SUPPLEMENTARY INFORMATION: Statistical process control is the application of statistical methods to the monitoring, or quality control, of a manufacturing process. The implementation of acceptable statistical process controls ensures that a process performs predictably to manufacture a product that meets specific standards. FDA monitors manufacturing procedures, validation summaries, and quality control data prior to licensure and during periodic inspection of facilities.

Millions of units of Whole Blood and blood components, including those collected by apheresis, are manufactured in the United States annually. Blood establishments manufacture these products in accordance with specific standards established by FDA regulations and guidance, as well as in accordance with specifications established by device manufacturers and industry standards. To ensure that product standards are met, blood establishments validate manufacturing processes at implementation and then monitor these processes on a regular basis, using quality control methods.

Manufacturing biologic products, including Whole Blood and blood components, comes with specific challenges due to biologic variability and the potential risk to recipients if products are not manufactured appropriately. Recognizing these issues, FDA has developed statistical plans that are capable of identifying when the manufacturing process varies or has a high frequency of nonconformance.

The goal of the workshop is to educate participants on statistical process control theory and options for the implementation of scientifically sound sampling plans in blood establishments. The public workshop will include presentations and discussions on the following topics: (1) The evolution of statistical process control for Whole Blood and blood components; (2) statistical methods used for biologic product quality control; (3) FDA considerations for sampling plans for blood establishments; and (4) industry perspectives and case studies on implementing statistical process controls.

Transcripts: Please be advised that a transcript of the public workshop will be posted as soon as possible on the Internet 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: July 27, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–18854 Filed 8–1–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer at (301) 443–1984.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the Agency; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Telehealth Resource Center Performance Measurement Tool (OMB No. 0915–xxxx)–[New]

To ensure the best use of public funds and to meet the Government Performance Review Act (GPRA) requirements, HRSA's Office for the Advancement of Telehealth (OAT), in collaboration with the Telehealth Resource Centers (TRCs), created a set of performance measures that grantees can use to evaluate the technical assistance services provided by the TRCs. Grantee goals are to customize the provision of telehealth technical assistance across the country. The TRCs provide technical assistance to health care organizations, health care networks and health care providers in the implementation of cost-effective telehealth programs to serve rural and medically underserved areas and populations. The TRC Performance Indicator Data Collection Tool contains the data elements that would need to be collected by the TRCs in order to report on the performance metrics. This tool can be easily translated into the web-based data collection system, Performance Improvement and Measurement System (PIMS). Reporting via PIMS allows the TRCs and OAT to track project performance. The tool assists in the production of annual reports, available to Congress, that demonstrate the value added from the TRC Grant Program.

The annual estimate of burden is as follows:

Instrument	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Telehealth Resource Center Performance Data Collection Tool	14	72	1,008	0.07	70.56
Total	14	.....	1,008	.....	70.56

Email comments to *paperwork@hrsa.gov* or mail the HRSA Reports Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: July 25, 2012.

Wendy Ponton,

Director, Office of Management.

[FR Doc. 2012–18945 Filed 8–1–12; 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 77 FR 38071–38072 dated June 26, 2012).

This notice reflects organizational changes to the Health Resources and Services Administration. This notice updates the functional statement for the Healthcare Systems Bureau (RR) and the Bureau of Primary Health Care (RC). Specifically, this notice: (1) Transfers the Division of National Hansen's Disease Program from the Bureau of Primary Health Care (RC), to the Healthcare Systems Bureau (RR); and (2) updates the functional statement for the Office of the Associate Administrator Healthcare Systems Bureau (RR).

Chapter RR—Healthcare Systems Bureau

Section RR–10, Organization

Delete in its entirety and replace with the following:

The Healthcare Systems Bureau (RR) is headed by the Associate Administrator, who reports directly to the Administrator, Health Resources and Services Administration. The Healthcare Systems Bureau includes the following components:

(1) Office of the Associate Administrator (RR);

(2) Division of Transplantation (RR1);

(3) Division of Vaccine Injury Compensation (RR4);

(4) Office of Pharmacy Affairs (RR7);

(5) Division of Poison Control and Healthcare Facilities (RR9); and

(6) Division of National Hansen's Disease Program (RRH).

Section RR–20, Functions

(1) Delete the functional statement for the Office of the Associate Administrator (RR) and replace in its entirety; and (2) add the functional statement for the Division of National Hansen's Disease Program (RRH).

Office of the Associate Administrator (RR)

The Healthcare Systems Bureau leads the Agency in providing health care programs to eligible organizations around the country. Specifically, (1) Administers the Organ Transplantation Program to include the Organ Procurement and Transplantation Network to facilitate the allocation of donor organs to patients waiting for an organ transplant and the Scientific Registry of Transplant Recipients that provides analytic support to the Organ Procurement and Transplantation Network in the development and assessment of organ allocation and other Organ Procurement and Transplantation Network policies; (2) administers the C.W. Bill Young Cell Transplantation Program to increase the number of unrelated blood stem cell transplants and improve the outcomes of blood stem cell transplants; (3) administers the National Cord Blood Inventory to increase the number of high quality cord blood units available for transplantation; (4) develops and maintains a national program of grants and contracts to organ procurement organizations and other entities to increase the number of organs made available for transplantation; (5) manages the national program for compliance with the Hill-Burton uncompensated care requirement and other assurances; (6) directs and administers a congressionally-directed grant program for the construction/renovation/equipping of health care and other facilities; (7) directs and administers the National Vaccine Injury Compensation Program; (8) manages and promotes the 340B Drug Pricing Program; (9) directs and administers the Poison Center Support, Enhancement, and Awareness Act; (10) implements and administers the Countermeasures Injury Compensation Program under PREP Act authorities; and (11) manages the National Hansen's Disease Programs in accordance with regulations of the Public Health Service.

Division of National Hansen's Disease Program (RRH)

Manages the National Hansen's Disease Program in accordance with regulations of the Public Health Service. Specifically: (1) Provides care and treatment for persons with Hansen's disease, including managing a national outpatient health care delivery program; (2) conducts research and provides education and training on Hansen's disease; and (3) provides consultation to and coordinates activities within HRSA and HHS, and with other Federal agencies, State and local governments, and other public and private organizations involved in Hansen's disease activities.

Chapter RC—Bureau of Primary Health Care

Section RC–10, Organization

(1) 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 Training and Technical Assistance Coordination (RCS);

(4) Office of Policy and Program Development (RCH);

(5) Office of Quality and Data (RCK);

(6) Office of Special Population Health (RCG);

(7) Northeast Division (RCU);

(8) Central Southeast Division (RCV);

(9) North Central Division (RCT); and

(10) Southwest Division (RCW).

Section RC–20, Functions

(1) Delete the functional statement for the Office of the Associate Administrator (RC) and replace in its entirety.

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, provides oversight to their execution; (2) plans, directs, coordinates 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.