DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Health Center Program

AGENCY: Health Resources and Services Administration, HHS

ACTION: Notice of Noncompetitive Replacement Award to Regional Health Care Affiliates.

SUMMARY: The Health Resources and Services Administration (HRSA) will be transferring Health Center Program (section 330 of the Public Health Service Act) funds originally awarded to Trover Health System to Regional Health Care Affiliates to ensure the provision of critical primary health care services to underserved populations in Webster and McLean Counties, Kentucky.

SUPPLEMENTARY INFORMATION:

Former Grantee of Record: Trover Health System.

Original Period of Grant Support: June 1, 2009 to February 28, 2011.

Replacement awardee: Regional Health Care Affiliates.

Amount of Replacement Award: $17,000.

Period of Replacement Award: The period of support for the replacement award is September 1, 2009, to February 28, 2011.

Authority: Section 330 of the Public Health Service Act, 42 U.S.C. 245b.

CFDA Number: 93.224.

Justification For The Exception To Competition: Under the original grant application approved by HRSA, Regional Health Care Affiliates (RHCA) was identified as the provider of health care services on behalf of the Trover Health System, while Trover Health System was to serve in an administrative capacity for the grant. After the award was issued, Trover Health System and RHCA notified HRSA that RHCA's organizational structure had changed to enable it to carry out both administrative and programmatic requirements. The two parties requested that full responsibility for the grant be transferred from Trover Health System to RHCA. RHCA provided documentation that it meets Section 330 statutory and regulatory requirements as well as applicable grant management requirements.

Regional Health Care Affiliates will directly initiate primary health care services in Webster and McLean Counties to the more than 5,250 low income, underserved and uninsured individuals in the original service area, Webster and McLean Counties, KY, as had been proposed in funded grant application.

Regional Health Care Affiliates can provide primary health care services immediately, is located in the same geographical area where the Trover Health System's primary health care services have been provided, and will be able to provide continuity of care to patients of the former grantee.

This underserved target population has an immediate need for vital primary health care services and would be negatively impacted by any delay caused by a competition. As a result, in order to ensure that critical primary health care services are available to the original target population in a timely manner, this replacement award will not be competed.

FOR FURTHER INFORMATION CONTACT: Marquita Cullom-Stott via email at *MCullom-Stott@hrsa.gov* or 301–594–4300.

Dated: January 11, 2010.

Mary K. Wakefield,

Administrator.

[FR Doc. 2010–673 Filed 1–14–10; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of Biotechnology Activities; Office of Science Policy; Office of the Director; Notice of a Meeting of the NIH Blue Ribbon Panel

The purpose of this notice is to inform the public about a meeting of the NIH Blue Ribbon Panel to Advise on the Risk Assessment of the National Emerging Infectious Diseases Laboratories at Boston University Medical Center.

There will be a meeting of the NIH Blue Ribbon Panel to advise on the Risk Assessment of the National Emerging Infectious Diseases Laboratories (NEIDL) at Boston University Medical Center. The meeting will be held on Friday, February 12, 2010, at the Hyatt Regency Bethesda Hotel, located at 7400 Wisconsin Avenue, Bethesda, Maryland 20814, from approximately 8:30 a.m. to 2 p.m. This meeting is the second in a series of public meetings with the National Research Council to review the ongoing supplementary risk assessment study.

Sign up for public comment will begin at approximately 8 a.m. In the event that time does not allow for all those interested in presenting oral comments, anyone may file written comments using the following address below.

An agenda and slides for the meeting can be obtained prior to the meeting by connecting to *http://nihblueribbonpanel-bumc-neidl.od.nih.gov/*. For additional information concerning this meeting, contact Ms. Laurie Lewallen, Advisory Committee Coordinator, Office of Biotechnology Activities, Office of Science Policy, Office of the Director, National Institutes of Health, 6705 Rockledge Drive, Room 750, Bethesda, MD 20892–7985; telephone 301–496–9838; e-mail *lewallenl@od.nih.gov*.

Dated: January 11, 2010.

Kelly R. Fennington,

Special Assistant to the Director, Office of Biotechnology Activities, National Institutes of Health.

[FR Doc. 2010–730 Filed 1–14–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0604]

Clinical Accuracy Requirements for Point of Care Blood Glucose Meters; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

The Food and Drug Administration (FDA) is announcing a public meeting entitled: Clinical Accuracy Requirements for Point of Care Blood Glucose Meters. The purpose of the public meeting is to discuss the clinical accuracy requirements of blood glucose meters and other topics related to their use in point of care settings.

Dates and Times: The public meeting will be held on March 16, 2010, from 9 a.m. to 5 p.m. and on March 17, 2010, from 9 a.m. to 3:40 p.m.

Location: The public meeting will be held at the Hilton Hotel in Gaithersburg, MD, 620 Perry Pkwy., Gaithersburg, MD 20877. For directions, please refer to the meeting Web page at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm187406.htm*.

Contact Person: Arleen Pinkos, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5618, Silver Spring, MD 20993, 301–796–6152, FAX: 301–847–8573, e-mail: *Arleen.Pinkos@fda.hhs.gov*.

Registration: Persons interested in attending the meeting must register by February 15, 2010. If you wish to attend this public meeting, you must register

online at *http://www.fda.gov/MedicalDevices/NewsEvents/MeetingsConferences/ucm187406.htm* by close of business on February 15, 2010. Those without Internet access may register by contacting Christine Kellerman at 301–796–5711. When registering, you must provide your name, title, company or organization (if applicable), address, phone number, and e-mail address. There is no fee to register for the public meeting and registration will be on a first-come, first-served basis. Early registration is recommended because seating is limited. Registration on the day of the public meeting will be permitted on a space-available basis beginning at 8:45 a.m.

If you need special accommodations due to a disability, please contact the hotel at 301–977–8900 at least 7 days prior to the meeting.

Directions to the hotel and other information about the meeting may be found at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm187406.htm*.

Comments: FDA is holding this public meeting to raise public awareness about the accuracy and clinical use of blood glucose meters, to share ideas on the challenges associated with their use, to seek public comments on this topic and to work towards identifying solutions. The deadline for submitting comments regarding this public meeting is April 20, 2010, by 5 p.m. EST.

Regardless of attendance at the meeting, interested persons may submit written or electronic comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

SUPPLEMENTARY INFORMATION: The workshop will include 3 sessions on the following: (1) Clinical accuracy for blood glucose meters, (2) tight glycemic control in clinical settings, and (3) medications and other substances that interfere with the technologies the devices employ. Each session will include presentations from physicians, laboratories, government and industry representatives, and patient advocates who are experts in each area. Presentations will be followed by panel discussions of session topics and questions from the audience.

Glucose meters are used by millions of people with diabetes every day. These devices have become smaller, faster, and more accurate over the past 3 decades and now allow for better glycemic control by diabetics than in the past. Glucose meters are not only used by diabetics at home, they are also used by health care providers in a variety of settings such as hospitals, emergency response units, nursing homes, and physicians' offices.

Some in the clinical and patient communities have questioned whether the current FDA-recognized accuracy standards for blood glucose meters are acceptable and have challenged FDA to require tighter performance standards. Blood glucose meters are being used in clinical settings and at home in ways that are not within the intended use of the devices as evaluated by FDA. For example, glucose meters are increasingly being used to achieve tight glycemic control despite the fact that these devices have not been cleared for this use. There is currently no consensus that blood glucose meters currently on the market are accurate enough to be used in this way. Still, other stakeholders believe the current analytical performance of glucose meters is adequate and that there is no evidence to support the need for higher standards. Other factors affecting the performance of blood glucose meters include administered drugs, common physiological conditions (such as diabetic ketoacidosis), and user-interface issues. For example, the administration of therapies containing maltose, which are commonly prescribed to patients in the hospital, have resulted in falsely elevated glucose results. (FDA issued a Public Health Notification about this risk. See *http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm176992.htm* and *http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PatientAlerts/ucm177189.htm* for more information.)

In response to the issues identified previously, FDA is reconsidering the current FDA-recognized glucose meter accuracy standards, and is considering whether FDA review criteria for these devices should be changed for reasons of public health. FDA is interested in hearing from clinical experts about the clinical requirements for blood glucose meter accuracy and precision, and the benefits and risks of using glucose meters to achieve and maintain tight glycemic control. The appropriate analytical and clinical accuracy requirements for blood glucose meters will be discussed during this meeting, as well as the potential benefits and challenges of meeting those requirements. We are seeking participation from all stakeholders including, but not limited to: Physicians, nurses, health care providers who work in intensive care settings, industry, diabetes educators, professional societies, consumers, and patient advocate groups.

Transcripts: Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page. A transcript of the public workshop will be available on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm187406.htm.*

Dated: January 8, 2010.

Jeffrey Shuren,

Acting Director, Center for Devices and Radiological Health.

[FR Doc. 2010–742 Filed 1–14–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health: Notice of Closed Meetings

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 meetings.

The meetings 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 Institute of Mental Health Special Emphasis Panel; ITVA Conflicts.

Date: February 24, 2010.

Time: 1:30 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Francois Boller, MD, PhD, Scientific Review Officer, Division of