

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form Name	Number of respondents/ POCs	Total burden hours	Average hourly wage rate*	Total cost burden
Eligibility/Registration Form	304	15	\$53.17	\$798
Data Use Agreement	304	15	53.17	798
Hospital Information Form	304	76	53.17	4,041
Data Files Submission	304	304	53.17	16,164
Total	1,216	410	NA	21,801

* Wage rates were calculated using the mean hourly wage based on occupational employment and wage estimates from the Dept. of Labor, Bureau of Labor Statistics' May 2014 National Industry-Specific Occupational Employment and Wage Estimates NAICS 622000—Hospitals, located at http://www.bls.gov/oes/current/naics3_622000.htm. Wage rate of \$53.17 is based on the mean hourly wages for Medical and Health Services Managers (11–9111).

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,
Acting Director.

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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 availability of new formats for public review and comment, Common Formats for Event Reporting for Hospitals Version 2.0.

DATES: May 9, 2016.

ADDRESSES: The Common Formats for Event Reporting for Hospitals Version 2.0, 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: Cathryn Bach, 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 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 quality and safety problems.

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 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, nursing homes, and retail pharmacies—in order to facilitate standardized data collection and analysis. The scope of the 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 and individual event summaries 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 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).

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 and updates to current versions of the Common Formats for public review and comment. The prior version of Common Formats for Event Reporting for Hospitals, Version 1.2, was released in April 2013. 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 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 formats.

Commenting on Common Formats for Event Reporting—Hospital Version 2.0

AHRQ used a tiered approach to develop Hospital Version 2.0. This approach was done in response to feedback from PSOs and the public to decrease the number of questions for each module of the formats in order to

reduce the burden on health care providers and to facilitate data transmission. These formats have two tiers, or data sets. The first tier, or national data set, contains elements that are collected for submission to the PSOPPC. The second tier, or local data set, is optional and is designed for use at the local level for additional analyses. This local data set is not meant for transmission to the PSOPPC.

The Agency is specifically interested in obtaining feedback from both the private and public sectors on the updated Common Formats for Event Reporting—Hospitals Version 2.0. At this time, only the event descriptions—which define adverse events of interest in the inpatient hospital setting—are available. Other elements of the Common Formats, including aggregate reports and technical specifications, will be developed following revision of the Common Formats for Hospital Version 2.0 based on public comment and NQF advice. Information on how to comment and provide feedback on the Common Formats for Hospital Version 2.0 is available at the NQF Web site: http://www.qualityforum.org/Project_Pages/Common_Formats_for_Patient_Safety_Data.aspx.

AHRQ appreciates the time and effort individuals invest in providing comments. The Agency will review and consider all feedback received to help guide the development of a revised version. The process for updating and refining the formats will continue to be an iterative one.

Further information on the Common Formats can be obtained through AHRQ's PSO Web site: <http://www.pso.ahrq.gov/>. To receive notifications about final versions of AHRQ Common Formats, please subscribe to "E-Mail Updates" at: <https://pso.ahrq.gov/about/subscribe>.

Sharon B. Arnold,
Acting Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

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Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.