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 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.

Dated: January 29, 2014.

Richard Kronick,

AHRQ Director.

[FR Doc. 2014–03482 Filed 2–14–14; 8:45 am]

BILLING CODE 4160–90–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), 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 common definitions and reporting formats (Common Formats) for reporting patient safety events to Patient Safety Organizations (PSOs) and other entities. The purpose of this notice is to announce the availability of a new type of Common Formats for public review and comment—*Common Formats for Surveillance—Hospital.*

DATES: Ongoing public input.

ADDRESSES: The newly released *Common Formats for Surveillance—Hospital*—which includes modules entitled Generic Adverse Event Information, Blood or Blood Product, Delivery-Maternal, Delivery-Neonatal, Device or Medical/Surgical Supply Including Health Information Technology (HIT), Fall, Medications, Pressure Ulcer, Readmissions, Surgery or Anesthesia, Venous Thromboembolism, and Other Outcomes of Interest—can be accessed electronically at the following HHS Web site: *http://www.PSO.AHRQ.gov/index.html*

FOR FURTHER INFORMATION CONTACT: Glenn Egelman, M.D., 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; 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 70731–70814, provide for the formation of 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-24(b)(1)(F)) requires PSOs to collect information from providers in a standardized manner that permits valid comparisons of similar cases among similar providers, to the extent practical and appropriate. As explained in 42 CFR 3.102(b)(1)(iii)(A)(1), one option for a PSO to satisfy this requirement is by certifying that it is using the Secretary's published guidance for common formats and definitions in its collection of information from healthcare providers.

The Patient Safety Act and Patient Safety Rule establish a framework by which doctors, hospitals, skilled nursing facilities, and other healthcare 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/REGULATIONS/REGULATIONS.htm.*

Definition of Common Formats

The term Common Formats refers to the common definitions and reporting formats, specified by AHRQ, that allow healthcare providers to collect and submit standardized information regarding patient safety events. 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 healthcare 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 two settings of care—acute care hospitals and skilled nursing facilities—in order to facilitate standardized data collection. 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.

Until now, Common Formats have been designed to support only traditional event reporting. *Common Formats for Surveillance—Hospital* are designed to provide, through retrospective review of medical records, information that is complementary to that derived from event reporting systems. These formats will facilitate improved detection of events and calculation of adverse event rates in populations reviewed.

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 provides an evidence base that informed construction of the Common Formats. The inventory includes many systems from the private sector, including 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).

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 and 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 event reporting systems from a variety of health care organizations. In collaboration with the PSWG and Federal subject matter experts, AHRQ drafts and releases beta versions of the Common Formats for public review and comment. 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 for patient safety.

Commenting on Common Formats: Common Formats for Surveillance—Hospital

To allow for greater participation by the private sector in the subsequent development of the Common Formats, AHRQ engaged the 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 then convenes an expert panel to review the comments received and provide feedback. Based upon the expert panel's feedback, AHRQ, in conjunction with the PSWG, revises and refines the Common Formats.

The Agency is specifically interested in obtaining feedback from both the private and public sectors to guide the improvement of the formats. Information on how to comment and provide feedback on the *Common Formats for Surveillance—Hospital* is available at: *http://www.Qualityforum.ORG/projects/commonformats.aspx.*

More information about the Common Formats can be obtained through AHRQ's PSO Web site: *http://www.PSO.AHRQ.gov/index.html.*

Dated: February 6, 2014.

Richard Kronick,

Director.

[FR Doc. 2014–03492 Filed 2–14–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0283]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Final Guidance for Industry on Chemistry, Manufacturing, and Controls Postapproval Manufacturing Changes To Be Documented in Annual Reports

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Final Guidance for Industry on Chemistry, Manufacturing, and Controls Postapproval Manufacturing Changes to be Documented in Annual Reports '' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: On November 6, 2013; the Agency submitted a proposed collection of information entitled ''Final Guidance for Industry on Chemistry, Manufacturing, and Controls Postapproval Manufacturing Changes to be Documented in Annual Reports'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0758. The approval expires on January 31, 2017. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: *February 10, 2014.*

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–03350 Filed 2–14–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0795]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Medical Devices; Third Party Review Under the Food and Drug Administration Modernization Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Medical Devices; Third Party Review Under the Food and Drug Administration Modernization Act (FDAMA)'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On December 19, 2013, the Agency submitted a proposed collection of information entitled ''Medical Devices; Third Party Review Under FDAMA'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0375. The approval expires on January 31, 2017. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: February 10, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–03354 Filed 2–14–14; 8:45 am]

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