

reactions to vaccines. The National Vaccine Advisory Committee was established to provide advice and make recommendations to the Director of the National Vaccine Program on matters related to the Program's responsibilities. The Assistant Secretary for Health serves as Director of the National Vaccine Program.

Among the topics to be discussed at the NVAC meeting are: Implementation of the National Vaccine Plan, pertussis, immunizations and health information technology, Healthy People 2020, immunization goals, and vaccine hesitancy. The meeting agenda will be posted on the NVAC Web site: <http://www.hhs.gov/nvpo/nvac> prior to the meeting.

Public attendance at the meeting is limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the National Vaccine Program Office at the address/phone listed above at least one week prior to the meeting. Members of the public will have the opportunity to provide comments at the NVAC meeting during the public comment periods on the agenda. Individuals who would like to submit written statements should email or fax their comments to the National Vaccine Program Office at least five business days prior to the meeting.

Dated: August 21, 2012.

Bruce Gellin,

*Director, National Vaccine Program Office,
Executive Secretary, National Vaccine
Advisory Committee.*

[FR Doc. 2012-20910 Filed 8-23-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meetings of the National Biodefense Science Board

AGENCY: Department of Health and Human Services, Office of the Secretary.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services is hereby giving notice that the National Biodefense Science Board (NBSB) will be holding a closed session under exemption 9(B) of the Government in Sunshine Act, 5 U.S.C. section 552b(c).

DATES: The closed session of the NBSB will take place on September 17, 2012, and is tentatively scheduled from 1:30 p.m. to 3:30 p.m. EST. The agenda and time for the session are subject to

change as priorities dictate. Please check the NBSB Web site for the most up-to-date information.

ADDRESSES: The closed session will be held by teleconference and/or webinar and will not be open to the public as stipulated under exemption 9(B) of the Government in Sunshine Act, 5 U.S.C. section 552b(c).

FOR FURTHER INFORMATION CONTACT: The National Biodefense Science Board mailbox: NBSB@HHS.GOV.

SUPPLEMENTARY INFORMATION: Pursuant to section 319M of the Public Health Service Act (42 U.S.C. 247d-7f) and section 222 of the Public Health Service Act (42 U.S.C. 217a), the Department of Health and Human Services established the National Biodefense Science Board. The Board shall provide expert advice and guidance to the Secretary on scientific, technical, and other matters of special interest to the Department of Health and Human Services (HHS) regarding current and future chemical, biological, nuclear, and radiological agents, whether naturally occurring, accidental, or deliberate. The Board may also provide advice and guidance to the Secretary and/or the Assistant Secretary for Preparedness and Response (ASPR) on other matters related to public health emergency preparedness and response.

Background: The NBSB continues to review and evaluate the 2012 Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy and Implementation Plan (SIP). Therefore, the Board's deliberations on the PHEMCE SIP task are being conducted in closed sessions in accordance with provisions set forth under exemption 9(B) of the Government in Sunshine Act, 5 U.S.C. section 552b(c), and with approval by the ASPR. For a full description for the basis for closing this session, please see the previous meeting notice published at 77 FR 13129 (2012).

Availability of Materials: The meeting agenda and materials will be posted on the NBSB Web site at www.PHE.GOV/NBSB.

Procedures for Providing Public Input: All written comments should be sent by email to NBSB@HHS.GOV with "NBSB Public Comment" as the subject line.

Dated: August 20, 2012.

Nicole Lurie,

Assistant Secretary for Preparedness and Response.

[FR Doc. 2012-20930 Filed 8-23-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3258-FN]

Medicare and Medicaid Programs; Continued Approval of Det Norske Veritas Healthcare's (DNVHC's) Hospital Accreditation Program

AGENCY: Centers for Medicare and Medicaid Services, HHS.

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve the 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. A hospital that participates in Medicaid must also meet the Medicare conditions of participation as referenced in 42 CFR 488.5(3)(b) and 42 CFR 488.6(b). This approval is effective September 26, 2012, through September 26, 2018.

DATES: This final notice is effective September 26, 2012, through September 26, 2018.

FOR FURTHER INFORMATION CONTACT: Barbara Easterling, (410) 786-0482; Cindy Melanson, (410) 786-0310; or 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. Section 1861(e) of the Social Security Act (the 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 to participate in the Medicare program, the scope of covered services and the conditions for Medicare payment for hospitals.

Generally, 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. 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 accrediting organization (AO) 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 of the Department of Health and Human Services 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.

Det Norske Veritas Healthcare's current term of approval for their hospital accreditation program expires September 26, 2012.

II. Application Approval Process

Section 1865(a)(3)(A) of the Act provides a statutory timetable to ensure that our review of applications for CMS-approval of an accreditation program is conducted in a timely manner. The statute provides CMS 210 days after the date of receipt of a complete application, with any documentation necessary to make the 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 accrediting 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

In the March 23, 2012 **Federal Register** (77 FR 17070), we published a proposed notice in the announcing

DNVHC's request for approval of its hospital accreditation program. In the March 23, 2012 proposed notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and in our regulations at § 488.4 and § 488.8, 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.

- The comparison of DNVHC's accreditation to our current Medicare hospital conditions of participation.

- A documentation review of DNVHC's survey process to determine the following:

- + 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 hospitals 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 the organization's survey process.

- + Determine the adequacy of staff and other resources.

- + Confirm 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 March 23, 2012 proposed notice also solicited public comments regarding whether DNVHC's requirements met or exceeded the Medicare conditions of participation for hospitals. We received two comments in response to our proposed notice. The commenters expressed continued support for DNVHC's hospital accreditation program. In addition, the commenters stated DNVHC's standards are closely aligned with the hospital conditions of participation, thus allowing hospitals to be in compliance with the Medicare requirements.

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

- To meet the requirements at § 482.13(a), DNVHC revised its standards to include language to address the hospital's responsibility to protect and promote each patient's rights.

- To meet the requirements at § 482.13(a)(2), DNVHC revised its standards to require prompt resolution of patient grievances.

- To meet the requirements at § 482.13(b)(3), DNVHC revised its standards to include the requirements at § 489.100, § 489.102, § 489.104 regarding advanced directive.

- To meet the requirements at § 482.52(b), DNVHC revised its standards to ensure anesthesia services are consistent with the needs and resources of the hospital.

- To meet the requirements at § 489.13, DNVHC modified its policies related to the accreditation effective date.

- To meet the survey process requirements in Appendix A of the SOM, DNVHC revised its policy outlining the minimum number of inpatient records required for review during an accreditation survey.

- To meet the requirements at § 488.4, DNVHC revised its policies to require a copy of the surveyor's annual evaluation be included in the surveyor's file.

- DNVHC revised its complaint policies to ensure all complaint investigations are conducted in

accordance with the requirements at SOM chapter five.

- DNVHC revised its policies and procedures to clarify that they do not have authority to advise facilities regarding certification issues. Instead, DNVHC must contact the CMS Regional Office on facility specific certification issues for consultation and direction.

B. Term of Approval

Based on our 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 DVNHC as a national accreditation organization for hospitals that request participation in the Medicare program, effective September 26, 2012, through September 26, 2018.

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).

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—Supplementary Medical Insurance Program)

Dated: August 9, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2012-20199 Filed 8-23-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1452-NC]

Medicare and Medicaid Programs; Announcement of Application From a Hospital Requesting Waiver for Organ Procurement Service Area

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

ACTION: Notice with comment period.

SUMMARY: This notice with comment period announces a hospital's request for a waiver from the requirement to have an agreement with its designated

Organ Procurement Organization (OPO). The request was made in accordance with section 1138(a)(2) of the Social Security Act (the Act). In addition, this notice requests comments from OPOs and the general public for our consideration in determining whether we should grant the requested waiver.

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

ADDRESSES: In commenting, please refer to file code CMS-1452-NC. 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 to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1452-NC, P.O. Box 8010, Baltimore, MD 21244-1850.

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 to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1452-NC, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses:

- a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(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, call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously 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: Patricia Taft, (410) 786-4561.

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, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

I. Background

Organ Procurement Organizations (OPOs) are not-for-profit organizations that are responsible for the procurement, preservation, and transport of organs to transplant centers throughout the country. Qualified OPOs are designated by the Centers for Medicare & Medicaid Services (CMS) to recover or procure organs in CMS-defined exclusive geographic service areas, pursuant to section 371(b)(1) of the Public Health Service Act (42 U.S.C. 273(b)(1)) and our regulations at 42 CFR 486.306. Once an OPO has been designated for an area, hospitals in that area that participate in Medicare and Medicaid are required to work with that OPO in providing organs for transplant, pursuant to section 1138(a)(1)(C) of the Social Security Act (the Act) and our regulations at 42 CFR 482.45.

Section 1138(a)(1)(A)(iii) of the Act provides that a hospital must notify the