permanent records. The privacy rule also covers permissible uses and disclosures of protected health information and requires that appropriate safeguards are used to ensure against misuse of such information. This final rule neither conflicts with the privacy rule, nor does it impose any privacy provisions of its own. Moreover, nothing in this final rule affects a State's or any other covered entity's responsibilities under the privacy rule. We reference the privacy rule at §§438.100(b)(2)(vi), 438.208(b)(4), and 438.224, to the extent that it is applicable.

Comment: One commenter expressed concern that proposed §438.100(a)(2) specifies that all MCOs and PCCMs must comply with any applicable Federal and State laws that pertain to enrollees rights. The commenter was concerned that State laws on

enrollee rights might be in conflict with this section. The commenter expressed the concern that requiring MCOs to comply with two sets of regulations addressing the same operational areas is unnecessarily confusing and burdensome for MCOs and for managed care enrollees. The commenter requested that this provision be restated such that if State law on enrollee rights is consistent with section 1932(b) of the Act, CMS does not have the authority to impose additional regulation.

Response: As Federal law supercedes State law, all States must conform with Federal regulations for Medicaid managed care enrollees, so there would not be a situation in which two conflicting sets of requirements would apply, and this concern of the commenter is not valid. We proposed these standards because interpersonal aspects of care are highly important to most patients and closely related to quality of care. Enrollees' interactions with the organization and its providers can have an important bearing on their willingness and ability to understand and comply with recommended treatments and hence on outcomes and costs. While many States have requirements in place that would assure these rights, not all States do. We believe that these minimum standards are justified for all Medicaid beneficiaries. We accordingly do not accept the commenter's suggestion that we defer totally to State law with respect to enrollee rights. However, we note that these Federal regulations set a floor for the level of enrollee standards. States may establish more stringent standards that are not inconsistent with these requirements

2. Provider-Enrollee Communications (Proposed §438.102)

Medicaid beneficiaries are entitled to receive from their health care providers the full range of medical advice and counseling that is appropriate for their condition. Section 1932(b)(3)(A), added by the BBA, clarifies and expands on this basic right by expressly precluding an MCO from establishing restrictions that interfere with enrollee-provider communications, and expressly ensuring the right of a health care professional to give medical advice, without regard to whether the course of treatment advised is covered under the MCO's plan. In §438.102 of the proposed rule, we provided a definition of the term "health care professional" (as discussed above, in this final rule, the definition is located at §438.2), and outlined the general rule prohibiting interference with provider-enrollee communications. We also included language reflecting the provision in section 1932(b)(3)(B) specifying that the requirements in section 1932(b)(3)(A) should not be construed to require the MCO cover, furnish or pay for a particular counseling or referral service if the MCO objects to the provision of that service on moral or religious grounds, and provides information to the State, prospective enrollees, and to current enrollees within 90 days after adopting the policy with respect to objections of any particular service. In proposed §438.102, under the authority in section 1902(a)(4), we extended both the explicit right to give advice in section 1932(b)(3)(A) and the moral or religious objection exception in section 1932(b)(3)(B) to PIHPs and PAHPs.

Comment: Several commenters believe that enrollees should receive information from their providers about treatment options in a culturally competent manner so that enrollees can better understand information about their health care. One commenter suggested that if information about treatment options is not delivered in a culturally

sensitive way, it could affect patient compliance with medical advice, and trigger health conditions and medical care episodes that escalate the cost of care. The commenter also felt that this would adversely affect not only patients' health status, and ultimately health plans, but States' and CMS' combined efforts to eliminate ethnic and racial health disparities. Another commenter pointed out that many enrollees who have disabilities come from another country and do not speak English, or have a low education level that limits their ability to understand their medical care and insurance. In other instances enrollees have disabilities that can be a barrier to engaging a health care provider. The commenter believes that this could be true for people with mental disabilities, making it difficult for certain enrollees to get the health care that they need. Several of the commenters recommended that we include a provision, which mirrors a Medicare+Choice requirement, to require that MCOs, PIHPs, and PAHPs take steps to ensure that health professionals furnish information about treatment options (including option of no treatment) in a culturally competent manner, and ensure that enrollees with disabilities have effective communication in making decisions with respect to treatment options.

Response: We believe it is important for enrollees to receive information in a culturally competent manner, however, we do not agree that additional regulatory provisions are necessary. The regulation already requires, at §438.206(c)(2), that each MCO and PIHP participate in the State's efforts to promote the delivery of services in a culturally competent manner to all enrollees, including those with limited English proficiency and diverse cultural and ethnic backgrounds. It is up to each State to design

its own cultural competency efforts to fit its individual needs and place responsibilities on its providers. In addition, we require at §438.10(b) that information be provided to all enrollees in a manner and format that may be easily understood, taking into consideration cultural and linguistic needs and disabilities of enrollees. Finally, at §438.100(b)(2)(iv), MCO, PIHP, and PAHP enrollees have the right to participate in decisions regarding his or her care, including the right to refuse treatment. We believe these provisions address the commenters' concerns.

Comment: One commenter suggested that §438.102 make clear that States have the affirmative responsibility to provide race, ethnicity, and language data to health plans.

Response: It is not clear why the commenter believes that such a requirement would belong in the section dealing with provider-enrollee communications. In any event, §438.204(b)(2) already requires that the State quality strategy identify the race, ethnicity and primary language spoken of each Medicaid enrollee, and that States provide this information to MCOs and PIHPs for each Medicaid enrollee at the time of enrollment. We therefore do not believe it is necessary to include additional regulatory requirements in this section of the regulations.

Comment: We received numerous comments on the definition of health care professional. One commenter recommended that language be added that would permit expansion of the disciplines based on recognition of new medical providers/additional licensed individuals offering services. Others recommended a more general definition, that does not rely on identifying specific disciplines, or at a minimum adding "and any other health care professional identified by the State" at the end of the definition.

Commenters were concerned that the definition in the proposed rule did not include all health care professionals authorized to provide care in all States, and that as the health care industry continues to evolve, the list will become outdated.

Response: We recognize the commenters' concerns, however we will not be making any changes to the definition, as section 1932(b)(3)(C) of the Act provides an exact list of professions that are covered under this provision. As noted above, we have moved the definition of health care professional to §438.2.

Comment: A few commenters noted that the provisions in paragraphs (c)(1), (c)(1)(ii)(B) and (c)(2) of §438.102 make references to a paragraph (b)(3), which does not exist.

Response: We appreciate these comments and have corrected the erroneous references.

Comment: A few commenters raised concerns about the fact that under proposed §438.102(b)(2), health plans that exclude coverage of certain counseling or referral services on moral or religious grounds are not required to provide information on how and where to obtain information about the service. One commenter believes that any responsibility to provide information to beneficiaries eliminates what the commenter saw as the crucial means for women to access information at the point of service. The commenter felt that this provision discounts the moral and religious beliefs, and health care needs, of female Medicaid beneficiaries. Another commenter pointed out that the proposed rule transfers the responsibility for providing information on services the MCO declines to cover under §438.102(b)(2) to the State, with no mention on how the State

would provide that information to enrollees on a timely basis. The commenter urged that health plans be required to inform enrollees that it does not provide certain services on moral or religious grounds, and at a minimum, provide a referral to a State-sponsored toll-free number that informs beneficiaries about how and where to access these services.

Response: Ultimately, it is the State's responsibility to deliver information on, and furnish, these services. As discussed above in section A., §438.10(e) requires that information on each MCO, PIHP, or PAHP, be provided to potential enrollees (at the time the potential enrollee is first required to enroll in a mandatory enrollment program and within a timeframe that enables the potential enrollee to use the information in choosing among available MCOs, PIHPs, or PAHPs), including the benefits covered by the MCO, PIHP, or PAHP and the benefits available under the State plan, but not covered under the MCO's, PIHP's, or PAHP's contract. In addition, §438.10(f) provides that for a counseling or referral service not covered because of moral or religious reasons, the State must furnish information about how and where to obtain the services. Section 438.102(b) requires the MCO, PIHP or PAHP to notify potential enrollees of services it does not cover because of moral or religious reasons. Further, this provision does not preclude health providers from providing information on how and where to obtain services, if they so choose. In addition, we do not believe that these provisions compromise the needs of female Medicaid beneficiaries, as the Medicaid statute guarantees freedom of choice for family planning services. An enrollee may seek family planning services out-of-network. We also permit enrollees to disenroll if services are not covered because of moral or religious objections, though because of the freedom of

choice provisions, disenrollment is not necessary in order to access family planning services.

3. Marketing Activities (Proposed §438.104)

Consistent with the rules in section 1932(d)(2) of the Act that apply to MCOs and PCCMs, and in part under our authority in section 1902(a)(4), proposed §438.104 set forth requirements for, and restrictions on, marketing activities by MCOs, PIHPs, PAHPs and PCCMs. Proposed §438.104 included definitions of “cold-call marketing,” “marketing,” and “marketing materials.” It also set forth requirements and prohibitions for MCO, PIHP, PAHP or PCCM contracts, specifically: 1) the entity must not distribute any marketing materials without first obtaining State approval; 2) the entity must distribute the materials to its entire service area as indicated in the contract; 3) the entity complies with the information requirements of §438.10 to ensure that before enrolling, the beneficiary receives from the entity or State, the accurate oral and written information he or she needs to make an informed decision on whether to enroll; 4) the entity does not seek to influence enrollment in conjunction with the sale or offering of any other insurance; and 5) the entity does not, directly or indirectly, engage in door-to-door, telephone, or other cold-call marketing activities. Proposed §438.104(b)(2) requires that MCOs, PIHPs, PAHPs, and PCCMs specify the methods by which the entity assures the State agency that marketing plans and materials are accurate and do not mislead, confuse, or defraud the beneficiaries or State agency. Finally, §438.104(c) proposed to require the State to consult with a Medical Care Advisory Committee or an advisory committee with similar membership in reviewing marketing materials.

General Comments

Comment: Several commenters believe that proposed §438.104 should apply to current enrollees rather than just potential enrollees, and that the fact that it does not do so is inconsistent with the marketing requirements in the BBA.

Response: We have defined marketing as any communication, from an MCO, PIHP, PAHP, or PCCM to a Medicaid beneficiary who is not enrolled in that entity, that can reasonably be interpreted as intended to influence the beneficiary to enroll in that MCO, PIHP, PAHP, or PCCM, or either to not enroll in, or to disenroll from, another MCO's, PIHP's, PAHP's, or PCCM's Medicaid product. We believe that MCOs, PIHPs, PAHPs, and PCCMs are not engaged in marketing for the purposes of influencing enrollment or disenrollment when communicating with current enrollees. We do not believe this is a violation of the BBA marketing provisions in section 1932(d)(2), as this section does not address to whom the marketing covered by its provisions is directed. We believe that our interpretation of the word marketing is reasonable, and consistent with section 1932(d)(2).

Cold-Call Marketing

Proposed §438.104(a) defines cold-call marketing as any unsolicited personal contact by the MCO, PIHP, PAHP, or PCCM with a potential enrollee for the purpose of influencing the individual to enroll in that particular MCO, PIHP, PAHP, or PCCM. Cold-call marketing includes door-to-door, telephone or other related marketing activities performed by MCOs, PIHPs, PAHPs, or PCCMs and their employees (that is, direct marketing) or by agents, affiliated providers, or contractors (that is, indirect marketing).

In the preamble to the proposed rule, we noted that cold-call marketing included such activities as a physician, other member of the medical staff, a salesperson, other MCO, PIHP, PAHP, or PCCM employees, or independent contractors approaching a beneficiary in order to influence his or her decision to enroll with a particular MCO, PIHP, PAHP, or PCCM. In proposed §438.104(b)(1)(v), we expressly prohibited MCOs, PIHPs, PAHPs, or PCCMs from directly or indirectly engaging in door-to-door, telephone, or other cold-call marketing activities.

Comment: Numerous commenters stated that the definition of cold-call marketing is too broad and might impede legitimate marketing efforts.

Response: The prohibition on cold-call marketing only applies to unsolicited contact by the MCO, PIHP, PAHP, or PCCM. For example, if a beneficiary attends a health fair or similar event, he or she would be seeking out information about health care and, therefore, the contact between the MCO, PIHP, PAHP, or PCCM and the beneficiary would not be considered unsolicited. We note, however, that MCO, PIHP, PAHP, or PCCM participation in health fairs and other community activities is considered marketing and, therefore, must have State approval.

Section 1932(d)(2)(E) of the Act prohibits direct or indirect door-to-door, telephonic, or other cold-call marketing of enrollment. Our interpretation of Congressional intent is that the statutory language was meant to minimize the potential for abusive marketing practices in both voluntary and mandatory programs. There are several other types of marketing that are permitted under section 1932(d) and this regulation. For example, States may permit the use of billboards, newspaper, television,

and other media to advertise MCOs, PIHPs, PAHPs, or PCCMs. Mailings are also permitted as long as they are distributed to the MCO's, PIHP's, PAHP's, or PCCM's entire service area covered by the contact. States may also provide marketing materials on behalf of MCOs, PIHPs, PAHPs, and PCCMs.

This regulation does not prohibit educational activities on the part of MCOs, PIHPs, PAHPs, or PCCMs. However, any contacts other than patient counseling by any MCO, PIHP, PAHP, or PCCM staff or representative, would be considered marketing subject to State oversight. The regulation does not prohibit States from permitting MCOs, PIHPs, PAHPs, or PCCMs to market to groups in schools, churches, day care centers, etc. States are responsible for approving and monitoring these types of presentations and ensuring that beneficiaries attend voluntarily with knowledge that they are attending a marketing presentation.

States may permit and establish rules for marketing in public places. However, States may not permit uninvited personal solicitations in public places such as eligibility offices and supermarkets. Some States allow representatives of available MCOs, PIHPs, PAHPs, and PCCMs to be in eligibility offices or other locations on certain days or on a rotating basis to answer questions and provide information to beneficiaries. In these situations, there should be provisions to monitor contacts to ensure that unbiased information is available about all options and that beneficiaries are not coerced. However, marketing or other MCO, PIHP, PAHP, or PCCM representatives who approach beneficiaries as they enter or exit eligibility offices or other public places, call at residences uninvited, etc., are considered cold-call contacts and are not permitted.

We believe the regulation gives States broad authority to determine what marketing activities are permitted, with the exception of unsolicited personal contacts by MCOs, PIHPs, PAHPs, and PCCMs or their representatives. States are free to use MCOs, PIHPs, PAHPs, and PCCMs in community-based efforts. However, those efforts are considered marketing; therefore the materials (activities, materials, presentations, etc.) are subject to State review and approval.

Service Area

Proposed §438.104(b)(1)(ii) required that marketing materials be distributed to the entire service area as indicated in the contract.

Comment: Some commenters believe that the proposed requirement was unnecessary, unduly burdensome and costly. One commenter suggested that MCOs should not have to distribute marketing materials to areas they already serve and should be allowed to limit distribution to new areas only. Another commenter thought it reasonable to require materials be sent only to those who are eligible or potentially eligible for Medicaid in a given service area and recommended that we require MCOs, PIHPs, PAHPs, and PCCMs to distribute materials to all eligible enrollees in a specified county or region to avoid confusion to those in a particular sector in which the marketing materials do not apply.

Response: Section 1932(d)(2)(B) of the Act requires that marketing materials be distributed to the entire service area. The intent of this provision is to prohibit marketing practices that favor certain geographic areas over those thought to produce more costly enrollees. Section 438.104(b)(1)(ii) requires that each MCO, PIHP, PAHP, and PCCM

contract must provide that the entity “distributes the materials to its entire service area as indicated in the contract.” (Emphasis added.) The phrase “as indicated in the contract” is intended to provide States and MCOs, PIHPs, PAHPs, and PCCMs with some flexibility in designing and implementing marketing plans and in developing marketing materials. We expect that when States review MCO, PIHP, PAHP, and PCCM marketing and informing practices, they will not only consider accuracy of information, but also factors such as language, reading level, understandability, cultural sensitivity, and diversity. In addition, State review should ensure that MCOs, PIHPs, PAHPs, and PCCMs do not target or avoid populations based on their perceived health status, cost, or for other discriminatory reasons.

For example, a State may permit distribution of materials customized for a Hispanic population group as long as the materials are comparable to those distributed to the English speaking population. While the presentation and formats of the information may be varied based on the culture and distinct needs of the population, the information conveyed should be the same, in accordance with §438.10. In the above example, the materials for the Hispanic population group must be distributed to all those Medicaid eligibles or enrollees who require or request Hispanic-related materials. States that use this flexibility to allow selective marketing may permit distribution by zip code, county, or other criteria within a service area if the information to be distributed pertains to a local event such as a health fair, or provider, such as a hospital or clinic. However, States must ensure that health fairs are not held only in areas known to have or perceived as having a more desirable population. We have chosen not to limit the distribution

requirement only to mailings because broadcast advertising and other marketing activities can also be done selectively. All marketing activities should be conducted in a manner that provides for equitable distribution of materials and without bias toward or against any group.

Sale of Other Insurance

Proposed §438.104(b)(1)(iv) requires MCO, PIHP, PAHP, and PCCM contracts to assure that the entity does not seek to influence enrollment in conjunction with the sale or offering of any other insurance. We interpreted this provision to mean that MCOs, PIHPs, PAHPs, and PCCMs may not entice a potential enrollee to join the MCO, PIHP, PAHP, or PCCM by selling or offering any other type of insurance as a bonus for enrollment. However, we invited comment on this provision, because we did not have any legislative history to consider when developing our interpretation.

Comment: Several commenters strongly recommended that CMS clarify that this provision does not apply to Medicaid enrollees who are eligible for Medicare. As it is worded, commenters believe that this section precludes a Medicare sales representative from telling a potential enrollee eligible for Medicare and Medicaid services about Medicare. Another commenter indicated that this section could impede coordination efforts between Medicare and Medicaid programs. Another commenter stated that the section should not apply to Medicare, since the Medicare program is subject to marketing regulations.

Response: We agree with the commenters that the proposed regulatory text could impede the interaction of marketing to dual eligibles by MCOs, PIHPs, PAHPs or

PCCMs. We have clarified the regulation text at §438.104(b)(1)(iv) by adding language clarifying that this provision applies to the sale or offering of any private insurance. This would not preclude a Medicare sales representative from telling a dually eligible beneficiary about the health plan's Medicare+Choice benefits. Rather, it is intended to apply to such types of insurance as burial insurance.

State Agency Review

Proposed §438.104(c) provides that, in reviewing the marketing materials submitted by MCOs, PIHPs, PAHPs, and PCCMs, the State must consult with its Medical Care Advisory Committee (MCAC) or an advisory committee with similar membership. Section §431.12, of existing rules, sets forth the requirements for establishment of an MCAC. The MCAC must include Board-certified physicians and other representatives of the health professions who are familiar with the medical needs of low-income populations and with the resources available and required for their care. The MCAC must also include the Director of the Public Welfare Department or the Public Health Department, whichever does not head the Medicaid agency, as well as members of consumer groups including Medicaid beneficiaries and consumer organizations such as labor unions, cooperatives, and consumer-sponsored prepaid group practice plans.

Comment: Several commenters felt that the MCAC review of marketing materials would be cumbersome, an administrative burden to the States, and may create delays in distributing marketing information to potential enrollees. The commenters indicated that States should consult the MCAC on marketing policy, regulations, and guidelines, rather than review each piece of marketing materials submitted. One

commenter felt that if the MCAC were to review pieces of marketing material, then it should be done in a timely manner.

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

States may also consult with the committee in the development of standardized guidelines or protocols that are intended to facilitate State review. States may consult with the committee to develop suggested language and deem approval of an MCO's, PIHP's, PAHP's, or PCCM's materials if that language is used. MCOs, PIHPs, PAHPs, and PCCMs could also use some of the suggested language and then identify areas where different language has been used, and States could then limit review and/or consultation to that particular portion of the materials.

4. Liability for Payment (Proposed §438.106)

Proposed §438.106, consistent with section 1932(b)(6) of the Act, requires MCOs, PIHPs, and PAHPs to provide that their Medicaid enrollees will not be held liable for (a) the debts of the MCO, PIHP, or PAHP in the event of insolvency; (b) covered

services provided to the enrollee for which the State does not pay the MCO, PIHP, or PAHP; or (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 enrollees would owe if the MCO, PIHP, or PAHP provided the services directly.

Comment: One commenter expressed support for this provision.

Response: We acknowledge and thank the commenter for their support.

5. Cost Sharing (Proposed §438.108)

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

Comment: Two commenters supported this provision. One commenter expressed concern about the inappropriate use of hospital emergency rooms. The commenter recommended that we allow and encourage States to charge beneficiaries a \$25 copayment per visit for inappropriate use of the emergency room. Under the commenter's recommended approach, MCOs would require that hospitals collect the copayment at the time of the visit; provided, however, that enrollees would not be denied care because of inability to pay the copayment. Under the commenter's suggested policy, if it was determined that a true emergency existed, the copayment would be refunded. The commenter believes that this would serve as an incentive to enrollees to seek care in

the appropriate setting, at the appropriate time and would allow the primary care physician to establish a medical relationship with the beneficiary.

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

We believe that allowing the collection of an "upfront" copayment in a hospital emergency room as the commenter suggested violate §447.53(b)(4), and be inconsistent with the enrollee's right to coverage of emergency services when a "prudent layperson" would reasonably believe that an emergency exists (see discussion above). However, enrollees should be aware that if they seek services in an emergency room when it is clear that the standard in §447.53(b)(4) is not met, coverage of these services may be denied entirely.

6. Emergency and Post-Stabilization Services (Proposed §438.114)

Section 4704(a) of the BBA added section 1932(b)(2) to the Act to assure that

Medicaid managed care beneficiaries have the right to immediately obtain emergency care and services, and the right to post-stabilization services following an emergency medical condition under certain circumstances. (Post-stabilization services are medically necessary services related to an emergency medical condition that are received at the site at which the patient is treated for an emergency medical condition, after the individual's condition is sufficiently stabilized that he or she could alternatively be safely discharged or transferred to another facility.) Each contract with an MCO and PCCM must require the organization to provide for coverage of emergency services and post-stabilization services as described below. In section 1932(b)(2)(A)(i) of the Act, while the Congress required MCOs and PCCMs to provide coverage of emergency services, it did not define the word "coverage," even though these health care models generally do not cover emergency services in the same manner. In proposed §438.114, we interpreted the obligation in section 1932(b)(2)(A)(i) of the Act to provide for coverage of emergency services to mean that an MCO or State (as payer in the case of a PCCM) that pays for hospital services generally, must pay for the cost of emergency services obtained by Medicaid managed care enrollees. We interpreted coverage in the PCCM context to mean that the PCCM must allow direct access to emergency services without prior authorization. We applied different meanings to the word "coverage" because while PCCMs are individuals paid on a fee-for-service basis, they receive a State payment to manage an enrollee's care. Unlike MCOs, PCCMs would not likely be involved in a payment dispute involving emergency services, though they could be involved in an authorization dispute over whether a self-referral to an emergency room is authorized

without prior approval of the PCCM. Accordingly, in proposed §438.114(c)(2), we provided that enrollees of PCCMs are entitled to the same emergency services coverage without prior authorization that is available to MCO enrollees under section 1932(b)(2) of the Act.

Section 1932(b)(2)(A)(i) stipulates that emergency services must be covered without regard to prior authorization, or the emergency care provider's contractual relationship with the organization. This assures a Medicaid enrollee of the right to immediately obtain emergency services at the nearest provider when and where the need arises.

Section 1932(b)(2)(B) of the Act defines emergency services as covered inpatient or outpatient services that are furnished by a provider qualified to furnish these services under Medicaid that are needed to evaluate or stabilize an "emergency medical condition." An "emergency medical condition" is in turn defined in section 1932(b)(2)(C) of the Act as a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in placing the health of the individual (or for a pregnant woman, the health of the woman or her unborn child) in serious jeopardy, serious impairment to body functions, or serious dysfunction of any bodily organ or part. While this standard encompasses clinical emergencies, it also clearly requires MCOs to base coverage decisions for emergency services on the apparent severity of the symptoms at the time of presentation, and to cover examinations when the presenting symptoms are

of sufficient severity to constitute an emergency medical condition in the judgment of a prudent layperson. The above definitions are set forth in proposed §438.114(a).

In some cases, the “emergency” services required to diagnose or treat an “emergency medical condition” may fall within the scope of services that a PIHP, or even a PAHP, is required to cover under its contract. In this case, we believe that enrollees should have the same rights to have these services covered without delay, and “out of plan” as in the case of services covered by an MCO or through a PCCM. Accordingly, through our authority in section 1902(a)(4) of the Act, we provided in proposed §438.114(f) that the requirements in §438.114 apply to PIHPs and PAHPs to the extent that the services required to treat the emergency medical condition, or the required post-stabilization services in question, fall within the scope of the services for which the PIHP or PAHP is responsible.

Proposed §438.114(b) requires that MCOs, PIHPs, PAHPs (to the extent applicable), at-risk PCCMs, or the State agency pay for emergency and certain post-stabilization services without prior authorization (other than the pre-approval of post-stabilization services no later than within one hour of a request for approval).

Proposed §438.114(c)(1)(i) provides that an MCO or, to the extent applicable, a PIHP or PAHP, must pay for emergency services regardless of whether the entity that furnishes the services has a contract with the MCO, PIHP, or PAHP. In proposed §438.114(c)(1)(ii), MCOs, PIHPs, or PAHPs may not deny payments if, on the basis of symptoms identified by the enrollee, he or she appeared to have an emergency medical condition, but turned out not to have a condition in which the absence of immediate

medical care would have resulted in serious jeopardy to the health of the individual or, in the case of a pregnant woman, the health of her unborn child, serious impairment of bodily function, or serious dysfunction of any bodily organ or part. Likewise, the MCO, PIHP, PAHP, or PCCM cannot deny payment if the enrollee obtained services based on instructions of a practitioner or other representative of the MCO, PIHP, or PAHP. Proposed §438.114(c)(2) provides that if a PCCM contract is a risk contract that covers the services, a PCCM system must allow enrollees to obtain emergency services outside of the PCCM system.

Proposed §438.114(d) further clarified financial responsibility. Proposed §438.114(d)(1) provided that MCOs, PIHPs and PAHPs (to the extent applicable), at-risk PCCMs, or States may not limit what constitutes an emergency medical condition through lists of symptoms or final diagnoses/conditions and may not refuse to process a claim because it does not contain the primary care provider's authorization number. Proposed §438.114(d)(2) provided that an enrollee who, based on the treating emergency provider's determination, has an emergency medical condition, may not be held liable for payment concerning the screening and treatment of that condition necessary to stabilize the enrollee. Proposed §438.114(d)(3) provided that the attending physician or practitioner actually treating the enrollee determines when the enrollee is sufficiently stabilized for transfer or discharge, and that this determination is binding on the MCO, PIHP, or PAHP for coverage purposes.

Section 1932(b)(2)(A)(ii) of the Act also provides MCO and PCCM enrollees with the right, under certain circumstances, to coverage of "post-stabilization" services

after they have been “stabilized” (that is, they no longer have an emergency medical condition, and could be safely discharged or transferred to another facility) following an admission for an emergency medical condition. Specifically, the services that must be covered are those that must be covered under Medicare rules implementing section 1852(d)(2) of the Act, in the same manner as these rules apply to M+C plans offered under Part C of Title XVIII. In section 1932(b)(2)(A) of the Act, this requirement was effective 30 days after the Medicare rules were established, which was August 26, 1998. The Medicare+Choice post-stabilization requirements referenced by section 1932(b)(2)(A)(ii) of the Act are set forth in proposed §438.114(e), which referenced §422.113(c) of the Medicare+Choice final regulation. Post-stabilization care means covered services, related to an emergency medical condition, that are provided after an enrollee is stabilized in order to maintain the stabilized condition, and under the circumstances described in paragraph §422.113(c)(2)(iii), to improve or resolve the enrollee’s condition. Under these latter circumstances, either the health plan has authorized post-stabilization services in the facility in question, or there has been no authorization and (1) the hospital was unable to reach the health plan; or (2) the hospital reached the health plan, but did not get instructions within an hour of a request.

The above emergency provisions are consistent with most of the emergency services provisions in the Medicare+Choice regulations. However, these regulations deviate from Medicare in two ways. First, the Medicare statute has specific provisions for non-emergency, but urgently needed services, while the Medicaid statute does not contain any similar references. Second, the PCCM, PIHP, and PAHP models are

delivery systems unique to Medicaid; and there is no Medicare counterpart to the special rules described above that apply to PCCM enrollees.

Comment: One commenter urged that the applicable definitions, including an emergency medical condition and post-stabilization services, be set forth in §438.114, rather than simply referencing §422.113. The commenter felt this would make the Medicaid regulations easier to understand.

Response: We agree. In response to this comment, we have set forth the full definitions of emergency medical condition, emergency services and post-stabilization services in §438.114.

Comment: Several commenters noted that the Emergency Treatment and Active Labor Act (EMTALA) requires hospitals and emergency providers to screen and treat those Medicaid enrollees that present at the emergency room, and argued that managed care organizations (MCOs) and States should have to cover costs that EMTALA mandates. A few commenters expressed the view that EMTALA was being enforced on hospitals with more vigilance than the prudent layperson standard is on MCOs, PIHPs, and States.

Response: While MCOs, PIHPs, and States are responsible for covering emergency medical conditions, this is not the same mandate as the services that must be covered under EMTALA. For example, if a prudent layperson would not reasonably believe that an emergency medical condition existed, MCOs, PIHPs, or States would not be liable for costs when the individual presents at an emergency room without prior authorization. Under EMTALA, however, obligations to at least perform screening exist

regardless of the condition of the presenting individual. Hence, the scope of a hospital's obligations under EMTALA is broader than the scope of an MCO's or State's obligation under section 1932(b)(2) (or, by extension under this regulation, a PIHP where applicable). However, we agree that the mandates under each rule overlap significantly in most cases. We encourage parties who have concerns about violations or enforcement to contact either the State or CMS regional office responsible for the area in question.

Comment: One commenter suggested that we remove the provision which precludes an MCO, PIHP or State from refusing to cover services without the primary care provider's (PCP) authorization number. The commenter was concerned that without such a number, there was not a practical mechanism to alert a State or health plan that its enrollee had presented to the emergency room. The commenter also said that its computer system would have to be reconfigured in order to leave out this information, costing a significant amount of money.

Response: Originally, we added this requirement because we were concerned that MCOs, PIHPs, and States could attempt to avoid their obligations under §438.114 by refusing to pay claims based on technicalities concerning the submission of claims. However, we agree with the commenter that there is a vested interest in MCOs, PIHPs, and States tracking individual enrollees' emergency room presentation rates. Therefore, we are allowing MCOs, PIHPs, and States to require the PCP number to be on a claim before it will be processed for payments. However, we have provided in §438.114(d)(1)(ii) that MCO, PIHPs, and States must provide hospitals, emergency room providers, or their fiscal intermediaries, when applicable, a minimum of 10 business days

to notify the primary care provider or other designated contact before a payment may be denied for a failure to provide notice.

Comment: One commenter was concerned about the prohibition against denying claims based on lists of symptoms or final diagnosis codes. A number of States require MCOs to pay a screening fee even if there was no emergency, but do not require them to pay for the service based on their emergency services fee schedule. The commenter wanted to know if there was a conflict with the regulation.

Response: There is no conflict in this situation if the determination was made taking into account the presenting symptoms rather than the final diagnosis. We prohibit the use of codes (either symptoms or final diagnosis) for denying claims because there is no way a list can capture every scenario that could indicate an emergency medical condition as required in the BBA. An MCO, PIHP, or State may pay claims using those lists and require coverage of screens even if no emergency medical condition exists. However, we do not require coverage of a screen if it reveals no emergency medical condition (as opposed to EMTALA requirements on Medicare participating hospitals).

Comment: A few commenters were concerned that the Federal rules provide little State flexibility when it comes to setting State rules involving claims coverage, or educating enrollees about emergency room use. One commenter was concerned that, if read literally, the rule prohibits denial of a claim for any reason other than not meeting the prudent layperson standard. The commenter stated that under the proposed rule, reasons for denial could include claims not submitted in a timely manner, claims that are not clean, or claims submitted by providers who refuse to sign provider agreements.

Response: We never intended this rule to prevent States from setting reasonable claim filing deadlines, asking for charts or other information before making a decision, or covering claims submitted by providers refusing to sign provider agreements. The purpose of the rule is to ensure that enrollees have unfettered emergency room access for emergency medical conditions, and that hospitals receive payment for those claims meeting that definition without having to navigate through unreasonable administrative loopholes. However, as long as filing deadlines specifically outlined for an appeals process are not used to deny initial claims, a State may set its own filing timeframes and other administrative rules (as long as it is not contrary to specific Federal provisions such as the 10 business day post-notification minimum timeframe requirement).

Comment: One commenter was concerned about the application of proposed §438.114 to situations involving mental health emergencies. The commenter felt that the present definition cannot be readily understood in the context of emergencies related to mental disorders.

Response: We agree that the present definition is primarily designed to cover physical rather than mental health. However, since the definition comes directly from the BBA, we do not have the legal authority to expand or change it. The present definition does apply to mental health as well when its standards are met (for example, “placing the health of the individual in serious jeopardy”).

Comment: A few commenters believe that the one-hour rule for MCOs to notify hospitals before post-stabilization services may be performed is too short a timeframe, and is contrary to their own State rules. One commenter indicated that it follows a 2-hour

timeframe before post-stabilization services may be performed, finding it much more reasonable in order to give MCOs and PCPs an opportunity to coordinate an enrollee's non-emergent care.

Response: Section 1932(b)(2)(a)(ii) of the Act requires MCOs and PCCMs to comply with guidelines established under section 1852(d)(2) of the Act regarding coordination of post-stabilization care in the same manner as the guidelines apply to Medicare+Choice plans under Part C of title XVIII. Therefore, according to statute, we must follow the rules that apply under the Medicare+Choice program. In this case, that is a 1-hour timeframe for MCOs or PCCMs to notify a hospital before post-stabilization services may begin.

Comment: A few commenters pointed out that proposed §438.114(c)(1) contains an error by referring to entities identified in subparagraph (c) when it should refer to paragraph (b).

Response: The commenters are correct. We have made the change in the final rule.

7. Solvency Standards (Proposed §438.116)

Section 4706 of the BBA added new solvency standards to section 1903(m)(1) of the Act, requiring that an MCO's provision against the risk of insolvency meet the requirements of a new section 1903(m)(1)(C)(i), unless exceptions in section 1903(m)(1)(C)(ii) apply. Under section 1903(m)(1)(C)(i), the organization must meet "solvency standards established by the State for private health maintenance organizations" (or be "licensed or certified by the State as a risk-bearing entity.") The

exceptions to this new requirement in section 1903(m)(1)(C)(ii) apply if the MCO, (1) is not responsible for inpatient services, (2) is a public entity, (3) has its solvency guaranteed by the State, or (4) is, or is controlled by FQHCs, and meets standards the State applies to FQHCs. Section 4710(b)(4) of the BBA provided that the new solvency standards applied to contracts entered into or renewed on or after October 1, 1998. Proposed §438.116 reflects these statutory provisions. We received no comments on this section and are implementing it as proposed.