ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Administrative Subpoena	35,286	1	0.50	17,643

Estimated Total Annual Burden Hours: 17,643

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–7285, E-mail: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Dated: October 19, 2010.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2010–26693 Filed 10–21–10; 8:45 am]

BILLING CODE 4184–01–P

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—revised and enhanced event-specific common format.

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 purpose of this notice is to announce the availability of a significant revision of a previously released Common Format for public review and comment.

DATES: Ongoing public input.

ADDRESSES: The revised Device or Medical/Surgical Supply including Health Information Technology (HIT) Device format and the remaining Common Formats Version 1.1 can be accessed electronically at the following HHS Web site: *http:// www.PSO.AHRQ.gov/index.html.*

FOR FURTHER INFORMATION CONTACT: Deborah Perfetto, 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. Both the Patient Safety Act and Patient Safety Rule can be accessed electronically at: *http:// www.PSO.AHRQ.gov/regulations/ regulations.htm.*

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. In August 2008, AHRQ issued the initial release of the formats, Version 0.1 Beta. The second release of the Common Formats, Version 1.0, was announced in the **Federal Register** on September 2, 2009: 74 FR 45457–45458. This release was later replaced by Version 1.1, as announced in the **Federal Register** on March 31, 2010: 75 FR 16140–16142.

Version 1.1 includes updated event descriptions, forms, and technical specifications for software developers.

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. 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.

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.

Common Formats Version 1.1 is currently limited to patient safety reporting for acute care hospitals and is designed to support the first stage in the improvement cycle. Version 1.1 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.

As part of the Agency's efforts to continually refine and update the formats, AHRQ has issued a significant revision of the previously released Common Format—Device or Medical/Surgical Supply. In conjunction with the Food and Drug Administration (FDA) and the Office of the National Coordinator for Health Information Technology (ONC), AHRQ developed the beta version of this event-specific format to capture information about patient safety events that are related to HIT. Subsequently, the format was reviewed and revised by an interagency Federal Patient Safety Work Group (PSWG). The enhanced format, Device or Medical/Surgical Supply including HIT Device, will be incorporated into the next version of the Common Formats (Version 1.2).

This revised format includes a description of patient safety events and unsafe conditions to be reported (event description) and a sample patient safety aggregate report and individual event summary. The Device or Medical/Surgical Supply including HIT Device Common Format is available at the Patient Safety Organization (PSO) Privacy Protection Center (PPC) Web site: *https://www.psoppc.org/web/patientsafety.*

Commenting on Device or Medical/Surgical Supply Including HIT Device Common Format, Version 1.1

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 health care quality, to solicit comments and advice to guide the further refinement of the Common

Formats. The NQF began this process with feedback on AHRQ's 0.1 Beta release of the Common Formats. Based upon the expert panel's feedback, AHRQ, in conjunction with the PSWG, further revised and refined the Common Formats and released Version 1.0.

The review process above was repeated again from September 2009 through February 2010 to further refine Common Formats Version 1.0 and incorporate public comments prior to finalization of the technical specifications for electronic implementation. These revised formats are now available as Version 1.1.

As evidenced by the release of this Device or Medical/Surgical Supply including HIT Device format, 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. Information on how to comment and provide feedback on the Common Formats, Version 1.1 and the Device or Medical/Surgical Supply including HIT Device beta version, is available at the National Quality Forum (NQF) Web site for Common Formats: *http://www.Quality.forum.org/projects/commonformats.aspx.*

Common Formats Development

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 69 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), FDA, the Department of Defense (DOD), and the Department of Veterans Affairs (VA).

Since February 2005, AHRQ has coordinated the PSWG to assist AHRQ with developing and maintaining the Common Formats. The PSWG includes major health agencies within the HHS—CDC, Centers for Medicare & Medicaid Services, FDA, Health Resources and Services Administration, the Indian Health Service, the National Institutes of Health, the National Library of Medicine, ONC, the Office of Public Health and Science, the Substance

Abuse and Mental Health Services Administration—as well as the DoD and the VA.

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 the extent practicable, the Common Formats are also aligned with World Health Organization (WHO) concepts, framework, and definitions contained in their draft International Classification for Patient Safety (ICPS).

The process for updating and refining the formats will continue to be an iterative one. More information on the Common Formats Version 1.1 can be obtained through AHRQ's PSO Web site: *http://www.PSO.AHRQ.qov/index.html.*

Dated: October 12, 2010.

Carolyn M. Clancy,
Director.

[FR Doc. 2010–26667 Filed 10–21–10; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2326–PN]

Medicare and Medicaid Programs; Application by the Joint Commission for Deeming Authority for Psychiatric Hospitals

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed notice.

SUMMARY This proposed notice with comment period acknowledges the receipt of an application from the Joint Commission for recognition as a national accrediting organization for psychiatric hospitals that wish to participate in the Medicare or Medicaid programs. Section 1865(a)(3)(A) of the Social Security Act requires that within 60 days of receipt of an organization's complete application, we publish a notice that identifies the national accrediting body making the request, describes the nature of the request, and provides at least a 30-day public comment period.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on November 22, 2010.

ADDRESSES: In commenting, please refer to file code CMS–2326–PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.