ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Continuous Miner Operator	Continuous Miner Operator Form	5	1	10/60	1
Foreman	Foreman Form	5	1	10/60	1
Maintenance Shift Worker	Maintenance Shift Worker Form	10	1	10/60	2
Mobile Bridge Operator	Mobile Bridge Operator Form	10	1	10/60	2
Roof Bolter Operator	Roof Bolter Operator Form	14	1	10/60	2
Scoop Operator	Scoop Operator Form	6	1	10/60	1
Shuttle Car Operator	Shuttle Car Operator Form	6	1	10/60	1
Mechanic	Mechanic Form	6	1	10/60	1
Beltman	Beltman Form	2	1	10/60	0.5
Total					12

Dated: June 11, 2009.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E9–14834 Filed 6–23–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0275]

Convener of Active Medical Product Surveillance Discussion (U13)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of a neutral, independent institution and/or organization that proposes appropriate methods and processes for convening a broad range of stakeholders with relevant expertise to manage and support conferences and meetings. The focus of the conferences and meetings is to explore and address methodological, data development, technical, and communication issues related to active medical product surveillance. The awardee would be expected to synthesize, summarize, and communicate findings from these conferences and meetings to a broad range of organizations and individuals who have the capability to use the information to further develop and create active medical product surveillance methods and systems.

DATES: The application due date is July 15, 2009. The earliest start date is in September 2009.

FOR FURTHER INFORMATION AND ADDITIONAL REQUIREMENTS CONTACT:

Programmatic/Peer Review Contact: Melissa Robb, Office of Critical Path Programs, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, rm. 14B–45, Rockville, MD 20857, 301–827–1516, e-mail: *melissa.robb@fda.hhs.gov*.

Financial or Grants Management Contact: Gladys M. Bohler, Office of Acquisitions and Grant Services, Food and Drug Administration, 5630 Fishers Lane, rm. 2105, Rockville, MD 20857, 301–827–7168, FAX: 301–827–7101, e-mail: *gladys.bohler@fda.hhs.gov*.

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at *http://www.fda.gov/Safety/FDAsSentinelInitiative/ucm149345.htm*.

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

Request for Applications (RFA) Number: RFA–FD09–012

Catalog of Federal Domestic Assistance Number: 93.103

A. Background

In 2007, Congress enacted the Food and Drug Administration Amendments Act of 2007 (FDAAA). Section 905 of this statute calls for the Secretary of Health and Human Services (the Secretary) to develop methods to obtain access to disparate data sources and to establish an active postmarket risk identification and analysis system that links and analyzes safety data from multiple sources. The law sets a goal of access to data from 25 million patients by July 1, 2010, and 100 million patients by July 1, 2012. The law also requires FDA to work closely with partners from public, academic, and private entities.

In May 2008, the Secretary and the Commissioner of Food and Drugs announced the launch of the Sentinel Initiative, a long-term effort to create a national electronic system for monitoring regulated product safety. Once implemented, the Sentinel System is intended to augment FDA's existing postmarket (primarily passive) safety surveillance systems and to enable FDA to actively gather information about the postmarket safety and performance of its regulated products. FDA views its Sentinel Initiative as a mechanism through which some of the requirements mandated in FDAAA can be carried out.

As currently envisioned, the Sentinel System will enable FDA to capitalize on the capabilities of multiple, existing automated healthcare data systems (e.g. electronic health record systems, administrative claims databases, registries). The Sentinel System will enable queries of disparate data sources quickly and securely for relevant regulated product safety information. Data will continue to be managed by its owners, and only data of organizations who agree to participate in this system will be involved. FDA questions would be sent to appropriate, participating data holders, who would, in accordance with existing privacy and security safeguards, evaluate their data and send results summaries to FDA for review.

Following announcement of the Sentinel Initiative in May 2008, FDA's first step has been to create a broad public forum for discussion of issues related to developing and implementing the Sentinel System. During 2008, FDA sponsored a series of exploratory meetings with a broad variety of stakeholders to identify key issues that will need to be addressed before, during, and after implementation of the Sentinel System. Key questions include, for example, what level of collaboration between public and private entities would best ensure the success of the initiative; how a possible governance model could be identified and developed; what kind of methods and tools will be needed to facilitate the

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,