

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. 2010–N–0001]

**2010 Scientific Meeting of the National Antimicrobial Resistance Monitoring System; 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 “2010 Scientific Meeting of the National Antimicrobial Resistance Monitoring System.” The topic to be discussed is the results from the National Antimicrobial Resistance Monitoring System (NARMS) and related antimicrobial resistance monitoring and research, including activities in other national programs.

**Date and Time:** The public meeting will be held on July 15 and 16, 2010, from 8 a.m. to 5 p.m.

**Location:** The public meeting will be held at Hyatt Regency-Atlanta hotel, 265 Peachtree St. NE, Atlanta, GA 30303, 404–577–1234, FAX: 404–588–4137.

**Contact Person:** Joanne Kla, Center for Veterinary Medicine (HFV–12), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20857, 240–276–9129, e-mail: [NARMSinternationalMeeting@fda.hhs.gov](mailto:NARMSinternationalMeeting@fda.hhs.gov), FAX: 240–276–9115.

**Registration and Requests for Oral Presentations:** Send registration information (including name, title, firm name, address, telephone and fax number, and e-mail address), and written material and requests to make oral presentations, to the contact person (see *Contact Person*) on or before July 7, 2010. There is no registration fee for the public meeting. Early registration is recommended because seating is limited. Registration on the day of the public meeting will be provided on a space available basis beginning at 8 a.m. on the day of the meeting.

If you need special accommodations due to a disability, please contact the Hyatt Regency-Atlanta hotel, (see *Location*) at least 7 days in advance.

Interested persons may present data, information, or views, orally or in writing, on the topic of the discussion of the meeting. Written submissions may be made to the contact person on or before July 1, 2010, for distribution at the meeting. Oral presentations from the public during the open public comment period will be scheduled between

approximately 4 p.m. and 5 p.m. on July 16, 2010. Those desiring to make oral presentations should notify the contact person by July 1, 2010, and submit a brief statement of the general nature of information they wish to present and an indication of the approximate time requested to make their presentation. Time allotted for each presentation may be limited. The contact person will inform each speaker of their schedule prior to the meeting.

**Comments:** Regardless of attendance at the public meeting, interested persons may submit written 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. The docket will remain open for written or electronic comments for 30 days following the meeting.

**Agenda:** The meeting will address goals and challenges of monitoring antimicrobial susceptibility in foodborne bacteria, and present research on the microbiology and epidemiology of resistance. The agenda for the public meeting will be made available on the agency's Web site at <http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/ucm059135.htm>.

**Transcripts:** FDA will prepare a meeting transcript and make it available on the agency's Web site (see *Agenda*) after the meeting. FDA anticipates that transcripts will be available approximately 30 business days after the meeting. The transcript will be available for public examination at the Division of Dockets Management (HFA–305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857.

Dated: March 30, 2010.

**Leslie Kux,***Acting Assistant Commissioner for Policy.*

[FR Doc. 2010–7496 Filed 4–1–10; 8:45 am]

BILLING CODE 4160–01–S

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Agency for Healthcare Research and Quality****Meeting for Software Developers on the Technical Specifications for Common Formats for Patient Safety Data Collection and Event Reporting****AGENCY:** Agency for Healthcare Research and Quality (AHRQ), HHS.**ACTION:** Notice of public meeting.

**SUMMARY:** This notice announces a meeting to discuss the technical specifications for AHRQ's common definitions and reporting formats (Common Formats) Version 1.1 that allow for reporting of patient safety information to Patient Safety Organizations (PSOs). The Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b–21 to b–26, (Patient Safety Act) provides for the formation of PSOs, which collect, aggregate, and analyze confidential information regarding the quality and safety of healthcare delivery. The Patient Safety Act (at 42 U.S.C. 299b–23) authorizes the collection of this information in a standardized manner, as explained in the related Patient Safety and Quality Improvement Final Rule, 42 CFR part 3 (Patient Safety Rule), published in the **Federal Register** on November 21, 2008: 73 FR 70731–70814. As authorized by the Secretary of HHS, AHRQ coordinates the development of the Common Formats that allow healthcare providers to voluntarily collect and submit standardized information regarding patient safety events. More information on the Common Formats Version 1.1, including the technical specifications, can be obtained through AHRQ's PSO Web site: <http://www.PSO.AHRQ.gov/index.html>.

Technical specifications promote standardization by ensuring that data collected by PSOs and other entities are clinically and electronically comparable. This meeting is designed as an interactive forum where PSOs and software developers can provide input on these technical specifications for the Common Formats Version 1.1. AHRQ especially requests input from those entities which have implemented, or

plan to implement, the formats electronically.

**DATES:** The meeting will be held from 10 a.m. to 5 p.m. on May 5, 2010.

**ADDRESSES:** The meeting will be held at the Hyatt Regency Baltimore, 300 Light Street, Baltimore, Maryland 21202.

**FOR FURTHER INFORMATION CONTACT:** Susan Grinder, Center for Quality Improvement and Patient Safety, AHRQ, 540 Gaither Road, Rockville, MD 20850; Telephone (toll free): (866) 403-3697; Telephone (local): (301) 427-1111; TTY (toll free): (866) 438-7231; TTY (local): (301) 427-1130; E-mail: [PSO@AHRQ.hhs.gov](mailto:PSO@AHRQ.hhs.gov).

If sign language interpretation or other reasonable accommodation for a disability is needed, please contact the Food and Drug Administration (FDA) Office of Equal Employment Opportunity and Disability Management on (301) 827-4840, no later than April 21, 2010.

**SUPPLEMENTARY INFORMATION:**

**Background**

The Patient Safety Act and Patient Safety Rule establish a framework by which doctors, hospitals, and other healthcare providers may voluntarily report information regarding patient safety events and quality of care. AHRQ develops and maintains the Common Formats to improve the safety and quality of healthcare delivery. AHRQ's Common Formats Version 1.1 includes:

- Descriptions of patient safety events and unsafe conditions to be reported (event descriptions),
- Specifications for patient safety aggregate reports and individual event summaries,
- Delineation of data elements to be collected for specific types of events,
- A user's guide and quick guide, and
- Technical specifications for electronic data collection and reporting.

This meeting will focus on presentation and discussion of these new technical specifications, which provide direction to software developers that plan to implement the Common Formats electronically. The technical specifications are a critical component that will allow for the aggregation of patient safety event data by standardizing the patient safety event information collected and specifying standard rules for data collection, as well as providing guidance for how and when to create data elements, their valid values, and conditional and go-to logic for the data elements. In addition to standardizing the information collected, they specify the data submission file format.

The technical specifications consist of the following:

- Data dictionary—defines data elements and their attributes (data element name, answer values, field length, guide for use, etc.) included in Common Formats Version 1.1;
- Clinical document architecture (CDA) implementation guide—provides instructions for developing a Health Level Seven (HL7) CDA Extensible Markup Language (XML) file to transmit the Common Formats Patient Safety data from the PSO to the PPC using the Common Formats;
- Validation rules and errors document—specifies and defines the validation rules that will be applied to the Common Formats data elements submitted to the PPC;
- Common Formats flow charts—diagrams the valid paths to complete generic and event specific formats (a complete event report);
- Local specifications—provides specifications for processing, linking and reporting on events and details specifications for reports; and
- Metadata registry—includes descriptive facts about information contained in the data dictionary to illustrate how such data corresponds with similar data elements used by other Federal agencies and standards development organizations [e.g., HL-7, International Standards Organization (ISO)].

**Agenda, Registration and Other Information About the Meeting**

On Wednesday, May 5, 2010, the meeting will convene at 10 a.m. with an overview of the Common Formats Version 1.1, including the technical specifications. Next, AHRQ staff and contractors who developed the formats will review the different components of the technical specifications. Throughout the meeting there will be interactive discussion to allow meeting participants not only to provide input, but also to respond to the input provided by others. A more specific proposed agenda will be posted before the meeting at <https://www.psoppc.org/web/patientsafety>.

AHRQ requests that interested persons register with the PSO Privacy Protection Center (PSO PPC) on the Internet at <https://www.psoppc.org/web/patientsafety> to participate in the meeting. The contact at the PSO PPC is Lauren Richie who can be reached by telephone at (630) 792-5977 and by e-mail at [support@psoppc.org](mailto:support@psoppc.org). Additional logistical information for the meeting is also available from the PSO PPC. The meeting space will accommodate approximately 130 participants. Interested persons are encouraged to

register as soon as possible for the meeting. Non-registered individuals will be able to attend the meeting in person if space is available.

We invite review of the technical specifications for Common Formats Version 1.1 prior to the meeting. The formats can be accessed through AHRQ's PSO Web site at <http://www.pso.AHRQ.gov/formats/commonfmt.htm>. AHRQ is committed to continuing refinement of the Common Formats. AHRQ welcomes questions from prospective meeting participants and interested individuals on the technical specifications for Common Formats Version 1.1. These questions should be e-mailed to [support@psoppc.org](mailto:support@psoppc.org) no later than April 28, 2010. AHRQ will use the input received at this meeting as we continue to update and refine the Common Formats.

A summary of the meeting will be provided to all meeting participants. If you are unable to participate in the meeting and would like a copy of the summary, please send an e-mail to [support@psoppc.org](mailto:support@psoppc.org) and it will be sent as soon as it is available after the meeting.

Dated: March 24, 2010.

**Carolyn M. Clancy,**  
*Director.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Eye Institute; Notice of Closed Meeting**

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 meeting.

The meeting 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 Eye Institute Special Emphasis Panel; NEI Training Grants.

*Date:* April 21-22, 2010.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.