

- barriers to broader biomarker data aggregation, dissemination, and application; and
- possible strategies to address these barriers.

**Registration:** Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 4 p.m. (EST), February 22, 2016. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the public workshop will be provided beginning at 7 a.m.

If you need special accommodations due to a disability, please contact Susan Monahan, Office of Communication and Education, Center for Devices and Radiological Health, Food and Drug Administration, 301-796-5661, email: [susan.monahan@fda.hhs.gov](mailto:susan.monahan@fda.hhs.gov) no later than February 16, 2016.

To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this meeting/public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. Those without Internet access should contact Susan Monahan to register. Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

**Streaming Webcast of the Public Workshop:** This public workshop will also be Webcast. The webcast link will be available on the workshop Web page after February 25, 2016. Please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public workshop from the posted events list.) If you have never attended a Connect Pro event before, test your connection at [https://collaboration.fda.gov/common/help/en/support/meeting\\_test.htm](https://collaboration.fda.gov/common/help/en/support/meeting_test.htm). To get a quick overview of the Connect Pro program, visit [http://www.adobe.com/go/connectpro\\_overview](http://www.adobe.com/go/connectpro_overview). (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

**Requests for Oral Presentations:** This public workshop includes a public

comment session and topic-focused sessions. During online registration you may indicate if you wish to present during a public comment session or participate in a specific session, and which topics you wish to address. FDA has included general topics in this document. FDA will do its best to accommodate requests to make public comments and participate in the focused sessions. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by February 25, 2016. All requests to make oral presentations must be received by the close of registration on February 22, 2016, by 4 p.m. (EST). If selected for presentation, any presentation materials must be emailed to Lakshmi Kannan (see **FOR FURTHER INFORMATION CONTACT**) no later than February 25, 2016. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

FDA is holding this public workshop to obtain information on development of TBI biomarkers and data standardization. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. The deadline for submitting comments related to this public workshop is May 3, 2016.

**Transcripts:** Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (see **ADDRESSES**). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at <http://www.fda.gov>. A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public workshop from the posted events list).

Dated: February 1, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016-02592 Filed 2-9-16; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Proposed Collection: Public Comment Request

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on this ICR should be received no later than April 11, 2016.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Information Collection Clearance Officer, Room 14N-39, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** 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](mailto:paperwork@hrsa.gov) or call the HRSA Information Collection Clearance Officer at (301) 443-1984.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the information request collection title for reference.

**Information Collection Request Title:** Rural Opioid Overdose Reversal Grant Program OMB No. 0906-xxxx-New.

**Abstract:** This program is authorized by Section 711(b) of the Social Security Act (U.S.C. 912(b), as amended and the Consolidated and Further Continuing Appropriations Act (Pub. L. 114-113). The purpose of this grant program is to reduce the incidences of morbidity and mortality related to opioid overdoses in rural communities through the purchase and placement of emergency devices

used to rapidly reverse the effects of opioid overdose and training of licensed healthcare professionals and emergency responders on their use.

**Need and Proposed Use of the Information:** For this program, performance measures have been drafted to provide data useful to the program and to enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Act (GPRA) of 1993 (Pub. L. 103–62). These measures cover the principal topic areas of interest to the Federal Office of Rural Health Policy including: (1) The number of counties served by the program; (2)

the number and type of devices purchased and distributed and the location of the distribution; (3) the number of training sessions and the number of individuals trained; and (4) the number of individuals who were administered Narcan and the outcome. These measures will speak to the Office's progress toward meeting the set goals.

**Likely Respondents:** Rural Opioid Overdose Reversal Grant Program award recipients.

**Burden Statement:** Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information

requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

#### TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Rural Opioid Overdose Reversal Grant Program .....	18	1	18	4	72
Total .....	18	1	18	4	72

HRSA specifically requests comments on: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**Jackie Painter,**

*Director, Division of the Executive Secretariat.*

[FR Doc. 2016–02571 Filed 2–9–16; 8:45 am]

**BILLING CODE 4165–15–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Advisory Council on Blood Stem Cell Transplantation; 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:** Advisory Council on Blood Stem Cell Transplantation (ACBSCT).

**Date and Time:** March 3, 2016, from 12:00 p.m. to 4:00 p.m. Eastern Standard Time.

**Place:** The meeting will be via audio conference call and Adobe Connect Pro.

**Status:** The meeting will be open to the public.

**Purpose:** Pursuant to Public Law 109–129, 42 U.S.C. 274k (section 379 of the Public Health Service Act, as amended), the ACBSCT advises the Secretary of Health and Human Services and the Administrator, Health Resources and Services Administration (HRSA), on matters related to the activities of the C.W. Bill Young Cell Transplantation Program (Program) and the National Cord Blood Inventory Program.

**Agenda:** The Council will hear a report from the ACBSCT Work Group on Cord Blood. The Council also will hear presentations and discussions on topics including the National Institutes of Health's Late Effects Initiative and the Center for International Blood and Marrow Transplant Research. Agenda items are subject to changes as priorities indicate.

After Council discussions, members of the public will have an opportunity to provide comment. Because of the Council's full agenda and timeframe in which to cover the agenda topics, public comment may be limited. All public comments will be included in the record of the ACBSCT meeting. Meeting summary notes will be posted on the HRSA's Program Web site at [http://bloodcell.transplant.hrsa.gov/ABOUT/Advisory\\_Council/index.html](http://bloodcell.transplant.hrsa.gov/ABOUT/Advisory_Council/index.html).

The draft meeting agenda will be posted on <https://www.blsmmeetings.net/ACBSCT/>. Those participating at this meeting should register by visiting <https://www.blsmmeetings.net/ACBSCT/>. The deadline to register for this meeting

is Tuesday, March 1, 2016. For all logistical questions and concerns, please contact Anthony Rodell, Seamon Corporation, at (301) 658–3457 or send an email to [arodell@SeamonCorporation.com](mailto:arodell@SeamonCorporation.com).

The public can join the meeting by:

1. (Audio Portion) Calling the Conference Phone Number (1–800–988–9777) and providing the Participant Code (6253775); and

2. (Visual Portion) Connecting to the ACBSCT Adobe Connect Pro Meeting using the following URL and entering as GUEST: [https://hrsa.connectsolutions.com/acbsct\\_webinar/](https://hrsa.connectsolutions.com/acbsct_webinar/) (copy and paste the link into your browser if it does not work directly).

Participants should call and connect 15 minutes prior to the meeting in order for logistics to be set up. If you have never attended an Adobe Connect meeting, please test your connection using the following URL: [https://hrsa.connectsolutions.com/common/help/en/support/meeting\\_test.htm](https://hrsa.connectsolutions.com/common/help/en/support/meeting_test.htm) and get a quick overview by following URL: [http://www.adobe.com/go/connectpro\\_overview](http://www.adobe.com/go/connectpro_overview). Call (301) 443–0437 or send an email to [ptongele@hrsa.gov](mailto:ptongele@hrsa.gov) if you are having trouble connecting to the meeting site.

**Public Comment:** It is preferred that persons interested in providing an oral presentation email a written request, along with a copy of their presentation, to Patricia Stroup, MBA, MPA, Executive Secretary, Advisory Council on Blood Stem Cell Transplantation,