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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3373-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 specialty and subspecialty areas listed in this notice under CLIA. 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: Re-approval is effective **February 22, 2019** and COLA deeming authority is granted from **February 22, 2019** to **February 22, 2025.**

FOR FURTHER INFORMATION CONTACT:

Raelene Perfetto, (410) 786-6876.

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, Virology.
- Diagnostic Immunology, including Syphilis Serology, General Immunology.
- Chemistry, including Routine Chemistry, Urinalysis, Endocrinology, Toxicology.
- Hematology.
- Immunohematology, including ABO Group and Rh Group, Antibody Detection, Antibody Identification, Compatibility Testing.

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, we 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, Virology.
- Diagnostic Immunology, including Syphilis Serology, General Immunology.
- Chemistry, including Routine Chemistry, Urinalysis, Endocrinology, Toxicology.
- Hematology.
- Immunohematology, including ABO Group and Rh Group, Antibody Detection, Antibody Identification, Compatibility Testing.

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 with respect to 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, 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 42 CFR §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 part 493, subpart B. 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

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

COLA's requirements are equal to the CLIA requirements at §§493.1100 through 493.1105.

D. Subpart K--Quality System for Nonwaived Testing

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

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 us within 30 days. COLA also provides an appeals process for laboratories that have had accreditation denied, suspended, or revoked.

We have determined that COLA 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 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 our 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. Denial of Re-Approval as an Accrediting Organization

Our regulations provide that we may deny the re-approval of an accreditation organization, such as that of COLA, for cause at any time. 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, not to exceed 1 year, in which COLA would be allowed to address any identified issues, under our rules at §493.575(b). Should COLA be unable to address the identified issues within that timeframe, 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 OMB-approved under OMB control number 0938-0686 and expire July 31, 2021. 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 the Office of Management and Budget (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.

Dated: February 6, 2019.

Seema Verma,

Administrator,

Centers for Medicare & Medicaid Services.

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