# SUPPORTING STATEMENT

## Part A

# Hospital Survey on Patient Safety Culture Comparative Database

**June 22, 2016**

Agency of Healthcare Research and Quality (AHRQ)

## Table of contents

A. Justification..... 3
1. Circumstances that make the collection of information necessary.....3
2. Purpose and Use of Information.....5
3. Use of Improved Information Technology.....6
4. Efforts to Identify Duplication.....6
5. Involvement of Small Entities.....6
6. Consequences if Information Collected Less Frequently.....6
7. Special Circumstances.....6
8. Federal Register Notice and Outside Consultations.....6
8.b. Outside Consultations.....7
9. Payments/Gifts to Respondents.....7
10. Assurance of Confidentiality.....8
11. Questions of a Sensitive Nature.....8
12. Estimates of Annualized Burden Hours and Costs.....8
13. Estimates of Annualized Respondent Capital and Maintenance Costs.....9
14. Estimates of Annualized Cost to the Government.....9
15. Changes in Hour Burden.....9
16. Time Schedule, Publication and Analysis Plans.....10
17. Exemption for Display of Expiration Date.....10

## A. Justification

### *1. Circumstances that make the collection of information necessary*

**AHRQ's mission.** The mission of the Agency for Healthcare Research and Quality (AHRQ) set out in its authorizing legislation, The Healthcare Research and Quality Act of 1999 (see http://www.ahrq.gov/hrqa99.pdf), is to enhance the quality, appropriateness, and effectiveness of health services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical and health systems practices, including the prevention of diseases and other health conditions. AHRQ shall promote health care quality improvement by conducting and supporting:

1. research that develops and presents scientific evidence regarding all aspects of health care; and

2. the synthesis and dissemination of available scientific evidence for use by patients, consumers, practitioners, providers, purchasers, policy makers, and educators; and

3. initiatives to advance private and public efforts to improve health care quality.

Also, AHRQ shall conduct and support research and evaluations, and support demonstration projects, with respect to (A) the delivery of health care in inner-city areas, and in rural areas (including frontier areas); and (B) health care for priority populations, which shall include (1) low-income groups, (2) minority groups, (3) women, (4) children, (5) the elderly, and (6) individuals with special health care needs, including individuals with disabilities and individuals who need chronic care or end-of-life health care.

**Background on the Hospital SOPS**. 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 error, 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.** The Agency for Healthcare Research and Quality (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.

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 (see Attachment A). 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 (see Attachment B).

3) **Hospital Site Information Form** – The purpose of the site information form (see Attachment C) 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 patient safety manager in the hospital or a survey vendor who contracts with a hospital to collect and submit their 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.

This study is being conducted by AHRQ through its contractor, Westat, pursuant to AHRQ's statutory authority to conduct and support research on healthcare and on systems for the delivery of such care, including activities with respect to: the quality, effectiveness, efficiency, appropriateness and value of healthcare services; quality measurement and improvement; and database development. 42 U.S.C. 299a(a)(1) (2), and (8).

### *2. Purpose and Use of Information*

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 that 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, their survey feedback report also presents trend data, comparing their 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.

### *3. Use of Improved Information Technology*

All information collection for the Hospital SOPS Comparative Database is done electronically, except the Data Use Agreement (DUA) that hospitals sign in hard copy and fax, scan and email, or mail back. Registration, submission of hospital information, and data upload is handled online through a secure web site. Delivery of confidential hospital survey feedback reports is also done electronically by having submitters enter a username and password and downloading their reports from a secure web site. In the future, AHRQ may produce the Hospital SOPS Comparative Database Report as an online, interactive tool similar to the online interactive reporting system that the Consumer Assessment of Healthcare Providers and Systems (CAHPS) has recently developed for the CAHPS Database.

### *4. Efforts to Identify Duplication*

While there are survey vendors that administer the AHRQ Hospital Survey on Patient Safety Culture and hospital systems that may maintain a small database of data on the survey, AHRQ is the only entity that serves as a central U.S. repository for data on the survey and AHRQ houses the largest database of the survey's results.

### *5. Involvement of Small Entities*

The collection of information associated with data submission does not unduly burden small businesses or small hospitals. The information being requested has been held to the absolute minimum required for the intended uses. In addition, AHRQ has produced toolkit materials to make it easy for small and large hospitals to administer the survey and analyze and report their results.

### *6. Consequences if Information Collected Less Frequently*

Hospitals administer the AHRQ Hospital SOPS on average every 23 months. Because hospitals administer the survey voluntarily, on their own schedule, most hospitals would only submit their data once every two years (depending on their survey administration schedule), and greater frequency may not be immediately feasible. Hospital data submission will be available in June 2017.

### *7. Special Circumstances*

This request is consistent with the general information collection guidelines of 5 CFR 1320.5(d)(2). No special circumstances apply.

### *8. Federal Register Notice and Outside Consultations*

### *8.a. Federal Register Notice*

As required by 5 CFR 1320.8(d), notice was published in the Federal Register on April 8, 2016 for 60 days.

### *8.b. Outside Consultations*

AHRQ has convened five external Technical Expert Panels (TEPs) to provide expertise and guidance to the development, functioning, and expansion of the SOPS Comparative Databases. The first TEP was convened on January 27, 2006 in Rockville, MD, and was comprised of 13

individuals who provided guidance on the strategy and plan for the initial hospital comparative database, including key components of the database: data submission process; data submission eligibility criteria; data submission timeline; calculation of comparative data; and access to and reporting format of comparative data.

The second TEP was convened on December 3, 2008 in Scottsdale, AZ and was comprised 14 individuals with expertise for each of four different settings: hospital, medical office, nursing home, and international. The experts provided guidance on issues such as 1) number of years to include in the rolling comparative database; 2) minimum N of facilities to produce overall comparative data; 3) minimum number of respondents to produce facility-level comparative data; 4) trending criteria; 5) comparative database reports for submitters to the database; and 6) international user issues. The TEP also provided input on the development of new databases for the medical office and nursing home patient safety culture surveys recently developed by AHRQ.

The third TEP was convened on April 19, 2010 in Baltimore, MD and was comprised of 15 individuals with expertise for each of five different settings: hospital, medical office, nursing home, international, and U.S. Department of Defense. The experts provided guidance on numerous issues, including the cycle for producing Hospital SOPS comparative database reports and developing processes for fulfilling requests from researchers for deidentified and identifiable research datasets.

The fourth TEP was convened virtually on October 21, 2013 and again on March 19, 2014 and was comprised of 16 individuals with expertise for each of six different settings: hospital, medical office, nursing home, community pharmacy, international, and U.S. Department of Defense. The experts provided guidance on the timing of the safety culture databases and Hospital SOPS version 2.0.

The fifth TEP was convened virtually on August 6, 2015 and was comprised of 19 individuals with expertise for each of six different settings: hospital, medical office, nursing home, community pharmacy, international and U.S. Department of Defense (see Attachment F). The experts provided guidance on Hospital SOPS version 2.0 and the Health Information Technology Supplemental Item Set.

### *9. Payments/Gifts to Respondents*

No payment or remuneration is provided to hospitals for submitting data to the comparative database.

### *10. Assurance of Confidentiality*

Individuals and organizations will be assured of the confidentiality of their replies under Section 944(c) of the Public Health Service Act, 42 USC 299c-3(c). That law requires that information collected for research conducted or supported by AHRQ that identifies individuals or establishments be used only for the purpose for which it was supplied.

**Confidentiality of the Point of Contact for a Hospital.** The hospital POC, who submits data on behalf of a hospital, is asked to provide his/her name, phone number, and email address during the data submission process to ensure that the hospital's individual survey feedback report is delivered to that person for use by the hospital. In addition, the POC's contact information is

important when any clarifications or corrections of the submitted data set are required and follow up is needed. However, the name of the hospital POC and name of the hospital is kept confidential and not reported. Only aggregated, de-identified results are displayed in any reports.

**Confidentiality of the Survey Data Submitted by a Hospital.** Hospitals are assured of the confidentiality of their hospital patient safety culture survey data through a Data Use Agreement (DUA) that they must sign that has been approved by AHRQ's general counsel (see Attachment B). The DUA states that their data will be handled in a secure manner using necessary administrative, technical and physical safeguards to limit access to it and maintain its confidentiality. In addition, the DUA states the data will be used for the purposes of the database, that only aggregated results will be reported, and that the hospital is not be identified by name.

### *11. Questions of a Sensitive Nature*

There are no questions of a sensitive nature.

### *12. Estimates of Annualized Burden Hours and Costs*

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 and data submission takes about 1 hour (1.05 hours total). The Hospital Information Form is completed by all POCs for each of their hospitals (304 x 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 and Data Submission | 304 | 1 | 1.05 | 319 |
| Data Use Agreement | 304 | 1 | 3/60 | 15 |
| Hospital Information Form | 304 | 3 | 5/60 | 76 |
| Total | 912 | 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 and Data Submission | 304 | 319 | $53.17 | $16,961 |
| Data Use Agreement | 304 | 15 | $53.17 | $798 |
| Hospital Information Form | 304 | 76 | $53.17 | $4,041 |

| | | | | |
|---|---|---|---|---|
| Total | 912 | 410 | NA | $21,800 |

*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).

### *13. Estimates of Annualized Respondent Capital and Maintenance Costs*

Capital and maintenance costs include the purchase of equipment, computers or computer software or services, or storage facilities for records, as a result of complying with this data collection. There are no direct costs to respondents other than their time to participate in the study.

### *14. Estimates of Annualized Cost to the Government*

Exhibit 3 shows the estimated annualized cost to the government for developing, maintaining, and managing the database and analyzing the data and producing reports for each year in which data are collected. The cost is estimated to be $180,000 each data submission year.

**Exhibit 3. Estimated Annualized Cost**

| Cost Component | Annualized Cost |
|---|---|
| Database Development and Maintenance | $30,000 |
| Data Submission | $50,000 |
| Data Analysis & Reports | $100,000 |
| **Total** | $180,000 |

**Exhibit 4: Estimated Annual cost to AHRQ for project oversight**

| | | |
|---|---|---|
| Project Officer GS- 15 Step 5 | 5% | $7,258 |
| Health Scientist Administrator GS 13 Step 5 | 5% | $5,226 |
| Program Specialist GS 12, Step 5 | 5% | $4,391 |
| Total | | $16,875 |

https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2016/DCB.pdf

### *15. Changes in Hour Burden*

The estimated hour burden for data file submission decreased from 5.5 hours in the previous information collection request (ICR) to 1 hour in this ICR. As a result, the total burden hours

have decreased from 1,793 to 410, a decrease of 1,383 hours. These decreases are due to efficiencies and improvements made in the data submission system.

### *16. Time Schedule, Publication and Analysis Plans*

Information for the Hospital SOPS database is collected by AHRQ through its contractor, Westat, since 2006. Hospitals are asked to voluntarily submit their Hospital SOPS survey data to the comparative database approximately every other year between June 1 and June 15. The data are then cleaned and aggregated and used to produce a Comparative Database Report that is published in a limited number of hard copies and also posted on the AHRQ web site. Hospitals are also automatically provided with their own customized survey feedback report.

### *17. Exemption for Display of Expiration Date*

AHRQ does not seek this exemption.

### List of Attachments:

| | |
|---|---|
| Attachment A: | Hospital Eligibility and Registration Form |
| Attachment B: | Hospital Data Use Agreement |
| Attachment C: | Hospital Site Information Form |
| Attachment D: | Hospital Data Submission Emails |
| Attachment E: | Hospital Survey Data File Specifications |
| Attachment F: | SOPS Databases TEP List |
| Attachment G: | Example Screen Shots of Hospital SOPS Data Submission Web Site |
| Attachment H: | Federal Register Notice |