

(2) Evaluate the continuity and coordination of care furnished to enrollees.

(3) If the organization uses written protocols for utilization review, the organization must—

(i) Base those protocols on current standards of medical practice; and

(ii) Have mechanisms to evaluate utilization of services and to inform enrollees and providers of services of the results of the evaluation.

(f) *Requirements for all types of plans—*

(1) *Health information.* For all types of plans that it offers, an organization must—

(i) Maintain a health information system that collects, analyzes, and integrates the data necessary to implement its quality assessment and performance improvement program;

(ii) Ensure that the information it receives from providers of services is reliable and complete; and

(iii) Make all collected information available to CMS.

(2) *Program review.* For each plan, there must be in effect a process for formal evaluation, at least annually, of the impact and effectiveness of its quality assessment and performance improvement program.

(3) *Remedial action.* For each plan, the organization must correct all problems that come to its attention through internal surveillance, complaints, or other mechanisms.

[63 FR 35082, June 26, 1998, as amended at 65 FR 40323, June 29, 2000]

§ 422.154 External review.

(a) *Basic rule.* Except as provided in paragraph (c) of this section, each M+C organization must, for each M+C plan it operates, have an agreement with an independent quality review and improvement organization (review organization) approved by CMS to perform functions of the type described in part 466 of this chapter.

(b) *Terms of the agreement.* The agreement must be consistent with CMS guidelines and include the following provisions:

(1) Require that the organization—

(i) Allocate adequate space for use of the review organization whenever it is conducting review activities; and

(ii) Provide all pertinent data, including patient care data, at the time the review organization needs the data to carry out the reviews and make its determinations.

(2) Except in the case of complaints about quality, exclude review activities that CMS determines would duplicate review activities conducted as part of an approved accreditation process or as part of CMS monitoring.

(c) *Exceptions.* The requirement of paragraph (a) of this section does not apply for an M+C private fee-for-service plan or a non-network M+C MSA plan if the organization does not carry out utilization review with respect to the plan.

[63 FR 35082, June 26, 1998, as amended at 65 FR 40323, June 29, 2000]

§ 422.156 Compliance deemed on the basis of accreditation.

(a) *General rule.* An M+C organization is deemed to meet all of the requirements of any of the areas described in paragraph (b) of this section if—

(1) The M+C organization is fully accredited (and periodically reaccredited) for the standards related to the applicable area under paragraph (b) of this section by a private, national accreditation organization approved by CMS; and

(2) The accreditation organization used the standards approved by CMS for the purposes of assessing the M+C organization's compliance with Medicare requirements.

(b) *Deemable requirements.* The requirements relating to the following areas are deemable:

(1) Quality assurance.

(2) Antidiscrimination.

(3) Access to services.

(4) Confidentiality and accuracy of enrollee records.

(5) Information on advance directives.

(6) Provider participation rules.

(c) *Effective date of deemed status.* The date on which the organization is deemed to meet the applicable requirements is the later of the following:

(1) The date on which the accreditation organization is approved by CMS.

(2) The date the M+C organization is accredited by the accreditation organization.

(d) *Obligations of deemed M+C organizations.* An M+C organization deemed to meet Medicare requirements must—

(1) Submit to surveys by CMS to validate its accreditation organization's accreditation process; and

(2) Authorize its accreditation organization to release to CMS a copy of its most recent accreditation survey, together with any survey-related information that CMS may require (including corrective action plans and summaries of unmet CMS requirements).

(e) *Removal of deemed status.* CMS removes part or all of an M+C organization's deemed status for any of the following reasons:

(1) CMS determines, on the basis of its own investigation, that the M+C organization does not meet the Medicare requirements for which deemed status was granted.

(2) CMS withdraws its approval of the accreditation organization that accredited the M+C organization.

(3) The M+C organization fails to meet the requirements of paragraph (d) of this section.

(f) *Enforcement authority.* CMS retains the authority to initiate enforcement action against any M+C organization that it determines, on the basis of its own survey or the results of an accreditation survey, no longer meets the Medicare requirements for which deemed status was granted.

[63 FR 35082, June 26, 1998, as amended at 65 FR 40323, June 29, 2000; 65 FR 59749, Oct. 6, 2000]

§ 422.157 Accreditation organizations.

(a) *Conditions for approval.* CMS may approve an accreditation organization with respect to a given standard under this part if it meets the following conditions:

(1) In accrediting M+C organizations, it applies and enforces standards that are at least as stringent as Medicare requirements with respect to the standard or standards in question.

(2) It complies with the application and reapplication procedures set forth in § 422.158.

(3) It ensures that:

(i) Any individual associated with it, who is also associated with an entity it accredits, does not influence the ac-

creditation decision concerning that entity.

(ii) The majority of the membership of its governing body is not comprised of managed care organizations or their representatives.

(iii) Its governing body has a broad and balanced representation of interests and acts without bias.

(b) *Notice and comment—(1) Proposed notice.* CMS publishes a notice in the FEDERAL REGISTER whenever it is considering granting an accreditation organization's application for approval. The notice—

(i) Announces CMS's receipt of the accreditation organization's application for approval;

(ii) Describes the criteria CMS will use in evaluating the application; and

(iii) Provides at least a 30-day comment period.

(2) *Final notice.* (i) After reviewing public comments, CMS publishes a final FEDERAL REGISTER notice indicating whether it has granted the accreditation organization's request for approval.

(ii) If CMS grants the request, the final notice specifies the effective date and the term of the approval, which may not exceed 6 years.

(c) *Ongoing responsibilities of an approved accreditation organization.* An accreditation organization approved by CMS must undertake the following activities on an ongoing basis:

(1) Provide to CMS in written form and on a monthly basis all of the following:

(i) Copies of all accreditation surveys, together with any survey-related information that CMS may require (including corrective action plans and summaries of unmet CMS requirements).

(ii) Notice of all accreditation decisions.

(iii) Notice of all complaints related to deemed M+C organizations.

(iv) Information about any M+C organization against which the accrediting organization has taken remedial or adverse action, including revocation, withdrawal or revision of the M+C organization's accreditation. (The accreditation organization must provide this information within 30 days of taking the remedial or adverse action.)