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. 2017–10066 Filed 5–17–17; 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 for Event Reporting—Hospital Version 2.0.

DATES: Ongoing public input.

ADDRESSES: The Common Formats for Event Reporting—Hospital Version 2.0 and the remaining Common Formats can be accessed electronically at the following Web site: *https://www.psoppc.org/psoppc_web/.*

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. 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''—allows for 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 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 standardized reporting formats—using common language and definitions—that AHRQ has developed for reporting safety concerns from a variety of health care settings and throughout the quality improvement cycle. The Common Formats allow health care providers to collect and submit standardized information and facilitate aggregation of comparable data at local, PSO, regional, and national levels. 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 Common 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 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);
- 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 concerns 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 (PSOPPC) for non-identification and data transmission to the Network of Patient Safety Databases.

Common Formats Development

In anticipation of the need for Common Formats, AHRQ began its 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. 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 work 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.

Common Formats for Event Reporting—Hospital Version 2.0

On April 8, 2016, AHRQ announced the availability of the Common Formats for Event Reporting—Hospital Version 2.0 for review and comment in the **Federal Register** (81 FR 20642–20643). At the time of the initial release of the formats, only the event descriptions—which define adverse events of interest in the inpatient hospital setting—were made available. Based on public comment and NQF Expert Panel advice, AHRQ updated the event descriptions and developed additional documentation for the Common Formats for Event Reporting—Hospital Version 2.0, including data element definitions, algorithms, and technical specifications. Beginning with this version, AHRQ will no longer publish aggregate report specifications, which were initially provided for versions 1.0, 1.1, and 1.2 as a local resource for providers, because the report specifications are no longer needed to guide providers regarding aggregating output.

The Common Formats for Event Reporting—Hospital Version 2.0 constitutes a major release of the AHRQ Common Formats and reflects these key changes:

- Data elements are designated as either 'core' or 'supplemental' for reporting purposes;
- Event descriptions for each module are condensed; and
- Module-specific paper forms are eliminated.

The formats have two tiers, or data sets. The first tier, or core data set, contains elements that are collected for submission at the national level to the PSOPPC. The second tier, or supplemental data set, is optional for use at the local level to support additional analyses, and is not required for transmission to the PSOPPC. All documentation for the Common Formats for Event Reporting—Hospital Version 2.0 is posted on 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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: ''*The AHRQ Safety Program for Enhancing Surgical Care and Recovery.*''

DATES: Comments on this notice must be received by July 17, 2017.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at *doris.lefkowitz@AHRQ.hhs.gov.*

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at *doris.lefkowitz@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, AHRQ invites the public to comment on this proposed information collection. The AHRQ Safety Program for Enhancing Surgical Care and Recovery is a quality improvement project that aims to provide technical assistance to hospitals to help them implement evidence-based practices to improve outcomes and prevent complications among patients who undergo surgery. Enhanced recovery pathways are a constellation of preoperative, intraoperative, and postoperative practices that decrease complications and accelerate recovery. A number of studies and meta-analyses have demonstrated successful results. In order to facilitate broader adoption of these evidence-based practices among U.S. hospitals, this AHRQ project will adapt the Comprehensive Unit-based Safety Program (CUSP), which has been demonstrated to be an effective approach to reducing other patient harms, to enhanced recovery after surgery. The approach uses a combination of clinical and cultural (*i.e.,* technical and adaptive) intervention components, which include promoting leadership and frontline staff engagement, close teamwork among surgeons, anesthesia providers, and nurses, as well as enhancing patient communication and engagement. Interested hospitals will voluntarily participate.

This project has the following goals:

- Improve outcomes of surgical patients by disseminating and supporting implementation of evidence-based enhanced recovery practices within the CUSP framework
- Develop a bundle of technical and adaptive interventions and associated tools and educational materials to support implementation
- Provide technical assistance and training to hospitals for implementing enhanced recovery practices
- Assess the adoption, and evaluate the effectiveness of, the intervention among the participating hospitals