

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-2363-N]

Medicare, Medicaid and CLIA Programs; COLA (Formerly the Commission on Office Laboratory Accreditation) Voluntary Withdrawal From the Specialty of Pathology

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

ACTION: Notice.

SUMMARY: This notice announces COLA's voluntary withdrawal from the specialty of Pathology. COLA is an accreditation organization for clinical laboratories under the Clinical Laboratory Improvement Amendments (CLIA) program.

DATES: *Effective Date:* This notice is effective on August 27, 2010.

FOR FURTHER INFORMATION CONTACT: Raelene Peretto, (410) 786-6876.

SUPPLEMENTARY INFORMATION:

I. Background

In a **Federal Register** notice published on February 23, 2007(72 FR 8171), we granted COLA approval as an accreditation organization under 42 CFR part 493 subpart E. The approval was effective from February 23, 2007 until February 25, 2013. During this time, COLA was allowed to accredit laboratories for purposes of establishing their compliance with CLIA requirements in 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 and Rh Group, Antibody Detection, Antibody Identification, Compatibility Testing.
- Pathology, including Histopathology, Oral Pathology, Cytology.

In a letter dated June 15, 2010, COLA provided official notice of its intent to voluntarily withdraw from accreditation in the specialty of Pathology. This withdrawal was effective June 30, 2010. All laboratories accredited by COLA in the specialty of Pathology (to include Histopathology, Oral Pathology or Cytology) will have 60 days from the

date of this **Federal Register** notice to seek either CLIA inspection by the State Agency where the laboratory is located or accreditation with another accrediting organization that is currently CMS-approved for the specialty of Pathology.

This notice only addresses COLA's accreditation for the specialty of Pathology. As discussed below, COLA's accreditation status in the other specialties is not affected by this notice.

II. Provisions of the Notice

This notice announces COLA's withdrawal as an accreditation organization from the specialty of Pathology. COLA retains deeming authority as an accreditation organization under 42 CFR part 493 subpart E in a number of specialties. It may continue to accredit laboratories for purposes of establishing their compliance with CLIA requirements in 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 and Rh Group, Antibody Detection, Antibody Identification, Compatibility Testing.

A. Options for Laboratories Testing in Both Pathology and Other Specialties and Subspecialties

Laboratories currently accredited by COLA and performing testing in both the specialty of Pathology (to include Histopathology, Oral Pathology, or Cytology) and the other specialties and subspecialties for which COLA retains deeming authority may choose one of the following courses of action:

- Remain with COLA for purposes of the accreditation of non-Pathology specialties and subspecialties only and seek accreditation services for Pathology from another CMS-approved accrediting organization. The Certificate of Accreditation (CoA) will remain.
- Seek certification for all applicable specialties and subspecialties from the State Agency where the laboratory is located. A laboratory may not combine accreditation from a CMS-approved accrediting organization with a certification from the State Agency where the laboratory is located. Laboratories must seek a single path, either accreditation through one or more accreditation organizations with the

appropriate deeming authorities, or certification through the appropriate State Agency.

B. Options for Laboratories Testing Only in Pathology

Laboratories currently accredited by COLA and performing testing in only the specialty of Pathology (to include Histopathology, Oral Pathology or Cytology) have the following options:

- Seek CLIA accreditation with another CMS-approved accrediting organization that currently possesses deeming authority in the specialty of Pathology.

- Seek certification with the State Agency where the laboratory is located.

III. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

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

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance Program; No. 93.774, Medicare—Supplementary Medical Insurance Program; and No. 93.778, Medical Assistance Program.)

Dated: July 27, 2010.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Council on Migrant Health; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting:

Name: National Advisory Council on Migrant Health.

Dates and Times: October 19, 2010, 8:30 a.m. to 5 p.m. October 20, 2010, 8:30 a.m. to 5 p.m.

Place: Charleston Marriott Hotel, 170 Lockwood Boulevard, Charleston, South Carolina 29403, Telephone: 800-968-3569, Fax: 843-723-0276.

Status: The meeting will be open to the public.

Purpose: The purpose of the meeting is to discuss services and issues related to the