## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Healthcare Research and Quality

### Meeting for Software Developers on the 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:** 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 Patient Safety Organizations (PSOs), which collect, aggregate, and analyze confidential information regarding the quality and safety of health care 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. AHRQ coordinates the development of common definitions and reporting formats (Common Formats) that allow health care providers to voluntarily collect and submit standardized information regarding patient safety events. In order to support the Common Formats, AHRQ has provided technical specifications to promote standardization by ensuring that data collected by PSOs and other entities are clinically and electronically comparable. More information on the Common Formats, including the technical specifications, can be obtained through AHRQ's PSO Web site: *http://www.PSO.AHRQ.GOV/index.html.*

The purpose of this notice is to announce a meeting to discuss the Common Formats. This meeting is designed as an interactive forum where PSOs and software developers can provide input on the formats. AHRQ especially requests participation by and input from those entities which have used AHRQ's technical specifications and implemented, or plan to implement, the formats electronically.

**DATES:** The meeting will be held from 10:00 a.m. to 3:30 p.m. on Friday, April 25, 2014.

**ADDRESSES:** The meeting will be held at the John M. Eisenberg Conference Center, Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850.

**FOR FURTHER INFORMATION CONTACT:** Glenn Egelman, M.D., 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; Email: *PSO@AHRQ.HHS.GOV.*

**SUPPLEMENTARY INFORMATION:**

#### Background

The Patient Safety Act and Patient Safety Rule establish a framework by which doctors, hospitals, skilled nursing facilities, and other health care providers may voluntarily report information regarding patient safety events and quality of care. Information that is assembled and developed by providers for reporting to PSOs and the information received and analyzed by PSOs—called patient safety work product—is privileged and confidential. Patient safety work product is used to identify events, patterns of care, and unsafe conditions that increase risks and hazards to patients. Definitions and other details about PSOs and patient safety work product are included in the Patient Safety Rule.

The Patient Safety Act and Patient Safety Rule require PSOs, to the extent practicable and appropriate, to collect patient safety work product from providers in a standardized manner in order to permit valid comparisons of similar cases among similar providers. The collection of patient safety work product allows the aggregation of sufficient data to identify and address underlying causal factors of patient safety problems. Both the Patient Safety Act and Patient Safety Rule, including any relevant guidance, can be accessed electronically at: *http://www.PSO.AHRQ.GOV/REGULATIONS/REGULATIONS.htm*

In collaboration with the interagency Federal Patient Safety Workgroup (PSWG), the National Quality Forum (NQF) and the public, AHRQ has developed Common Formats for two settings of care — acute care hospitals and skilled nursing facilities — in order to facilitate standardized data collection. The term Common Formats refers to the common definitions and reporting formats that allow health care providers to collect and submit standardized information regarding patient safety events. AHRQ's Common Formats include:

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

AHRQ convenes the PSWG to assist AHRQ with developing and maintaining the Common Formats. The PSWG includes major health agencies within the Department of Health and Human Services (HHS)—the Centers for Disease Control and Prevention, Centers for Medicare and Medicaid Services, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, National Library of Medicine, Office of the National Coordinator for Health Information Technology, Office of Public Health and Science, and Substance Abuse and Mental Health Services Administration—as well as the Department of Defense and Department of Veterans Affairs.

When developing Common Formats, AHRQ first reviews existing patient safety event reporting systems from a variety of health care organizations. In collaboration with the PSWG and Federal subject matter experts, AHRQ drafts and releases beta versions of the Common Formats for public review and comment.

Through a contract with AHRQ, NQF solicits feedback on the beta (and subsequent) versions of the Common Formats from private sector organizations and individuals. The NQF, a nonprofit organization that focuses on health care quality, then convenes an expert panel to review the comments received and provide feedback to AHRQ. Based upon the expert panel's feedback, AHRQ, in conjunction with the PSWG, further revises the Common Formats.

The technical specifications promote standardization of collected patient safety event information by specifying rules for data collection and submission, as well as by providing guidance for how and when to create data elements, their valid values, conditional and go-to logic, and reports. These specifications will ensure that data collected by PSOs and other entities have comparable clinical meaning.

The technical specifications also provide direction to software developers, so that the Common Formats can be implemented electronically, and to PSOs, so that the Common Formats can be submitted electronically to the PSO Privacy Protection Center (PSOPPC) for data de-identification and transmission to the

Network of Patient Safety Databases (NPSD).

The Software Developer's meeting will focus on discussion of the implementation and use of Common Formats for Event Reporting—Hospital 1.1 and 1.2; the technical specifications, which provide direction to software developers that plan to implement the Common Formats electronically; and future development plans for the Common Formats. The technical specifications are a critical component that allow for the aggregation of patient safety event data.

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;

○ clinical document architecture (CDA) implementation guide—provides instructions for developing a file to transmit the Common Formats Patient Safety data from the PSO to the PSO 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 PSO 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**

The 2014 meeting will be an interactive forum designed to allow meeting participants not only to provide input, but also to respond to the input provided by others. The meeting agenda will include: an overview of Federal efforts related to the Common Formats; presentations and discussion of implementations of Common Formats Event Reporting—Hospital Version 1.1 and 1.2; discussion of next steps for upcoming Common Formats releases; and a review of data submission both by PSOs and by vendors on behalf of PSOs.

AHRQ requests that interested persons send an email to the PSO PPC at *support@psoppc.ORG* for registration information. The meeting space will accommodate approximately 150 participants. A detailed agenda and logistical information will be provided to meeting registrants before the meeting. Prior to the meeting, AHRQ invites review of the technical specifications for Common Formats which can be accessed through AHRQ's PSO Web site at *http://www.pso.AHRQ.GOV/formats/commonfmt.htm.*

Dated: January 14, 2014.

**Richard Kronick,**

*AHRQ Director.*

[FR Doc. 2014–01242 Filed 1–22–14; 8:45 am]

**BILLING CODE 4160–90–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Public Meeting of the Presidential Commission for the Study of Bioethical Issues

**AGENCY:** Presidential Commission for the Study of Bioethical Issues, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

**ACTION:** Notice of meeting.

**SUMMARY:** The Presidential Commission for the Study of Bioethical Issues (the Commission) will conduct its sixteenth meeting on February 10–11, 2014. At this meeting, the Commission will discuss the BRAIN Initiative and ongoing work in neuroscience.

**DATES:** The meeting will take place Monday, February 10, 2014, from 9 a.m. to approximately 5 p.m. and Tuesday, February 11, 2014, from 9 a.m. to approximately 5 p.m.

**ADDRESSES:** Washington Marriott, 1221 22nd St. NW., Washington, DC 20037. Telephone (202) 872–1500.

**FOR FURTHER INFORMATION CONTACT:** Hillary Wicai Viers, Communications Director, Presidential Commission for the Study of Bioethical Issues, 1425 New York Avenue NW., Suite C–100, Washington, DC 20005. Telephone: 202–233–3960. Email: *Hillary.Viers@bioethics.gov.* Additional information may be obtained at *www.bioethics.gov.*

**SUPPLEMENTARY INFORMATION:** Pursuant to the Federal Advisory Committee Act of 1972, Public Law 92–463, 5 U.S.C. app. 2, notice is hereby given of the sixteenth meeting of the Commission. The meeting will be open to the public with attendance limited to space available. The meeting will also be webcast at *www.bioethics.gov.*

Under authority of Executive Order 13521, dated November 24, 2009, the President established the Commission. The Commission is an expert panel of not more than 13 members who are drawn from the fields of bioethics, science, medicine, technology, engineering, law, philosophy, theology, or other areas of the humanities or social sciences. The Commission advises the President on bioethical issues arising from advances in biomedicine and related areas of science and technology. The Commission seeks to identify and promote policies and practices that ensure scientific research, health care delivery, and technological innovation are conducted in a socially and ethically responsible manner.

The main agenda item for the Commission's sixteenth meeting is to discuss the BRAIN Initiative and ongoing work in neuroscience.

The draft meeting agenda and other information about the Commission, including information about access to the webcast, will be available at *www.bioethics.gov.*

The Commission welcomes input from anyone wishing to provide public comment on any issue before it. Respectful debate of opposing views and active participation by citizens in public exchange of ideas enhances overall public understanding of the issues at hand and conclusions reached by the Commission. The Commission is particularly interested in receiving comments and questions during the meeting that are responsive to specific sessions. Written comments will be accepted at the registration desk and comment forms will be provided to members of the public in order to write down questions and comments for the Commission as they arise. To accommodate as many individuals as possible, the time for each question or comment may be limited. If the number of individuals wishing to pose a question or make a comment is greater than can reasonably be accommodated during the scheduled meeting, the Commission may make a random selection.

Written comments will also be accepted in advance of the meeting and are especially welcome. Please address written comments by email to *info@bioethics.gov,* or by mail to the following address: Public Commentary, Presidential Commission for the Study of Bioethical Issues, 1425 New York Avenue NW., Suite C–100, Washington, DC 20005. Comments will be made publicly available, including any personally identifiable or confidential business information that they contain. Trade secrets should not be submitted.

Anyone planning to attend the meeting who needs special assistance,