§ 488.7 Validation survey.

(a) Basis for survey. CMS may require a survey of an accredited provider or supplier to validate its organization’s accreditation process. These surveys will be conducted on a representative sample basis, or in response to substantial allegations of noncompliance.

(1) When conducted on a representative sample basis, the survey is comprehensive and addresses all Medicare conditions or is focused on a specific condition or conditions.

(2) When conducted in response to a substantial allegation, the State survey agency surveys for any condition that CMS determines is related to the allegations.

(b) If the State survey agency substantiates a deficiency and CMS determines that the provider or supplier is out of compliance with any Medicare condition, the State survey agency conducts a full Medicare survey.

(b) Effect of selection for survey. A provider or supplier selected for a validation survey must—

(1) Authorize the validation survey to take place; and

(2) Authorize the State survey agency to monitor the correction of any deficiencies found through the validation survey.

(c) Refusal to cooperate with survey. If a provider or supplier selected for a validation survey fails to comply with the requirements specified in paragraph (b) of this section, it will no longer be deemed to meet the Medicare conditions but will be subject to full review by the State survey agency in accordance with § 488.11 and may be subject to termination of its provider agreement under § 489.53 of this chapter.

(d) Consequences of finding of noncompliance. If a validation survey results in a finding that the provider or supplier is out of compliance with one or more Medicare conditions, the provider or supplier will no longer be deemed to meet any Medicare conditions. Specifically, the provider or supplier will be subject to the participation and enforcement requirements applied to all providers or suppliers that are found out of compliance following a State agency survey under § 488.24 and to full review by a State agency survey in accordance with § 488.11 and may be subject to termination of the provider agreement under § 439.53 of this chapter and any other applicable intermediate sanctions and remedies.

(e) Reinstating effect of accreditation. An accredited provider or supplier will again be deemed to meet the Medicare conditions in accordance with this section if—

(1) It withdraws any prior refusal to authorize its accreditation organization to release a copy of the provider’s or supplier’s current accreditation survey;

(2) The provider or supplier otherwise satisfies the requirements of paragraphs (a) and (b) of this section.

§ 488.8 Federal review of accreditation organizations.

(a) Review and approval of national accreditation organization. CMS’s review and evaluation of a national accreditation organization will be conducted in accordance with, but will not necessarily be limited to, the following general criteria—

(1) The equivalency of an accreditation organization’s accreditation requirements of an entity to the comparable CMS requirements for the entity;

(2) The organization’s survey process to determine—

(i) The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training;

(ii) The comparability of survey procedures to those of State survey agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities;

(iii) The organization’s procedures for monitoring providers or suppliers found by the organization to be out of compliance with program requirements. These monitoring procedures are to be used only when the organization identifies noncompliance. If noncompliance is identified through validation surveys, the State survey agency monitors corrections as specified at § 488.7(b)(3);

(iv) The ability of the organization to report deficiencies to the surveyed facilities and respond to the facility’s plan of correction in a timely manner;

(v) The ability of the organization to provide CMS with electronic data in ASCII comparable code and reports necessary for effective validation and assessment of the organization survey process;

(vi) The adequacy of staff and other resources;

(vii) The organization’s ability to provide adequate funding for performing required surveys; and

(viii) The organization’s policies with respect to whether surveys are announced or unannounced; and

(3) The accreditation organization’s agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as CMS may require (including corrective action plans).

(b) Notice and comment. (1) CMS will publish a proposed notice in the Federal Register whenever it contemplates approving an accreditation organization’s application for deeming authority. The proposed notice will specify the basis for granting approval of deeming authority and the types of providers and suppliers accredited by the organization for which deeming authority would be approved. The proposed notice will also describe how the accreditation organization’s accreditation program provides reasonable assurance that entities accredited by the organization meet Medicare requirements. The proposed notice will also provide opportunity for public comment.

(2) CMS will publish a final notice in the Federal Register whenever it grants deeming authority to a national accreditation organization. Publication of the final notice will follow publication of the proposed notice by at least six months. The final notice will specify the effective date of the approval of deeming authority and the term of approval (which will not exceed six years).

(c) Effects of approval of an accreditation organization. CMS will deem providers and suppliers accredited by an approved accreditation organization to meet the Medicare conditions for which the approval of deeming authority has specifically been granted. The deeming authority will take effect 90 days following the publication of the final notice.