

with the FAR provision 52.225–18, Place of Manufacture. This provision requires offerors of manufactured end products to indicate in response to a solicitation, by checking a box, whether the place of manufacture of the end products it expects to provide is predominantly manufactured in the United States or outside the United States. Contracting officers use the information as the basis for entry into the Federal Procurement Data System for further data on the rationale for purchasing foreign manufactured items. The data is necessary for analysis of the application of the Buy American statute and the trade agreements.

### C. Annual Burden

*Respondents:* 50,106.

*Total Annual Responses:* 2,600,361.

*Total Burden Hours:* 26,004.

*Obtaining Copies:* Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division by calling 202–501–4755 or emailing [GSARegSec@gsa.gov](mailto:GSARegSec@gsa.gov). Please cite OMB Control No. 9000–0161, Reporting Purchases from Sources Outside the United States, in all correspondence.

#### Janet Fry,

*Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.*

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unwarranted invasion of personal privacy.

*Name of Committee:* Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—RFA–OH–22–002, NIOSH Centers for Agricultural Safety and Health.

*Date:* March 7, 2023.

*Time:* 11:00 a.m.–6:00 p.m., EST.

*Place:* Video-Assisted Meeting.

*Agenda:* To review and evaluate grant applications.

*For Further Information Contact:* Marilyn Ridenour, B.S.N., M.P.H., Scientific Review Officer, Office of Extramural Programs, National Institute for Occupational Safety and Health, CDC, 1095 Willowdale Road, Morgantown, West Virginia, 26505; Telephone: (304) 285–5879; Email: [MRidenour@cdc.gov](mailto:MRidenour@cdc.gov).

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

#### Kalwant Smagh,

*Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.*

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Erin Imhoff, (410) 786–2337.

Caecilia Blondiaux, (410) 786–2190.

### SUPPLEMENTARY INFORMATION:

#### I. Background

Under the Medicare program, eligible beneficiaries may receive covered services from a hospital, provided certain requirements are met. Section 1861(e) of the Social Security Act (the Act) establishes statutory authority for the Secretary of the Department of Health and Human Services (Secretary) to set 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 42 CFR part 488. The regulations at 42 CFR part 482 specify the minimum conditions of participation that a hospital must meet to participate in the Medicare program.

Generally, to enter into an agreement, a hospital must first be certified by a state survey agency (SA) as complying with the conditions or requirements set forth in part 482 of our regulations. Thereafter, the hospital is subject to regular surveys by a SA to determine whether it continues to meet these requirements.

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

If an AO is recognized by the Secretary of the Department of Health and Human Services (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 meet the Medicare requirements. A national AO applying for approval of its accreditation program under part 488, subpart A, must provide CMS with reasonable assurance that the AO requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare requirements. Our regulations concerning the approval of AOs are set forth at §§ 488.4, 488.5 and 488.5(e)(2)(i). The regulations at § 488.5(e)(2)(i) require AOs to reapply for continued approval of its accreditation program every 6 years or sooner, as determined by CMS.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting 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, and the Determination of the Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, CDC, pursuant to Public Law 92–463. 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

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS–3429–FN]

#### Medicare and Medicaid Programs: Application From the Center for Improvement in Healthcare Quality for Continued Approval of Its Hospital Accreditation Program

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

**ACTION:** Notice.

**SUMMARY:** This notice announces our decision to approve the Center for Improvement in Healthcare Quality (CIHQ) for continued recognition as a national accrediting organization for hospitals that wish to participate in the Medicare or Medicaid programs.

**DATES:** The decision announced in this notice is applicable January 1, 2023 through January 1, 2028.

**FOR FURTHER INFORMATION CONTACT:**

Center for Improvement in Healthcare Quality (CIHQ)'s current term of approval for their hospital accreditation program expires July 26, 2023. As discussed in the proposed notice (87 FR 43525), CIHQ submitted its application for renewal earlier than expected and therefore CMS will adjust their future term of approval accordingly.

## 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 Act provides us 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

On July 21, 2022, we published a proposed notice in the **Federal Register** (87 FR 43525), announcing CIHQ's request for continued approval of its Medicare hospital accreditation program. In that proposed notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and in our regulations at §§ 488.5 and 488.8(h), we conducted a review of CIHQ's Medicare hospital accreditation application in accordance with the criteria specified by our regulations, which include, but are not limited to the following:

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

- A review of CIHQ's survey processes to confirm that a provider or supplier, under CIHQ's hospital deeming accreditation program, meets or exceeds the Medicare program requirements.

- A documentation review of CIHQ's survey process to do the following:

- ++ Determine the composition of the survey team, surveyor qualifications,

and CIHQ's ability to provide continuing surveyor training.

- ++ Compare CIHQ's processes to those we require of state survey agencies, including periodic resurvey and the ability to investigate and respond appropriately to complaints against CIHQ accredited hospitals.

- ++ Evaluate CIHQ's procedures for monitoring accredited hospitals it has found to be out of compliance with its program requirements.

- ++ Assess CIHQ's ability to report deficiencies to the surveyed hospitals and respond to the hospitals plan of correction in a timely manner.

- ++ Determine the adequacy of CIHQ's staff and other resources.

- ++ Confirm CIHQ's ability to provide adequate funding for performing required surveys.

- ++ Confirm CIHQ's policies with respect to surveys being unannounced.

- ++ Confirm CIHQ's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions.

- ++ Obtain CIHQ's agreement to provide CMS 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.

## IV. Analysis of and Responses to Public Comments on the Proposed Notice

In accordance with section 1865(a)(3)(A) of the Act, the July 21, 2022 proposed notice also solicited public comments regarding whether CIHQ's requirements met or exceeded the Medicare conditions of participation for hospitals. We received approximately 19 timely public comments from hospitals and individuals, and another that was out of scope of the proposed rule.

*Comment:* Most commenters expressed support for CIHQ and their hospital accreditation program and encouraged CMS to approve them for continued recognition as a national AO for hospitals.

*Response:* We appreciate the support from those hospitals who have experience with CIHQ's Medicare hospital accreditation program and agree that CIHQ should be approved for continued recognition as a national AO for hospitals that wish to participate in the Medicare or Medicaid programs.

*Comment:* A commenter expressed concern about hospital accreditation programs overall and the responsibility of CMS to oversee the process. The comment was not specific to CIHQ.

*Response:* We appreciate this comment and the concern for patient safety and quality of care. We continue to prioritize patient safety and our responsibility for oversight of AOs. As described in section III. Provisions of the Proposed Notice of this notice, CMS takes various steps when considering whether to approve or not approve a national AO. Each AO wishing to be recognized by Medicare as a national AO must go through a rigorous process for CMS approval. We remain steadfast in our commitment to keeping the public informed of our evaluation process for AOs seeking approval from CMS.

*Comment:* A commenter expressed concern for paying out of pocket for chronic diseases.

*Response:* We thank the commenter for expressing concern, but this comment is outside the scope of the notice.

*Final Decision:* After consideration of the public comments received, we are finalizing our decision to approve CIHQ's application for continued recognition as a national AO for hospitals that wish to participate in the Medicare or Medicaid programs.

## V. Provisions of the Final Notice

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

We compared CIHQ's hospital accreditation requirements and survey process with the Medicare conditions of participation of part 482, and the survey and certification process requirements of parts 488 and 489. Our review and evaluation of CIHQ's renewal application, which were conducted as described in section III. of this final notice, yielded the following areas where, as of the date of this notice, CIHQ has completed revising its standards and certification processes in order to—

- Meet the requirements of all of the following Medicare regulations:

- ++ Section 482.41(a)(1), to include the appropriate Life Safety Code (LSC) references that address hospitals classified as new occupancies.

- ++ Section 482.41(b)(1)(i), to include the appropriate National Fire Protection Agency (NFPA) 101 requirements for hospitals classified as Business Occupancies.

- ++ Section 482.41(d)(4), to include compliance with the 2008 American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) Standard 170—Ventilation of Health Care Facilities, in accordance with 2012

NFPA requirements and to ensure sterile supply and medical equipment manufacturer instructions for use (IFUs) are considered before hospitals reduce relative humidity levels.

++ Section 488.5(a)(3), to correct formatting and technical errors in the crosswalk as requested by CMS.

In addition to the standards review, CMS reviewed CIHQ's comparable survey processes, which was conducted as described in section III. of this notice, and also reviewed corporate policies, which yielded the following areas where, as of the date of this notice, CIHQ has completed revising its survey processes to demonstrate that it uses survey processes that are comparable to state survey agency processes by:

++ Revising Facility & Life Safety worksheets for surveyors to explain that the worksheet does not include all 2012 LSC & Health Care Facilities Code requirements in accordance with survey comparability at § 488.5(a)(4)(ii).

++ Providing additional training to surveyors related to the number of medical records that should be reviewed during the survey of larger hospitals in accordance with survey comparability at § 488.5(a)(4)(ii).

++ Improving the level of detail in survey documentation in accordance with survey comparability at § 488.5(a)(4)(ii).

++ Providing CMS with the job description required for CIHQ's LSC Consultants in accordance with the description of education and experience requirements surveyors must meet at § 488.5(a)(7).

++ Revising complaint procedures to ensure the survey investigation process is clearly documented in accordance with the organizations complaint procedures at § 488.5(a)(12).

#### B. Term of Approval

Based on our review and observations described in section III. and section V. of this notice, we approve CIHQ as a national accreditation organization for hospitals that request participation in the Medicare program. The decision announced in this notice is effective January 1, 2023 through January 1, 2028 (5 years). Due to the timing of the start of the fiscal year and associated travel restrictions, CMS was unable to conduct a hospital survey observation of CIHQ surveyors in accordance with 42 CFR 488.8(h), which is one component of the comparability evaluation. Therefore, we are providing CIHQ with a reduced term of approval. In accordance with 42 CFR 488.5(e)(2)(i), CMS may not give a term of the approval that exceeds 6 years.

Based on our discussions with CIHQ and the information provided in its

application, we are confident that CIHQ will continue to ensure that its deemed hospitals will continue to meet or exceed Medicare standards.

Additionally, CIHQ has applied for critical access hospital deeming authority and as part of that application we will complete a survey observation. Critical access hospitals have similar CoPs and survey process to hospitals and therefore we are confident in a 5-year approval term for this application.

#### VI. Collection of Information and Regulatory Impact Statement

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: December 14, 2022.

**Lynette Wilson,**

*Federal Register Liaison, Centers for Medicare & Medicaid Services.*

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**BILLING CODE 4120-01-P**

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. FDA-2022-N-2810]

#### Vaccines and Related Biological Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

**AGENCY:** Food and Drug Administration, Department of Health and Human Services (HHS).

**ACTION:** Notice; establishment of a public docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC). The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. On January 26, 2023, the committee will meet in open session to discuss the future vaccination

regimens addressing COVID-19. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

**DATES:** The meeting will be held virtually on January 26, 2023, from 8:30 a.m. to 5:30 p.m. Eastern Time.

**ADDRESSES:** Please note that due to the impact of this COVID-19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings, including information regarding special accommodations due to a disability, may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>. The online web conference meeting will be available at the following link on the day of the meeting: <https://youtu.be/ZjULNuSYfd0>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2022-N-2810. Please note that late, untimely filed comments will not be considered. The docket will close on January 25, 2023. Either electronic or written comments on this public meeting must be submitted by January 25, 2023. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 25, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Comments received on or before January 18, 2023, will be provided to the committee. Comments received after January 18, 2023, and by January 25, 2023, will be taken into consideration by FDA. In the event that the meeting is canceled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your