DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Lead Exposure and Prevention Advisory Committee (LEPAC)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the CDC announces the following meeting for the Lead Exposure and Prevention Advisory Committee (LEPAC). This is a virtual meeting and is open to the public. Advance registration by April 28, 2022, is needed to receive the information to join the meeting. The registration link is provided in the **ADDRESSES** section below.

DATES: The meeting will be held on May 12, 2022, from 9:00 a.m. to 4:30 p.m., EDT.

ADDRESSES: Register in advance at *https://www.zoomgov.com/webinar/register/WN_JpapSgFXRKmeHVU9hW4jVQ* to receive information to join the meeting.

FOR FURTHER INFORMATION CONTACT: Alexis Pullia, M.P.H., C.P.H., Committee Management Specialist, National Center for Environmental Health, CDC, 4770 Buford Highway, Atlanta, Georgia 30341, Telephone: 770–488–3300; Email: *LEPAC@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Background: The Lead Exposure and Prevention Advisory Committee was established under Section 2203 of Public Law 114–322, the Water Infrastructure Improvements for the Nation Act; 42 U.S.C. 300j-21, Registry for Lead Exposure and Prevention Advisory Committee.

Purpose: The LEPAC is charged with providing advice and guidance to the Secretary, Department of Health and Human Services (HHS), and the Director, CDC and Administrator, ATSDR, on (1) reviewing Federal programs and services available to individual communities exposed to lead; (2) reviewing current research on lead exposure to identify additional research needs; (3) reviewing and identifying best practices, or the need for best practices regarding lead screening and the prevention of lead poisoning; (4) identifying effective services, including services relating to healthcare, education, and nutrition for individuals and communities affected by lead exposure and lead poisoning, including in consultation with, as appropriate, the lead exposure registry as established in Section 2203(b) of Public Law 114–322; and 5) undertaking any other review or activities that the Secretary determines to be appropriate.

Matters To Be Considered: The agenda will include updates on the Flint Lead Registry and lead-related activities from LEPAC Members; information on lead exposure in Clarksburg, West Virginia; and discussions on the following: Infrastructure initiatives related to lead; lead in air, soil, and blood; navigating multiple funding streams at the local level; and policy approaches to improve childhood blood lead testing rates. Agenda items are subject to change as priorities dictate.

Public Participation

Oral Public Comment: The public comment period is scheduled on May 12, 2022, from 12:00 p.m. until 12:15 p.m., EDT. Individuals wishing to make a comment during the public comment period, please email your name, organization, and phone number by April 28, 2022, to *LEPAC@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.

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

[FR Doc. 2022–05801 Filed 3–18–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3416–FN]

Medicare and Medicaid Programs; Continued Approval of the American Association for Accreditation of Ambulatory Surgery Facilities' Rural Health Clinic Accreditation Program

AGENCY: Centers for Medicare & Medicaid Services, Department of Health and Human Services (HHS).

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF) for continued recognition as a national accrediting organization for Rural Health Clinics (RHCs) that wish to participate in the Medicare or Medicaid programs.

DATES: The decision in this final notice is effective March 23, 2022, through March 23, 2026.

FOR FURTHER INFORMATION CONTACT: Lillian Williams, (410) 786–8636, or Shonte Carter, (410) 786–3532.

SUPPLEMENTARY INFORMATION:

I. Background

A healthcare provider may enter into an agreement with Medicare to participate in the program as a Rural Health Clinic (RHC) provided certain requirements are met. Section 1861(aa)(2) and 1905(l)(1)of the Social Security Act (the Act), establish distinct criteria for facilities seeking designation as RHCs for Medicare and Medicaid, respectively. Regulations concerning Medicare provider agreements are at 42 CFR part 489 and those pertaining to the survey and certification for Medicare participation of certain providers and suppliers are at 42 CFR part 488. The regulations at 42 CFR part 491 specify the conditions that a facility must meet to participate in the Medicare program as an RHC.

Generally, to enter into a Medicare provider agreement, an RHC must first be certified by a State survey agency as complying with the conditions set forth in part 491 of our Medicare regulations. Thereafter, the RHC is subject to periodic surveys by a State survey agency to determine whether it continues to meet these conditions. However, there is an alternative to certification surveys by State agencies. Accreditation by an approved, nationally recognized Medicare accreditation program may substitute for both initial and ongoing review.

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

Subpart A of part 488 requires in part that a national accrediting organization applying for approval of its Medicare accreditation program provide us with reasonable assurance that the accrediting organization requires its

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 § 488.5. Section 488.5(e)(2)(i) requires an accrediting organization to reapply for continued approval of its Medicare accreditation program every 6 years or sooner as determined by CMS. The American Association for Accreditation of Ambulatory Surgery Facilities' (AAAASF) current term of approval for their RHC accreditation program expires March 23, 2022.

II. Application Approval Process

Section 1865(a)(3)(A) of the Act requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accreditation body making the request, describing the nature of the request, and providing at least a 30-day public comment period. We have 210 days after the date of receipt of a complete application to publish a notice announcing our approval or denial of an application.

III. Provisions of the Proposed Notice

On October 15, 2021, we published a proposed notice in the **Federal Register** (86 FR 57429) entitled ''Application from the American Association for Accreditation of Ambulatory Surgery Facilities for Continued Approval of its Rural Health Clinic (RHC) Accreditation Program'' announcing AAAASF's request for continued approval of its Medicare RHC accreditation program. In that notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and per §§ 488.5 and 488.8(h), we conducted a review of AAAASF's application in accordance with the criteria authorized by our regulations, which include, but are not limited to the following:

- An administrative review of AAAASF's: (1) Corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its RHC surveyors; (4) ability to investigate and respond appropriately to complaints against accredited RHCs; and, (5) survey review and decision-making process for accreditation.
- The equivalency of AAAASF's standards for RHCs as compared with CMS' RHC CoPs.
- AAAASF's survey process to determine the following:

++ The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing survey training.

++ The comparability of AAAASF's processes to those of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited RHCs.

++ AAAASF processes and procedures for monitoring RHCs found out of compliance with AAAASF's program requirements. These monitoring procedures are used only when AAAASF identifies noncompliance. If noncompliance is identified through validation reviews or complaint surveys, the State survey agency monitors corrections as specified at § 488.9(c).

++ AAAASF's capacity to report deficiencies to the surveyed RHCs and respond to the RHC's plan of correction in a timely manner.

++ AAAASF's capacity to provide us with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

++ The adequacy of AAAASF's staff and other resources, and its financial viability.

++ AAAASF's capacity to adequately fund required surveys.

++ AAAASF's policies with respect to whether surveys are announced or unannounced, to assure that surveys are unannounced.

++ AAAASF'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.

++ AAAASF'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 October 15, 2021 proposed notice also solicited public comments regarding whether AAAASF's requirements met or exceeded the Medicare conditions for certification for RHCs. The comments we received support the approval of AAAASF for continued recognition as a national accrediting organization for RHCs. We did not receive any comments opposing the approval.

IV. Provisions of the Final Notice

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

We compared AAAASF's RHC accreditation requirements and survey process with the Medicare conditions for certification of 42 CFR part 491 and the survey and certification process requirements of parts 488 and 489. Our review and evaluation of AAAASF's RHC 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, AAAASF has completed revising its standards and survey processes in order to meet the requirements at:

- Section 491.7(a)(1) to ensure that their crosswalk and standards included the requirement that an RHC must have a health care staff that meets the requirements of § 491.8.
- Section 491.8(a)(2) to ensure that their crosswalk and standards include the correct reference that a physician member of the staff may be the owner of the RHC, an employee of the clinic or center, or under agreement with the clinic or center to carry out the responsibilities required under this section.
- Section 491.9(b)(4) to include the correct reference to § 491.9(b)(2), identifying the group of professional personnel.
- Section 491.9(c)(2) to include a reference to 42 CFR part 493.
- Revised and clarified survey processes and organizational policies, consistent with § 488.5(a)(4)(i), to ensure all surveys are unannounced. AAAASF clarified its organizational policies to reflect that surveys are not conducted based on the availability of administrators, clinic directors, or any other individual of authority, and for the same reasons, are not delayed.

In accordance with comparability requirements to those of the State Survey Agency at § 488.5(a)(4)(ii), AAAASF's revised its policies, procedures and survey processes to include:

- Revising policies to ensure the sample of the medical records used in surveyor guidance is consistent with the type of medical records to be reviewed.
- Providing a corrective action plan and clarifications to AAAASF's policies to ensure that documentation of patient and staff observations and record reviews include separate identifier keys used to ensure the security of patients and staff.
- Developing additional policies and procedures and surveyor guides to clarify deficiency citations, specifically how surveyors determine the appropriateness of the level of citation is assessed during an RHC survey for compliance (that is, condition level v. standard level deficiency citation) and in accordance with § 488.26(b).
- Section 488.5(a)(5) describing the method AAAASF uses for determining

the size and composition of the RHC survey team and AAAASF's comparable criteria on determining the parameters for each survey to be comparable to those of the State Survey Agency as outlined per § 488.5(a)(4).

B. Term of Approval

Based on our review and observations described in section III. of this final notice, we approve AAAASF as a national accreditation organization for RHCs that request participation in the Medicare program. The decision announced in this final notice is effective March 23, 2022 through March 23, 2026. Due to travel restrictions and the reprioritization of survey activities brought on by the 2019 Novel Coronavirus Disease (COVID–19) Public Health Emergency (PHE), CMS was unable to observe an RHC survey completed by AAAASF surveyors as part of the application review process, which is typically one component of the comparability evaluation. Therefore, we are providing AAAASF with a shorter period of approval. Based on our discussions with AAAASF and the information provided in its application, we are confident that AAAASF will continue to ensure that its accredited RHCs will continue to meet or exceed the required standards. While AAAASF has taken actions based on the findings noted in section IV. of this final notice (Differences Between AAAASF's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements), as authorized under § 488.8, we will continue ongoing review of AAAASF's RHC survey processes and will conduct a survey observation once the COVID–19 PHE has expired.

V. Collection of Information Requirements

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. chapter 35).

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: March 16, 2022.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2022–05910 Filed 3–18–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0412]

Revocation of Authorization of Emergency Use of an In Vitro Diagnostic Device for Detection and/or Diagnosis of COVID–19; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorization (EUA) (the Authorization) issued to Abbott Diagnostics Scarborough, Inc. (Abbott) for the BinaxNOW COVID–19 Ag Card 2 Home Test. FDA revoked this Authorization under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The revocation, which includes an explanation of the reasons for revocation, is reprinted in this document.

DATES: The Authorization for the BinaxNOW COVID–19 Ag Card 2 Home Test is revoked as of February 24, 2022.

ADDRESSES: Submit a written request for a single copy of the revocation to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the revocation may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocation.

FOR FURTHER INFORMATION CONTACT: Jennifer J. Ross, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993–0002, 240–402–8155 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) as amended by the Project BioShield Act of 2004 (Pub. L. 108–276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113–5) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. On March 31, 2021, FDA issued an EUA to Abbott for the BinaxNOW COVID–19 Ag Card 2 Home Test, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on July 23, 2021 (86 FR 39040), as required by section 564(h)(1) of the FD&C Act. Subsequent updates to the Authorization were made available on FDA's website. The authorization of a device for emergency use under section 564 of the FD&C Act may, pursuant to section 564(g)(2) of the FD&C Act, be revoked when the criteria under section 564(c) of the FD&C Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the FD&C Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the FD&C Act).

II. EUA Revocation Request

In a request received by FDA on February 21, 2022, Abbott requested revocation of, and on February 24, 2022, FDA revoked, the Authorization for the BinaxNOW COVID–19 Ag Card 2 Home Test. Because Abbott notified FDA that the EUA for BinaxNOW COVID–19 Ag Card 2 Home Test is no longer required and requested FDA revoke the EUA for the BinaxNOW COVID–19 Ag Card 2 Home Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization.

III. Electronic Access

An electronic version of this document and the full text of the revocation is available on the internet at *https://www.regulations.gov/.*

IV. The Revocation

Having concluded that the criteria for revocation of the Authorization under section 564(g)(2)(C) of the FD&C Act are met, FDA has revoked the EUA of Abbott for the BinaxNOW COVID–19 Ag Card 2 Home Test. The revocation in its entirety follows and provides an explanation of the reasons for revocation, as required by section 564(h)(1) of the FD&C Act.

BILLING CODE 4164–01–P