

survey or the results of an accreditation survey, no longer meets the Medicare requirements for which deemed status was granted.

§ 423.168 Accreditation organizations.

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

(1) In accrediting Part D sponsors and Part D plans, it applies and enforces standards that are at least as stringent as Medicare requirements for the standard or standards in question.

(2) It complies with the application and reapplication procedures set forth in § 423.171.

(3) It ensures that—

(i) Any individual associated with it, who is also associated with an entity it accredits, does not influence the accreditation decision concerning that entity;

(ii) The majority of the membership of its governing body is not comprised of managed care organizations, Part D sponsors or their representatives; and

(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 uses 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 notice in the FEDERAL REGISTER 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 that 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 Part D sponsors.

(iv) Information about any Part D sponsor against which the accrediting organization has taken remedial or adverse action, including revocation, withdrawal, or revision of the Part D sponsor'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 CMS approval, CMS may withdraw its approval of the accreditation organization.

(2) Within 30 days of a change in CMS requirements, submit the following to CMS—

(i) An acknowledgment of CMS's notification of the change.

(ii) A revised crosswalk reflecting the new requirements.

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

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

(4) Within 3 days of identifying, in an accredited Part D sponsor, a deficiency that as determined by the accrediting organization poses immediate jeopardy to the plan's enrollees or to the general public, give CMS written notice of the deficiency.

(5) Within 10 days of CMS's notice of withdrawal of approval, give written notice of the withdrawal to all accredited Part D sponsors.

(6) On an annual basis, provide summary data specified by CMS that relate to the past year's accreditation activities and trends.

(d) *Continuing Federal oversight of approved accreditation organizations.* Specific criteria and procedures for continuing oversight and for withdrawing approval of an accreditation organization include the following:

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

(i) CMS 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.* CMS 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 to validate the organization's accreditation process. At the conclusion of the review, CMS identifies any accreditation programs for which validation survey results indicate—

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

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

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

(3) *Onsite observation.* CMS 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 the following:

(i) Reviewing documents.

(ii) Auditing meetings concerning the accreditation process.

(iii) Evaluating survey results or the accreditation status decision-making process.

(iv) Interviewing the organization's staff.

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

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

(i) Deeming, based on accreditation, no longer guarantees that the Part D sponsor meets the requirements for offering qualified prescription drug coverage, and failure to meet those requirements may 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 § 423.165 or § 423.171.

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

§ 423.171 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 CMS all of the following information and materials (when reapplying for approval, the organization need furnish only the particular information and materials requested by CMS):