Policy and Requirements for an Application for Deeming Authority

Laws and Regulations

Section 1865(b)(1) of the Social Security Act (the Act) permits providers and suppliers "accredited" by an approved national accreditation organization (AO) to be exempt from routine surveys by State survey agencies to determine compliance with Medicare conditions. Accreditation by an AO is voluntary and is not required for Medicare certification. Section 1865(b)(1) of the Act provides that if the Secretary finds that accreditation of a provider entity by a national accreditation body demonstrates that all applicable conditions are met or exceeded, the Secretary may deem those requirements to be met by the provider or supplier. Before permitting deemed status for an AO's accredited provider entities, Section 1865(b)(2) of the Act further requires that CMS consider the AO's:

- requirements for accreditation;
- survey procedures;
- ability to provide adequate resources for conducting required surveys;
- ability to supply information for use in enforcement activities;
- monitoring procedures for provider entities found out of compliance with the conditions or requirements; and
- ability to provide CMS with the necessary data for validation.

In order to be granted deeming authority for Medicare, an AO must apply and demonstrate its ability to meet or exceed the Medicare conditions of participation/coverage as cited in the Code of Federal Regulations:

- Ambulatory Surgical Centers (ASCs) in accordance with 42 CFR 416
- Critical Access Hospitals (CAHs) in accordance with 42 CFR485 Subpart F
- Home Health Agencies (HHAs) in accordance with 42 CFR 484
- Hospice in accordance with 42 CFR 418
- Hospitals in accordance with 42 CFR 482

The regulations at 42 CFR 488.4 set forth the procedures for reviewing and approving national accreditation organizations that request recognition as providing reasonable assurance that their standards meet or exceed Medicare conditions. The regulations at 42 CFR 488.8 set six years as a maximum term of approval and details the Federal review and approval process of applications to continue recognition as an accreditation organization.

For all applications or reapplications submitted under section 1865(b)(3) of the Act, CMS is required to publish a proposed notice in the **Federal Register,** 60 days after the receipt of a complete, written request for recognition as a national accreditation body. Section 1865(b)(3) further requires that CMS publish a notice of approval or denial within 210 days after receipt of a complete application package from the accrediting body.

CMS is required to specify the materials it requires for application and reapplications. CMS will specify the deadline for reapplication by an approved accrediting body. In addition, AOs are subject to ongoing Federal oversight. CMS has elected to improve the efficiency of its oversight by clarifying its informational requests and by focusing on items under 42 CFR 488.4. These items enhance Federal oversight, as permitted by 42 CFR 488.8(d) and 488.9.

CMS' application requirements are attached. As part of the application or reapplication review process, CMS will conduct a corporate onsite visit and survey observation to review and validate the AO's operations, as permitted at 42 CFR 488.9.

If you have any questions regarding this document or the application requirements, you may contact Patricia Chmielewski, Deputy Director of the Division of Acute Care Services, at (410) 786-6899, via E-mail, patricia.chmielewski@cms.hhs.gov

DEEMING AUTHORITY APPLICATION REQUIREMENTS

A. Administration

1. A description of the type of facilities and categories of accreditation covered by this application.
    (a) A list of all types of accreditation offered and a clear indication of which types are being requested for deemed status recognition.
    (b) A list of all accredited facilities by type of accreditation and expiration date.
2. The requested term of approval.
3. The name, address, telephone, and E-mail address of the *authorized contact person* (one with the ability to make decisions and answer questions and provide clarifications for the specific program for which your organization seeks deeming authority).
4. A key personnel list and resumes of staff critical to the management and oversight of the program for which your organization is applying for deeming authority.

B. General Policies and Procedures Requirements

1. A signed statement permitting CMS to observe on-site:
    (a) A full accreditation survey (initial or continuing, not focused) performed by the applicant to validate current practices and requirements of its survey process, and
    (b) An evaluation of program administration at the corporate offices.
2. A flow chart (diagram) of the accreditation survey process with explanatory notes of updates or changes, including:
    (a) The procedures for notifying facilities of deficiencies;
    (b) The procedures and timeframes for monitoring deficiencies;
    (c) The procedures for responding to and investigating complaints, including appropriate interactions with CMS regarding complaints, immediate jeopardy investigations, and accreditation decisions;
    (d) The procedures for developing and updating the content of surveyor training materials, the frequency of formal training, and the frequency and method(s) of assuring surveyor competence and consistent implementation of standards and survey process. and,
    (e) If this is a renewal application, include explanatory notes of updates or changes.
3. A copy of the current surveyors' instruction manual and standards used to evaluate accredited facilities.
4. A crosswalk (table of relationships) from Medicare conditions to the accreditation organization's standards in the following format:
    - CFR Number
    - Medicare Standards
    - Organization's Equivalent Number
    - Organization's Standards

5. A flow chart (diagram) and a crosswalk (table of relationships) from Medicare decision points of accreditation status decision-making process with explanatory notes of updates or changes. For example, immediate jeopardy; condition level deficiencies; standard deficiencies; recommended actions for provider or supplier improvement; validation of requested corrections made by the provider or supplier.
6. A signed and dated attestation complying with 42 CFR 488.4(b)(3).

C. Policies and Procedures for Identifying Fraud and Abuse and Coordination With or Reporting to CMS

1. The criteria that surveyors use to determine when to report suspicious or unusual activities to CMS.
2. Specification of the process (to whom and timeframes) to be used to report violations of CMS fraud and abuse policies in compliance with the basic agreement.

D. Surveyor Evaluation and Training on Medicare Conditions of Participation or Coverage

1. A plan to provide appropriately knowledgeable trainers or training materials to be used to train surveyors on Medicare fraud and abuse for the facility type in the application;
2. The procedures and criteria to evaluate surveyor performance and the method of correcting surveyors' skill or knowledge deficiencies on both the individual and group levels.

E. Provision of Electronic Data Exchange

1. A description of the data management system, standard reports, tables, and displays produced.
2. Evidence of the ability to supply electronic files to CMS in the requested format.
3. A list of reports with sample formats that are available for validation processes via specified CMS compatible PC software.

F. Adequacy of Resources

1. Three years of audited financial reports, including revenues and expenditures.
2. The projected number of accreditation surveys and resource allocations of staff to provide these services.
3. Informational and professional support practices for keeping staff updated on health care practices and accreditation organization policies and procedures.

G. CMS Validation Data Reports

1. A sample of your ability to provide CMS with the following data on a periodic basis:
   (a) Administrative tracking reports, e.g.,
      (i) Provide a list of facilities surveyed and accredited indicating the type of survey conducted (i.e. initial, re-accreditation, complaint) and accreditation decision quarterly (i.e., Facility List);
      (ii) Survey Schedules for the prospective quarter of all deemed provider/supplier programs.
   (b) Provider/supplier deficiencies and their resolution, including—
      (i) The number, percentage, and related Medicare tag number (as appropriate) of the AO's top 10 deficiencies identified during accreditation surveys;
      (ii) The number of immediate jeopardy or adverse events by program and the type of action taken.
      (iii) The outcomes (accreditation awarded and decision as related to surveyor recommendation) of Board, Accreditation Committee, or other person/body making final accreditation decision actions on deficiencies, with all types of information used, e.g., full survey, focused survey, written report by facility, and longevity of deficiency (was this deficiency cited multiple visits).
      (iv) The number complaints received, broken down by:
         1. number of written resolutions, number of focused surveys, follow-up actions,
         2. number greater than 90 to 120 days by reason for lag, and
         3. average resolution time (calculated across all facility complaints).

2. A statement of your understanding that CMS validation requests may change at least annually, with 1 quarter advance notice to allow for data collection and data software changes when implementing new requests.