

analysis, and data management issues; (3) perspectives in developing multiplex devices for donor screening; and (4) workshop summary and conclusions.

Transcripts: Please be advised that as soon as possible after a transcript of the public workshop is available, it will be accessible at: <http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/TranscriptsMinutes/default.htm>. Transcripts of the public workshop may also be requested in writing from the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857.

Dated: March 11, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Secretary's Advisory Committee on Heritable Disorders in Newborns and Children; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463, codified at 5 U.S.C. App. 2), notice is hereby given of the following meeting:

Name: Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC).

Date and Time: April 19, 2013, 9:30 a.m. to 3:00 p.m.

Place: Virtual via Webinar.

Status: The meeting is open to the public. Pre-registration is required. For more information on registration and webinar details, please visit the SACHDNC Web site: <http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders>.

Purpose: The Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC), as authorized by Public Law 106-310, which added section 1111 of the Public Health Service Act, codified at 42 U.S.C. 300b-10, was established by Congress to advise the Secretary of the Department of Health and Human Services regarding the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. The SACHDNC's recommendations regarding additional conditions/inherited disorders for screening that have been adopted by the Secretary are included in the Recommended Uniform Screening Panel (RUSP) that constitutes part of the comprehensive guidelines supported by the Health Resources and Services

Administration. Pursuant to section 2713 of the Public Health Service Act, codified at 42 U.S.C. 300gg-13, non-grandfathered health plans are required to cover screenings included in the comprehensive guidelines without charging a co-payment, co-insurance, or deductible for plan years (i.e., policy years) beginning on or after the date that is one year from the Secretary's adoption of the condition for screening. The SACHDNC also provides advice and recommendations concerning grants and projects authorized under section 1109 of the Public Health Service Act (42 U.S.C. 300b-8).

Agenda: The meeting will include: (1) A policy paper report on the impact of recommendations related to sickle cell trait testing; (2) a presentation on the Affordable Care Act and the impact on individuals with heritable disorders; (3) a presentation by the Agency for Healthcare Research and Quality regarding the processes behind the U.S. Preventive Services Task Force review process; and (4) project reports on screening for Tyrosinemia Type I and Point of Care Screening and Lessons Learned.

Proposed agenda items are subject to change as priorities dictate. The agenda, webinar information, Committee Roster, Charter, presentations, and meeting materials are located on the Advisory Committee's Web site at <http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders>.

Public Comments: Members of the public can submit written comments and/or register to present oral comments. All comments, whether oral or written, are part of the official Committee record and will be available for public inspection and copying. Individuals who wish to make public comments are required to register for the webinar and email Lisa Vasquez (lvasquez@hrsa.gov) by April 10, 2013. The public comment period is scheduled for the morning of April 19, 2013. Written comments should be emailed to Lisa Vasquez (lvasquez@hrsa.gov) by April 10, 2013.

Written comments should identify the individual's name, address, email, telephone number, professional or business affiliation, type of expertise (i.e., parent, researcher, clinician, public health, etc.) and the topic/subject matter of comment. To ensure that all individuals who have registered to make oral comments can be accommodated, the allocated time may be limited. Individuals who are associated with groups or have similar interests may be requested to combine their comments and present them through a single representative. No audiovisual presentations are permitted.

Contact Person: Anyone interested in obtaining other relevant information should contact the designated federal officer (DFO), Debi Sarkar, Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18A-19, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857; telephone: 301-443-1080; email: dsarkar@hrsa.gov.

More information on the Advisory Committee is available at <http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders>.

Dated: March 11, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at 78 FR 14311-14312, dated March 5, 2013).

This notice reflects organizational changes to the Health Resources and Services Administration. This notice updates the functional statement for the Bureau of Primary Health Care (RC). Specifically, this notice: (1) Establishes the Office of National Assistance and Special Populations (RCE); (2) abolishes the Office of Training and Technical Assistance Coordination (RCS) and the Office of Special Population Health (RCG); and (3) updates the functional statement for the Office of the Associate Administrator (RC), the Office of Administrative Management (RCM), the Office of Policy and Program Development (RCH), and the Office of Quality and Data (RCK).

Chapter RC—Bureau of Primary Health Care

Section RC-10, Organization

Delete in its entirety and replace with the following:

The Bureau of Primary Health Care (RC) is headed by the Associate Administrator, who reports directly to the Administrator, Health Resources and Services Administration. The Bureau of Primary Health Care includes the following components:

- (1) Office of the Associate Administrator (RC);
- (2) Office of Administrative Management (RCM);
- (3) Office of Policy and Program Development (RCH);
- (4) Office of Quality and Data (RCK);
- (5) Office of National Assistance and Special Populations (RCE);
- (6) Northeast Division (RCU);
- (7) Central Southeast Division (RCV);
- (8) North Central Division (RCT); and

(9) Southwest Division (RCW).

Section RC-20, Functions

(1) Delete the functional statement for the Office of Training and Technical Assistance Coordination (RCS) and the Office of Special Population Health (RCG); (2) update the functional statement for the Office of the Associate Administrator (RC), the Office of Administrative Management (RCM), the Office of Policy and Program Development (RCH), and the Office of Quality and Data (RCK); and (3) establish the functional statement for the Office of National Assistance and Special Populations (RCE).

Office of the Associate Administrator (RC)

Provides overall leadership, direction, coordination, and planning in support of BPHC programs. Specifically: (1) Establishes program goals, objectives, and priorities, and provides oversight to their execution; (2) plans, directs, coordinates, supports, and evaluates BPHC-wide management activities; and (3) maintains effective relationships within HRSA and with other Department of Health and Human Services (HHS) organizations, other federal agencies, state and local governments, and other public and private organizations concerned with primary health care, eliminating health disparities, and improving the health status of the nation's underserved and vulnerable populations.

Office of Administrative Management (RCM)

Plans, directs, and coordinates BPHC-wide administrative management activities. Specifically: (1) Serves as BPHC's principal source for administrative and management advice, analysis, and assistance; (2) provides guidance and coordinates personnel activities for BPHC; (3) provides organization and management analysis, coordinating the allocation of personnel resources, developing policies and procedures for internal operations, interpreting and implementing BPHC management policies, procedures and systems; (4) develops and coordinates BPHC program and administrative delegations of authority activities; (5) provides guidance to BPHC on financial management activities; (6) provides BPHC-wide support services such as continuity of operations and emergency planning, contracts, procurement, supply management, equipment utilization, printing, property management, space management, records management, and management reports; (7) serves as BPHC Executive

Secretariat; (8) serves as BPHC's focal point for the design and implementation of management information systems to assess and improve program performance and internal operations; and (9) coordinates BPHC administrative management activities with other components within HRSA and HHS, and with other federal agencies, state and local governments, and other public and private organizations, as appropriate.

Office of Policy and Program Development (RCH)

Serves as the organizational focus for the development of BPHC programs and policies. Specifically: (1) Leads and monitors the development and expansion of primary care programs, including health centers and other health systems; (2) identifies and provides assistance to communities, community-based organizations, and BPHC programs related to the development and expansion of primary care programs; (3) manages BPHC capital and loan guarantee programs; (4) leads and coordinates the analysis, development, and drafting of policy impacting BPHC programs; (5) consults and coordinates with other components within HRSA and HHS, and with other federal agencies, state and local governments, and other public and private organizations on issues affecting BPHC programs and policies; (6) performs environmental scanning on issues that affect BPHC programs; and (7) monitors BPHC activities in relation to the HRSA and HHS Strategic Plan.

Office of Quality and Data (RCK)

Serves as the organizational focus for BPHC program performance, clinical and operational quality improvement, data reporting, and program evaluation. Specifically: (1) Provides leadership for implementing BPHC clinical quality and performance improvement strategies/initiatives, including health information technology; (2) oversees BPHC Federal Tort Claims Act (FTCA) medical malpractice liability programs, reviewing clinical, quality improvement, risk management, and patient safety activities to improve policies and programs for primary health care services, including clinical information systems; (3) leads and coordinates BPHC accreditation and national quality recognition programs; (4) oversees BPHC health center network programs related to health information technology and quality improvement; (5) coordinates BPHC clinical, quality and performance reporting activities within HRSA and HHS, and with other federal agencies,

state and local governments, and other public and private organizations concerned with primary health care, eliminating health disparities, and improving the health status of the nation's underserved and vulnerable populations; (6) identifies and provides assistance to BPHC programs around clinical, quality and performance reporting activities; and (7) serves as BPHC's focal point for the design and implementation of program evaluations.

Office of National Assistance and Special Populations (RCE)

Serves as the organizational focus for BPHC technical assistance activities, including activities relating to the delivery of health services to special populations. Specifically: (1) Leads national technical assistance activities for BPHC; (2) advises BPHC about the needs of special populations; (3) identifies key technical assistance needs of BPHC programs, including programs related to the development, delivery and expansion of services targeted to special populations, and develops resources to address them; (4) manages BPHC technical assistance programs and contracts; (5) serves as BPHC's focal point for communication and program information resources; (6) coordinates and supports emergency preparedness and response for BPHC programs; (7) provides support to the National Advisory Council on Migrant Health; and (8) coordinates BPHC technical assistance activities, including activities targeted to special populations, within HRSA and HHS, and with other federal agencies, state and local governments, and other public and private organizations concerned with primary health care, eliminating health disparities, and improving the health status of the nation's underserved and vulnerable populations.

Section RC-30, Delegations of Authority

All delegations of authority and re-delegations of authority made to HRSA officials that were in effect immediately prior to this reorganization, and that are consistent with this reorganization, shall continue in effect pending further re-delegation.

This reorganization is effective upon date of signature.

Dated: March 10, 2013.

Mary K. Wakefield,
Administrator.

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