



Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-09-02

DATE: October 3, 2008
TO: State Survey Agency Directors
FROM: Director
Survey and Certification Group
SUBJECT: Approval of Deeming Authority of Det Norske Veritas Healthcare, Inc. for Hospitals

Memorandum Summary

This memorandum announces the Centers for Medicare & Medicaid Services' (CMS) decision to approve Det Norske Veritas Healthcare, Inc. (DNV Healthcare) for recognition as a national accreditation program for hospitals seeking to participate in the Medicare program.

Section 1865(b) of the Social Security Act (the Act) permits providers and suppliers accredited by an approved national accrediting body to be "*deemed*" to meet Medicare Conditions for Coverage or Participation. To receive approval, accreditation organizations must demonstrate to CMS that their requirements meet or exceed the Medicare conditions.

CMS reviewed DNV Healthcare's application for approval of deeming authority for hospitals in accordance with 42 CFR 488.4 and 42 CFR 488.8. CMS' review included DNV Healthcare's survey and accrediting process as well as its health and safety standards. CMS' review found DNV Healthcare's accreditation program for hospitals to meet or exceed the Medicare Conditions of Participation (CoP).

CMS announced DNV Healthcare's approval as a deemed status accreditation program for hospitals in the September 29, 2008, *Federal Register* (see attachment A). This is an initial 4 year approval effective September 26, 2008 through September 26, 2012. Deeming authority for this program is limited to the Medicare CoPs and does not apply to ownership, enrollment, or other Medicare requirements. Attachment B contains talking points for use by Regional Office and State Agency staff.

This approval provides hospitals with another accreditation option in addition to the Joint Commission and the American Osteopathic Association. DNV Healthcare's hospital accreditation program is unique in that it integrates the ISO 9001 standards (international quality standards that define minimum requirements for a quality management system) and the Medicare hospital CoPs.

If you have any questions regarding this memorandum, please contact Cindy Melanson at 410-786-0310 or via E-mail at cindy.melanson@cms.hhs.gov.

Effective date: Immediately. The State agency should disseminate this information within 30 days of the date of this memorandum.

Training: The information contained in this announcement should be shared with relevant survey and certification staff, their managers, and the State/RO training coordinator.

/s/
Thomas E. Hamilton

Attachments

cc: Survey and Certification Regional Office Management

**CMS-2895-FN Approval of Det Norske Veritas Healthcare, Inc. for
Deeming Authority for Hospitals**

- 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.
- This is an initial 4-year approval effective September 26, 2008 through September 26, 2012.
- This approval provides hospitals with another accreditation option in addition to the Joint Commission and the American Osteopathic Association.
- DNVHC's hospital accreditation program is unique in that it integrates the ISO 9001 standards (international quality standards that define minimum requirements for a quality management system) and the Medicare hospital conditions of participation.

to lengthy delays due to heightened security precautions.

The FTC Act and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives, whether filed in paper or electronic form. Comments received will be available to the public on the FTC website, to the extent practicable, at www.ftc.gov. As a matter of discretion, the FTC makes every effort to remove home contact information for individuals from the public comments it receives before placing those comments on the FTC website. More information, including routine uses permitted by the Privacy Act, may be found in the FTC's privacy policy at (<http://www.ftc.gov/ftc/privacy.shtm>).

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be addressed to Jock K. Chung, Attorney, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, NJ-2122, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580, (202) 326-2984.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act ("PRA"), 44 U.S.C. 3501-3520, federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. On June 18, 2008, the FTC sought comment on the information collection requirements pertaining to the Commission's Amplifier Rule (OMB Control Number 3084-0105).² No comments were received. Pursuant to the OMB regulations that implement the PRA (5 CFR Part 1320), the FTC is providing this second opportunity for public comment while seeking OMB approval to extend the existing paperwork clearance for the Commission's Amplifier Rule. All comments should be filed as prescribed in the **ADDRESSES** section above, and must be received on or before October 29, 2008.

The Amplifier Rule assists consumers by standardizing the measurement and disclosure of power output and other performance characteristics of amplifiers in stereos and other home entertainment equipment. The Rule also specifies the test conditions necessary to make the disclosures that the Rule requires.

Estimated annual hours burden: 450 hours (300 testing-related hours; 150 disclosure-related hours).

The Rule's provisions require affected entities to test the power output of amplifiers in accordance with a specified FTC protocol. The Commission staff estimates that approximately 300 new amplifiers and receivers come on the market each year. High fidelity manufacturers routinely conduct performance tests on these new products prior to sale. Because manufacturers conduct such tests, the Rule imposes no additional costs except to the extent that the FTC protocol is more time-consuming than alternative testing procedures. In this regard, a warm-up ("precondition") period that the Rule requires before measurements are taken may add approximately one hour to the time testing would otherwise entail. Thus, staff estimates that the Rule imposes approximately 300 hours (1 hour x 300 new products) of added testing burden annually.

In addition, the Rule requires disclosures if a manufacturer makes a power output claim for a covered product in an advertisement, specification sheet, or product brochure. This requirement does not impose any additional costs on manufacturers because, absent the Rule, media advertisements, as well as manufacturer specification sheets and product brochures, would contain a power specification obtained using an alternative to the Rule-required testing protocol. The Rule, however, also requires disclosure of harmonic distortion, power bandwidth, and impedance ratings in manufacturer specification sheets and product brochures that might not otherwise be included.

Staff assumes that manufacturers produce one specification sheet and one brochure each year for each new amplifier and receiver. The burden of disclosing the harmonic distortion, bandwidth, and impedance information on the specification sheets and brochures is limited to the time needed to draft and review the language pertaining to the aforementioned specifications. Staff estimates the time involved for this task to be a maximum of fifteen minutes for each new specification sheet and brochure for a total of 150 hours ([300 new products x 1 specification sheet] + [300 new products x 1 brochure]) x 15 minutes).

The total annual burden imposed by the Rule, therefore, is approximately 450 burden hours for testing and disclosures.

Estimated annual cost burden: \$19,000, rounded to the nearest thousand.³

Generally, electronics engineers perform the testing of amplifiers and receivers. Staff estimates a labor cost of \$12,300 for such testing (300 hours for testing x \$41 per hour). Staff assumes advertising or promotions managers prepare the disclosures contained in product brochures and manufacturer specification sheet and estimates a labor cost of \$6,600 (150 hours for disclosures x \$44 per hour). Accordingly, staff estimates the total labor costs associated with the Rule to be approximately \$19,000 per year, rounded to the nearest thousand (\$12,300 for testing + \$6,600 for disclosures).

The Rule imposes no capital or other non-labor costs because its requirements are incidental to testing and advertising done in the ordinary course of business.

William Blumenthal,
General Counsel.

[FR Doc. E8-22811 Filed 9-26-08; 8:45 am]

[BILLING CODE 6750-01-S]

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

³ Staff's 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>).

² 73 FR 34750.

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 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.

[FR Doc. E8–22585 Filed 9–25–08; 11:15 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Child Care and Development Fund Plan for States/Territories for FFY 2010–2011 (ACF–118).

OMB No.: 0970–0114.

Description: The Child Care and Development Fund (CCDF) Plan (the Plan) for States and Territories is required from each CCDF Lead agency in accordance with Section 658E of the Child Care and Development Block Grant Act of 1990, as amended (Pub. L. 101–508, Pub. L. 104–193, and 42 U.S.C. 9858). The implementing regulations for the statutorily required Plan are set forth at 45 CFR 98.10 through 98.18. The Plan, submitted on the ACF–118, is required biennially, and remains in effect for two years. The Plan provides ACF and the public with a description of, and assurance about, the States or the Territories child care program. The ACF–118 is currently approved through June 30, 2009, making it available to States and Territories needing to submit Plan Amendments through the end of the FY 2009 Plan Period. However, in July 2009, States and Territories will be required to submit their FY 2010–2011