laws passed since the previous collection document was approved. While the OMB control number for this proposed collection will remain the same as the previously approved collection, this proposed collection will be given a new CMS Form Number. *Form Number:* CMS–10430 (OCN: 0938–0702); *Frequency:* Annually; Occasionally; *Affected Public:* Private Sector; Business or other for-profits and Not-for-profit institutions, and State, Local, or Tribal Governments; *Number of Respondents:* 8,716; *Total Annual Responses:* 39,831,442; *Total Annual Hours:* 3,760,422 hours. (For policy questions regarding this collection contact Lisa Campbell at 301–492–4114. For all other issues call 410–786–1326.)

2. *Type of Information Collection Request:* Reinstatement with a change of a previously approved collection; *Title:* Medicare Electronic Data Interchange (EDI) Registration and Electronic Data Interchange (EDI) Enrollment Form; *Use:* The purpose of this collection is to obtain information that will be subsequently used during transaction exchange for identification of Medicare providers/suppliers and authorization of requested Electronic Data Interface (EDI) functions. The EDI Enrollment and the Medicare Registration Forms are completed by Medicare providers, suppliers, or both suppliers and submitted to Medicare contractors. Authorization is needed for providers and suppliers to send and receive HIPAA standard transactions directly (or through a designated 3rd party) to and from Medicare contractors. Medicare contractors would use the information for initial set-up and maintenance of the access privileges. The use of the standard form provides an efficient uniform means by which Medicare captures information necessary to drive Medicare EDI security and EDI access privileges. All EDI providers will complete and sign the EDI Enrollment Form along with the Medicare EDI Registration Form. They will also reconfirm their access privileges annually.

The information collected will be uploaded into Medicare contractor computer systems. Medicare contractors will store this information in a database accessed at the time of provider connection to the Medicare Data Contractor Network (MDCN). When authentication is successful and connectivity is established, transactions may be exchanged. The information will be stored in a computer data base and used to authenticate the user on day-to-day electronic commerce, support the submitter and password administration function, and validate access relationships between providers/suppliers and their designated EDI submitter/receiver on a per transaction basis. *Form Number:* CMS–10164 (OCN: 0938–0983); *Frequency:* Once; *Affected Public:* Private Sector—Business or other for-profits, Not for-profit institutions; *Number of Respondents:* 240,000; *Total Annual Responses:* 240,000; *Total Annual Hours:* 80,000. (For policy questions regarding this collection contact Claudette Sikora at 410–786–5618. For all other issues call 410–786–1326.)

3. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection. *Title of Information Collection:* Medicare Credit Balance Reporting Requirements and Supporting Regulations in 42 CFR 405.371, 405.378 and 413.20; *Use:* Section 1815(a) of the Social Security Act authorizes the Secretary to request information from providers which is necessary to properly administer the Medicare program. Quarterly credit balance reporting is needed to monitor and control the identification and timely collection of improper payments. The information obtained from Medicare credit balance reports will be used by the contractors to identify and recover outstanding Medicare credit balances and by Federal enforcement agencies to protect Federal funds. The information will also be used to identify the causes of credit balances and to take corrective action. *Form Number:* CMS–838 (OCN: 0938–0600); *Frequency:* Yearly; *Affected Public:* Private sector—Business or other for-profits; *Number of Respondents:* 45,838; *Total Annual Responses:* 183,352; *Total Annual Hours:* 550,056. (For policy questions regarding this collection contact Milton Jacobson at 410–786–7553. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or Email your request, including your address, and phone number as well the OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on March 25, 2013.

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–6974, Email: *OIRA_submission@omb.eop.gov.*

Dated: February 19, 2013.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2013–04135 Filed 2–21–13; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3279–N]

Announcement of the Re-Approval of the Commission on Office Laboratory Accreditation (COLA) as an Accreditation Organization 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 Office Laboratory Accreditation (COLA) for approval as an accreditation organization for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program. We have determined that COLA meets or exceeds the applicable CLIA requirements. In this notice, we announce the approval and grant COLA deeming authority for a period of 6 years.

DATES: *Effective Date:* This notice is effective from February 22, 2013 to February 22, 2019.

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 (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 Commission on Office Laboratory Accreditation (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 & 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 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 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 the COLA Request for Approval as an Accreditation Organization Under CLIA

The following describes the process used to determine that the 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. COLA formally applied to CMS for 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 & 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

The 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. The COLA policies and procedures for oversight of laboratories performing laboratory testing for the submitted CLIA specialties and subspecialties are equivalent to those of CLIA in the matters of inspection, monitoring proficiency testing (PT) performance, investigating complaints, and making PT information available. The COLA submitted requirements for monitoring and inspecting laboratories in the areas of accreditation organization, data management, the inspection process, procedures for removal or withdrawal of accreditation, notification requirements, and accreditation organization resources. The requirements of the accreditation programs submitted for approval are equal to or more stringent than the requirements of the CLIA regulations.

Our evaluation identified the COLA requirements pertaining to waived testing that are more stringent than CLIA requirements. The 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. The CLIA requirements at § 493.15(e) 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.

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

The COLA's requirements are equal to the CLIA requirements at § 493.801 through § 493.865. Like CLIA, all of the COLA's accredited laboratories are required to participate in an HHS-approved PT program for tests listed in subpart I. The 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

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

D. Subpart K—Quality System for Nonwaived Testing

The COLA requirements are equal to or more stringent than the CLIA requirements at § 493.1200 through § 493.1299. For instance, when a laboratory establishes performance specifications for a test not approved by the Food and Drug Administration (FDA) or a test that has been approved by the FDA but modified, the COLA requires its accredited laboratories to submit all data obtained for review and approval by the COLA prior to adding the test to the laboratory's menu.

E. Subpart M—Personnel for Nonwaived Testing

We have determined that the COLA 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—Inspections

We have determined that the COLA requirements are equal to the CLIA requirements at § 493.1771 through § 493.1780. The COLA will continue to conduct biennial onsite inspections. An unannounced inspection would be performed when a complaint, lodged against a laboratory accredited by the 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

The COLA meets the requirements of subpart R to the extent that it applies to accreditation organizations. The 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, the COLA will deny, suspend, or revoke accreditation in a laboratory accredited by the COLA and report that action to us within 30 days. The COLA also provides an appeals process for laboratories that have had accreditation denied, suspended, or revoked.

We have determined that the 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 the 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 the COLA remain in compliance with CLIA requirements. This federal monitoring is an ongoing process.

V. Removal of Approval as an Accrediting Organization

Our regulations provide that we may rescind the approval of an accreditation organization, such as that of the COLA, for cause, before the end of the effective date of approval. If we determine that the 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 the COLA would be allowed to address any identified issues. Should the 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 the 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 notice does not impose any information collection and record keeping requirements subject to the Paperwork Reduction Act (PRA). Consequently, it does not need to be reviewed by the Office of Management and Budget (OMB) under the authority of the PRA. 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 approval number 0938–0686.

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.

Authority: Section 353 of the Public Health Service Act (42 U.S.C. 263a).

Dated: February 8, 2013.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2013–03927 Filed 2–21–13; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3280–PN]

Medicare and Medicaid Programs; Application From the Center for Improvement in Healthcare Quality (CIHQ) for CMS-Approval of Its Hospital Accreditation Program

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Proposed notice.

SUMMARY: This proposed notice with comment period acknowledges the receipt of an application from the Center for Improvement in Healthcare Quality (CIHQ) for recognition as a national accrediting organization for hospitals that wish to participate in the Medicare or Medicaid programs.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on March 25, 2013.

ADDRESSES: In commenting, refer to file code (CMS–3280–PN). Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.regulations.gov*. Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3280–PN, P.O. Box 8016, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3280–PN, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written ONLY to the following addresses.

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Cindy Melanson, (410) 786–0310. Patricia Chmielewski, (410) 786–6899. Monda Shaver, (410) 786–3410.