DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3482-N]

Announcement of the Approval of COLA as an Accreditation Organization for the Specialties of Clinical Cytogenetics and Radiobioassay 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 the Commission on Laboratory Accreditation (COLA) for approval as an accreditation organization for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program for the specialties of Clinical Cytogenetics and Radiobioassay. We have determined that COLA meets or exceeds the applicable CLIA requirements. Consequently, we are granting COLA deeming authority for the specialties of Clinical Cytogenetics and Radiobioassay for a period of 5 years.

DATES: This notice is applicable from [**INSERT DATE 30 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER**] to January 20, 2031.

FOR FURTHER INFORMATION CONTACT:

Sam Cyrus, (443) 896-4827.

SUPPLEMENTARY INFORMATION:

I. Background

On October 31, 1988, 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 COLA for the Specialties of Clinical Cytogenetics and Radiobioassay

In this notice, we approve the Commission on Laboratory Accreditation (COLA) as an organization that may accredit laboratories for purposes of establishing their compliance with CLIA requirements for the specialties of Clinical Cytogenetics and Radiobioassay. We have examined the initial COLA 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 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 subpart R. Therefore, we grant COLA approval as an accreditation organization under subpart E of part 493, for the period stated in the **DATES** section of this notice for the specialties of Clinical Cytogenetics and Radiobioassay. 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 specialties of Clinical Cytogenetics and Radiobioassay, 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 Approval as an Accreditation Organization Under CLIA for the Specialties of Clinical Cytogenetics and Radiobioassay

The following describes the process used to determine that COLA 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. In reviewing these materials, we reached the following determinations for each applicable part of the CLIA regulations:

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

COLA submitted its mechanism 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 the individual accreditation requirements with the comparable condition-level requirements. We have determined that COLA policies and procedures for oversight of laboratories performing laboratory testing for the specialties of Clinical Cytogenetics and Radiobioassay are equivalent to those required under the CLIA regulations in the matters of inspection, monitoring proficiency testing (PT) performance, investigating complaints, and making PT information available. COLA submitted documentation regarding its requirements for monitoring and inspecting laboratories and describing its standards regarding 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 COLA's requirements for monitoring and inspecting laboratories are equivalent to those required under our regulations for 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. Therefore, 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.

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

We have determined that COLA's requirements are equal to or more stringent than the CLIA requirements at §§ 493.801 through 493.865.

Subpart J—Facility Administration for Nonwaived Testing

We have determined that COLA's requirements for the specialties of Clinical Cytogenetics and Radiobioassay are equal to or more stringent than the CLIA requirements at §§ 493.1100 through 493.1105.

Subpart K—Quality System for Nonwaived Testing

We have determined that COLA's requirements for the specialties of Clinical Cytogenetics and Radiobioassay are equal to or more stringent than the CLIA requirements at §§ 493.1200 through 493.1299.

Subpart M—Personnel for Nonwaived Testing

We have determined that COLA's requirements for the specialties of Clinical Cytogenetics and Radiobioassay are equal to or more stringent than the CLIA requirements at §§ 493.1403 through 493.1495 for laboratories that perform moderate and high complexity testing.

Subpart Q—Inspection

We have determined that COLA's requirements for the specialties of Clinical Cytogenetics and Radiobioassay are equal to or more stringent than the CLIA requirements at §§ 493.1771 through 493.1780.

Subpart R—Enforcement Procedures

We have determined that COLA's requirements for the specialties of Clinical Cytogenetics and Radiobioassay meet the requirements of subpart R to the extent that it applies 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 appeal process for laboratories that have had accreditation denied, suspended, or revoked.

We have determined that COLA'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 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. Removal of Approval as an Accrediting Organization

CLIA regulations at § 493.575 provide that we may rescind the approval of an accreditation organization, such as that of COLA, before the end of the effective date of approval in certain circumstances. For example, 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. 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 approval, we will publish a notice in the **Federal Register** explaining the basis 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 of 1995 (44 U.S.C. 3501 *et seq*). The requirements associated with the accreditation process for clinical laboratories under the CLIA program, codified in 42 CFR part 493 subpart E, are currently approved by OMB under OMB control number 0938-0686.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Mehmet Oz, having reviewed and approved this document, authorizes Vanessa Garcia, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Vanessa Garcia,

Federal Register Liaison,

Centers for Medicare & Medicaid Services.

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