supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact or withhold submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near-duplicate examples of a mass-mail campaign. CDC will carefully consider all comments submitted into the docket.

Oral Statements: CDC will allocate 15 minutes for the public to present oral comments during the meeting. Oral statements will be limited to three minutes per person during the public comment period. It is preferred that only one person present a statement on behalf of a group or organization. Persons interested in presenting an oral statement should send an email to *wnv.vaccine@cdc.gov* by 12 p.m., eastern time, on March 29, 2024. A limited number of time slots are available and will be assigned on a first come-first served basis.

Written Public Comment: Written comments will also be accepted per the instructions provided in the addresses section above. Comments should be submitted on or before April 4, 2024.

Noah Aleshire,

Chief Regulatory Officer, Centers for Disease Control and Prevention.

[FR Doc. 2024–04745 Filed 3–5–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3448–N]

Medicare Program; Announcement of the Re-Approval of COLA Under the Clinical Laboratory Improvement Amendments of 1988

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

ACTION: Notice.

SUMMARY: This notice announces the application of COLA for re-approval as an accreditation organization for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program for the following specialty and subspecialty areas under CLIA: Microbiology, including Bacteriology, Mycobacteriology, Mycology, Parasitology, and Virology; Diagnostic Immunology, including Syphilis Serology, and General Immunology; Chemistry, including Routine Chemistry, Toxicology, and Endocrinology; Hematology, including routine hematology and coagulation; Immunohematology, including ABO Group, D (Rho) typing, Unexpected Antibody Detection, Compatibility Testing, and Antibody Identification; Pathology, including Histopathology, Oral Pathology, and Cytology. We have determined that COLA meets or exceeds the applicable CLIA requirements. We are announcing the re-approval and grant COLA deeming authority for a period of 6 years.

DATES: *Effective Date:* This notice is effective from March 6, 2024 to March 6, 2030.

FOR FURTHER INFORMATION CONTACT: Jelani Sanaa, (410) 786–1139.

SUPPLEMENTARY INFORMATION:

I. Background and Legislative Authority

On October 31, 1988, the Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (Pub. L. 100–578) (CLIA). 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, we 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 Re-Approval of COLA as an Accreditation Organization

In this notice, we approve COLA as an organization that may accredit laboratories for purposes of establishing their compliance with CLIA requirements for the following specialty and subspecialty areas under CLIA:

- Microbiology, including Bacteriology, Mycobacteriology, Mycology, Parasitology, and Virology.
- Diagnostic Immunology, including Syphilis Serology, and General Immunology.
- Chemistry, including Routine Chemistry, Toxicology, and Endocrinology.
- Hematology, including routine hematology and coagulation.
- Immunohematology, including ABO Group, D (Rho) typing, Unexpected Antibody Detection, Compatibility Testing, and Antibody Identification.
- Pathology, including Histopathology, Oral Pathology, and Cytology.

We have examined the initial COLA application and all subsequent submissions to determine its accreditation program's equivalency with the requirements for re-approval of an accreditation organization under subpart E of part 493. We have determined that COLA meets or exceeds the applicable CLIA requirements. We have also determined that COLA will ensure that its accredited laboratories will meet or exceed the applicable requirements in subparts H, I, J, K, M, Q, and the applicable sections of R. Therefore, we grant COLA re-approval as an accreditation organization under subpart E of part 493, for the period stated in the **DATES** section of this notice for the submitted specialty and subspecialty areas under CLIA. As a result of this determination, any laboratory that is accredited by COLA 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, is subject to validation and complaint investigation surveys performed by CMS, or its agent(s).

III. Evaluation of COLA's Request for Re-Approval as an Accreditation Organization Under CLIA

The following describes the process we used to determine that COLA's accreditation program meets the necessary requirements to be approved by CMS and that, as such, CMS may approve COLA as an accreditation program with deeming authority under the CLIA program. COLA formally applied to CMS for re-approval as an accreditation organization under CLIA for the following specialties and subspecialties:

- Microbiology, including Bacteriology, Mycobacteriology, Mycology, Parasitology, and Virology.
- Diagnostic Immunology, including Syphilis Serology, and General Immunology.

- Chemistry, including Routine Chemistry, Toxicology, and Endocrinology.
- Hematology, including routine hematology and coagulation.
- Immunohematology, including ABO Group, D (Rho) typing, Unexpected Antibody Detection, Compatibility Testing, and Antibody Identification.
- Pathology, including Histopathology, Oral Pathology, and Cytology.

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

COLA submitted a description of its mechanisms for monitoring compliance with all requirements equivalent to condition-level requirements, a list of all its current laboratories and the expiration date of their accreditation, and a detailed comparison of COLA's individual accreditation requirements with the comparable condition-level requirements. We determined COLA's policies and procedures for oversight of laboratories performing laboratory testing for the submitted CLIA specialties and subspecialties for inspection, monitoring proficiency testing (PT) performance, investigating complaints, and making PT information available, are equivalent to those of CLIA. COLA also submitted descriptions of its infrastructure and procedures for monitoring and inspecting laboratories in the areas of data management, the inspection process, procedures for removal or withdrawal of accreditation, notification requirements for laboratories out of compliance, and accreditation organization resources. We have determined that the requirements of COLA's accreditation program are equal to or more stringent than our requirements of the CLIA regulations.

Our evaluation determined that COLA requirements regarding waived testing are more stringent than the CLIA requirements at § 493.15(e) that require eligible laboratories to follow the manufacturer's instructions for performing tests and obtain a certificate of waiver as outlined in subpart B, Certificate of Waiver. COLA requires the laboratory director to review quality control results for waived tests monthly and also requires that competency be assessed and documented for personnel performing waived testing.

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

We have determined that COLA's requirements are equal to the CLIA requirements at §§ 493.801 through 493.865. Like CLIA, all of COLA's accredited laboratories are required to participate in an HHS-approved PT program for tests listed in subpart I. COLA also encourages its accredited laboratories to participate in PT for tests that are waived under CLIA.

C. Subpart J—Facility Administration for Nonwaived Testing

We have determined that COLA's requirements are equal to the CLIA requirements at §§ 493.1100 through 493.1105.

D. Subpart K—Quality System for Nonwaived Testing

We have determined that COLA's requirements are equal to the CLIA requirements at §§ 493.1200 through 493.1299.

E. Subpart M—Personnel for Nonwaived Testing

We have determined that COLA's requirements are equal to the CLIA requirements at §§ 493.1403 through 493.1495 for laboratories that perform moderate and high complexity testing.

F. Subpart Q—Inspection

We have determined that COLA's requirements are equal to the CLIA requirements at §§ 493.1771 through 493.1780. COLA will continue to conduct biennial onsite inspections. An unannounced inspection would be performed when a complaint, lodged against a laboratory accredited by COLA, indicates that problems may exist within the laboratory that may have a serious or immediate impact on patient care.

G. Subpart R—Enforcement Procedures

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

IV. Federal Validation Inspections and Continuing Oversight

The Federal validation inspections of laboratories accredited by COLA 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 CMS agents, or the State survey agencies, will be our principal means for verifying that the laboratories accredited by COLA remain in compliance with CLIA requirements. This Federal monitoring is an ongoing process.

V. Removal of Deeming Authority as an Accreditation Organization

CLIA regulations provide that we may withdraw the approval of an accreditation organization, such as that of COLA, before the end of the effective date of approval in certain circumstances, in accordance with § 493.575. If we determine that COLA 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 30 days following the date of CMS' determination, not to exceed 1 year, in which COLA would be allowed to address any identified issues, pursuant to our rules at § 493.575(b). Should COLA be unable to address the identified issues, CMS may, in accordance with the applicable regulations, revoke COLA's deeming authority under CLIA.

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

VI. Collection of Information Requirements

The information collection requirements associated with the accreditation process for clinical laboratories under the CLIA program are currently the Office of Management and Budget (OMB)-approved under OMB control number 0938–0686 and expires May 31, 2025. Additionally, this notice does not impose any new or revised information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, it does not need to be reviewed by OMB under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq*).

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 Trenesha Fultz-Mimms, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Trenesha Fultz-Mimms,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2024–04674 Filed 3–5–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0021]

Agency Information Collection Activities; Proposed Collection; Comment Request; Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Restaurant and Retail Foodservice Facility Types

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on ''Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Restaurant and Retail Foodservice Facility Types.''

DATES: Either electronic or written comments on the collection of information must be submitted by May 6, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 6, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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–2024–N–0021 for ''Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Restaurant and Retail Foodservice Facility Types.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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 Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each