and is authorized to assist States in the prevention and suppression of communicable diseases. Under this authority, FDA participates with State regulatory agencies, some foreign nations, and the molluscan shellfish industry in the National Shellfish Sanitation Program (NSSP).

NSSP is a voluntary, cooperative program to promote the safety of molluscan shellfish by providing for the classification and patrol of shellfish growing waters and for the inspection and certification of shellfish processors. Each participating State and foreign nation monitors its molluscan shellfish processors and issues certificates for those that meet the State or foreign shellfish control authority's criteria. Each participating State and nation provides a certificate of its certified shellfish processors to FDA on Form FDA 3038, ''Interstate Shellfish Dealer's Certificate.'' FDA uses this information to publish the ''Interstate Certified Shellfish Shippers List,'' a monthly comprehensive listing of all molluscan shellfish processors certified under the cooperative program. If FDA did not collect the information necessary to compile this list, participating States would not be able to identify and keep out shellfish processed by uncertified processors in other States and foreign nations. Consequently, NSSP would not be able to control the distribution of uncertified and possibly unsafe shellfish in interstate commerce, and its effectiveness would be nullified.

In the **Federal Register** of November 15, 2012 (77 FR 68129), FDA published a 60-day notice requesting public comment on the proposed extension of this collection of information. FDA received one letter in response to the notice, containing multiple comments on the testing methods used by certified shellfish processors in the NSSP. These comments were outside the scope of the four collection-of-information topics on which the notice requested comments, and will not be discussed in this document. FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Submission of Interstate Shellfish Dealer's Certificate	3038	40	57	2,280	0.10	228

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates that 40 respondents will submit 2,280 Interstate Shellfish Dealer's Certificates annually, for a total burden of 228 hours (2,280 submissions × 0.10 hours = 228 hours). This estimate is based on FDA's experience and the number of certificates received in the past 3 years.

Dated: March 11, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–05970 Filed 3–14–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Application of Advances in Nucleic Acid and Protein Based Detection Methods to Multiplex Detection of Transfusion-Transmissible Agents and Blood Cell Antigens in Blood Donations; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled: ''Application of Advances in Nucleic Acid and Protein Based Detection Methods to Multiplex Detection of Transfusion-Transmissible Agents and Blood Cell Antigens in Blood Donations.'' The purpose of this public workshop is to discuss research and development of multiplex assays and the use of these tests in blood donor screening and blood cell antigen typing. The public workshop has been planned in partnership with the AABB (formerly known as the American Association of Blood Banks), Advanced Medical Technology Association (AdvaMed), America's Blood Centers, Department of Defense, Department of Health and Human Services Office of the Assistant Secretary for Health, and the National Heart, Lung and Blood Institute, National Institutes of Health. The public workshop will include presentations and panel discussions by experts from academic institutions, blood establishments, industry, and government agencies.

Date and Time: The public workshop will be held on April 10, 2013, from 8 a.m. to 5:30 p.m., and April 11, 2013, from 8 a.m. to 5 p.m.

Location: The public workshop will be held in the Main Auditorium, Natcher Conference Center, National Institutes of Health, Bldg. 45, Bethesda, MD 20892.

Contact Person: Jennifer Scharpf, Center for Biologics Evaluation and Research (HFM–300), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, 301–827–6128, FAX: 301–827–2843, email: *CBEROBRRWorkshops@fda.hhs.gov*.

Registration: Mail, fax, or email your registration information (including name, title, firm name, address, telephone and fax numbers, and email address) to Jennifer Scharpf (see *Contact Person*) by April 1, 2013. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 7:30 a.m. If you need special accommodations due to a disability, please contact Jennifer Scharpf (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The objectives of the workshop are to review the status of multiplex platforms and the technological advances in gene based and protein based pathogen and blood cell antigen detection methods and to discuss the scientific pathways to support the development of multiplex assays to screen blood donors for blood-borne pathogens and blood cell antigen typing.

The first day of this workshop will include presentations and panel discussions on the following topics: (1) Blood safety and infectious agents, (2) advances in blood-borne pathogen detection, and (3) molecular DNA-based typing of blood cell antigens.

The second day of the workshop will include presentations and discussion on the following topics: (1) Highly multiplexed technologies in blood donor screening; (2) bioinformatics, data

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.

[FR Doc. 2013–05987 Filed 3–14–13; 8:45 am]

BILLING CODE 4160–01–P

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.

[FR Doc. 2013–06042 Filed 3–14–13; 8:45 am]

BILLING CODE 4165–15–P

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