

## Memorandum

### **RE: Part 438, Subpart C--Enrollee Rights and Protections, Final Medicaid Managed Care Rules**

From: Randy Boyle  
Date: March 26, 2001

Below is a review of the changes contained in the Enrollee Rights and Protections provisions of the final with comment period regulations. This memorandum summarizes the proposed rules and notes the changes that have been made. It does not present a full discussion of either the statute or proposed regulations. For fuller explanation of the proposed rules and NHeLP's reactions and suggestions concerning each rule, see Health Advocate No. 194 (Fall 1998); for similar discussion of the statute, see Health Advocate No. 190 (Fall 1997).

### **§ 438.100 Enrollee Rights**

The requirements in proposed § 438.100 (Enrollee Protections) were completely removed in the final version. The requirements of the proposed section are now found in §§ 438.10, 438.206, and 438.210. The final rule at § 438.100 comes from the proposed rule § 438.320. The analysis below compares proposed rule § 438.320 to final rule § 438.100.

The proposed rule only applied to MCO's. Under the final rule, the State must ensure that both MCO's and PHP's have written policies regarding the enrollee rights in this section. The State must also ensure that each MCO, PHP, and PCCM complies with *applicable* (word added in final version) Federal and State laws pertaining to enrollee rights and that its staff and provider affiliates "take those rights into account" when furnishing services.

(b): Enrollees' *Basic rights* are now termed *Specific rights* in response to comments that the rights were too subjective and capable of being misconstrued. The wording of the rights has been expanded. The former Basic rights only pertained to MCO's. The revised

*Specific Rights*

under (b)(2) apply to MCO's, PHP's and PCCM's, while those under (b)(3) just apply to MCO's and PHP's. This entire subsection (b) as been rearranged with changes of significance pointed out below. NHeLP suggested making the rule consistent with the Patients Bill of Rights and Responsibilities. Many of the rights in that legislation are mentioned in various parts of the BBA rules.

States do not merely need to ensure that each enrollee has these rights, but must ensure that each managed care enrollee is *guaranteed* these rights. This appears to be an effort to put more force into the rights.

(b)(2)(i): The right to receive the information in § 438.10 (proposed rule also included information in § 438.318 which now has been incorporated into § 438.10).

(b)(2)(iii): An enrollee not only has the right to "receive information on available treatment options and alternatives," but under the revised rule these must be "presented in a manner appropriate to the enrollee's condition and ability to understand." This subsection also references § 438.10(e) pertaining to information requirements for services that are not covered because of moral or religious objections.

(b)(2)(iv): "The right to refuse treatment" is added to the right to participate in decisions regarding one's health care, a point that NHeLP suggested in our comments.

(b)(2)(v): The right "[t]o 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" was added.

(b)(3)(i): The revised regulation speaks of health care services "furnished" to an enrollee, rather than "provided" to an enrollee.

(b)(3)(ii): Adds the right "[t]o obtain a second opinion from an appropriately qualified health care professional in accordance with § 438.206(d)(3)."

(b)(3)(iii): This section significantly improves enrollees' rights regarding their medical records. The proposed rule only granted access to medical records in accordance with applicable Federal and State laws (which may be nonexistent). The revised section grants the right of an enrollee to "request and review a copy of his or her medical records, and to request that they be amended or corrected, as specified in §438.224." NHeLP had suggested including the right to review, copy, and request amendments to medical records. The rule does not require that the copies be provided at no cost to the patient.

(c): This entire subsection, *Free exercise of rights*, has been added in response to comments suggesting that people should be able to exercise their rights without fear of reprisal. The State must ensure that enrollees are free to exercise their rights and that exercising one's rights does not lead to reprisal from an MCO, PHP, PCCM, providers, or the State agency.

(d): This subsection was derived from proposed subsection (c). The subsection title changed from *Other statutory requirements* to *Compliance with other Federal and State laws*. The State must ensure that MCO's and (now added:) PHP's and PCCM's comply with "applicable" Federal and State laws. The proposed subsection included the Civil Rights Act of 1964, the Age Discrimination Act of 1975, and the Americans with Disabilities Act as examples of laws with which a State must ensure compliance. The revised subsection adds specificity to examples by adding "Title VI" to the Civil Rights Act of 1964 and the implementing regulations, the implementing regulations to the Age Discrimination of 1975, and specifying "Titles II and III" of the ADA. The Rehabilitation Act of 1973 and "other laws regarding privacy and confidentiality" are added as examples.

Effects of postponing these rules: Without these rules, a patient does not necessarily have a right to a second opinion (will depend on state law or the managed care contract.) Some states do not provide for access to or opportunities to correct inaccurate information in medical records. Without this regulation, a patient may be kept from his/her medical records. This makes it difficult for a patient to switch health providers and maintain continuity of care. Incorrect information can follow a patient and interfere with relations with other health care providers or even with employers. Without these regulations, it is not clear that a MCO, PHP, or PCCM could not interfere with the patient's attempts to assert his/her rights, (e.g. through retaliation.)

Implementation of Federal law: HCFA says that subsections (a)(2), (b)(1), (b)(4), (b)(5), (b)(6), (b)(8), (c), and (d) are supported by its authority under § 1902(a)(19) of the Act to assure that States provide safeguards as may be necessary to assure that care and services will be provided in the best interests of the recipients. This rule and other subparts of Part 438 implement the Consumer Bill of Rights and Responsibilities (CBRR).

#### **§ 438.102 Provider-enrollee communications**

(a): This subsection originally defined "practitioner." Comments noted that the term and the definition failed to include many professionals. The subsection now defines a "health care professional," and the definition includes all of the professionals found in § 1932(b)(3)(C) of the BBA. NHeLP had commented that the list of providers should be broadened.

(b): This section on the physician "gag rule" has been expanded. The proposed rule only covered MCO's; now it also includes PHP's. The proposed rule only prohibited an MCO from limiting or restricting a practitioner from advising a patient about the patient's health status or about medical care or treatment regardless of whether the MCO provides benefits for the particular type of care or treatment.

Under the revised rule, an MCO or PHP may not prohibit or otherwise restrict a health care professional acting within the *lawful* (word added) scope of his or her practice from "advising or advocating on behalf" of a patient with respect to several items. The included items are: the patient's health status; medical care; treatment options (including alternative treatments that

may be self-administered); information needed to decide among relevant treatment options; risks, benefits, and consequences of treatment or non-treatment; and the patient'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. The changed provisions now parallel those found in the Medicare+Choice regulations, thus implementing one of NHeLP's comments.

(b)(2): The revised regulation also contains access provisions not found in the proposed version. MCO's and PHP's are required to take steps to ensure that health care professionals furnish information about treatment options (including refusal of treatment) in a culturally competent manner and ensure that enrollees with disabilities have effective communication with "all health system participants" with respect to treatment options. The new access provisions address some of NHeLP's concerns about culturally and linguistically appropriate notices.

(b)(3): This subsection and the balance of § 438.102 incorporate the "Conscience protection" provisions of proposed § 438.102(c). The proposed version made it clear that an MCO did not need to provide or pay for services with which the MCO objected on moral or religious grounds if it provided written information on these policies: To the State at the time it applied for a Medicaid contract; to prospective enrollees before and during enrollment; and to current enrollees within 90 days of adopting the policy.

Subsection (b)(3) continues the right of an MCO (and now also a PHP) to object to a service on moral or religious grounds. The comments to the revised regulations note that there is nothing to preclude a governmental entity from expressing a moral objection. NHeLP had suggested that HCFA clarify that the conscience clause cannot apply to any public managed care entity.

(c): This revised section increases the notice requirements for MCO's and PHP's that choose not to provide certain services based on moral or religious grounds. In the proposed regulation, these entities only needed to give notice to the state that they would not provide these services at the time they apply for a Medicaid contract. Now they must also give notice if they adopt the policy during the term of the contract. Potential enrollees must still be advised before and during enrollment. The subsection keeps the requirement of notice to enrollees within 90 days after adopting the policy, but the subsection also notes that § 438.10(d)(1)(ii) requires the MCO or PHP to furnish the information at least 30 days before the effective date of the policy. A new subsection (c)(ii)(2) clarifies that these entities do not need to tell enrollees and potential enrollees how and where to get the excluded services, but only how and where to obtain information about the service. HCFA states that the revisions to this section provide clarification to confusing language in the preamble, as NHeLP suggested. However, the revisions do not

address our concerns about continuation of treatment that is begun before the change in policy. Moreover, merely providing information about services, rather than making direct referrals to the needed services, erects a substantial barrier to receiving those services.

(d): Former language said that nothing under the conscience provisions may be construed to affect disclosure under State law or ERISA. That language was entirely removed, and the comments do not indicate why or whether it was moved. The new (d) makes it the State's responsibility to furnish information on how and where to obtain any services that an MCO or PHP chooses to exclude.

(e): This new subsection clarifies that an MCO or PHP that violates the anti-gag rule provisions is subject to sanctions under §§ 438.700 *et. seq.*

Effects of postponing these rules: While some of the anti-gag rule provisions may also be covered under former President Clinton's Executive Order and HCFA transmittals prohibiting gag rules, we should not count on the current administration to continue this policy. Without these regulations, the anti-gag rule provisions of the BBA read alone are vague and of limited effectiveness. The regulations clarify that patients must be made aware of alternative treatments. While the BBA requires an MCO to inform prospective enrollees and enrollees of policies objecting to the provision of certain services, the BBA is silent about what, if anything, MCO's must inform enrollees or potential enrollees regarding access to the services. While the regulations do not go far enough in providing referrals to and comprehensive information about denied services, the regulations at least require MCO's and PHP's to provide information about where and how to get information about the service. Without the regulations, women will not know how and where to receive reproductive health information when their providers do not offer these services. People living with HIV will not get information about family planning services that can prevent transmission of HIV to a partner. Without these rules, there will be more unwanted pregnancies and more HIV infections. Without these rules, patients may not be informed that one of their choices is to refuse treatment, and they will not make crucial healthcare decisions based on all currently available options.

Implementation of Federal law: This rule prohibits gag rules and clarifies other prohibitions on limiting provider-patient communications. The rule also spells out how a health care provider can assert conscience protections while giving adequate notice to patients. The rule clarifies BBA § 4704(a) [Social Security Act § 1932(b)(3), 42 U.S.C. § 1396v(b)(3).]

## § 438.104 Marketing activities

(a): This section defines the marketing terms. The definition of "cold-call" marketing was expanded. The new definition applies to MCO's, PCCM's, and PHP's, not just the first two entities, and includes calls to enrollees as well as potential enrollees. Cold-calling is not only for the purpose of influencing a person to enroll in the entity, but also for the purpose of influencing a person to reenroll or disenroll from another entity. The comments indicate that the definition would prohibit approaching homeless people in a shelter (or elsewhere) or institutionalized individuals. The revised subsection removes the definitions for "choice counseling," "enrollment activities," and "enrollment broker." These definitions were moved to § 438.810, Expenditures for Enrollment Broker Services. NHeLP had suggested moving the definitions to the enrollment and disenrollment provisions.

Marketing materials now include materials sent to current enrollees, not only potential enrollees. MCO's, PHP's, and PCCM's are now all included under marketing materials restrictions. Subsection (b)(2) is amended to include examples of marketing statements that would be considered inaccurate, false, or misleading. These assertions, whether oral or written, include (but are not limited to), statements that a recipient must enroll in the MCO, PHP, or PCCM in order to obtain benefits or in order to not lose benefits or that the MCO, PHP, or PCCM is endorsed by HCFA, the Federal or State government, or similar entity. NHeLP suggested the wording for this subsection.

The balance of the provisions in this section were moved around, but left largely unchanged. HCFA did not incorporate NHeLP's suggestion to prohibit marketing at health fairs, physician offices, health facilities, check cashing facilities, laundromats, WIC sites, or other social service sites. The revised regulations also do not include NHeLP's suggestions to prohibit inducements or incentives to entice people to enroll.

NHeLP supported HCFA's requirement to have a committee review marketing materials. HCFA did not revise (c) which pertains to state agency review of marketing materials; however, the comments state that HCFA did not intend that the committee itself review and approve marketing materials. Rather, the State must consult with this committee during the State's own process of review and approval.

Effects of postponing this rule: The BBA does not define "cold-call" marketing and it leaves the explanation of marketing fraud up to HHS. Unless prohibited by State law, people may be

subject to cold call marketing, misleading or confusing statements regarding a health plan or the effects of not choosing a health plan. Health plans may trash the competition with inaccurate comparisons or they may infer that a particular plan is endorsed by a government agency. Plans may scare beneficiaries into thinking that they will lose benefits if they do not choose a plan.

Implementation of federal law: The rule effectuates BBA § 4707(a) [adding Social Security Act § 1932d(2), 42 U.S.C. § 1396v(d)(2).] The provision on State review of marketing materials is not effective until the Secretary specifies a date in consultation with the State. Thus, the regulations are necessary in order to effectuate the State review provisions.

### **§ 438.106 Liability for payment**

The amended regulation now provides that not only MCO's, but also PHP's must provide that their Medicaid enrollees are not liable for the entities' debts. These entities cannot hold enrollees liable for *covered* (word added in final version) services provided to the enrollee. For services provided outside of the regular contract with the MCO or PHP, an enrollee would not be liable for payment for *covered* (word added in final version) services in excess of what he or she would owe if the MCO or PHP provided the services directly. The comments to these changes state that "covered" services "include any service that the State covers through its managed care program, whether it is a service that is covered under the contract between the State and the MCO or a service that is carved out of the capitation rate and paid fee for service, as long as the service is obtained appropriately." The balance of this regulation remains essentially the same.

HCFA reaffirmed the point that NHeLP made in our comments that Medicaid beneficiaries should not "owe" an MCO any payment amounts beyond nominal cost sharing. HCFA noted that Section 1916 of the Social Security Act prohibits States and plans from imposing additional cost sharing.

Effects of postponing this rule: This regulation only provides clarification to BBA § 4704(a)(6).

Implementation of Federal law: Clarifies BBA § 4704(a)(6) [adding Social Security Act § 1932(b)(6)(A), 42 U.S.C. § 1396v(b)(6)(A).]



### **§ 438.108 Cost sharing**

The only change to this section was to change the reference to § 447.58 to § 447.60. The revision picks up the section requiring that contracts with MCO's must provide that any cost sharing imposed on enrollees be in accordance with other requirements regarding cost sharing.

Effects of postponing this rule: Little major effect.

Implementation of Federal law: This section clarifies BBA § 4708(b) [amending Social Security Act § 1916, 42 U.S.C. § 1396o.]

### **§ 438.110 Assurances of adequate capacity and services**

This section appears in the proposed rules, but was redesignated as § 438.207 in the revised rules because the provisions are better read in conjunction with § 438.206.

### **§ 438.114 Emergency and post-stabilization services**

The proposed definitions for "Emergency medical condition," "emergency services," and "post-stabilization care services" have been deleted from this section. The revised regulation cross- references the terms with §§ 422.113(b) and (c) where those terms are defined in the

Medicare+Choice rules. The Medicare+Choice definitions of "emergency medical condition" and "emergency services" are identical to those in the proposed regulation. However, the definition of "post-stabilization care services" is significantly different. The proposed definition refers to "medically necessary non-emergency services," while the Medicare+Choice rule refers only to "covered services."

Section (b) concerns advising enrollees about emergency and post-stabilization services. The section was renamed *Information requirements* from the proposed *Disclosure requirements*. Under the proposed regulation, MCE's were only required to give a notice at the time of enrollment and at least annually. Under the revised rule, each State, or at the State's option, each MCO, PHP, and PCCM, also must give a notice to enrollees and potential enrollees upon request (as suggested by NHeLP.) Under the proposed rule, the list of items for the notice is what entities must provide "at a minimum." Under the revised rule, entities must provide "at least" the items listed. HCFA did not incorporate NHeLP's suggestion to require posting of information about emergency services and post-stabilization services in emergency rooms and providers' offices.

The revised rule deleted (b)(2) of the proposed rule which required that the notice include information about "the appropriate use of emergency services." Section (b)(1) required an explanation of what constitutes an "emergency," but now requires descriptions of what constitute an "emergency medical condition" and "emergency services." The prior version of the rule required the notice to give the locations of any emergency settings and other locations where MCE physicians and hospitals provide emergency and post-stabilization services. The current version of the rule requires this notice of *MCO, PHP, and PCCM providers* and hospitals.

This section adds (b)(5) which requires that the notice include 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." The revision seems to address NHeLP's and other advocate's concern that the notice inform beneficiaries that they can seek emergency treatment from out-of-plan providers. The revised subsections (b)(6) and (c) delete most of the wording regarding preauthorization for post-stabilization care unless the MCE does not provide preauthorization within an hour or the MCE cannot be reached for preauthorization. The revised subsections (b)(6) and (f) now refer to the post-stabilization provisions in the Medicare+Choice regulations at § 422.113(c). The Medicare+Choice provisions give a more extensive outline of the process for preauthorization for post-stabilization care, including the one hour period for a Medicare+Choice plan to respond.

The new subsection (c) gives the general rule for coverage and payment of emergency and post-stabilization care services. If the entity is an MCO or a PHP, that entity is responsible for coverage and payment. If the entity is a PCCM that has a risk contract covering such services,

the PCCM is responsible. If the PCCM has a fee-for-service contract, then the State is responsible for coverage and payment.

Proposed subsection (d)(1) required an MCO to pay for emergency services regardless of whether the entity that furnished the services has a contract with the MCO. The final rule expands this provision to include PHP's and PCCM's as well. Subsection (d)(1)(ii) also now includes the provisions of proposed subsection (e)(1). The subsection delineates several circumstances under which an MCO, PHP, or PCCM may not deny payment for treatment. In keeping with the earlier sections, (d)(1)(ii)(A) now refers to the definition of emergency medical condition found in the Medicare+Choice regulations. Under the proposed subsection, an MCO could not deny payment if a "practitioner or other representative of the MCO instructs the enrollee to seek emergency services." Under the revised rule, an MCO, PHP, or PCCM cannot deny payment for services if a representative (practitioner was deleted) of the entity instructs an enrollee to seek emergency services. Furthermore, in any event, whether the PCCM referred the enrollee or not, the PCCM must allow the enrollee to obtain emergency services outside of the PCCM system and must pay for those services if the manager's contract is a risk contract covering those services.

Section (e), *Additional rules for emergency services*, has been rewritten and includes the provisions of proposed section (f). Under this section, an MCO, PHP, or PCCM may not limit what constitutes an emergency medical condition on the basis of lists of diagnoses or symptoms. The entity also may not refuse to process any claim because it does not contain the PCP's authorization number. Under (e)(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. Proposed section (f) is incorporated with changes as subsection (e)(3). The revised rule clarifies that the attending

*emergency  
physician or  
provider*

(changed from practitioner) is responsible for determining when the enrollee is sufficiently stabilized for transfer or discharge, and that determination is binding on the entity (not just an MCO) as

*responsible for coverage and payment*

(added in revised rule). This rule matches a similar one found under Medicare+Choice rules. Proposed subsection (e)(2), which stated that an MCO is not responsible for out of network services that do not constitute an emergency or post-stabilization services, was deleted.

Section (f) *Stabilized condition* was renumbered (e)(3) with the changes noted in the previous paragraph. New section (f) replaces all of proposed subsection (c) regarding coverage and payment for post-stabilization services. The new subsection (f) refers to the Medicare+Choice §

422.113(c) for guidance as to what is covered and paid for. This revised section incorporates some of NHeLP's concerns about post-stabilization care.

HCFA did not accept NHeLP's suggestions to incorporate provisions to enforce compliance with EMTALA.

Effects of postponing this rule: The BBA provision on post-stabilization care refers to the similar provision under Medicare+Choice. That provision in turn leaves it to the Secretary of HHS to define post-stabilization care. Thus, these regulations are vital for defining the requirements of post-stabilization care for Medicaid managed care beneficiaries. Without the notice provisions in these regulations, beneficiaries would not know that they may seek emergency services at out of plan facilities. These beneficiaries may experience delays in care with tragic consequences. Hospitals may incorrectly bill beneficiaries for emergency services. The rules, but not the BBA, clarify that a plan may not refuse to process a claim because it did not contain the PCP's authorization number, and a plan cannot refuse to pay for emergency services merely because the emergency condition does not appear on a list of diagnoses or symptoms. Without the rules, there may be confusion over who determines when a patient is sufficiently stabilized for transfer or discharge.

Implementation of Federal law: This rule clarifies BBA § 4704(a) [adding Social Security Act §§ 1932(b)(1)-(b)(2), 42 U.S.C. §§1396v(b)(1)-(b)(2).]

### **§ 438.116 Solvency standards**

(a) *Basic Rule*: The name of the section was changed to *Requirement for assurances*. This section previously only applied to MCO's; now it also applies to PHP's. A federally qualified HMO is exempted from this requirement under the revised rule, adding language to (a)(1) and a new subsection (a)(2). The comments explain that section 1903(m)(1)(A) provides that a federally qualified HMO is deemed to meet the solvency requirements of that section. Under the proposed rule, an entity must meet the State's solvency standards and must provide satisfactory assurances to the State of its solvency. In the final rule, the need to meet the State's solvency standards was moved to (b)(1).

Section (b) has been renumbered as (b)(1), with the addition of wording from (a)(1) as noted in the previous paragraph. *State solvency standards* requirement has been renamed *Other requirements--(1) General rule*

. The general rule now applies to PHP's as well as MCO's. HCFA did not accept NHeLP's suggestion to include PCCM's.

Proposed Section (c), *Exceptions to State solvency requirement*, has been renumbered as (b)(2). Exceptions (1) through (4) are renumbered as (i) through (iv), and it is clarified that any one of the exceptions may apply, rather than separating them by "or." The revised rule deletes (c)(5) and (c)(6) pertaining to contracts entered into before October 1998 and an exemption expiring on August 5, 2000 since all contracts are now subject to the new requirements.

Effects of postponing this rule: No major effects.

Implementation of Federal law: This rule clarifies BBA § 4706 [amending Social Security Act § 1903(m)(1), 42 U.S.C. § 1396b(m)(1).]