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§ 488.2 Statutory basis.

This part is based on the indicated provisions of the following sections of the Act:

1128—Exclusion of entities from participation in Medicare.

1128A—Civil money penalties.

1814—Conditions for, and limitations on, payment for Part A services.

1819—Requirements for SNFs.

1861(f)—Requirements for psychiatric hospitals.

1861(z)—Institutional planning standards that hospitals and SNFs must meet.

1861(ee)—Discharge planning guidelines for hospitals.

1861(ss)(2)—Accreditation of religious non-medical health care institutions.

1864—Use of State survey agencies.

1865—Effect of accreditation.

1880—Requirements for hospitals and SNFs of the Indian Health Service.

1883—Requirements for hospitals that provide SNF care.

1902—Requirements for participation in the Medicaid program.

1913—Medicaid requirements for hospitals that provide NF care.

1919—Medicaid requirements for NFs.

[60 FR 50443, Sept. 29, 1995, as amended at 64 FR 67052, Nov. 30, 1999]

§ 488.3 Conditions of participation; conditions for coverage; and long-term care requirements.

(a) *Basic rules.* In order to be approved for participation in or coverage under the Medicare program, a prospective provider or supplier must:

(1) Meet the applicable statutory definition in section 1138(b), 1819, 1832(a)(2)(F), 1861, 1881, or 1919 of the Act; and

(2) Be in compliance with the applicable conditions or long-term care requirements prescribed in subpart N, Q or U of part 405, part 416, subpart C of part 418, part 482, part 483, part 484, part 485, subpart A of part 491, or part 494 of this chapter.

(b) *Special Conditions.* (1) The Secretary, after consultation with the JCAHO or AOA, may issue conditions of participation for hospitals higher or more precise than those of either those accrediting bodies.

(2) The Secretary may, at a State's request, approve health and safety requirements for providers and suppliers in that State, which are higher than

those otherwise applied in the Medicare program.

(3) If a State or political subdivision imposes higher requirements on institutions as a condition for the purchase of health services under a State Medicaid Plan approved under Title XIX of the Act, (or if Guam, Puerto Rico, or the Virgin Islands does so under a State plan for Old Age Assistance under Title I of the Act, or for Aid to the Aged, Blind, and Disabled under the original Title XVI of the Act), the Secretary is required to impose similar requirements as a condition for payment under Medicare in that State or political subdivision.

[53 FR 22859, June 17, 1988, as amended at 58 FR 61838, Nov. 23, 1993]

§ 488.4 Application and reapplication procedures for accreditation organizations.

(a) A national accreditation organization applying for approval of deeming authority for Medicare requirements under § 488.5 or 488.6 of this subpart must furnish to CMS the information and materials specified in paragraphs (a)(1) through (10) of this section. A national accreditation organization reapplying for approval must furnish to CMS whatever information and materials from paragraphs (a)(1) through (10) of this section that CMS requests. The materials and information are—

(1) The types of providers and suppliers for which the organization is requesting approval;

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

(3) A detailed description of the organization's survey process, including—

(i) Frequency of the surveys performed;

(ii) Copies of the organization's survey forms, guidelines and instructions to surveyors;

(iii) Accreditation survey review process and the accreditation status decision-making process;

(iv) Procedures used to notify accredited facilities of deficiencies and the

procedures used to monitor the correction of deficiencies in accredited facilities; and

(v) Whether surveys are announced or unannounced;

(4) Detailed information about the individuals who perform surveys for the accreditation organization, including—

(i) The size and composition of accreditation survey teams for each type of provider and supplier accredited;

(ii) The education and experience requirements surveyors must meet;

(iii) The content and frequency of the in-service training provided to survey personnel;

(iv) The evaluation systems used to monitor the performance of individual surveyors and survey teams; and

(v) Policies and procedures with respect to an individual's participation in the survey or accreditation decision process of any facility with which the individual is professionally or financially affiliated;

(5) A description of the organization's data management and analysis system with respect to its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system;

(6) The organization's procedures for responding to and for the investigation of complaints against accredited facilities, including policies and procedures regarding coordination of these activities with appropriate licensing bodies and ombudsmen programs;

(7) The organization's policies and procedures with respect to the withholding or removal of accreditation status for facilities that fail to meet the accreditation organization's standards or requirements, and other actions taken by the organization in response to noncompliance with its standards and requirements;

(8) A description of all types (for example, full, partial, type of facility, etc.) and categories (provisional, conditional, temporary, etc.) of accreditation offered by the organization, the duration of each type and category of accreditation and a statement specifying the types and categories of accreditation for which approval of deeming authority is sought;

(9) A list of all currently accredited facilities, the type and category of ac-

creditation currently held by each facility, and the expiration date of each facility's current accreditation; and

(10) A list of all full and partial accreditation surveys scheduled to be performed by the organization.

(b) The accreditation organization must also submit the following supporting documentation—

(1) A written presentation that demonstrates the organization's ability to furnish CMS with electronic data in ASCII comparable code;

(2) A resource analysis that demonstrates that the organization's staffing, funding and other resources are adequate to perform the required surveys and related activities; and

(3) A statement acknowledging that as a condition for approval of deeming authority, the organization will agree to—

(i) Notify CMS in writing of any facility that has had its accreditation revoked, withdrawn, or revised, or that has had any other remedial or adverse action taken against it by the accreditation organization within 30 days of any such action taken;

(ii) Notify all accredited facilities within 10 days of CMS's withdrawal of the organization's approval of deeming authority;

(iii) Notify CMS in writing at least 30 days in advance of the effective date of any proposed changes in accreditation requirements;

(iv) Within 30 days of a change in CMS requirements, submit to CMS an acknowledgement of CMS's notification of the change as well as a revised crosswalk reflecting the new requirements and inform CMS about how the organization plans to alter its requirements to conform to CMS's new requirements;

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

(vi) [Reserved]

(vii) Notify CMS in writing within ten days of a deficiency identified in any accreditation entity where the deficiency poses an immediate jeopardy to the entity's patients or residents or a hazard to the general public; and

(viii) Conform accreditation requirements to changes in Medicare requirements.

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(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