meeting will commence in open session before closing to the public for the duration of the meeting. The subcommittee meetings will be closed to the public in accordance with the provisions set forth in 5 U.S.C. App. 2 section 10(d), 5 U.S.C. 552b(c)(4), and 5 U.S.C. 552b(c)(6) 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.

Agenda items for these meetings are subject to change as priorities dictate.

Sharon B. Arnold,

AHRQ Deputy Director.

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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), Department of Health and Human Services (HHS).

ACTION: Notice of public meeting.

SUMMARY: AHRQ coordinates the development of sets of common definitions and reporting formats (Common Formats) for reporting on health care quality and patient safety. In order to support the Common Formats, AHRQ has provided technical specifications to promote standardization by ensuring that data collected by Patient Safety Organizations (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/.*

The purpose of this notice is to announce a meeting to discuss the Common Formats. This meeting is designed as an interactive forum where software developers and PSOs 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 8:00 a.m.–2:30 p.m. on Friday, April 15, 2016.

ADDRESSES: The meeting will be held at 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: A. Gretchen Buckler, MD MPH, CDR, USPHS Commissioned Corps, Medical Officer, Center for Quality Improvement and Patient Safety, AHRQ, 5600 Fishers Lane, Rockville, MD 20857; 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 and Quality Improvement Act of 2005, 42 U.S.C. 299b-21 to b-26, (Patient Safety Act) and 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 70732–70814), provide for the formation of PSOs, which collect, aggregate, and analyze confidential information regarding the quality and safety of health care delivery. The collection of patient safety work product allows the aggregation of data that help to identify and address underlying causal factors of patient quality and safety problems.

The Patient Safety Act and Patient Safety Rule establish a framework by which doctors, hospitals, skilled nursing facilities, and other healthcare providers may assemble 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 conduct patient safety activities, which may include identifying 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 Act and Patient Safety Rule which can be accessed electronically at: *http://www.pso.ahrq.gov/legislation/.*

Definition of Common Formats

The term ''Common Formats'' refers to the common definitions and reporting formats, specified by AHRQ, that allow health care providers to collect and submit standardized information regarding patient quality and safety to PSOs and other entities. The Common Formats are not intended to replace any current mandatory reporting system, collaborative/voluntary reporting system, research-related reporting system, or other reporting/recording system; rather the formats are intended to enhance the ability of health care providers to report information that is standardized both clinically and electronically.

In collaboration with the interagency Federal Patient Safety Workgroup (PSWG), the National Quality Forum (NQF), and the public, AHRQ has developed Common Formats for three settings of care — acute care hospitals, skilled nursing facilities, and retail pharmacies — in order to facilitate standardized data collection and analysis. The scope of Common Formats applies to all patient safety concerns including: incidents—patient safety events that reached the patient, whether or not there was harm; near misses or close calls—patient safety events that did not reach the patient; and unsafe conditions—circumstances that increase the probability of a patient safety event.

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.

Common Formats Development

In anticipation of the need for Common Formats, AHRQ began their development by creating an inventory of functioning private and public sector patient safety reporting systems. This inventory provided an evidence base to inform construction of the Common Formats. The inventory included many systems from the private sector, including prominent academic settings, hospital systems, and international reporting systems (*e.g.,* from the United Kingdom and the Commonwealth of Australia). In addition, virtually all major Federal patient safety reporting systems were included, such as those from the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Department of Defense (DoD), and the Department of Veterans Affairs (VA).

Since February 2005, AHRQ has convened the PSWG to assist AHRQ with developing and maintaining the Common Formats. The PSWG includes

major health agencies within HHS—CDC, Centers for Medicare & Medicaid Services, FDA, 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 DoD and VA.

When developing Common Formats, AHRQ first reviews existing patient safety practices and event reporting systems. 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. The PSWG assists AHRQ with assuring the consistency of definitions/formats with those of relevant government agencies as refinement of the Common Formats continues.

Since the initial release of the Common Formats in August 2008, AHRQ has regularly revised the formats based upon public comment. AHRQ solicits feedback on beta (and subsequent) versions of Common Formats from private sector organizations and individuals. Based upon the feedback received, AHRQ further revises the Common Formats. To the extent practicable, the Common Formats are also aligned with World Health Organization (WHO) concepts, frameworks, and definitions.

Participation by the private sector in the development and subsequent revision of the Common Formats is achieved through working with the NQF. The Agency engages the NQF, a non-profit organization focused on health care quality, to solicit comments and advice regarding proposed versions of the Common Formats. AHRQ began this process with the NQF in 2008, receiving feedback on AHRQ's 0.1 Beta release of the Common Formats for Event Reporting—Hospital. After receiving public comment, the NQF solicits the review and advice of its Common Formats Expert Panel and subsequently provides feedback to AHRQ. The Agency then revises and refines the Common Formats and issues them as a production version. AHRQ has continued to employ this process for all subsequent versions of 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 Patient Safety Organization Privacy Protection Center (PSOPPC) for data de-identification and transmission to the NPSD.

Common Formats 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 PSOPPC 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 PSOPPC;
- 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 2016 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 update of Federal efforts related to the Common Formats, including development of formats for new settings; Common Formats software products demonstrations; a discussion of data integrity related to submission of patient safety adverse events; and a question and answer session.

AHRQ requests that interested persons send an email to the PSOPPC at *support@psoppc.org* for registration information. Before the meeting, a detailed agenda and logistical information will be provided to registrants. 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 *https://www.psoppc.org/psoppc_web/publicpages/commonFormatsOverview.*

Sharon B. Arnold,

AHRQ Deputy Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Request for Nominations of Candidates To Serve on the Advisory Committee on Immunization Practices (ACIP)

The Centers for Disease Control and Prevention (CDC) is soliciting nominations for membership on ACIP. The ACIP consists of 15 experts in fields associated with immunization, who are selected by the Secretary of the U.S. Department of Health and Human Services (HHS) to provide advice and guidance to the Secretary, the Assistant Secretary for Health, and the CDC on the control of vaccine-preventable diseases. The role of the ACIP is to provide advice that will lead to a reduction in the incidence of vaccine preventable diseases in the United States, and an increase in the safe use of vaccines and related biological products. The committee also establishes, reviews, and as appropriate, revises the list of vaccines for administration to children eligible to receive vaccines through the Vaccines for Children (VFC) Program.

Nominations are being sought for individuals who have expertise and qualifications necessary to contribute to the accomplishments of the committee's objectives. Nominees will be selected based on expertise in the field of immunization practices; multi-disciplinary expertise in public health; expertise in the use of vaccines and immunologic agents in both clinical and preventive medicine; knowledge of vaccine development, evaluation, and vaccine delivery; or knowledge about consumer perspectives and/or social and community aspects of immunization programs. Federal employees will not be considered for membership. Members may be invited to serve for four-year terms.

The next cycle of selection of candidates will begin in the fall of 2016,