

## 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.*

[FR Doc. 2010-19675 Filed 8-10-10; 8:45 am]

**BILLING CODE 4120-01-P**

## 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

health of migrant and seasonal farmworkers and their families and to formulate recommendations for the Secretary of Health and Human Services.

**Agenda:** The agenda includes an overview of the Council's general business activities. The Council will also hear presentations from experts on farmworker issues, including the status of farmworker health at the local and national levels.

The Council meeting is being held in conjunction with the East Coast Migrant Stream Forum sponsored by the North Carolina Community Health Center Association, which is being held in Charleston, South Carolina, October 21–23, 2010.

Agenda items are subject to change as priorities indicate.

**For Further Information Contact:** Marcia Gomez, M.D., Office of Minority and Special Populations, Bureau of Primary Health Care, Health Resources and Services Administration, 5600 Fishers Lane, Maryland 20857; telephone (301) 594-4897.

Dated: August 5, 2010.

**Wendy Ponton,**

*Director, Office of Management.*

[FR Doc. 2010-19751 Filed 8-10-10; 8:45 am]

**BILLING CODE 4165-15-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

**Name of Committee:** National Cancer Institute Initial Review Group, Subcommittee I—Career Development, NCI-I Career Development.

**Date:** September 21, 2010.

**Time:** 8 a.m. to 6 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** Hilton Alexandria Old Town, 1767 King Street, Alexandria, VA 22314.

**Contact Person:** Sergei Radaev, PhD, Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Blvd, Rm

8113, Bethesda, Md 20892, 301-435-5655, [sradaev@mail.nih.gov](mailto:sradaev@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: August 5, 2010.

**Anna Snouffer,**

*Deputy Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010-19787 Filed 8-10-10; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Advisory Committee to the Director (ACD), Centers for Disease Control and Prevention (CDC)—National Biosurveillance Advisory Subcommittee (NBAS)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the CDC announces the following meeting of aforementioned subcommittee:

**Time and Date:** 8 a.m.–3:30 p.m., August 24, 2010.

**Place:** Emory Conference Center Hotel, 1615 Clifton Road, N.E., Atlanta, GA 30329.

**Status:** Open to the public, limited only by the space available. The meeting room accommodates approximately 75 people. The public is welcome to participate during the public comment periods. The public comment periods are tentatively scheduled for 10 a.m.–10:05 a.m. and 3:25 p.m.–3:30 p.m.

**Purpose:** As a subcommittee to the CDC's ACD, the NBAS will provide counsel to the CDC and the Federal government through the ACD regarding a broad range of human health surveillance issues arising from the development and implementation of a roadmap for the human health component of a national biosurveillance system.

**Matters to be Discussed:** Agenda items will include establishing task force action plans for developing recommendations and guidance in order to expand and strengthen the national portfolio of activities in biosurveillance practice and scientific assessment.

The agenda is subject to change as priorities dictate.

**Contact Person for More Information:**

Pamela Diaz, M.D., Designated Federal Officer, ACD.CDC—NBAS, 1600 Clifton Road, NE., M/S E-33, Atlanta, GA 30333.

Telephone: (770) 488-8806. E-mail: [pdiaz@cdc.gov](mailto:pdiaz@cdc.gov). For security reasons, members of the public interested in attending

the meeting should contact Mark Byers, Telephone: (770) 488-8619, E-mail: [mbyers@cdc.gov](mailto:mbyers@cdc.gov). The deadline for notification of attendance is August 13, 2010.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: August 4, 2010.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 2010-19783 Filed 8-10-10; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0004]

[FDA 225-10-0010]

#### Memorandum of Understanding Between United States Food and Drug Administration and the Centers for Medicare and Medicaid Services

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between FDA and the Centers for Medicare and Medicaid Services (CMS), both part of the U.S. Department of Health and Human Services. The purpose of the MOU is to promote collaboration and enhance knowledge of efficiency by providing for the sharing of information and expertise between the Federal partners. The goals of the collaboration are to explore ways to further enhance information sharing efforts through more efficient and robust inter-agency activities; promote efficient utilization of tools and expertise for product analysis, validation, and risk identification; and build infrastructure and processes that meet the common needs for evaluating the safety, efficacy, utilization, coverage, payment, and clinical benefit of drugs, biologics, and medical devices.

**DATES:** The agreement became effective June 25, 2010.

**FOR FURTHER INFORMATION CONTACT:**

David H. Dorsey, Office of Policy, Planning and Budget, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4222, Silver Spring, MD 20993, 301-796-4800.

**SUPPLEMENTARY INFORMATION:** In accordance with 21 CFR 20.108(c),