Authority: Section 1833(t) of the Act (42 U.S.C. 1395l(t)). The Panel is governed by the provisions of Pub. L. 92–463, as amended (5 U.S.C. Appendix 2).(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare-Hospital Insurance; and Program No. 93.774, Medicare-Supplementary Medical Insurance Program).

Dated: February 15, 2007.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E7–3040 Filed 2–22–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2221–N]

RIN 0938–ZA98

Medicare, Medicaid, and CLIA Programs; Approval of COLA (Formerly the Commission on Office Laboratory Accreditation) as a CLIA Accreditation Organization

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: In this notice, we grant COLA (formerly the Commission on Office Laboratory Accreditation) deeming authority as an accrediting organization for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program. We have determined that the requirements of the COLA accreditation process are equal to or more stringent than the CLIA condition level requirements, and that COLA has met the requirements of subpart E of 42 CFR Part 493. Consequently, laboratories that are voluntarily accredited by COLA and continue to meet COLA requirements will be deemed to meet the CLIA condition-level requirements for laboratories and therefore are not subject to routine inspection by State survey agencies to determine their compliance with Federal requirements. They are, however, subject to Federal validation and complaint investigation surveys conducted by us or our designee.

DATES: *Effective Date:* This notice is effective from February 23, 2007 to February 25, 2013.

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), Public Law 100–578. CLIA replaced in its entirety section 353(e)(2) of the Public Health Service Act, as enacted by the Clinical Laboratories Improvement Act of 1967. We issued a final rule implementing the accreditation provisions of CLIA on July 31, 1992, (57 FR 33992). Under the CLIA program, CMS approves a grant of deeming authority to an accreditation organization to accredit clinical laboratories if the organization meets certain requirements. An organization's requirements for accredited laboratories must be equal to, or more stringent than, the applicable CLIA program requirements in 42 CFR part 493 (Laboratory Requirements). The regulations in subpart E (Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program) specify the requirements an accreditation organization must meet to be an approved accreditation organization. We approve an accreditation organization for a period not to exceed 6 years.

In general, the approved accreditation organization must:

- Use inspectors qualified to evaluate laboratory performance and agree to inspect laboratories with the frequency determined by us.
- Apply standards and criteria that are equal to, or more stringent than, those condition-level requirements established by us.
- Assure that laboratories accredited by the accreditation organization continually meet these standards and criteria.
- Provide us with the name of any laboratory that has had its accreditation denied, suspended, withdrawn, limited, or revoked within 30 days of the action taken.
- Notify us at least 30 days before implementing any proposed changes in its standards.
- If we withdraw our approval, notify the accredited laboratories of the withdrawal within 10 days of the withdrawal.

CLIA requires that we perform an annual evaluation by inspecting a sufficient number of laboratories accredited by an approved accreditation organization as well as by any other means that we determine to be appropriate.

II. Notice of Approval of COLA as an Accreditation Organization

In this notice, we approve COLA (formerly the Commission on Office Laboratory Accreditation) as an organization that may accredit laboratories for purposes of establishing their compliance with CLIA requirements. We have examined the COLA application and all subsequent submissions to determine equivalency with our requirements under subpart E of part 493 that an accreditation organization must meet to be approved under CLIA. We have determined that COLA complied with the applicable CLIA requirements and grant COLA approval as an accreditation organization under subpart E, as for the period stated in the ''Effective Date'' section of this notice for the following specialty and subspecialty areas:

- 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.
- Pathology, including Histopathology, Oral Pathology, Cytology.

As a result of this determination, any laboratory that is accredited by COLA during the effective time period for an approved specialty or subspecialty is deemed to meet the CLIA requirements for the laboratories found in part 493 of our regulations and, therefore, is not subject to routine inspection 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 us, or by any other validly authorized agent.

III. Evaluation of COLA Request for Approval as an Accreditation Organization Under CLIA

The following describes the process used to determine that requirements of the COLA accreditation program are equal to or more stringent than the CLIA condition level requirements, and that COLA has met the requirements of subpart E of 42 CFR part 493.

COLA formally reapplied to us 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.
- Pathology, including Histopathology, Oral Pathology, Cytology.

We evaluated the COLA application to meet or exceed our implementing and enforcement regulations, and the deeming/exemption requirements of the CLIA rules.

We verified that the COLA accreditation program requirements and methods require the laboratories it accredits to be, and that the organization meets or exceeds the following subparts of part 493 as explained below:

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

COLA submitted the specialties and subspecialties that it would accredit; a comparison of individual accreditation and condition-level requirements; a description of its inspection process; proficiency testing (PT) monitoring process; its data management and analysis system; a listing of the size, composition, education and experience of its inspection teams; its investigative and complaint response procedures; its notification agreements with us; its removal or withdrawal of laboratory accreditation procedures; its current list of accredited laboratories; and its announced or unannounced inspection process.

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 a CMS-approved proficiency test (PT) program for any of tests listed in subpart I. COLA also encourages its accredited laboratories to participate in PT for tests that are waived under CLIA.

Subpart J—Facility Administration for Nonwaived Testing

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

Subpart K—Quality System for Nonwaived Testing

COLA requirements are equal to the CLIA requirements at § 493.1200 through § 493.1299. COLA makes educational material available to its accredited laboratories, which provide further information on quality assurance. As part of good laboratory practice and to ensure accuracy, COLA encourages development of a QC program for tests that are waived under CLIA.

Subpart M—Personnel for Nonwaived Testing

COLA states as general policy that its personnel standards for accreditation are identical to CLIA. A qualified individual must fulfill the responsibilities of each required position in the laboratory. The laboratory director and laboratory personnel must meet educational and experience requirements. Although certain duties of the laboratory director may be delegated to qualified individuals, the laboratory director remains ultimately responsible. We have determined that COLA requirements are equal to the CLIA requirements at § 493.1403 through § 493.1495 for laboratories that perform moderate and high complexity testing.

Subpart Q—Inspections

We have determined that the COLA requirements are equal to the CLIA requirements at § 493.1771 through § 493.1780. COLA will continue to perform onsite inspections every 2 years.

Subpart R—Enforcement Procedures

COLA meets 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 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 COLA accredited laboratories 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 us or our agents, 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

Our regulations provide that we may rescind the approval of an accreditation organization, such as that of COLA, for cause, before the end of the effective date of approval. If we determine that COLA failed to adopt requirements that are equal to, or more stringent than, the CLIA requirements, or that systemic problems exist in its inspection process, we may give it a probationary period, not to exceed 1 year to allow COLA to adopt comparable requirements.

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 Clinical Laboratory Improvement Amendments of 1988 (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: December 7, 2006.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E7–3025 Filed 2–22–07; 8:45 am]

BILLING CODE 4120–01–P