

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[CDC–2018–0050; Docket Number NIOSH–314]

### Final National Occupational Research Agenda for Healthcare and Social Assistance

**AGENCY:** National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice of availability.

**SUMMARY:** NIOSH announces the availability of the final *National Occupational Research Agenda for Healthcare and Social Assistance*.

**DATES:** The final document was published on February 15, 2019 on the CDC website.

**ADDRESSES:** The document may be obtained at the following link: <https://www.cdc.gov/nora/councils/hcsa/agenda.html>.

#### FOR FURTHER INFORMATION CONTACT:

Emily Novicki, M.A., M.P.H., (NORACoordinator@cdc.gov), National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Mailstop E–20, 1600 Clifton Road NE, Atlanta, GA 30329, phone (404) 498–2581 (not a toll free number).

**SUPPLEMENTARY INFORMATION:** On June 21, 2018, NIOSH published a request for public review in the **Federal Register** [83 FR 28849] of the draft version of the *National Occupational Research Agenda for Healthcare and Social Assistance*. All comments received were reviewed and addressed where appropriate.

**Frank J Hearl,**

Chief of Staff, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

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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.