development and sharing of highly technical summary results derived from automated healthcare data in disparate systems; and what privacy and security safeguards will be needed and how will they be maintained.

B. Research Objectives

These initial discussions have focused on many of the policy and procedural needs of developing the Sentinel System. However, to proceed, additional meetings and working groups need to be formed to explore in greater depth the science of safety needed to support this initiative, as well as methods for communicating about the information learned from the system. Topics to be addressed include specific topics, issues, and questions related to the development of active medical product surveillance methodologies and tools. Subsequently, the information from these meetings and working groups must be described, managed, and made available to the public using a transparent and open approach.

C. Eligibility Information

The following organizations/institutions are eligible to apply: Non-profit organizations.

Foreign institutions are not eligible to apply for conference grant support. An international conference can be supported through the U.S. representative organization of an established international scientific or professional society.

II. Award Information/Funds Available

A. Award Amount

FDA anticipates providing up to $600,000 (direct cost only) during fiscal year (FY) 2009 to support efforts outlined in this FOA. One award will be made.

This Cooperative Agreement ensures substantial FDA involvement in this program and will include, but not be limited to, co-development of the meeting(s) priorities and agendas and providing feedback on reports and publications related to meeting proceedings on identified topics.

B. Length of Support

Subject to the availability of Federal funds and successful performance, and if the FOA stated objectives are met, an additional 4 years of support up to $600,000 (direct and indirect costs combined) per year may be available.

III. Electronic Application, Registration, and Submission

Only electronic applications will be accepted. To submit an electronic application in response to this FOA, applicants should first review the full announcement located at *http://www.fda.gov/Safety/FDAsSentinelInitiative/ucm149345.htm*.

For all electronically submitted applications, the following steps are required.

- Step 1: Obtain a Dun and Bradstreet (DUNS) Number
- Step 2: Register With Central Contractor Registration
- Step 3: Obtain Username & Password
- Step 4: Authorized Organization Representative (AOR) Authorization
- Step 5: Track AOR Status
- Step 6: Register With Electronic Research Administration (eRA) Commons

Steps 1 through 5, in detail, can be found at *http://www07.grants.gov/applicants/organization_registration.jsp*. Step 6, in detail, can be found at *https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp*. After you have followed these steps, submit electronic applications to *http://www.grants.gov*.

Dated: June 19, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–14904 Filed 6–23–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Center for Injury Prevention and Control Initial Review Group (NCIPC IRG)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC), announces the following meeting of the aforementioned committee:

Times and Date: 9 a.m.–9:30 a.m., July 14, 2009(Open) 9:30 a.m.–5 p.m., July 14, 2009(Closed) 9 a.m.–5 p.m., July 15, 2009(Closed)

Place: Doubletree Hotel Atlanta-Buckhead, 3342 Peachtree Road, Atlanta, GA 30326, Telephone: (404) 231–1234.

Status: Portions of the meetings will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5, U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Section 10(d) of Public Law 92–463.

Purpose: This group is charged with providing advice and guidance to the Secretary, Department of Health and Human Services, and the Director, CDC, concerning the scientific and technical merit of grant and cooperative agreement applications received from academic institutions and other public and private profit and nonprofit organizations, including State and local government agencies, to conduct specific injury research that focuses on prevention and control.

Matters To Be Discussed: The meeting will include the review, discussion, and evaluation of individual research cooperative agreement applications submitted in response to Fiscal Year 2009 Requests for Applications related to the following individual research announcement: RFA–CD–09–001 ''Translating Research to Protect Health through Health Promotion, Prevention, and Preparedness (R18)'' for the National Center for Injury Prevention and Control (NCIPC) applications.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Jane Suen, Dr.P.H., M.S., NCIPC, CDC, 4770 Buford Highway, NE., Mailstop F–62, Atlanta, Georgia 30341. Telephone: (770) 488–4281.

The Director, Management Analysis and Services Office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: June 12, 2009.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E9–14740 Filed 6–23–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Public Health Service Act, Section 330(e)

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notification of Exception to Competition—Replacement Grant.

SUMMARY: The Health Resources and Services Administration (HRSA) is issuing a non-competitive award to the Community Health Clinics of Northeast Texas (CHCNET) to avoid disruption and continue providing primary health care services to the population of Smith County, Texas, as an independent organization from the Northeast Texas Public Health District (NETPHD).

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award: Community Health Clinics of Northeast Texas.

Amount of the Award: $326,308.00 (initial seven-month supplement,

February 1, 2009, through August 31, 2009) and $601,308.00 (anticipated second 12-month supplement September 1, 2009, through August 31, 2010) to ensure ongoing clinical services to the target population.

Project Period: The current approved project period for NETPHD which will be supplemented began on September 1, 2007, and ends August 31, 2010; and its current budget period ends August 31, 2009.

Authority: This activity is under the authority of the Public Health Service Act, Section 330(e).

Catalogue of Federal Domestic Assistance Number: 93.224.

Justification for the Exception to Competition: Critical funding for Primary Health Care services to the population of Smith County, Texas, will be continued through a non-competitive award to Community Health Clinics of Northeast Texas as a new recipient. This non-competitive award is made because the previous grant recipient (NETPHD) serving this population notified HRSA that they would relinquish the grant and its responsibility to CHCNET. CHCNET has been responsible for the clinical operations of the program and will continue to operate the previously approved scope of project without significant changes in the organizational structure. This non-competitive replacement award will permit the new recipient to maintain the service delivery program and will ensure continuity of services. The initial supplemental funding will provide support for 7 months. Based on satisfactory performance, continued need, and availability of funds, a second and final supplemental award for these services will be awarded for 12 months. Further funding beyond August 31, 2010, for this service area will be competitively awarded during the next PHS Section 330 Health Center Program competing application process. The next available PHS Section 330 Health Center Program open competing cycle will occur in fiscal year 2009.

FOR FURTHER INFORMATION CONTACT: Monica Toomer, Chief, Southwest Branch, Central Mid-Atlantic Division, Bureau of Primary Health Care, Health Services and Resources Administration, 5600 Fishers Lane, Rockville, MD 20857; phone 301–594–4434; *Monica.Toomer@hrsa.hhs.gov.*

Dated: June 18, 2009.

Mary K. Wakefield,

Administrator.

[FR Doc. E9–14902 Filed 6–23–09; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

The Essentials of Medical Device Regulations: A Primer for Manufacturers and Importers; Public Seminar

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public seminar.

SUMMARY: The Food and Drug Administration's (FDA's) Center for Devices and Radiological Health and Office of Regulatory Affairs, in cooperation with AdvaMed's Medical Technology Learning Institute, is announcing a series of three public seminars on FDA medical device regulations.

These 2-day public seminars, which are designed to address the training needs of startup and small device manufacturers and their suppliers, will include both industry and FDA perspectives and a question and answer period.

DATES: For the dates of the public seminars, see table 1 in the **SUPPLEMENTARY INFORMATION** section of this document.

ADDRESSES: For the locations of the public seminars, see table 1 in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT:

For FDA:

William Sutton, Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, 10903 New Hampshire Ave., W066–4626, Silver Spring, MD 20993–0002, 301–796–5849, FAX: 301–847–8149, e-mail: *William.Sutton@fda.hhs.gov*.

For AdvaMed:

For hotel and general information: Veronica Allen, 202–434–7231, *vallen@advamed.org*.

For registration information: Katia Kunze, 202–434–7237, FAX: 202–783–8750, *kkunze@advamed.org*

SUPPLEMENTARY INFORMATION:

I. Background

The ''Essentials of Medical Device Regulations: A Primer for Manufacturers and Importers'' seminar helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health by educating new entrepreneurs on the essentials of FDA device regulations. FDA has made education of the medical device community a high priority to assure the quality of products reaching the marketplace and to increase the rate of voluntary industry compliance with regulations.

The seminar helps to implement the objectives of section 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393) and the FDA Plan for Statutory Compliance, which includes working more closely with stakeholders and ensuring access to needed scientific and technical expertise.

The seminar also furthers the goals of the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121) by providing outreach activities by Government agencies directed at small businesses.

The following topics, as well as others, will be discussed at the seminar:

- Doing business in a regulated industry;
- Organizational structure of FDA;
- Overview of the quality system regulation;
- Design controls;
- Documents, records, and change control;
- Purchasing controls and acceptance activities;
- Production and process control;
- Corrective and preventive actions;
- Complaints, medical device reports, corrections, and recalls;
- Compliance issues;
- Management responsibility;
- Interacting with FDA—Where do you go for assistance?
- General question and answer session;
- Manufacturers and suppliers—The chain regulatory responsibility;
- Reimbursement of medical technology;
- The AdvaMed code of ethics; and
- Fraud and abuse.

II. Public Seminar Locations and Dates

The locations and dates for the public seminars are listed in table 1 of this document.