

## 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.

[FR Doc. 2019–03072 Filed 2–21–19; 8:45 am]

**BILLING CODE 4163–19–P**

## 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.*

[FR Doc. 2019-03169 Filed 2-21-19; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-855R, CMS-2746, CMS-2728, and CMS-10065/10066]

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services, HHS.

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments must be received by April 23, 2019.

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following

address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number \_\_\_\_\_, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).

3. Call the Reports Clearance Office at (410) 786-1326.

**FOR FURTHER INFORMATION CONTACT:** William N. Parham at (410) 786-4669.

### SUPPLEMENTARY INFORMATION:

#### Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-855R Reassignment of Medicare Benefits

CMS-2746 End Stage Renal Disease Death Notification

CMS-2728 End Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration

CMS-10065/10066 Hospital Notices: IM/DND

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "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 requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

### Information Collection

1. *Type of Information Collection Request:* Extension; *Title of Information Collection:* Reassignment of Medicare Benefits; *Use:* The reassignment application is submitted at the time the provider/supplier first reassigns of his/her Medicare benefits to a group practice, as well as any subsequent reassignments, changes to current reassignment information or terminations of established reassignments as requested by the provider/supplier or group. The application is used by the Medicare Administrative Contractor (MAC) to collect data to assure the applicant has the necessary information that allows the MAC to correctly establish, change, or terminate the reassignment.

The collection and verification of reassignment information defends and protects our beneficiaries from illegitimate providers/suppliers. These procedures also protect the Medicare Trust Fund against fraud. It gathers information that allow Medicare contractors to ensure that the provider/supplier is not sanctioned from the Medicare and/or Medicaid program(s), or debarred, or excluded from any other Federal agency or program. The data (e.g., Social Security Numbers, Employer Identification Numbers) collected also ensures that the applicant has the necessary credentials to provide the health care services for which they intend to bill Medicare through the reassignment. This is sole instrument implemented for this purpose. *Form Number:* CMS-855R (OMB control number: 0938-1179); *Frequency:* Occasionally; *Affected Public:* Private Sector (Businesses or other for-profits, Not-for-profit institutions); *Number of Respondents:* 357,628; *Number of Responses:* 357,628; *Total Annual Hours:* 89,407. For policy questions regarding this collection, contact Kimberly McPhillips at 410-786-5374.

2. *Type of Information Collection Request:* Reinstatement of previously approved collection; *Title of Information Collection:* End Stage Renal Disease Death Notification; *Use:* The ESRD Death Notification form (CMS-2746) is completed by all Medicare-approved ESRD facilities upon death of an ESRD patient. Its primary purpose is to collect fact of death and cause of death of ESRD patients. The ESRD Program Management and Medical Information System (PMMIS) has the responsibility of collecting, maintaining and disseminating, on a national basis, uniform data pertaining to ESRD patients and their treatment of care. All renal facilities approved to participate