maximum total burden across all three years is thus 6568.5 hours.

TABLE 1—ESTIMATED ANNUALIZED BURDEN HOURS

Data collection type	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Interviews	375	2	1	750
Focus Groups/Small Discussions	420	1.5	1.5	945
Implementation Logs	20	8	1	160
Recruitment and Screening	139	1	0.5	69.5
Cognitive Testing	40	1	1	40
Questionnaires/Brief Surveys	1,000	1	0.2	200
Collection of Internal Documents	25	1	1	25
Total				2,189.5

TABLE 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
Interviews	250	500	[a] $95.05	$47,525.00
(Clinicians—line 1; Patients—line 2)	125	250	[b] 27.12	6780.00
Focus Groups/Small Discussions	420	945	[c] 27.12	25,628.40
Implementation Logs	20	160	[c] 27.12	4,339.20
Recruitment and Screening	139	69.5	[a] 95.05	6,605.98
Cognitive Testing	40	40	[c] 27.12	1,084.80
Questionnaires/Brief Surveys	1000	200	[c] 27.12	5,424.00
Collection of Internal Documents	25	25	[a] 95.05	2,376.25
Total				99,763.63

* National Compensation Survey: Occupational wages in the United States May 2015 "U.S. Department of Labor, Bureau of Labor Statistics:" *http://www.bls.gov/oes/current/oes_stru.htm.*

[a] Based on the mean wages for *29–1069 Physicians and Surgeons, All Other.*

[b] Based on the mean wages for *00–0000 All Occupations.*

[c] Based on the mean wages for *29–9099 Miscellaneous Health Practitioners and Technical Workers: Healthcare Practitioners and Technical Workers, All Other.*

Using average wage rates for relevant job categories from 2016 BLS data, the total annual costs associated with these data collections per year are $116,746.13 as shown in Table 2 above, for a total cost for all three years of $350,238.39.

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Sharon B. Arnold,

Deputy Director.

[FR Doc. 2016–30603 Filed 12–19–16; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Common Formats for Reporting on Health Care Quality and Patient Safety

AGENCY: Agency for Healthcare Research and Quality (AHRQ), Department of Health and Human Services (HHS).

ACTION: Notice of Availability—New Common Formats.

SUMMARY: As authorized by the Secretary of HHS, AHRQ coordinates the development of sets of common definitions and reporting formats (Common Formats) for reporting on health care quality and patient safety. The purpose of this notice is to announce the release of the Common Formats—Community Pharmacy Version 1.0.

DATES: Ongoing public input.

ADDRESSES: The Common Formats—Community Pharmacy Version 1.0 and the remaining Common Formats can be accessed electronically at the following HHS Web site: *http://www.pso.ahrq.gov/common/.*

FOR FURTHER INFORMATION CONTACT: Dr. Barbara Choo, Center for Quality Improvement and Patient Safety, AHRQ, 5600 Fishers Lane, Room 06N100B, 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 Patient Safety Organizations (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 safety and quality issues.

The Patient Safety Act and Patient Safety Rule establish a framework by which doctors, hospitals, skilled nursing facilities, and other health care 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 community 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 for patient safety event reporting include:

- Event descriptions (definitions of patient safety events, near misses, and unsafe conditions to be reported);
- Specifications for patient safety aggregate reports that derive from event descriptions;
- Delineation of data elements and algorithms to be used for collection of adverse event data to populate the reports; and
- Technical specifications for electronic data collection and reporting.

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. They 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 (PPC) for data de-identification and transmission to the Network of Patient Safety Databases.

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.

Since the initial release of the Common Formats in August 2008, AHRQ has regularly revised the formats based upon public comment. First, AHRQ reviews existing patient safety practices and event reporting systems. Then, AHRQ works in collaboration with the PSWG and Federal subject matter experts to develop and draft the Common Formats. In addition, the PSWG assists AHRQ with assuring the consistency of definitions/formats with those of relevant government agencies as refinement of the Common Formats continues. Next, AHRQ solicits feedback from private sector organizations and individuals. Finally, based upon the feedback received, AHRQ further revises the Common Formats.

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.

In 2014, representatives from U.S. community pharmacies approached AHRQ regarding collaboration to develop Common Formats for the community pharmacy setting. Development of the new Formats began using the existing AHRQ Common Formats Medication module from the AHRQ Common Formats for Event

Reporting—Hospital, Version 1.2, as a starting point. AHRQ, in conjunction with community pharmacy representatives, designed these new formats to facilitate improved detection and understanding of medication-related events originating in pharmacies. If implemented as specified, the Common Formats—Community Pharmacy Version 1.0 will allow aggregation of medication-related data across different pharmacy providers.

On October 6, 2015, AHRQ announced the availability of the—Common Formats Retail Pharmacy Version 0.1 Beta—for review and comment in the **Federal Register** (80 FR 60385–60387). After obtaining feedback from both the private and public sectors, the Agency finalized the format and renamed it Common Formats—Community Pharmacy Version 1.0. All elements—including the event description, aggregate reports, data elements and algorithms, and technical specifications—will be posted at the PSOPPC Web site: *https://www.psoppc.org/psoppc_web.*

More information on the Common Formats can be obtained through AHRQ's PSO Web site: *http://www.pso.ahrq.gov/.*

Sharon B. Arnold,

Deputy Director.

[FR Doc. 2016–30604 Filed 12–19–16; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Mine Safety and Health Research Advisory Committee: Notice of Charter Renewal

This gives notice under the Federal Advisory Committee Act (Pub. L. 92–463) of October 6, 1972, that the Mine Safety and Health Research Advisory Committee, Centers for Disease Control and Prevention, Department of Health and Human Services, has been renewed for a 2-year period through November 30, 2018.

For information, contact Jeffrey H. Welsh, B.A., Designated Federal Officer, Mine Safety and Health Research Advisory Committee, Centers for Disease Control and Prevention, Department of Health and Human Services, 626 Cochrans Mill Road, Mailstop P05, Pittsburgh, Pennsylvania 15236, Telephone (412) 386–4040 or fax (412) 386–6614.

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.

Catherine Ramadei,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2016–30525 Filed 12–19–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Board on Radiation and Worker Health (ABRWH or the Advisory Board), Subcommittee on Procedures Review (SPR), 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), the Centers for Disease Control and Prevention (CDC), announces the following meeting for the aforementioned subcommittee:

Time and Date: 11:00 a.m.–4:30 p.m., EST, January 10, 2017

Place: Audio Conference Call via FTS Conferencing.

Status: Open to the public, but without a public comment period. The public is welcome to submit written comments in advance of the meeting, to the contact person below. Written comments received in advance of the meeting will be included in the official record of the meeting. The public is also welcome to listen to the meeting by joining the teleconference at the USA toll-free, dial-in number at 1–866–659–0537 and the pass code is 9933701.

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 that 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 CDC. NIOSH implements this responsibility for CDC. The charter was issued on August 3, 2001, renewed at appropriate intervals, rechartered on March 22, 2016, pursuant to Executive Order 13708, and will expire on September 30, 2017.

Purpose: The 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. SPR was established to aid the Advisory Board in carrying out its duty to advise the Secretary, HHS, on dose reconstruction. SPR is responsible for overseeing, tracking, and participating in the reviews of all procedures used in the dose reconstruction process by the NIOSH Division of Compensation Analysis and Support (DCAS) and its dose reconstruction contractor (Oak Ridge Associated Universities—ORAU).

Matters for Discussion: The agenda for the Subcommittee meeting includes: discussion of procedures in the following ORAU and DCAS technical documents:

OCAS Technical Information Bulletin (TIB) 0013 and ORAUT Procedure 0042 (''Individual Dose Adjustment Procedure for Y–12 Dose Reconstruction'' and ''Accounting for Incomplete Personal Monitoring Data on Penetrating Gamma-Ray Doses to Workers in Radiation Areas at the Oak Ridge Y–12 Plant Prior to 1961''); Program Evaluation Report OCAS–PER–011, (''K–25 TBD and TIB Revisions''), PER–055 (''TBD 6000 Revisions''), PER–057 (''General Steel Industries''), PER 60 (''Blockson Chemical Company''), PER–064 (''DuPont Deep Water Works''), and PER–066 (''Huntington Pilot Plant''), and a continuation of the comment-resolution process for other dose