SUPPORTING STATEMENT

Part A

Collection of Information for
Agency for Healthcare Research and Quality's (AHRQ)
Hospital Survey on Patient Safety Culture Comparative Database

Version April 30, 2013

Agency of Healthcare Research and Quality (AHRQ)

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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.

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 May 5th, 2010. 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 database 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.

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 was designed to enable hospitals to assess staff opinions about patient safety issues, medical error, and error reporting and includes 42 items that measure 12 dimensions of patient safety culture. AHRQ released the

survey in the public domain along with a Survey User's Guide and other toolkit materials in November 2004 on the AHRQ web site. Since its release, the survey has been voluntarily used by hundreds of hospitals in the U.S.

Rationale for the information collection. The Hospital SOPS survey and the Hospital SOPS Comparative Database are supported by AHRQ to meet its goals of promoting improvements in the quality and safety of health care in hospital settings. The surveys, toolkit materials, and comparative database results are all made available to the public along with technical assistance, 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.

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 made publically available on the AHRQ web site; 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, but has ranged from 227 to 620 reports); and 3) Research data sets of individual-level and hospital-level de-identified data to enable researchers to conduct analyses.

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 between June 1 and June 15. 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 patient safety culture dimensions, 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.

AHRQ has produced annual Comparative Database Reports from 2007 through 2012. The latest AHRQ Hospital Survey on Patient Safety Culture Comparative Database Report for 2012 was based on data from 1,128 hospitals and 567,703hospital staff respondents. A copy of the 2012 report is included in Attachment A with the appendixes to the report in Attachment B (containing overall and trending results by hospital and respondent characteristics). The 2012 report (Part 1) and its appendixes (Part 2) can also be viewed on the AHRQ legacy web site at http://www.ahrq.gov/legacy/qual/hospsurvey12/ or requested in hard copy for free through AHRQ's publications clearinghouse (AHRQ publication number12-0017).

Data submitted by hospitals is also 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 more than once, their survey feedback report also presents trend data, comparing their previous and most recent data. A sample Individual Hospital Survey Feedback Report with trending is shown in Attachment C.

Hospitals use the Hospital SOPS Survey, 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 patient safety culture improvement.
- 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 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 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 survey on average every 20 months. Therefore, data submission will be available every two years beginning in 2015.

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 May 16th, 2013 for 60 days, and again on July 31st, 2013 for 30 days (see Attachment D). No comments were received.

8.b. Outside Consultations

AHRQ has convened three external Technical Expert Panels (TEPs) to provide expertise and guidance to the development, functioning, and expansion of the Hospital SOPS Comparative Database. The first TEP was convened on January 27, 2006 in Rockville, MD, and was comprised of 13 individuals (see Attachment E) 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 of 14 individuals (see Attachment E), with experts 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 (see Attachment E), with experts 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.

AHRQ plans to convene a fourth TEP virtually in 2013 or 2014 with membership to be determined but including members from all previous settings and adding members for the pharmacy setting.

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 point-of-contact, 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 point-of-contact'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 point-of-contact 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 F). 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 will 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

Hospitals administer the AHRQ Hospital Survey on Patient Safety Culture every 20 months on average. Therefore, the number of hospital submissions to the database varies because hospitals do not submit data every year. Data submission is typically handled by one point-of-contact (POC) who is either a hospital patient safety manager or a survey vendor. The POC completes a number of data submission steps and forms, beginning with completion of an online Eligibility and Registration Form (see Attachment G). 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. Exhibits 1 and 2 are based on an estimated 304 individual POCs who will complete the database submission steps and forms in the coming years, not based on the number of "hospitals." The Hospital Information Form (see Attachment H) is completed by all POCs for each of their hospitals. The total annual burden hours are estimated to be 1,793.

Exhibit 2 shows the estimated annualized cost burden based on the respondents' time to submit their data. The cost burden is estimated to be $91,297 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	5.6	1,702
Data Use Agreement	304	1	3/60	15
Hospital Information Form	304	3	5/60	76
Total	912	NA	NA	1,793

*The Eligibility and Registration Form requires 3 minutes to complete; however about 5.5 hours is required to prepare/plan for the data submission. This includes the amount of time POCs and other hospital staff (CEO, lawyer,

database administrator) typically spend deciding whether to participate in the database and preparing their materials and data set for submission to the database, and performing the submission.

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	1,702	$50.95	$86,717
Data Use Agreement	304	15	50.33	755
Hospital Information Form	304	76	50.33	3,825
Total	912	1,793	NA	$91,297

*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 2012 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 $50.33 is based on the mean hourly wages for Medical and Health Services Managers (11-9111). Wage rate of $50.95 is the weighted mean hourly wage for: Medical and Health Services Managers (11-9111;$50.33 x 2.6 hours = $130.86), Lawyers (23-1011; $72.71 x .5 hours =$36.36), Chief Executives (11-1011($95.36 x .5 hours = $47.68), and Database Administrators (15-1141; $35.20 x 2 hours = $70.40) [Weighted mean = ($130.86 + 36.36 + 47.68 + 70.40)/5.6 hours = $285.30/5.6 hours = $50.95/hour].

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 $150,000 each data submission year.

Exhibit 3. Estimated Annualized Cost

Cost Component	Annualized Cost
Database Development and Maintenance	$30,000
Data Submission	$45,000
Data Analysis & Reports	$75,000
Total	$150,000

15. Changes in Hour Burden

Although the Patient Safety Improvement Initiatives Form has been eliminated, the total estimated number of respondents has been increased from 875 in the previous information collection request (ICR) to 912 in this ICR. The total burden hours have also increased from 1,508 to 1,793, an increase of 285 hours. These increases are due to an anticipated increase in the number of submissions.

16. Time Schedule, Publication and Analysis Plans

Information for the Hospital SOPS database is collected by AHRQ through its contractor, Westat, on an annual basis since 2006 but is planned to continue every two years beginning in 2015. Hospitals are asked to voluntarily submit their Hospital SOPS survey data to the comparative database 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 during the first quarter of each year (Comparative Reports from 2007 through 2012 are available at www.ahrq.gov/legacy/qual/patientsafetyculture/hospsurvindex.htm). Hospitals are also 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 -- 2012 User Comparative Database Report, Part 1
Attachment B -- 2012 User Comparative Database Report, Parts 2 & 3
Attachment C -- Sample Individual Hospital Survey Feedback Report with Trending
Attachment D -- Federal Register Notice
Attachment E -- TEP List
Attachment F -- Data Use Agreement
Attachment G -- Eligibility and Registration Form
Attachment H -- Hospital Information Form
Attachment I -- Emails for Hospital SOPS Data Submission
Attachment J -- Screen shots of Hospital SOPS Data Submission Web Site Information Collection Forms
Attachment K -- Hospital SOPS Survey Data File Specifications