

§ 488.5

42 CFR Ch. IV (10–1–04 Edition)

(c) If CMS determines that additional information is necessary to make a determination for approval or denial of the accreditation organization's application for deeming authority, the organization will be notified and afforded an opportunity to provide the additional information.

(d) CMS may visit the organization's offices to verify representations made by the organization in its application, including, but not limited to, review of documents and interviews with the organization's staff.

(e) The accreditation organization will receive a formal notice from CMS stating whether the request for deeming authority has been approved or denied, the rationale for any denial, and reconsideration and reapplication procedures.

(f) An accreditation organization may withdraw its application for approval of deeming authority at any time before the formal notice provided for in paragraph (e) of this section is received.

(g) Except as provided in paragraph (i) of this section, an accreditation organization that has been notified that its request for deeming authority has been denied may request a reconsideration of that determination in accordance with subpart D of this part.

(h) Except as provided in paragraph (i) of this section, any accreditation organization whose request for approval of deeming authority has been denied may resubmit its application if the organization—

(1) Has revised its accreditation program to address the rationale for denial of its previous request;

(2) Can demonstrate that it can provide reasonable assurance that its accredited facilities meet applicable Medicare requirements; and

(3) Resubmits the application in its entirety.

(i) If an accreditation organization has requested, in accordance with part 488, subpart D of this chapter, a reconsideration of CMS's determination that its request for deeming approval is denied, it may not submit a new application for deeming authority for the type of provider or supplier that is at issue

in the reconsideration until the reconsideration is administratively final.

[58 FR 61838, Nov. 23, 1993]

§ 488.5 Effect of JCAHO or AOA accreditation of hospitals.

(a) *Deemed to meet.* Institutions accredited as hospitals by the JCAHO or AOA are deemed to meet all of the Medicare conditions of participation for hospitals, except—

(1) The requirement for utilization review as specified in section 1861(e)(6) of the Act and in § 482.30 of this chapter;

(2) The additional special staffing and medical records requirements that are considered necessary for the provision of active treatment in psychiatric hospitals (section 1861(f) of the Act) and implementing regulations; and

(3) Any requirements under section 1861(e) of the Act and implementing regulations that CMS, after consulting with JCAHO or AOA, identifies as being higher or more precise than the requirements for accreditation (section 1865(a)(4) of the Act).

(b) *Deemed status for providers and suppliers that participate in the Medicaid program.* Eligibility for Medicaid participation can be established through Medicare deemed status for providers and suppliers that are not required under Medicaid regulations to comply with any requirements other than Medicare participation requirements for that provider or supplier type.

(c) *Release and use of hospital accreditation surveys.*

(1) A hospital deemed to meet program requirements must authorize its accreditation organization to release to CMS and the State survey agency a copy of its most current accreditation survey together with any other information related to the survey that CMS may require (including corrective action plans).

(2) CMS may use a validation survey, an accreditation survey or other information related to the survey to determine that a hospital does not meet the Medicare conditions of participation.

(3) CMS may disclose the survey and information related to the survey to the extent that the accreditation survey and related survey information are

related to an enforcement action taken by CMS.

[58 FR 61840, Nov. 23, 1993]

§ 488.6 Other national accreditation programs for hospitals and other providers and suppliers.

(a) In accordance with the requirements of this subpart, a national accreditation program for hospitals; psychiatric hospitals; SNFs; HHAs; ASCs; RHCs; CORFs; hospices; religious non-medical health care institutions; screening mammography services; critical access hospitals; or clinic, rehabilitation agency, or public health agency providers of outpatient physical therapy, occupational therapy or speech pathology services may provide reasonable assurance to CMS that it requires the providers or suppliers it accredits to meet requirements that are at least as stringent as the Medicare conditions when taken as a whole. In such a case, CMS may deem the providers or suppliers the program accredits to be in compliance with the appropriate Medicare conditions. These providers and suppliers are subject to validation surveys under § 488.7 of this subpart. CMS will publish notices in the FEDERAL REGISTER in accordance with § 488.8(b) identifying the programs and deeming authority of any national accreditation program and the providers or suppliers it accredits. The notice will describe how the accreditation organization's accreditation program provides reasonable assurance that entities accredited by the organization meet Medicare requirements. (See § 488.5 for requirements concerning hospitals accredited by JCAHO or AOA.)

(b) Eligibility for Medicaid participation can be established through Medicare deemed status for providers and suppliers that are not required under Medicaid regulations to comply with any requirements other than Medicare participation requirements for that provider or supplier type.

(c)(1) A provider or supplier deemed to meet program requirements under paragraph (a) of this section must authorize its accreditation organization to release to CMS and the State survey agency a copy of its most current accreditation survey, together with any information related to the survey that

CMS may require (including corrective action plans).

(2) CMS may determine that a provider or supplier does not meet the Medicare conditions on the basis of its own investigation of the accreditation survey or any other information related to the survey.

(3) Upon written request, CMS may disclose the survey and information related to the survey—

(i) Of any HHA; or

(ii) Of any other provider or supplier specified at paragraph (a) of this section if the accreditation survey and related survey information relate to an enforcement action taken by CMS.

[58 FR 61840, Nov. 23, 1993, as amended at 62 FR 46037, Aug. 29, 1997; 64 FR 67052, Nov. 30, 1999]

§ 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.

(3) 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