

Center for Medicaid, CHIP, and Survey & Certification/Survey & Certification Group

Ref: S&C-11-09-AO/CAHs

DATE: January 14, 2011

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Approval of Deeming Authority of Det Norske Veritas Healthcare (DNVHC) for Critical Access Hospitals (CAHs)

Memorandum Summary

Accreditation Organization (AO) Deeming Approval for Critical Access Hospitals:
The Centers for Medicare & Medicaid Services' (CMS) has approved DNVHC as a national accreditation program for CAHs seeking to participate in the Medicare or Medicaid programs.

Section 1865(a) 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 DNVHC's application for CAH deeming authority in accordance with 42 CFR 488.4 and 42 CFR 485, subpart F. CMS' review included DNVHC's survey and accrediting process as well as its health and safety standards. CMS' review found DNVHC' accreditation program for CAHs to meet or exceed the Medicare CoPs.

CMS announced DNVHC's approval as a deemed status accreditation program for CAHS in the November 15, 2010, Federal Register (see attachment A). This is an initial 4-year approval effective December 23, 2010 through December 23, 2014. 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 staffs.

This approval provides CAH's with another accreditation option in addition to the Joint Commission and the American Osteopathic Association.

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If you have any questions regarding this memorandum, please contact Lillian Williams at 410-786-8636 or via E-mail at lillian.williams@cms.hhs.gov.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/
Thomas E. Hamilton

Attachments

cc: Survey and Certification Regional Office Management

**CMS-2336-FN Approval of Det Norske Veritas Healthcare, Inc. for
Deeming Authority for Critical Access Hospitals**

- This notice announces our decision to approve Det Norske Veritas Healthcare, Inc. (DNVHC) for recognition as a national accreditation program for critical access hospitals (CAHs) seeking to participate in the Medicare or Medicaid programs.
- The final notice was published in the Federal Register November 15, 2010. This is an initial 4 year approval effective December 23, 2010 through December 23, 2014.
- This approval provides CAHs with another accreditation option in addition to the Joint Commission and the American Osteopathic Association.

free number 301–496–4675 or e-mail your request, including your address to: breenn@mail.nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of this publication.

Dated: November 9, 2010.

Vivian Horovitch-Kelley,
NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2010–28648 Filed 11–12–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Income Withholding for Support (IWO).

OMB No.: 0970–0154.

Description

Use of the OMB-approved Income Withholding for Support form falls under the authority of section 466 of the Act, 42 U.S.C. 666. Section 466(b)(6)(A)(ii) of the Act requires that the notice given to the employer for income withholding in IV–D cases shall be in a standard format prescribed by the Secretary, and contain only such information as may be necessary for the employer to comply with the withholding order for all IV–D cases. Section 466(a)(8)(B)(iii) of the Act requires that section 466(b)(6)(A)(ii) of the Act be applicable also to non-IV–D income withholding orders. These provisions clearly require all individuals and entities to use a form developed by the Secretary of HHS to notify employers of the income withholding order for child support in all IV–D and non-IV–D cases.

OCSE requires States' automated systems to be able to automatically generate and download data to the OMB approved income withholding form. If

child support orders are established by the child support agency, necessary information is already contained within the automated system for downloading into income withholding orders. If a court or other tribunal has issued a child support order, then agency staff enter the terms of the order into the automated system for use in issuing income withholding orders. Copies of the income withholding order are made for all necessary parties, and copies are transmitted to the employer/income withholdee by mail or through the OCSE electronic income withholding order (e-IWO) portal.

The Income Withholding for Support form and instructions were updated for consistency and clarity in light of numerous comments suggesting changes, based on comments received during the 60-day comment period of the 1st **Federal Register** Notice publication.

Respondents: State Child Support Agencies and Tribes.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Income Withholding for Support (Form)	58	0	0	0
e-IWO Record Layouts	58	0	0	0

Estimated Total Annual Burden Hours: 0.

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: infocollection@acf.hhs.gov.

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**.

Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project. Fax: 202–395–7285.

E-mail: OIRA_SUBMISSION@OMB.EOP.GOV.
Attn: Desk Officer for the Administration for Children and Families.

Robert Sargs,
Reports Clearance Officer.
[FR Doc. 2010–28615 Filed 11–12–10; 8:45 am]
BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2336–FN]

Medicare and Medicaid Programs; Approval of Det Norske Veritas Healthcare for Deeming Authority for Critical Access Hospitals

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

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve Det Norske Veritas Healthcare (DNVHC) for

recognition as a national accreditation program for critical access hospitals seeking to participate in the Medicare or Medicaid programs.

DATES: **Effective Date:** This final notice of approval is effective December 23, 2010, through December 23, 2014.

FOR FURTHER INFORMATION CONTACT: Lillian Williams, (410) 786–8636. Patricia Chmielewski, (410) 786–6899.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in a critical access hospitals (CAHs) provided certain requirements are met. Sections 1820(c)(2)(B) and 1861(mm) of the Social Security Act (the Act) establish distinct criteria for facilities seeking designation as a CAH. The minimum requirements that a CAH must meet to participate in Medicare are set forth in regulation at 42 CFR part 485, subpart F. Conditions for Medicare payment for CAHs are set forth at § 413.70. Applicable regulations concerning provider agreements are located in 42 CFR part 489, and those pertaining to facility survey and

certification are in 42 CFR part 488, subparts A and B.

For a CAH to enter into a provider agreement with the Medicare program, a CAH must first be certified by a State survey agency as complying with the conditions or requirements set forth in section 1820 of the Act, and 42 CFR part 485 of the regulations. Subsequently, the CAH is subject to ongoing review by a State survey agency to determine whether it continues to meet the Medicare requirements. However, there is 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 provides that, if a provider entity demonstrates through accreditation by an approved national accreditation organization (AO) that all applicable Medicare conditions are met or exceeded, we may “deem” that provider entity as having met the requirements. Accreditation by an AO is voluntary and is not required for Medicare participation. A national AO applying for deeming authority under 42 CFR part 488, subpart A must provide us with reasonable assurance that the AO requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions.

II. Deeming Application Approval Process

Section 1865(a)(3)(A) of the Act provides a statutory timetable to ensure that our review of applications for deeming authority is conducted in a timely manner. The statute provides us 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 process. Within 60 days after 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 a notice in the **Federal Register** approving or denying the application.

III. Provisions of the Proposed Notice and Response to Comments

In the July 26, 2010 **Federal Register** (75 FR 43531), we published a proposed notice announcing DNVHC's request for approval as a deeming organization for CAHs. In the proposed notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and in our regulations at § 488.4, we conducted a review of DNVHC'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 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 CAH accreditation standards to our current Medicare CAH conditions of participation (CoPs).

- 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's 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.

- + 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 section 1865(a)(3)(A) of the Act, the July 26, 2010 proposed notice also solicited public comments regarding whether DNVHC's requirements met or exceeded the Medicare CoPs for CAHs. We received five comments in response to our proposed notice.

All of the commenters expressed support for DNVHC's application for CAH deeming authority. The commenters stated that DNVHC's standards are clearly written and closely align with the Medicare CoPs, and that DNVHC's accreditation program provides CAHs with a viable alternative to other healthcare AOs.

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 CAH accreditation requirements and survey process with the Medicare 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:

- To meet the requirements at § 485.641(b)(4), DNVHC revised its crosswalk to ensure deficiencies regarding credentialing and quality assurance are correctly cited and cross-walked to the Medicare requirements.

- To ensure consistent and accurate documentation, DNVHC revised its onsite survey protocol to require surveyors use and forward all surveyor worksheets to the corporate office for inclusion in the survey file.

- To meet the survey process requirements at appendix W of the SOM, DNVHC revised its policies to require the medical record sample size be no less than 20 inpatient records.

- To meet the requirements at appendix W of the SOM, DNVHC revised its policies to require the conduct of patient interviews during the survey.

- To meet the requirements at section 5075.9 of the SOM, DNVHC revised its policies to require an onsite survey within 45 calendar days for complaints triaged as operational requiring a special survey.

- To meet the requirements at § 485.608(d), DNVHC revised its standards to address the certification or registration requirements of CAH personnel.

- To meet the requirements at § 485.618(c)(2) and § 485.618(d)(1), DNVHC revised its standards to replace the term physician with “doctor of medicine or osteopathy.”

- To meet the requirements at § 485.618(d)(3)(iii) through § 485.618(d)(4), DNVHC revised its onsite surveyor protocol to require surveyors to verify, if applicable, that the CAH has received permission from

CMS to use registered nurses with training and experience as qualified professionals in emergency care, on a temporary basis, be included in the list of personnel immediately available to provide emergency care.

- To meet the requirements at § 485.620, DNVHC revised its standards to address the number of beds and length of stay requirements for CAHs.
- To meet the requirements at § 485.623(b), DNVHC revised its standards to include housekeeping and preventive maintenance programs.
- To meet the requirements at § 485.623(c)(3), DNVHC revised its standards to ensure the CAH provides an emergency fuel supply.
- To meet the requirements at § 485.623(d)(7)(iv), DNVHC revised its standards to include the reference to the National Fire Protection Association (NFPA) Tentative Interim Amendments (TIA) 00–01 (101).
- To meet the requirements at § 485.623(d)(7)(i) through § 485.623(d)(7)(iv), DNVHC revised its standards to ensure alcohol-based dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code.
- To meet the requirements at § 485.635(a)(3)(i), DNVHC revised its standards to ensure the CAH's policies include a description of the services provided, either directly or through an agreement or arrangement.
- To meet the requirements at § 485.635(a)(3)(iii), DNVHC revised its standards to ensure the CAH's policies include guidelines for healthcare conditions that may require a patient referral.
- To meet the requirements at § 485.635(a)(4), DNVHC revised its standards to require that a group of professional personnel review the CAH policies on an annual basis.
- To meet the requirements at § 485.635(b)(1), DNVHC revised its standards to ensure direct services of the CAH include the medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions.
- To meet the requirements at § 485.635(b)(3), DNVHC revised its standards to ensure staff and patients of the CAH are not exposed to radiation hazards.
- To meet the requirements at § 485.635(d)(3), DNVHC revised its standards to ensure drugs and biologicals are administered by and under the supervision of a registered nurse, a doctor of medicine or osteopathy, or, where permitted, a

physician assistant, in accordance with written and signed orders.

- To meet the requirements at § 485.635(e), DNVHC revised its standards to ensure therapy services provided at the CAH are consistent with the requirements at § 409.17 of our rules.
- To meet the requirements at § 485.638(a)(4)(i), DNVHC revised its standards to ensure the patient's medical record include a brief summary of the episode.
- To meet the requirements at § 485.638(c), DNVHC revised its standards to ensure clinical records are retained longer than six years from the date of the record's last entry, if such is required by State statute, or if the records are needed for a pending proceeding.
- To meet the requirements at § 485.639(b)(3), DNVHC revised its standards to ensure patients receiving surgical services at the CAH are evaluated for proper anesthesia recovery by a qualified practitioner.
- To meet the requirements at § 485.641(b)(1), DNVHC revised its standards to ensure all CAH services that affect patient health and safety are evaluated.
- To meet the requirements at § 485.645(a)(2), DNVHC revised its standards to ensure the CAH provides no more than 25 inpatient beds.
- To meet the requirements at § 485.645(d)(8), DNVHC revised its standards to address the requirement that if the CAH provides or obtains dental services from an outside resource, that service must be in accordance with the requirements at § 483.55 and § 483.75(h).
- To meet the Skilled Nursing Facilities (SNF) requirements applicable to swing beds at § 483.12(a)(1), DNVHC revised its standards to ensure transfer and discharge of a patient includes transfer to a bed outside of the certified facility.
- To meet the SNF swing bed requirements at § 483.20(b)(2), DNVHC revised its standards to ensure the comprehensive assessment is completed within 14 calendar days after admission and not less than every 12 months.
- To meet the requirements at § 483.20(k)(1)(ii), DNVHC revised its standards to ensure that the comprehensive care plan addresses situations where services that would be otherwise required under § 483.25 are not provided due to the patient's right to refuse treatment under § 483.10(b)(4).
- To meet the requirements at § 483.20(l)(2), DNVHC revised its standards to ensure the discharge summary includes a final summary of the patient's status and is available for release to authorized persons and agencies, with the consent of the patient or legal representative.
- To meet the requirements at § 412.25(a)(2), DNVHC revised its standards to ensure the CAH's written admission criteria is applied uniformly to both Medicare and non-Medicare patients.
- To meet the requirements at § 412.25(d), DNVHC revised its standards to ensure the CAH has only one psychiatric or rehabilitation unit excluded from the prospective payment systems.
- To meet the requirements at § 412.27(d)(1), DNVHC revised its standards to ensure the CAH provides an adequate number of qualified doctors of medicine and osteopathy for essential psychiatric services.
- To meet the requirements at § 482.11(b)(2), DNVHC revised its standards to require hospitals located in States that do not provide licensure meet the approved standards established by that State.
- To meet the requirements at § 482.12(c)(2) through § 482.12(c)(4)(ii), DNVHC revised its standards to address who can admit patients.
- Regarding our capitalization and capital plan requirements for health maintenance organizations (HMOs) and civil monetary penalties (CMP) that operate hospitals, DNVHC revised its standards to ensure, with respect to such entities, the institutional plan and budget include the following requirements:
 - + The facilities do not provide common services at the same site.
 - + The facilities are not available under a contract of reasonable duration.
 - + Full and equal medical staff privileges in the facilities are not available.
 - + Arrangements with these facilities are not administratively feasible.
 - + The purchase of these services is more costly than if the health maintenance organization (HMO) or competitive medical plan (CMP) provided services directly.
- To meet the requirements at § 485.618, DNVHC revised its standards to clarify that emergency services must be provided directly.
- To meet the requirements at § 482.13(e)(13), DNVHC revised its standards to address the requirement that States are free to have restraint and seclusion requirements by statute or regulation that are more restrictive than CMS standards.
- To meet the requirements at § 482.21, DNVHC revised its standards to require that hospitals maintain and

demonstrate evidence of its quality assessment and performance improvement program (QAPI) program for review by CMS.

- To meet the requirements at § 482.21(a)(1), DNVHC revised its standards to ensure QAPI is an ongoing program that shows measurable improvements in indicators for which there is evidence that it will improve health outcomes and identify and reduce medical errors.
- To meet the requirements at § 482.21(a)(2), DNVHC revised its standards to ensure the hospital's QAPI program includes aspects of performance that assess process of care, hospital service, and operations.
- To meet the requirements at § 482.21(c)(2), DNVHC revised its standards to address the hospital's responsibility to, among other things, implement preventive actions and mechanisms that include feedback and learning throughout the hospital as part of its performance improvement activities.
- To meet the requirements at § 482.21(d)(2), DNVHC revised its standards to clarify that a hospital may choose, as one of its quality initiatives, to develop and implement an information technology system to improve patient safety and quality.
- To meet the requirements at § 482.23(c), DNVHC revised its standards to ensure all drugs and biologicals are administered under the orders of a practitioner responsible for the care of the patient as specified at § 482.12(c).
- To meet the requirements at § 482.23(c)(3), DNVHC revised its standards to include the requirement that blood transfusions and intravenous medications must be administered in accordance with State laws and approved medical staff policies and procedures.
- To meet the requirements at § 482.23(c)(4), DNVHC revised its standards to require blood transfusion reactions be reported immediately to the attending physician.
- To meet the requirements at § 482.30(a)(2), DNVHC revised its standards to address situations where CMS has determined that the utilization review (UR) procedures established by a State under title XIX of the Act are superior to those listed in 42 CFR part 482, thus requiring hospitals in that State to meet the utilization control requirements at § 456.50 through § 456.245 of this chapter of the regulations.
- To meet the requirements at § 482.30(c)(4) and § 482.30(e)(2), DNVHC revised its standards to require

that the CAH review cases where the patient's length of stay exceeds the mean length of stay for the applicable diagnostic-related group (DRG) and the hospital charges for covered services exceed the DRG payment rate.

- To meet the requirements at § 482.30(d)(1)(i) through § 482.30(d)(3), DNVHC revised its standards to ensure determinations regarding admissions or continued stays are made by the practitioner responsible for the patient as specified in § 482.12(c).
- To meet the requirements at § 482.30(e)(ii), DNVHC revised its standards to require that the utilization review committee conduct a periodic review of each current inpatient receiving hospital services during a continuous period of extended duration for hospitals not paid under the prospective payment system.
- To meet the requirements at § 482.42(a)(2), DNVHC revised its standards to require the infection control officer maintain a log of incidents related to infections and communicable diseases.
- To meet the requirements at § 482.43(e), DNVHC revised its standards to require that the CAH periodically reevaluate its discharge planning process.

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 CAHs meet or exceed our requirements. Therefore, we approve DNVHC as a national accreditation organization for CAHs that request participation in the Medicare program, effective December 23, 2010, through December 23, 2014.

V. 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).

VI. Regulatory Impact Statement

In accordance with the provisions of Executive Order 12866, this regulation was not reviewed by the Office of Management and Budget.

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) (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774,

Medicare—Supplementary Medical Insurance Program).

Dated: October 27, 2010.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2010-28666 Filed 11-12-10; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Special Emphasis Panel for R01 Applications.

Date: December 10, 2010.

Time: 11 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Xiaodu Guo, MD, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 761, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-4719, guox@extra.niddk.nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Liver Ancillary Studies.

Date: December 13, 2010.

Time: 10 a.m. to 11:30 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Paul A. Rushing, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 747, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-8895, rushingp@extra.niddk.nih.gov.