DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/ Survey & Certification Group

Policy and Requirements for an Application for Approval of an Accreditation Program

Laws and Regulations

Section 1865(a)(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(a)(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 deems those requirements to be met by the provider or supplier. Before permitting deemed status for an AOs accredited provider entities, Section 1865(a)(2) of the Act further requires that CMS consider the AOs:

- 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
Hospices in accordance with 42 CFR 418
Hospitals in accordance with 42 CFR 482
Organizations that provide Outpatient Physical Therapy and Speech Language Pathology Services (OPTs) in accordance with 42 CFR 485, subpart H
Psychiatric Hospitals in accordance with 42 CFR 482
Rural Health Clinics (RHCs) in accordance with 42 CFR 491

42 CFR 488.4 sets 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 regulation at 42 CFR 488.8 ("Federal review of accreditation organizations") sets six years as a maximum term of approval and details the

Federal review and approval process of applications to continue recognition as an accrediting organization.

For all applications or reapplications under section 1865(a)(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(a)(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 an onsite inspection and validation of the accreditation organizations 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, or via E-mail, patricia.chmielewski@cms.hhs.gov.