

helium requirement forecasts, discovers apparent serious discrepancies.

The information is used in administration of certain Federal contracts to ensure contractor compliance with contract clauses. Without the information, the required use of Government helium cannot be monitored and enforced effectively.

B. Annual Reporting Burden

Respondents: 26.

Responses per Respondent: 1.

Total Responses: 26.

Hours Per Response: 1.

Total Burden Hours: 26.

Obtaining Copies of Proposals:

Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (MVCB), 1275 1st Street, NE., Washington, DC 20417, telephone (202) 501-4755. Please cite OMB Control No. 9000-0113, Acquisition of Helium, in all correspondence.

Dated: February 24, 2011.

Millisa Gary,

Acting Director, Office of Governmentwide Acquisition Policy.

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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—new 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 new beta version of the Common Format for Skilled Nursing Facilities for public review and comment.

DATES: Ongoing public input.

ADDRESSES: The new beta version of the Ski/led Nursing Facilities format (version dated February 2011) and the remaining Common Formats, 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; ITY (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, skilled nursing facilities, 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, including any relevant guidance, 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, developed for acute care hospitals. 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. As an update to this release, AHRQ developed the beta version of an event-specific format—Device or Supply, including Health Information Technology—to capture information about patient safety events that are related to health information technology. This update was announced in the **Federal Register** on October 22, 2010: 75 FR 65359-65360. With the release of the beta version of the Skilled Nursing Facilities format, AHRQ has made available Common Formats for two settings of care—acute care hospitals and skilled nursing facilities.

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 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 health care providers to report information that is standardized both clinically and electronically.

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.

The Common Formats include 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 skilled nursing facilities event-specific formats are: Device or Supply, including Health Information Technology; Fall; Healthcare-Associated Infection; Medication or Other Substance; and Pressure Ulcer.

This new 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 in skilled nursing facilities. The Skilled Nursing Facilities Common Format is available at the PSO Privacy Protection Center (PPC) Web site: <https://www.psoppc.org/web/patientsafety>.

Commenting on Skilled Nursing Facilities Common Format

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. The latest version of the formats is Version 1.1.

The Agency is specifically interested in obtaining feedback from both the private and public sectors on this new format for skilled nursing facilities to guide their improvement. Information on how to comment and provide feedback on the Common Formats, the Skilled Nursing Facilities 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), the Food and Drug Administration (FDA), the Department of Defense (DoD), and the Department of Veterans Affairs (VA).

Since February 2005, AHRQ has coordinated 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 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, Office of the National Coordinator for Health Information Technology (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. When developing Common Formats, AHRQ first reviews existing patient safety event reporting systems from a variety of health care organizations. Working with the PSWG and Federal subject matter experts, AHRQ drafts and releases beta versions of the Common Formats for public review and comment. 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. Future versions of the Common Formats will be developed for ambulatory settings, such as ambulatory surgery centers and physician and practitioner offices. More information on the Common Formats can be obtained through AHRQ's PSO Web site: <http://www.PSO.AHRQ.gov/index.html>.

Dated: February 23, 2011.

Carolyn M. Clancy,

Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-11-0770]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639-5960 or send an e-mail to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

National HIV Behavioral Surveillance System (NHBS)—0920-0770 exp. 03/31/2011—Revision-National Center for HIV, Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The purpose of this data collection is to monitor behaviors related to human immunodeficiency virus (HIV) infection among persons at high risk for infection in the United States. The primary objectives of NHBS are to obtain data from samples of persons at risk to: (a) Describe the prevalence and trends in risk behaviors; (b) describe the prevalence of and trends in HIV testing and HIV infection; (c) describe the prevalence of and trends in use of HIV prevention services; (d) identify met and unmet needs for HIV prevention services in order to inform health departments, community-based organizations, community planning groups and other stakeholders. This project addresses the goals of CDC's HIV prevention strategic plan, specifically the goal of strengthening the national capacity to monitor the HIV epidemic to better direct and evaluate prevention efforts.

For the proposed data collection, CDC has revised the interview data collection instruments. A few questions were added (related to health care access and utilization, use of pre-exposure prophylaxis, homophobia, HIV stigma, and discrimination), some were removed, and others were revised from the previously approved instrument to make them easier for respondents to