

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-2895-FN]

Medicare and Medicaid Programs; Approval of Det Norske Veritas Healthcare, Inc. for Deeming Authority for Hospitals

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final notice.

SUMMARY: This notice announces our decision to approve Det Norske Veritas Healthcare, Inc. (DNVHC) for recognition as a national accreditation program for hospitals seeking to participate in the Medicare or Medicaid programs.

DATES: *Effective Date:* This final notice is effective September 26, 2008 through September 26, 2012.

FOR FURTHER INFORMATION CONTACT: Cindy Melanson, (410) 786-0310. Patricia Chmielewski (410) 786-6899.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in a hospital provided certain requirements are met. The regulations specifying the Medicare conditions of participation (CoPs) for hospitals are located at 42 CFR part 482. These conditions implement section 1861(e) of the Social Security Act (the Act), which specifies services covered as hospital care and the conditions that a hospital program must meet in order to participate in the Medicare program. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to the activities relating to the survey and certification of facilities are at 42 CFR part 488.

Generally, in order to enter into a provider agreement, a hospital must first be certified by a State survey agency as complying with the conditions set forth in the statute and part 482 of the regulations. Then, the hospital is subject to routine surveys by a State survey agency to determine whether it continues to meet the Medicare requirements.

There is, however, an alternative to State compliance surveys. Certification by a nationally recognized accreditation program can substitute for ongoing State review. Section 1865(a)(1) of the Act (as

amended by section 125(a) of the Medicare Improvements for Patients and Providers Act of 2008, Public Law 110-275, July 15, 2008) (MIPPA)) 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 approval of deeming authority 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.

II. Deeming Applications Approval Process

Section 1865(a)(3)(A) of the Act (as amended) provides a statutory time table 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 a complete application, with any documentation necessary to make a determination, to complete our survey activities and application review process. Within 60 days of receiving a complete 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. Provisions of the Proposed Notice and Response to Comments

On April 25, 2008, we published a proposed notice in the **Federal Register** (73 FR 22420) announcing DNVHC’s request for approval as a deeming organization for hospitals. In the proposed notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act (as amended) and our regulations at § 488.4 (Application and reapplication procedures for accreditation organizations), we conducted a review of DNVHC’s application in accordance with the criteria specified by our regulation, which include, but are not limited to the following:

- An onsite administrative review of DNVHC’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 DNVHC’s hospital accreditation standards to our current Medicare hospital CoPs; and,
- A documentation review of DNVHC’s survey processes to:

- Determine the composition of the survey team, surveyor qualifications, and DNVHC’s ability to provide continuing surveyor training;

- Compare DNVHC’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 DNVHC’s procedures for monitoring providers or suppliers found to be out of compliance with DNVHC program requirements. The monitoring procedures are used only when DNVHC identifies noncompliance. If noncompliance is identified through validation reviews, the State survey agency monitors corrections as specified at § 488.7(d);

- Assess DNVHC’s ability to report deficiencies to the surveyed facilities and respond to the facility’s plan of correction in a timely manner;

- Establish DNVHC’s ability to provide us with electronic data and reports necessary for effective validation and assessment of DNVHC’s survey process;

- Determine the adequacy of staff and other resources;

- Review DNVHC’s ability to provide adequate funding for performing required surveys;

- Confirm DNVHC’s policies with respect to whether surveys are announced or unannounced; and,

- Obtain DNVHC’s agreement to provide us with a copy of the most current accreditation survey together with any other information related to the survey as we may require, including corrective action plans.

In accordance with former section 1865(b)(3)(A) of the Act, (now section 1865(a)(3)(A) of the Act), the April 25, 2008 proposed notice also solicited public comments regarding whether DNVHC’s requirements met or exceeded the Medicare CoPs for hospitals. We received 33 public comments in response to our proposed notice.

The majority of commenters expressed support for DNVHC’s application for hospital deeming authority. Many of these commenters stated that it is important for hospitals

³ Staff’s labor labor cost estimates are based on recent data from the Bureau of Labor and Statistics found here: (<http://www.bls.gov/news.release/pdf/ocwage.pdf>).

to have alternatives for accreditation. Other commenters specifically voiced support for DNVHC's integration of the Medicare CoPs and the ISO 9001 quality management systems. These commenters stated that DNVHC's accreditation program provides hospitals with a unique, refreshing approach to ensure compliance with the Medicare requirements and facilitates continuous improvement.

Comment: One commenter stated that it would be inappropriate to issue DNVHC exclusive deeming authority to certify hospitals using the ISO 9001 standards and the Medicare CoPs.

Response: As a CMS approved national accreditation organization, DNVHC does not have exclusive deeming authority for hospitals based on a program that integrates the ISO 9001 standards and the Medicare hospital CoPs. Any accreditation organization that can demonstrate that its accreditation program meets or exceeds the Medicare requirements can apply for deeming authority. CMS' application process for deeming authority is outlined in the Code of Federal Regulations at § 488.4.

Comment: One commenter stated that although he agrees with DNVHC's premise, he believes that a single, standardized, regulatory approach to healthcare is necessary.

Response: The Medicare CoPs are the minimum health and safety requirements that all hospitals must meet to participate in the Medicare program and serves as a single, standardized federal regulatory approach. Accreditation by an accreditation organization is voluntary and is not required for Medicare participation. A hospital may opt for routine surveys by a State survey agency to determine whether it meets the Medicare requirements.

Comment: One commenter stated that it is CMS' responsibility to review DNVHC's application thoroughly to ensure DNVHC will meet the intent of the regulations. This commenter also expressed concerns related to a potential conflict of interest issue as DNVHC currently provides Joint Commission readiness consulting services to prepare hospitals for a Joint Commission accreditation survey.

Response: All deeming applications are reviewed in accordance with the requirements at § 488.4 and § 488.8 to ensure that the applicant's accreditation program meets or exceeds Medicare's requirements. In terms of the conflict of interest issue raised by the commenter, DNVHC has provided a written statement as part of its application that this consultative service will be discontinued when DNVHC is approved as a nationally recognized accreditation

organization for hospitals.

IV. Provisions of the Final Notice

A. Differences Between DNVHC's Standards and Requirements for Accreditation and Medicare's Conditions and Survey Requirements

We compared DNVHC's hospital accreditation requirements and survey process with the Medicare hospital CoPs and survey process as outlined in the State Operations Manual (SOM). Our review and evaluation of DNVHC's deeming application, which were conducted as described in section III of this final notice, yielded the following:

- DNVHC modified its policies related to the effective date of participation in Medicare for new providers in accordance with requirements at § 489.13;
- DNVHC modified its policies regarding time frames for sending and receiving a required plan of correction, and the required elements of an approved plan of correction in accordance with section 2728 of the SOM;
- DNVHC developed and conducted training for its surveyors to ensure that all deficiencies cited contain a regulatory reference, a clear and detailed description of the deficient practice and relevant finding;
- In accordance with § 488.3(a) and Appendix A of the SOM, DNVHC modified its policies to ensure that all off-campus provider based locations, satellite locations and services provided at remote locations that are under the hospital's CCN number will be surveyed at least once every three years;
- To meet the Medicare requirements at § 488.20(a) and § 488.28(a), DNVHC developed a policy regarding our requirements for submission of a plan of correction by the hospital and the completion of an onsite follow-up survey to determine compliance with Medicare CoPs after citing condition level noncompliance during a recertification survey;
- DNVHC developed a policy regarding condition level noncompliance identified during an initial certification survey for participation in Medicare in accordance with section 2005A2 of the SOM;
- DNVHC modified its policies regarding complaint investigation activities with appropriate licensing bodies and ombudsmen programs in accordance with the requirements at § 488.4(a)(6);
- DNVHC amended its interpretive guidance and surveyor tool to include the survey methods its surveyors would use to determine compliance with the requirements at § 482.12(f)(2), § 482.23(a), and § 482.23(c)(1);
- DNVHC amended its interpretive

guidance and surveyor tools to meet the requirements at § 482.13(c)(3), § 488.22(c)(3), § 482.23(c)(3), § 482.24(c)(1)(iii), § 482.25(b)(2)(i), § 482.25(b)(6), § 482.25(b)(7), § 482.30(b)(3)(i), § 482.43(e), § 482.45(a)(1), § 482.51(a), § 482.52, § 482.53(b), § 482.54, § 482.54(a), and § 482.56;

- DNVHC added language to its standards, and interpretive guidance to address the requirements at § 482.13(e)(9), § 482.30, and § 482.30(b)(1)(ii)(A)–(B);
- DNVHC amended its policies by eliminating recommendations referred to as “opportunities for improvement” from the written survey findings to meet the requirements at § 488.28(a) and Section 2726 of the SOM.

B. Term of Approval

Based on the review and observations described in section III of this final notice, we have determined that DNVHC's requirements for hospitals meet or exceed our requirements. Therefore, we approve DNVHC as a national accreditation organization for hospitals that request participation in the Medicare program, effective September 26, 2008 through September 26, 2012.

V. Collection of Information Requirements

This document does not impose information collection and record keeping 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).

Authority: Section 1865 of the Social Security Act (42 U.S.C. 1395bb). (Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773, Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplemental Medical Insurance Program)

Dated: August 21, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

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