to a provider or other person. To fulfill this requirement, CMS must collect information on any IDTF supplier who submits a claim to Medicare or who applies for a Medicare billing number before allowing the IDTF to enroll. This information must, minimally, clearly identify the provider and its' place of business as required by CFR 424.500 (Requirements for Establishing and Maintaining Medicare Billing Privileges) and provide all necessary documentation to show they are qualified to perform the services for which they are billing. The site inspection form allows inspectors to verify the information using a standardized information collection methodology. *Form Number:* CMS–10221 (OMB control number: 0938–1029); *Frequency:* Occasionally; *Affected Public Sector:* Private Sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 652; *Total Annual Responses:* 652; *Total Annual Hours:* 1,304. (For policy questions regarding this collection contact Angelika Broznowicz at 410–786–8242).

2. *Type of Information Collection Request:* Revision of currently approved collection; *Title of Information Collection:* Prescription Drug and Health Care Spending; *Use:* On December 27, 2020, the Consolidated Appropriations Act, 2021 (CAA) was signed into law. Section 204 of Title II of Division BB of the CAA added parallel provisions at section 9825 of the Internal Revenue Code (the Code), section 725 of the Employee Retirement Income Security Act (ERISA), and section 2799A–10 of the Public Health Service Act (PHS Act) that require group health plans and health insurance issuers offering group or individual health insurance coverage to annually report to the Department of the Treasury, the Department of Labor (DOL), and the Department of Health and Human Services (HHS) (collectively, ''the Departments'') certain information about prescription drug and health care spending, premiums, and enrollment under the plan or coverage. This information will support the development of public reports that will be published by the Departments on prescription drug reimbursements for plans and coverage, prescription drug pricing trends, and the role of prescription drug costs in contributing to premium increases or decreases under the plans or coverage. The 2021 interim final rules, ''Prescription Drug and Health Care Spending'' (2021 interim final rules), issued by the Departments and the Office of Personnel Management (OPM) implement the provisions of section 9825 of the Code, section 725 of ERISA, and section 2799A–10 of the PHS Act, as enacted by section 204 of Title II of Division BB of the CAA. OPM joined the Departments in issuing the 2021 interim final rules, requiring Federal Employees Health Benefits (FEHB) carriers to report information about prescription drug and health care spending, premiums, and plan enrollment in the same manner as a group health plan or health insurance issuer offering group or individual health insurance coverage. *Form Number:* CMS–10788 (OMB control number: 0938–1407); *Frequency:* Annually; *Affected Public Sector:* Private Sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 356; *Total Annual Responses:* 356; *Total Annual Hours:* 764,442. (For policy questions regarding this collection contact Christina Whitefield at 202–536–8676.)

Dated: March 21, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2023–06226 Filed 3–24–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3436–N]

Announcement of the Approval of the Accreditation Commission for Health Care (ACHC) as an Accreditation Organization Under the Clinical Laboratory Improvement Amendments of 1988

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

ACTION: Notice.

SUMMARY: This notice announces the approval of the application of the Accreditation Commission for Health Care (ACHC) as an accreditation organization for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program for all specialty and subspecialty areas under CLIA. We have determined that the ACHC meets or exceeds the applicable CLIA requirements. In this notice, we announce the approval and grant the ACHC deeming authority for a period of 6 years.

DATES: The approval announced in this notice is effective from March 27, 2023 to March 27, 2029.

FOR FURTHER INFORMATION CONTACT: Kathleen Todd, (410) 786–3385.

SUPPLEMENTARY INFORMATION:

I. Background and Legislative Authority

On October 31, 1988, the Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Pub. L. 100–578). CLIA amended section 353 of the Public Health Service Act. We issued a final rule implementing the accreditation provisions of CLIA on July 31, 1992 (57 FR 33992). Under those provisions, CMS may grant deeming authority to an accreditation organization if its requirements for laboratories accredited under its program are equal to or more stringent than the applicable CLIA program requirements in 42 CFR part 493 (Laboratory Requirements). Subpart E of part 493 (Accreditation by a Private, Nonprofit Accreditation Organization or Exemption under an Approved State Laboratory Program) specifies the requirements an accreditation organization must meet to be approved by CMS as an accreditation organization under CLIA.

II. Notice of Approval of the ACHC as an Accreditation Organization

In this notice, we approve and grant deeming authority to the Accreditation Commission for Health Care (ACHC) as an organization that may accredit laboratories for purposes of establishing their compliance with CLIA requirements for all specialty and subspecialty areas under CLIA. We have examined the initial ACHC application and all subsequent submissions to determine its accreditation program's equivalency with the requirements for approval of an accreditation organization under subpart E of part 493. We have determined that ACHC meets or exceeds the applicable CLIA requirements. We have also determined that ACHC will ensure that its accredited laboratories will meet or exceed the applicable requirements in subparts H, J, K, M, Q, and the applicable sections of R of part 493.

Therefore, we grant ACHC approval as an accreditation organization under subpart E of part 493, for the period stated in the **DATES** section of this notice for all specialty and subspecialty areas under CLIA. As a result of this determination, any laboratory that is accredited by ACHC during the time period stated in the **DATES** section of this notice will be deemed to meet the CLIA requirements for the listed subspecialties and specialties, and therefore, will generally not be subject to routine inspections by a state survey

agency to determine its compliance with CLIA requirements. The accredited laboratory, however, may be subject to validation and complaint inspection surveys performed by CMS, or its agent(s).

III. Evaluation of the ACHC Request for Approval as an Accreditation Organization Under CLIA

The following describes the process used to determine that the ACHC accreditation program meets the necessary requirements for approval by CMS and that, as such, CMS may approve ACHC as an accreditation program with deeming authority under the CLIA program. ACHC formally applied to CMS for approval as an accreditation organization under CLIA for all specialties and subspecialties under CLIA. In reviewing these materials, we reached the following determinations for each applicable part of the CLIA regulations.

A. Subpart E—Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program

The ACHC submitted a description of its mechanism for monitoring compliance with all those requirements equivalent to CMS condition-level requirements; a list of all its current laboratories and the expiration date of their accreditations; and a detailed comparison of the individual accreditation requirements with the comparable condition-level requirements. We have determined that the ACHC policies and procedures for oversight of laboratories performing all laboratory testing covered by CLIA are equivalent to those required by our CLIA regulations in the matters of inspection, monitoring proficiency testing (PT) performance, investigating complaints, and making PT information available. The ACHC submitted documentation regarding its requirements for monitoring and inspecting laboratories and describing its own standards regarding accreditation organization data management, inspection processes, procedures for removal or withdrawal of accreditation, notification requirements, and accreditation organization resources. We have determined that the requirements of the accreditation program submitted for approval are equal to or more stringent than the requirements of the CLIA regulations.

Our evaluation identified ACHC requirements pertaining to waived testing that are more stringent than the CLIA requirements. The ACHC waived testing requirements include the following:

- Identifying qualifications and responsibilities for the personnel performing waived testing and the supervisors of waived testing.
- Requirements for waived testing personnel competency.
- Conducting defined quality control checks (QC) for waived complexity tests including the review of results prior to reporting patient results and documenting corrective action taken when QC results do not meet acceptable limits.

The CLIA requirements at § 493.15(e) only require that to be eligible for a certificate of waiver, a laboratory performing waived testing follow the manufacturer's instructions and meet the requirements to obtain a certificate of waiver.

B. Subpart H—Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing

We have determined that the ACHC's requirements are equal to or more stringent than the CLIA requirements at §§ 493.801 through 493.865. Consistent with the CLIA requirements, all of ACHC's accredited laboratories are required to participate in an HHS-approved PT program for tests listed in subpart I.

C. Subpart J—Facility Administration for Nonwaived Testing

The ACHC's requirements are equal to or more stringent than the CLIA requirements at §§ 493.1100 through 493.1105.

D. Subpart K—Quality System for Nonwaived Testing

We have determined that the quality control requirements of the ACHC are equal to or more stringent than the CLIA requirements at §§ 493.1200 through 493.1299. Specific areas that are more stringent are the following:

- QC requirements for RPR needles and rotators used in syphilis testing.
- QC requirements for platelet poor plasma used in coagulation testing

E. Subpart M—Personnel for Nonwaived Testing

We have determined that the ACHC's requirements are equal or more stringent than to the CLIA requirements at §§ 493.1403 through 493.1495 for personnel for nonwaived testing for laboratories that perform moderate and high complexity testing.

F. Subpart Q—Inspections

We have determined that the ACHC's inspection requirements are equal to or more stringent than the CLIA requirements at §§ 493.1771 through 493.1780. ACHC will continue to conduct biennial onsite inspections consistent with the requirements at §§ 493.1771 through 493.1780.

G. Subpart R—Enforcement Procedures

We have determined that ACHC meets the requirements of subpart R to the extent that it applies to accreditation organizations. The ACHC policy sets forth the actions the organization takes when laboratories it accredits do not comply with its requirements and standards for accreditation. When appropriate, ACHC will deny, suspend, or revoke accreditation of a laboratory accredited by ACHC and report that action to us within 30 days. ACHC also provides an appeals process for laboratories that have had accreditation denied, suspended, or revoked.

We have determined that ACHC 's laboratory enforcement and appeal policies are equal to or more stringent than the requirements of part 493 subpart R as they apply to accreditation organizations.

IV. Federal Validation Inspections and Continuing Oversight

The Federal validation inspections of laboratories accredited by the ACHC may be conducted on a representative sample basis or in response to substantial allegations of noncompliance (that is, complaint inspections). The outcome of those validation inspections, performed by CMS or our agents, or the State survey agencies, will be our principal means for verifying that the laboratories accredited by the ACHC remain in compliance with CLIA requirements. This Federal monitoring is an ongoing process.

V. Removal of Approval as an Accrediting Organization

CLIA regulations at § 493.575 provide that we may withdraw the approval of an accreditation organization, such as that of the ACHC, before the end of the effective date of approval in certain circumstances. For example, if we determine that the ACHC has failed to adopt, maintain and enforce requirements that are equal to, or more stringent than, the CLIA requirements, or that systemic problems exist in its monitoring, inspection or enforcement processes, we may impose a probationary period, not to exceed 1 year, in which the ACHC would be allowed to address any identified issues. Should the ACHC be unable to address the identified issues within that timeframe, CMS may, in accordance

with the applicable regulations, revoke the ACHC's deeming authority under CLIA.

Should circumstances result in our withdrawal of ACHC 's approval, we will publish a notice in the **Federal Register** explaining the justification for removing its approval.

VI. 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 (OMB) under the authority of the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. chapter 35). The requirements associated with the accreditation process for clinical laboratories under the CLIA program, and the implementing regulations in 42 CFR part 493, subpart E, are currently approved under OMB control number 0938–0686.

VII. Executive Order 12866 Statement

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

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

Evell J. Barco Holland,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2023–06280 Filed 3–24–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–1149]

Transition Plan for Medical Devices Issued Emergency Use Authorizations Related to Coronavirus Disease 2019 (COVID–19); Guidance for Industry, Other Stakeholders, and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) Related to Coronavirus Disease 2019 (COVID–19).'' FDA recognizes that it will take time for device manufacturers, device distributors, healthcare facilities, healthcare providers, patients, consumers, and FDA to adjust from policies adopted and operations implemented during the COVID–19 pandemic to ''normal operations.'' To provide a clear policy for all stakeholders and FDA staff, the Agency is issuing this guidance to describe FDA's general recommendations for this transition process with respect to devices issued EUAs related to COVID–19, including recommendations regarding submitting a marketing submission, as applicable, and taking other actions with respect to these devices.

DATES: The announcement of the guidance is published in the **Federal Register** on March 27, 2023.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time 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 comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–D–1149 for ''Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) Related to Coronavirus Disease 2019 (COVID–19).'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management