

A. Purpose

The U.S. Government conducts criminal checks to establish that applicants or incumbents working for the Government under contract may have unescorted access to federally controlled facilities. GSA uses the Contractor Information Worksheet; GSA Form 850, and digitally captured fingerprints to conduct a FBI National Criminal Information Check (NCIC) for each contractor's physical access determination to GSA-controlled facilities and/or logical access to GSA-controlled information systems. Manual fingerprint card SF-87 is used for exception cases such as contractor's significant geographical distance from fingerprint enrollment sites.

The Office of Management and Budget (OMB) Guidance M-05-24 for Homeland Security Presidential Directive (HSPD) 12, authorizes Federal departments and agencies to ensure that contractors have limited/controlled access to facilities and information systems. GSA Directive CIO P 2181.1 Homeland Security Presidential Directive-12, Personal Identity Verification and Credentialing (available at <http://www.gsa.gov/hspd12>), states that GSA contractors must undergo a minimum of an FBI National Criminal Information Check (NCIC) to receive unescorted physical access to GSA-controlled facilities and/or logical access to GSA-controlled information systems.

Contractors' Social Security Number is needed to keep records accurate, because other people may have the same name and birth date. Executive Order 9397, Numbering System for Federal Accounts Relating to Individual Persons, also allows Federal agencies to use this number to help identify individuals in agency records.

B. Annual Reporting Burden

Respondents: 25,000.

Responses per Respondent: 1.

Total Annual Responses: 25,000.

Hours per Response: .25.

Total Burden Hours: 6,250.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected.

Obtaining Copies of Proposals: Requesters may obtain a copy of the

information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405, telephone 202-501-4755. Please cite OMB Control No. 3090-0283, Contractor Information Worksheet; GSA Form 850 in all correspondence. The form can be downloaded from the GSA Forms Library at <http://www.gsa.gov/forms>. Type GSA 850 in the form search field.

Dated: March 31, 2016.

David A. Shive,

Chief Information Officer.

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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: "Hospital Survey on Patient Safety Culture Comparative Database." In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501-3521, AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by June 7, 2016.

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

Hospital Survey on Patient Safety Culture Comparative Database

In 1999, the Institute of Medicine called for health care organizations to

develop a "culture of safety" such that their workforce and processes focus on improving the reliability and safety of care for patients (IOM, 1999; *To Err is Human: Building a Safer Health System*). To respond to the need for tools to assess patient safety culture in health care, AHRQ developed and pilot tested the Hospital Survey on Patient Safety Culture with OMB approval (OMB NO. 0935-0115; Approved 2/4/2003).

The survey is designed to enable hospitals to assess staff opinions about patient safety issues, medical errors, and error reporting. The survey includes 42 items that measure 12 composites of patient safety culture. AHRQ made the survey publicly available along with a Survey User's Guide and other toolkit materials in November 2004 on the AHRQ Web site (located at <http://www.ahrq.gov/professionals/quality-patient-safety/patientsafetyculture/hospital/index.html>). Since its release, the survey has been voluntarily used by hundreds of hospitals in the U.S.

The Hospital SOPS Comparative Database consists of data from the AHRQ Hospital Survey on Patient Safety Culture. Hospitals in the U.S. are asked to voluntarily submit data from the survey to AHRQ, through its contractor, Westat. The Hospital SOPS Database (OMB NO. 0935-0162, last approved on September 26, 2013) was developed by AHRQ in 2006 in response to requests from hospitals interested in knowing how their patient safety culture survey results compare to those of other hospitals in their efforts to improve patient safety.

Rationale for the information collection. The Hospital SOPS and the Comparative Database support AHRQ's goals of promoting improvements in the quality and safety of health care in hospital settings. The survey, toolkit materials, and comparative database results are all made publicly available on AHRQ's Web site. Technical assistance is provided by AHRQ through its contractor at no charge to hospitals, to facilitate the use of these materials for hospital patient safety and quality improvement.

Request for information collection approval. AHRQ requests that the Office of Management and Budget (OMB) reapprove, under the Paperwork Reduction Act of 1995, AHRQ's collection of information for the AHRQ Hospital Survey on Patient Safety Culture (Hospital SOPS) Comparative Database; OMB NO. 0935-0162, last approved on September 26, 2013.

This database will:

(1) Allow hospitals to compare their patient safety culture survey results with those of other hospitals,

(2) provide data to hospitals to facilitate internal assessment and learning in the patient safety improvement process, and

(3) provide supplemental information to help hospitals identify their strengths and areas with potential for improvement in patient safety culture.

This study is being conducted by AHRQ through its contractor, Westat, pursuant to AHRQ's statutory authority to conduct and support research on health care and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of health care services and with respect to quality measurement and improvement. 42 U.S.C. 299a(a)(1) and (2).

Method of Collection

To achieve the goal of this project the following activities and data collections will be implemented:

(1) Eligibility and Registration Form—The hospital point-of-contact (POC) completes a number of data submission steps and forms, beginning with the completion of an online eligibility and registration form. The purpose of this form is to determine the eligibility status and initiate the registration process for hospitals seeking to voluntarily submit their Hospital SOPS data to the Hospital SOPS Comparative Database.

(2) Data Use Agreement—The purpose of the data use agreement, completed by the hospital POC, is to state how data submitted by hospitals will be used and provides confidentiality assurances.

(3) Hospital Site Information Form—The purpose of the site information form is to obtain basic information about the characteristics of the hospitals submitting their Hospital SOPS data to the Hospital SOPS Comparative Database (e.g. number of providers and staff, ownership, and teaching status). The hospital POC completes the form.

(4) Data Files Submission—The number of submissions to the database is likely to vary each year because

hospitals do not administer the survey and submit data every year. Data submission is typically handled by one POC who is either a manager or a survey vendor who contracts with a hospital to collect its data. POCs submit data on behalf of 3 hospitals, on average, because many hospitals are part of a health system that includes many hospitals, or the POC is a vendor that is submitting data for multiple hospitals.

Survey data from the AHRQ Hospital Survey on Patient Safety Culture is used to produce three types of products: (1) A Hospital SOPS Comparative Database Report that is produced periodically and made publicly available on the AHRQ Web site (see <http://www.ahrq.gov/professionals/quality-patient-safety/patientsafetyculture/hospital/hosp-reports.html>); (2) Individual Hospital Survey Feedback Reports which are confidential, customized reports produced for each hospital that submits data to the database (the number of reports produced is based on the number of hospitals submitting each year); and (3) Research data sets of individual-level and hospital-level de-identified data to enable researchers to conduct analyses.

Hospitals are asked to voluntarily submit their Hospital SOPS survey data to the comparative database. The data are then cleaned and aggregated and used to produce a Comparative Database Report that displays averages, standard deviations, and percentile scores on the survey's 42 items and 12 composites of patient safety culture, as well as displaying these results by hospital characteristics (bed size, teaching status, ownership) and respondent characteristics (hospital work area, staff position, and those with direct interaction with patients). In addition, trend data, showing changes in scores over time, are presented from hospitals that have submitted to the database more than once.

Data submitted by hospitals are used to give each hospital its own customized survey feedback report that presents the hospital's results compared to the latest comparative database results. If the hospital submits data in two

consecutive database submission years, its survey feedback report also presents trend data, comparing its previous and most recent data.

Hospitals use the Hospital SOPS, Comparative Database Reports and Individual Hospital Survey Feedback Reports for a number of purposes, to:

- Raise staff awareness about patient safety.
- Diagnose and assess the current status of patient safety culture in their hospital.
- Identify strengths and areas for improvement in patient safety culture.
- Examine trends in patient safety culture change over time.
- Evaluate the cultural impact of patient safety initiatives and interventions.
- Facilitate meeting Joint Commission hospital accreditation standards in Leadership that require a regular assessment of hospital patient safety culture.
- Compare patient safety culture survey results with other hospitals in their efforts to improve patient safety and quality.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondents' time to participate in the database. An estimated 304 POCs, each representing an average of 3 individual hospitals each, will complete the database submission steps and forms annually. The POCs typically submit data on behalf of 3 hospitals, on average, because many hospitals are part of a multi-hospital system that is submitting data, or the POC is a vendor that is submitting data for multiple hospitals. Completing the registration form will take about 3 minutes. The Hospital Information Form is completed by all POCs for each of their hospitals (304 × 3 = 912). The total annual burden hours are estimated to be 410.

Exhibit 2 shows the estimated annualized cost burden based on the respondents' time to submit their data. The cost burden is estimated to be \$21,801 annually.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents/ POCs	Number of responses per POC	Hours per response	Total burden hours
Eligibility/Registration Form	304	1	3/60	15
Data Use Agreement	304	1	3/60	15
Hospital Information Form	304	3	5/60	76
Data Files Submission	304	1	1	304
Total	1,216	NA	NA	410

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form Name	Number of respondents/ POCs	Total burden hours	Average hourly wage rate*	Total cost burden
Eligibility/Registration Form	304	15	\$53.17	\$798
Data Use Agreement	304	15	53.17	798
Hospital Information Form	304	76	53.17	4,041
Data Files Submission	304	304	53.17	16,164
Total	1,216	410	NA	21,801

* 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 2014 National Industry-Specific Occupational Employment and Wage Estimates NAICS 622000—Hospitals, located at http://www.bls.gov/oes/current/naics3_622000.htm. Wage rate of \$53.17 is based on the mean hourly wages for Medical and Health Services Managers (11–9111).

Request for Comments

In accordance with the Paperwork Reduction Act, 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.

Sharon B. Arnold,
Acting Director.

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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 availability of new formats for public review and comment, Common Formats for Event Reporting for Hospitals Version 2.0.

DATES: May 9, 2016.

ADDRESSES: The Common Formats for Event Reporting for Hospitals Version 2.0, and the remaining Common Formats, can be accessed electronically at the following HHS Web site: <http://www.pso.ahrq.gov/common/>.

FOR FURTHER INFORMATION CONTACT: Cathryn Bach, Center for Quality Improvement and Patient Safety, AHRQ, 5600 Fishers Lane, 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. The collection of patient safety work product allows the aggregation of data that help to identify and address underlying causal factors of patient quality and safety problems.

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—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/legislation/>.

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 quality and safety to PSOs and other entities. 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 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, nursing homes, and retail 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