EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN—Continued

Form name	Number of respondents/ POCs	Total burden hours	Average hourly wage rate*	Total cost burden
Data Use Agreement	250	13	45.22	588
Patient Safety Improvement Initiatives Form (for trending hospitals only)	125	32	45.22	1,447
Hospital Information Form	250	63	45.22	2,849
Total	875	1,508	NA	69,438

*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 2008 National Industry-Specific Occupational Employment and Wage Estimates NAICS 622000—Hospitals, located at *http://www.bls.gov/oes/2008/may/naics3_622000.htm.* Wage rate of $46.22 is based on the mean hourly wages for Medical and Health Services Managers. Wage rate of $46.11 is the weighted mean hourly wage for: Medical and Health Services Managers ($45.22 × 2.6 hours = $117.57), Lawyers ($62.95 × .5 hours = $31.48), Chief Executives ($89.16 × .5 hours = $44.58), and Database Administrators ($32.30 × 2 hours = $64.60) [Weighted mean ($117.57 + 31.48 + 44.58 + 64.60)/5.6 hours = $258.23/5.6 hours = $46.11/hour].

Estimated Annual Costs to the Federal Government

Exhibit 3 shows the estimated annualized cost to the government for developing, maintaining, and managing the database and analyzing the data and producing reports. The cost is estimated to be $250,000 annually.

EXHIBIT 3—ESTIMATED ANNUALIZED COST

Cost component	Annualized cost
Database Development and Maintenance	$50,000
Data Submission	75,000
Data Analysis & Reports	125,000
Total	250,000

Request for Comments

In accordance with the above-cited Paperwork Reduction Act legislation, 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, quality improvement and 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.

Dated: August 26, 2009.

Carolyn M. Clancy,

Director.

[FR Doc. E9–21079 Filed 9–1–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Common Formats for Patient Safety Data Collection and Event Reporting

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Notice of Availability—Common Formats Version 1.0.

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 healthcare 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. As authorized by the Secretary of HHS, AHRQ coordinates the development of a set of common definitions and reporting formats (Common Formats) that allow healthcare providers to voluntarily collect and submit standardized information regarding patient safety events. The initial release of the formats, Version 0.1 Beta, was announced in the **Federal Register** on August 29, 2008: 73 FR 50974–50976. The purpose of this notice is to announce the availability of the expanded and enhanced Common Formats Version 1.0 and the process for their continued development and refinement.

DATES: Ongoing public input.

ADDRESSES: The Common Formats can be accessed electronically at the following HHS Web site: *http://www.pso.ahrq.gov/index.html.*

FOR FURTHER INFORMATION CONTACT: Susan Grinder, 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; E-mail: *pso@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Patient Safety Act and Patient Safety Rule establish a framework by which doctors, hospitals, and other healthcare 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. In order to facilitate standardized data collection, the Secretary of HHS authorized AHRQ to develop and maintain the Common Formats to improve the safety and quality of healthcare delivery.

Definition of Common Formats

The term ''Common Formats'' is used to describe clinical definitions and technical requirements developed for the uniform collection and reporting of patient safety data, including all supporting material. AHRQ's Common Formats include:

- Descriptions of patient safety events and unsafe conditions to be reported,
- Delineation of data elements to be collected for specific types of events,
- Specifications for patient safety population reports,
- Technical specifications for electronic data collection and reporting, and
- A user's guide.

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.

Score of Common Formats

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.

Version 1.0 includes two general types of formats, generic and event-specific. The generic Common Formats pertain to all patient safety concerns. The three generic formats are: Healthcare Event Reporting Form, Patient Information Form, and Summary of Initial Report. The event-specific Common Formats pertain to frequently-occurring and/or serious patient safety events. The eight event-specific formats are: Blood or Blood Product, Device or Medical/Surgical Supply, Fall, Healthcare-Associated Infection, Medication or Other Substance, Perinatal, Pressure Ulcer, and Surgery or Anesthesia.

The Common Formats Version 1.0 has a defined focus on patient safety reporting for acute care hospitals. It should be noted, however, that the Patient Safety Act and Patient Safety Rule confer both privilege and confidentiality on all patient safety work product developed under the aegis of a PSO with respect to healthcare in any setting. AHRQ anticipates expanding future versions of the Common Formats to include other settings such as: Nursing homes and other bedded facilities; ambulatory surgery centers; other ambulatory care settings, including community health centers, rehabilitation centers, and hemodialysis centers; physician and practitioner offices; and retail establishments such as pharmacies.

Common Formats Development

AHRQ established a process to develop Common Formats that: (1) Is evidence based; (2) harmonizes across governmental health agencies; (3) incorporates feedback from the private sector, including professional associations/organizations, those who use the formats, and the public; and (4) permits timely updating of these clinically-sensitive formats.

In anticipation of the need for Common Formats, AHRQ began their development in 2005 by creating an inventory of functioning private and public sector patient safety reporting systems. This inventory provides an evidence base that informs construction of the Common Formats. The inventory now numbers 66 and includes 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 are 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).

In addition, AHRQ convened an interagency Federal Patient Safety Work Group (PSWG) to assist AHRQ with developing and maintaining the Common Formats. The PSWG includes major health agencies within the Department—CDC, Centers for Medicare and Medicaid Services, FDA, Health Resources and Services Administration, the Indian Health Service, the National Institutes of Health, the National Library of Medicine, the Office of the National Coordinator for Health Information Technology, the Office of Public Health and Science, the Substance Abuse and Mental Health Services Administration—as well as the DoD and the VA.

Subsequently, AHRQ, in conjunction with the PSWG, developed and released Common Formats Version 0.1 Beta. To the extent practicable, the Common Formats were aligned with World Health Organization (WHO) concepts, framework, and definitions contained in their draft International Classification for Patient Safety (ICPS). The PSWG assists AHRQ with assuring the consistency of definitions/formats with those of relevant government agencies as refinement of the Common Formats continues.

To allow for greater participation by the private sector in the subsequent development of the Common Formats, AHRQ engaged the National Quality Forum (NQF), a non-profit organization focused on healthcare quality, to solicit comments and advice to guide the further refinement of the Common Formats. The NQF convened an expert panel to review the comments received on Version 0.1 Beta and provide feedback to AHRQ. Based upon the expert panel's feedback, AHRQ, in conjunction with the PSWG, further revised and refined the Common Formats that are now available as Version 1.0.

Commenting on Common Formats Version 1.0

AHRQ is committed to continuing refinement of the Common Formats. The Agency is specifically interested in obtaining feedback from both the private and public sectors—particularly from those who use the Common Formats—to guide their improvement. Although AHRQ's Version 1.0 has been developed based on evidence, consensus of the PSWG, public comments and input, and feedback from the NQF expert panel, the formats do not yet reflect the refinement that will come from large-scale use and repeated revision. The process for updating and refining the formats will be an iterative one. AHRQ anticipates that it will receive helpful guidance from early users of the Common Formats.

The NQF will continue to assist AHRQ in updating future versions of the formats by soliciting public comments from providers, professional organizations, the general public, PSOs, and other users of Common Formats. More information on the Common Formats Version 1.0, including the feedback process, can be obtained through AHRQ's PSO Web site: *http://www.pso.ahrq.gov/index.html.*

Dated: August 26, 2009.

Carolyn M. Clancy,

Director.

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