DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services

Medicare and Medicaid Programs;
Application From Det Norske Veritas Healthcare (DNVHC) for Continued Approval of Its Hospital Accreditation Program

AGENCY: Centers for Medicare and Medicaid Services, HHS.

ACTION: Proposed notice.

SUMMARY: This proposed notice with comment period acknowledges the receipt of an application from Det Norske Veritas Healthcare (DNVHC) for continued recognition as a national accrediting organization for hospitals that wish to participate in the Medicare or Medicaid programs.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on April 23, 2012.

ADDRESSES: In commenting, please refer to file code CMS–3258–PN. Because of staff and resource limitations, we cannot accept comments by facsimile (Fax) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):
1. Electronically. You may submit electronic comments on this regulation to http://www.regulations.gov. Follow the “Submit a comment” instructions.
2. By regular mail. You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3258–PN, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.
3. By express or overnight mail. You may send written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3258–PN, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.
4. By hand or courier. If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:
   (Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)
   b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the SUPPLEMENTARY INFORMATION section.

FOR FURTHER INFORMATION CONTACT: Barbara Easterling (410) 786–0482, Patricia Chmielewski, (410) 786–6899, or Cindy Melanson, (410) 786–0310.

SUPPLEMENTARY INFORMATION: Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: http://www.regulations.gov. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard,
I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in a hospital provided certain requirements are met. Section 1861(e) of the Social Security Act establishes distinct criteria for facilities seeking designation as a hospital. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at part 488. The regulations at part 482 specify the conditions that a hospital must meet in order to participate in the Medicare program, the scope of covered services and the conditions for Medicare payment for hospitals.

Generally, in order to enter into an agreement, a hospital must first be certified by a State survey agency as complying with the conditions or requirements set forth in part 482. Thereafter, the hospital is subject to regular surveys by a State survey agency to determine whether it continues to meet these requirements. However, there is an alternative to surveys by State agencies.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national accrediting organization that all applicable Medicare conditions are met or exceeded, we will deem those provider entities as having met the requirements. Accreditation by an accrediting organization is voluntary and is not required for Medicare participation.

If an accrediting organization is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body’s approved program would be deemed to have met the Medicare conditions. A national accrediting organization applying for approval of its accreditation program under part 488, subpart A, must provide us with reasonable assurance that the accrediting organization requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions.

Our regulations concerning the approval of accrediting organizations are set forth at § 488.4 and § 488.8(d)(3). The regulations at § 488.8(d)(3) require accrediting organizations to reapply for continued approval of its accreditation program every 6 years or sooner as determined by us.

DNVHC’s current term of approval for their hospital accreditation program expires September 26, 2012.

II. Approval of Deeming Organizations

Section 1865(a)(2) of the Act and our regulations at § 488.8(a) require that our findings concerning review and approval of a national accrediting organization’s requirements consider, among other factors, the applying accrediting organization’s:

- Requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and ability to provide us with the necessary data for validation.

- The purpose of this proposed notice is to inform the public of DNVHC’s request for continued approval of its hospital accreditation program. This notice also solicits public comment on whether DNVHC’s requirements meet or exceed the Medicare conditions for participation for hospitals.

III. Evaluation of Deeming Authority Request

DNVHC submitted all the necessary materials to enable us to make a determination concerning its request for continued approval of its hospital accreditation program. This application was determined to be complete on January 27, 2012. Section 1865(a)(3)(A) of the Social Security Act (the Act), requires that within 60 days of receipt of an organization’s complete application to be a CMS-approved accrediting organization, we publish a notice that identifies the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. We have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

The purpose of this proposed notice is to inform the public of DNVHC’s request for continued approval of its hospital accreditation program. This notice also solicits public comment on whether DNVHC’s requirements meet or exceed the Medicare conditions for participation for hospitals.

IV. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

V. Response to Public Comments

Because of the large number of public comments we normally receive on Federal Register documents, we are not able to acknowledge or respond to them individually. We will consider all
This authority, the minimum requirements that an HHA must meet to participate in Medicare are set forth in regulations at 42 CFR part 484, which determine the basis and scope of HHA covered services, and the conditions for Medicare payment for home health care. Regulations concerning provider agreements are at part 489 and those pertaining to activities relating to the survey and certification of facilities are at part 488.

Generally, in order to enter into a provider agreement with the Medicare program, HHAs must first be certified by a State survey agency as complying with conditions or requirements set forth in part 484. Thereafter, the HHA is subject to regular surveys by a State survey agency to determine whether it continues to meet these requirements. However, there is an alternative to State compliance surveys. Accreditation by a nationally-recognized accreditation program can substitute for ongoing State review.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national accreditation organization that all applicable Medicare conditions are met or exceeded, we may “deem” those provider entities as having met the requirements. Accreditation by an accreditation organization is voluntary and is not required for Medicare participation.

If an accreditation organization is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, a provider entity accredited by the national accrediting body’s approved program may be deemed to meet the Medicare conditions. A national accreditation organization applying for CMS-approval of its accreditation program under part 488, subpart A must provide us with reasonable assurance that the accreditation organization requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the reapproval of accreditation organizations are set forth at §488.4 and §488.8(d)(3). Section 488.8(d)(3) requires accreditation organizations to reapply for continued CMS-approval of its accreditation program every six years, or sooner as determined by us. CHAP’s term of approval as a recognized accreditation program for HHAs expires March 31, 2012.

II. Deeming Applications Approval Process

Section 1865(a)(3)(A) of the Act provides a statutory timetable to ensure that our review of deeming applications is conducted in a timely manner. The Act provides us with 210 calendar days after the date of receipt of an application to complete our survey activities and application review process. Within 60 days of receiving a completed application, we must publish a notice in the Federal Register that identifies the national accreditation body making the request, describes the request, and provides no less than a 30-day public comment period. At the end of the 210-day period, we must publish an approval or denial of the application.

III. Proposed Notice

In the September 23, 2011, Federal Register (76 FR 59136), we published a proposed notice announcing CHAP’s request for continued CMS approval of its HHA accreditation program. In the proposed notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and our regulations at §488.4 (Application and reapplication procedures for accreditation organizations), we conducted a review of CHAP’s application in accordance with the criteria specified by our regulations, which include, but are not limited to the following:

• An onsite administrative review of CHAP’s: (1) Corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its surveyors; (4) ability to investigate and respond appropriately to complaints against accredited facilities; and, (5) survey review and decision-making process for accreditation.

• A comparison of CHAP’s HHA accreditation standards to our current Medicare HHA conditions for participation.

• A documentation review of CHAP’s survey processes to:
  + Determine the composition of the survey team, surveyor qualifications, and the ability of CHAP to provide continuing surveyor training.
  + Compare CHAP’s processes to those of State survey agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.
  + Evaluate CHAP’s procedures for monitoring providers or suppliers found to be out of compliance with CHAP program requirements. The monitoring procedures are used only when the CHAP identifies noncompliance. If noncompliance is identified through validation reviews, the survey agency monitors corrections as specified at §488.7(d).