

OHRP and other offices or agencies within HHS responsible for human subjects protection. These evaluations may include, but are not limited to, a review of assurance systems, the application of minimal research risk standards, the granting of waivers, education programs sponsored by OHRP, and the ongoing monitoring and oversight of institutional review boards and the institutions that sponsor research.

Nominations: OHRP is requesting nominations to fill four positions for voting members of SACHRP. Two positions will become vacant in July and two in October, 2012. Nominations of potential candidates for consideration are being sought from a wide array of fields, including, but not limited to: public health and medicine, behavioral and social sciences, health administration, and biomedical ethics. To qualify for consideration of appointment to the Committee, an individual must possess demonstrated experience and expertise in any of the several disciplines and fields pertinent to human subjects protection or clinical research.

The individuals selected for appointment to the Committee can be invited to serve a term of up to four years. Committee members receive a stipend and reimbursement for per diem and any travel expenses incurred for attending Committee meetings or conducting other business in the interest of the Committee. Interested applicants may self-nominate.

Nominations should be typewritten. The following information should be included in the package of material submitted for each individual being nominated for consideration: (1) A letter of nomination that clearly states the name and affiliation of the nominee, the basis for the nomination (i.e., specific attributes which qualify the nominee for service in this capacity), and a statement that the nominee is willing to serve as a member of the Committee; (2) the nominator's name, address, daytime telephone number, and the home or work address, telephone number, and email address of the individual being nominated; and (3) a current copy of the nominee's curriculum vitae. Federal employees should not be nominated for consideration of appointment to this Committee.

The Department makes every effort to ensure that the membership of HHS Federal advisory committees is fairly balanced in terms of points of view represented and the committee's function. Every effort is made to ensure that individuals from a broad representation of geographic areas,

women and men, ethnic and minority groups, and the disabled are given consideration for membership on HHS Federal advisory committees. Appointment to this Committee shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, disability, and cultural, religious, or socioeconomic status.

Individuals who are selected to be considered for appointment will be required to provide detailed information regarding their financial holdings, consultancies, and research grants or contracts. Disclosure of this information is necessary in order to determine if the selected candidate is involved in any activity that may pose a potential conflict with the official duties to be performed as a member of SACHRP.

Dated: February 10, 2012.

Jerry Menikoff,

Director, Office for Human Research Protections Executive Secretary, Secretary's Advisory Committee on Human Research Protections.

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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: 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 a set 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 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 technical specifications. This meeting is designed as an interactive forum where PSOs and software developers can provide input on these technical specifications. AHRQ especially requests 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 a.m. to 3:30 p.m. on April 12, 2012.

ADDRESSES: The meeting will be held at the Hyatt Regency Bethesda, 7400 Wisconsin Avenue, Bethesda, MD 20814.

FOR FURTHER INFORMATION CONTACT:

Susan Grindler, 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.

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 at (301) 827-4840, no later than March 28, 2012.

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 practical 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 & 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 (PSO PPC) for data de-identification and transmission to the Network of Patient Safety Databases (NPSD).

Most recently, AHRQ and the PSWG released the beta version of the Venous Thromboembolism (VTE) format for reporting of VTE-related patient safety events as announced in the **Federal Register** on November 1, 2011: 76 FR 67456–67457.

The Software Developer’s meeting will focus on discussion of an anticipated Spring release—Hospital Common Formats 1.2—and the technical specifications, which provide direction to software developers that plan to implement the Common Formats electronically. 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

On Thursday, April 12, 2012, the meeting will convene at 10 a.m. with an overview of the Common Formats, including the Hospital Common Formats Version 1.2 technical specifications, and next steps for upcoming Common Formats releases. AHRQ staff and contractors will review database functionality, which is available through the PSO PPC, for PSOs to generate aggregate reports with technical specifications. Finally, the meeting will review data submission both by PSOs and by vendors on behalf of a PSO. 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 <http://www.cvent.com/d/0cQkQx>.

AHRQ requests that interested persons register with the PSO PPC on the Internet at <http://www.cvent.com/d/0cQkQx/4W> to participate in the meeting. The contact at the PSO PPC is Rhonda Davis who can be reached by telephone at (866) 571-7712 and by email at supportpsoppc.ORG. Additional logistical information for the meeting is also available from the PSO PPC. The meeting space will accommodate approximately 150 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. Prior to the meeting, AHRQ invites review of the technical specifications for Common Formats. 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, and welcomes questions from prospective meeting participants and interested individuals on the technical specifications. These questions should be emailed to support@psoppc.ORG no later than March 21, 2012. AHRQ will use the input received at this meeting to further update and refine the Common Formats.

A summary of the meeting will be provided upon request. If you are unable to participate in the meeting and would like a copy of the summary, please send an email to supportpsoppc.ORG and it will be sent as soon as it is available after the meeting.

Dated: January 25, 2012.

Carolyn M. Clancy,
Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Board on Radiation and Worker Health (ABRWH or Advisory Board), National Institute for Occupational Safety and Health (NIOSH)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), and pursuant to the requirements of 42 CFR 83.15(a), the Centers for Disease Control and Prevention (CDC), announces the following meeting of the aforementioned committee:

Board Public Meeting Times and Dates (All times are Pacific Time): 9:45 a.m.–5 p.m., February 28, 2012. 8:15 a.m.–6 p.m., February 29, 2012.

Public Comment Times and Dates (All times are Pacific Time): 5 p.m.–6:30 p.m.,* February 28, 2012.

* Please note that the public comment periods may end before the times indicated, following the last call for comments. Members of the public who wish to provide public comments should plan to attend public comment sessions at the start times listed.

Place: Waterfront Hotel, 10 Washington Street, Oakland, California 94607, Telephone: (510) 836-3800, Fax: (510) 832-5695, Audio Conference Call via FTS Conferencing, the USA toll-free number is 1-866-659-0537 with a pass code of 9933701.

Status: Open to the public, limited only by the space available. The meeting space accommodates approximately 150 people.

Background: The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines which have been promulgated by the Department of Health and Human Services (HHS) as a final rule, advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule, advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program, and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC).

In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to the CDC. NIOSH implements this responsibility for CDC. The charter was issued on August 3, 2001, renewed at appropriate intervals, and will expire on August 3, 2013.

Purpose: This Advisory Board is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advise the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class.

Matters To Be Discussed: The agenda for the Advisory Board meeting includes: NIOSH Program Update; Department of Labor (DOL) Program Update; Department of Energy (DOE) Program Update; NIOSH 10-Year Program Review Implementation; Status of Activities for Lawrence Berkeley National Laboratory and Stanford Linear Accelerator; SEC petitions for: Electro Metallurgical (Niagara Falls, NY), Hangar 481 (Kirtland Air Force Base); Weldon Spring Plant (Weldon Spring, MO), Sandia National Laboratories,

Clinton Engineering Works (Oak Ridge, TN), Feed Materials Production Center (Fernald, Ohio), and Brookhaven National Laboratory; SEC Petition Status Updates; and Board Work Sessions.

The agenda is subject to change as priorities dictate.

In the event an individual cannot attend, written comments may be submitted in accordance with the redaction policy provided below. Any written comments received will be provided at the meeting and should be submitted to the contact person below well in advance of the meeting.

Policy on Redaction of Board Meeting Transcripts (Public Comment): (1) If a person making a comment gives his or her name, no attempt will be made to redact that name. (2) NIOSH will take reasonable steps to ensure that individuals making public comment are aware of the fact that their comments (including their name, if provided) will appear in a transcript of the meeting posted on a public Web site. Such reasonable steps include: (a) A statement read at the start of each public comment period stating that transcripts will be posted and names of speakers will not be redacted; (b) A printed copy of the statement mentioned in (a) above will be displayed on the table where individuals sign up to make public comments; (c) A statement such as outlined in (a) above will also appear with the agenda for a Board Meeting when it is posted on the NIOSH Web site; (d) A statement such as in (a) above will appear in the **Federal Register** Notice that announces Board and Subcommittee meetings. (3) If an individual in making a statement reveals personal information (e.g., medical information) about themselves that information will not usually be redacted. The NIOSH FOIA coordinator will, however, review such revelations in accordance with the Freedom of Information Act and the Federal Advisory Committee Act and if deemed appropriate, will redact such information. (4) All disclosures of information concerning third parties will be redacted. (5) If it comes to the attention of the DFO that an individual wishes to share information with the Board but objects to doing so in a public forum, the Designated Federal Officer will work with that individual, in accordance with the Federal Advisory Committee Act, to find a way that the Board can hear such comments.

Contact Person for More Information: Theodore Katz, M.P.A., Executive Secretary, NIOSH, CDC, 1600 Clifton Road NE., MS E-20, Atlanta, Georgia 30333, Telephone: (513) 533-6800, toll