

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

(f) *Enforcement authority.* HCFA 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.

**§ 422.157 Accreditation organizations.**

(a) *Conditions for approval.* HCFA 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 is not controlled, as defined in § 413.17 of this chapter, by the entities it accredits.

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

(i) Specifies the basis for granting approval;

(ii) Describes how the accreditation organization's accreditation program meets or exceeds all of the Medicare requirements for which HCFA would deem compliance on the basis of the organization's accreditation; and

(iii) Provides opportunity for public comment.

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

(ii) If HCFA 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

HCFA must undertake the following activities on an ongoing basis:

(1) Provide to HCFA 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 HCFA may require (including corrective action plans and summaries of unmet HCFA 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.)

(v) Notice of any proposed changes in its accreditation standards or requirements or survey process. If the organization implements the changes before or without HCFA approval, HCFA may withdraw its approval of the accreditation organization.

(2) Within 30 days of a change in HCFA requirements, submit to HCFA—

(i) An acknowledgment of HCFA's notification of the change;

(ii) A revised cross-walk reflecting the new requirements; and

(iii) An explanation of how the accreditation organization plans to alter its standards to conform to HCFA's new requirements, within the timeframes specified in the notification of change it receives from HCFA.

(3) Permit its surveyors to serve as witnesses if HCFA takes an adverse action based on accreditation findings.

(4) Within 3 days of identifying, in an accredited M+C organization, a deficiency that poses immediate jeopardy to the organization's enrollees or to the general public, give HCFA written notice of the deficiency.

(5) Within 10 days of HCFA's notice of withdrawal of approval, give written notice of the withdrawal to all accredited M+C organizations.

(d) *Continuing Federal oversight of approved accreditation organizations.* This paragraph establishes specific criteria

and procedures for continuing oversight and for withdrawing approval of an accreditation organization.

(1) *Equivalency review.* HCFA compares the accreditation organization's standards and its application and enforcement of those standards to the comparable HCFA requirements and processes when—

(i) HCFA imposes new requirements or changes its survey process;

(ii) An accreditation organization proposes to adopt new standards or changes in its survey process; or

(iii) The term of an accreditation organization's approval expires.

(2) *Validation review.* HCFA or its agent may conduct a survey of an accredited organization, examine the results of the accreditation organization's own survey, or attend the accreditation organization's survey, in order to validate the organization's accreditation process. At the conclusion of the review, HCFA identifies any accreditation programs for which validation survey results—

(i) Indicate a 20 percent rate of disparity between certification by the accreditation organization and certification by HCFA or its agent on standards that do not constitute immediate jeopardy to patient health and safety if unmet;

(ii) Indicate any disparity between certification by the accreditation organization and certification by HCFA or its agent on standards that constitute immediate jeopardy to patient health and safety if unmet; or

(iii) Indicate that, irrespective of the rate of disparity, there are widespread or systematic problems in an organization's accreditation process such that accreditation no longer provides assurance that the Medicare requirements are met or exceeded.

(3) *Onsite observation.* HCFA may conduct an onsite inspection of the accreditation organization's operations and offices to verify the organization's representations and assess the organization's compliance with its own policies and procedures. The onsite inspection may include, but is not limited to, reviewing documents, auditing meetings concerning the accreditation process, evaluating survey results or the accreditation status decision making

process, and interviewing the organization's staff.

(4) *Notice of intent to withdraw approval.* If an equivalency review, validation review, onsite observation, or HCFA's daily experience with the accreditation organization suggests that the accreditation organization is not meeting the requirements of this subpart, HCFA gives the organization written notice of its intent to withdraw approval.

(5) *Withdrawal of approval.* HCFA may withdraw its approval of an accreditation organization at any time if HCFA determines that—

(i) Deeming based on accreditation no longer guarantees that the M+C organization meets the M+C requirements, and failure to meet those requirements could jeopardize the health or safety of Medicare enrollees and constitute a significant hazard to the public health; or

(ii) The accreditation organization has failed to meet its obligations under this section or under § 422.156 or § 422.158.

(6) *Reconsideration of withdrawal of approval.* An accreditation organization dissatisfied with a determination to withdraw HCFA approval may request a reconsideration of that determination in accordance with subpart D of part 488 of this chapter.

**§ 422.158 Procedures for approval of accreditation as a basis for deeming compliance.**

(a) *Required information and materials.* A private, national accreditation organization applying for approval must furnish to HCFA all of the following information and materials. (When reapplying for approval, the organization need furnish only the particular information and materials requested by HCFA.)

(1) The types of M+C plans that it would review as part of its accreditation process.

(2) A detailed comparison of the organization's accreditation requirements and standards with the Medicare requirements (for example, a crosswalk).

(3) Detailed information about the organization's survey process, including—