SUPPORTING STATEMENT

Part A

Medical Office Survey on Patient Safety Culture Comparative Database

Version February 8th, 2012

Agency of Healthcare Research and Quality (AHRQ)

Table of Contents

A. Justification....2
1. Circumstances that make the collection of information necessary....2
2. Purpose and Use of Information....4
3. Use of Improved Information Technology....5
4. Efforts to Identify Duplication....5
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
9. Payments/Gifts to Respondents....7
10. Assurance of Confidentiality....7
11. Questions of a Sensitive Nature....7
12. Estimates of Annualized Burden Hours and Costs....7
13. Estimates of Annualized Respondent Capital and Maintenance Costs....8
14. Estimates of Annualized Cost to the Government....9
15. Changes in Hour Burden....9
16. Time Schedule, Publication and Analysis Plans....9
17. Exemption for Display of Expiration Date....9
List of Attachments....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.

Request for information collection approval. The Agency for Healthcare Research and Quality (AHRQ) requests that the Office of Management and Budget (OMB) approve, under the Paperwork Reduction Act of 1995, AHRQ's collection of information for the AHRQ Medical Office Survey on Patient Safety Culture (Medical Office SOPS) Comparative Database. The Medical Office SOPS Comparative Database consists of data from the AHRQ Medical Office Survey on Patient Safety Culture. Medical offices in the U.S. are asked to voluntarily submit data from the survey to AHRQ, through its contractor, Westat. The Medical Office SOPS Database is modeled after the Hospital SOPS Database [OMB NO. 0935-0162; approved 05/04/2010] that was originally 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.

This information collection is part of a larger program of comparative databases that AHRQ supports for the CAHPS program, which includes a comparative database for the CAHPS Health Plan Survey and the Clinician and Group Survey. AHRQ also supports comparative databases on the Surveys on Patient Safety Culture, with comparative databases for the hospital, nursing home, and medical office surveys. All of these databases report similar types of statistics with the overall goal of making comparative information on these surveys available to survey users to facilitate quality and patient safety improvement.

Background on the Medical Office 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 outpatient ambulatory health care, AHRQ developed and pilot tested the Medical Office Survey on Patient Safety Culture with OMB approval (OMB NO.0935-0131; Approved July 5, 2007). The Medical Office Survey on Patient Safety Culture questionnaire is included as Attachment A.

The survey is designed to enable medical offices to assess provider and staff opinions about patient safety issues, medical error, and error reporting and includes 52 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 December 2008 on the AHRQ Web site (located at http://www.ahrq.gov/qual/patientsafetyculture/mosurvindex.htm). Since its release, the survey has been voluntarily used by hundreds of medical offices in the U.S.

Rationale for the information collection. The Medical Office SOPS and the Comparative Database are supported by AHRQ to meet its goals of promoting improvements in the quality and safety of health care in medical office settings. The survey, toolkit materials, and preliminary comparative database results are all made available in the public domain along with technical assistance provided by AHRQ through its contractor at no charge to medical offices, to facilitate the use of these materials for medical office patient safety and quality improvement.

The goal of this project is to create the Medical Office SOPS Comparative Database. This database will 1) allow medical offices to compare their patient safety culture survey results with those of other medical offices; 2) provide data to medical offices to facilitate internal assessment and learning in the patient safety improvement process; and 3) provide supplemental information to help medical offices identify their strengths and areas with potential for improvement in patient safety culture. De-identified data files will also be available to researchers conducting patient safety data analysis. The database will include 52 items that measure 12 areas, or composites, of patient safety culture:

1. Communication About Error
2. Communication Openness
3. Information Exchange With Other Settings
4. Office Processes and Standardization
5. Organizational Learning
6. Overall Perceptions of Patient Safety and Quality
7. Owner/Managing Partner/Leadership Support for Patient Safety
8. Patient Care Tracking/Followup
9. Patient Safety and Quality Issues
10. Staff Training
11. Teamwork
12. Work Pressure and Pace

The database will also include medical office staff's ratings of 5 areas of health care quality (patient-centeredness, effectiveness, timeliness, efficiency, and equity) and of patient safety overall in their medical office.

Medical offices that submit to the database receive reports that display their results compared to aggregate-level database results. The database does not provide the capability for them to compare their results to specific other individual medical offices. The report presents aggregate-level frequencies, means, standard deviations, minimum and maximum scores, and percentile scores.

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

1) Eligibility Form – The purpose of this form is to determine the eligibility status and initiate the registration process for medical offices seeking to voluntarily submit their MO SOPS data to the MO SOPS Comparative Database. The medical office point of contact (POC) will complete the form (see Attachment B). The POC is either an office manager, nurse manager, or a survey vendor who contracts with a medical office to collect their data. The POC may submit data on behalf of multiple medical offices because many medical offices are part of a larger practice with multiple sites or part of a larger health system that includes many medical office sites.

2) Data Use Agreement – The purpose of this form is to obtain authorization from medical offices to use their voluntarily submitted MO SOPS data for analysis and reporting according to the terms specified in the Data Use Agreement (DUA). The medical office POC will complete the form (see Attachment C).

3) Medical Office Information Form – The purpose of this form is to obtain basic information about the characteristics of the medical offices submitting their MO SOPS data to the MO SOPS Comparative Database (e.g. number of providers and staff, ownership, and type of specialty). The medical office POC will complete the form (see Attachment D).

4) Data Submission – After the medical office POC has completed the Medical Office Eligibility Form, the Data Use Agreement and the Medical Office Information Form, they will submit their data from the MO SOPS to the MO SOPS Comparative Database.

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 and with respect to quality measurement and improvement. 42 U.S.C. 299a(a)(1) and (2), and (a)(8).

2. Purpose and Use of Information

Data from the AHRQ Medical Office Survey on Patient Safety Culture are used to produce three types of products: 1) A Medical Office SOPS Comparative Database Report that is produced periodically and made available in the public domain on the AHRQ Web site (see http://www.ahrq.gov/qual/mosurvey10/moresults10.htm); 2) Medical Office Survey Feedback Reports that are confidential, customized reports produced for each medical office that submits data to the database; and 3) Research data sets of staff-level and medical office-level de-identified data that enable researchers to conduct additional analyses.

Medical offices are asked to voluntarily submit their Medical Office SOPS data to the comparative database. The data are then edited to detect and correct errors and aggregated and used to produce a Comparative Database Report that displays averages, standard deviations, and percentile scores on the survey's 52 items and 12 patient safety culture dimensions, as well as displaying these results by medical office characteristics (size of office, specialty, geographic region, etc.) and staff characteristics (staff position).

Because medical offices do not necessarily administer the Medical Office Survey on Patient Safety Culture every single year, but may administer it on an 18-month, 24-month, or other administration cycle, the comparative database is a "rolling" database that retains data from prior years when a medical office does not have new data to submit, replaces older data with more recent data when it is available, and adds new data from medical offices submitting for the first time.

Data submitted by medical offices are used to give each medical office its own customized survey feedback report comparing its results to the latest database. In future years, if a medical office submits data more than once, its feedback report may also present trending data, comparing its previous and most recent data submissions. A sample Individual Medical Office Survey Feedback Report is shown in Attachment E.

Medical offices use the Medical Office SOPS, Comparative Database Reports and Individual Medical Office Survey Feedback Reports for a number of purposes:

- Raise staff awareness about patient safety.
- Diagnose and assess the current status of patient safety culture in their medical office.
- Identify strengths and areas for improvement in patient safety culture.
- Examine trends in patient safety culture over time.
- Evaluate the cultural impact of patient safety initiatives and interventions.
- Compare patient safety culture survey results with other medical offices in their efforts to improve patient safety and health care quality.

3. Use of Improved Information Technology

All information collected for the Medical Office SOPS Comparative Database is done electronically, except the Data Use Agreement (DUA) that medical offices sign in hard copy and fax or mail back. Registration, submission of medical office information, and data upload are handled online through a secure Web site. Delivery of confidential medical office 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 Medical Office 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 Medical Office Survey on Patient Safety Culture and medical office 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 medical offices. The information that is requested is 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 medical offices to administer the survey and analyze and report their results.

6. Consequences if Information Collected Less Frequently

Data submission is currently accepted each year from September 15th to October 15th. AHRQ asks OMB to approve continuous data collection, that is, throughout the year or quarterly. Continuous acceptance of data is more convenient for medical offices because it enables them to submit data right after data collection rather than waiting to submit once per year. Medical office feedback reports could be provided to submitters in a more timely manner with more frequent data submission. However, because medical offices administer the AHRQ Medical Office SOPS voluntarily, on their own schedule, most medical offices would still only submit their data once in any given calendar year (depending on their survey administration schedule), and greater frequency may not be immediately feasible.

The main consequence of less frequent data collection is the less timely delivery of individual medical office feedback reports to medical offices participating in the MO SOPS Comparative Database. The Comparative Database Report would still only be produced periodically (once per year initially) if and when continuous submission of data is instituted.

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), a notice was published on [date] in the Federal Register for 60 days (see Attachment F).

8.b. Outside Consultations

AHRQ consulted experts to develop the Medical Office Survey on Patient Safety Culture. A list of the survey expert review panel that contributed to the development of the survey instrument is in Attachment G.

AHRQ has convened three external Technical Expert Panels (TEPs) to provide expertise and guidance to the development, functioning, and expansion of the SOPS Comparative Databases (see Attachment H for a list of experts who participated in each TEP). The first TEP convened on January 27, 2006 in Rockville, MD, and comprised 13 individuals who provided guidance on the strategy and plan for the initial Hospital comparative database, including all its key components: 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 convened on December 3, 2008 in Scottsdale, AZ and comprised 14 individuals. The third TEP convened in Baltimore, MD on April 19, 2010 and comprised 11 individuals. These two TEPs provided guidance on issues such as 1) number of years to include

in the rolling comparative database; 2) minimum number of facilities to produce overall comparative data; 3) minimum number of respondents to produce facility-level comparative data; 4) trending criteria; 5) the content and structure of the comparative database reports for submitters to the database; and 6) international user issues. These TEPs also provided input on the development of databases for the medical office and nursing home surveys on patient safety culture developed by AHRQ.

9. Payments/Gifts to Respondents

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

10. Assurance of Confidentiality

Individuals and organizations are assured of the confidentiality of their replies under Section 934(c) of the Public Health Service Act, 42 USC 299c-3(c). They are told the purposes for which the information is collected and that, in accordance with this statute, any identifiable information about them is not used or disclosed for any other purpose.

Confidentiality of the Point of Contact for a Medical Office. The medical office POC, who submits data on behalf of a medical office, is asked to provide their name, phone number and email address during the data submission process to ensure that the medical office's individual survey feedback report is delivered appropriately. In addition, the POC's contact information is important when any clarifications or corrections of the submitted data set are required or followup is needed. However, the name of the POC and name of the medical office are kept confidential and not reported. Only aggregated, de-identified results are displayed in any reports.

Confidentiality of the Survey Data Submitted by a Medical Office. Medical offices are assured of the confidentiality of the Medical Office Survey on Patient Safety Culture data they submit to the database through a Data Use Agreement (DUA) that they must sign and that has been approved by AHRQ's general counsel (see Attachment C). The DUA states that their data are 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 are used for the purposes of the database, that only aggregated results are reported, and that the medical office is not 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 medical office to participate in the Medical Office SOPS Comparative Database. The POC completes a number of data submission steps and forms, beginning with completion of the online Medical Office SOPS Database Eligibility Form and Data Use Agreement, which will be completed for 150 medical offices annually. The Medical Office Information Form will be completed for each medical office; since each POC represents an average of 10 medical offices, a total of 1,500 Information Forms will be completed annually, each requiring about 5 minutes to complete. The POC will submit data for all of the medical offices they represent which will take about 4 and ½ hours, including the amount of time POCs typically spend deciding whether to participate in the database,

preparing their materials and data set for submission to the database, and performing the submission. The total annual burden hours are estimated to be 816.

Medical offices administer the AHRQ Medical Office Survey on Patient Safety Culture on a periodic basis. Hospitals submitting to the Hospital SOPS Comparative Database administer the survey every 16 months on average. Similarly, the number of medical office submissions to the database is likely to vary each year because medical offices do not administer the survey and submit data every year. The 150 respondents/POCs shown in Exhibit 1 are based on an estimate.

Exhibit 1. Estimated annualized burden hours

Form Name	Number of respondents/ POCs	Number of responses per POC	Hours per response	Total burden hours
Eligibility Form	150	1	3/60	8
Data Use Agreement	150	1	3/60	8
Medical Office Information Form	150	10	5/60	125
Data Submission	150	1	4.5	675
Total	600	NA	NA	816

Exhibit 2 shows the estimated annualized cost burden based on the respondents' time to submit their data. The cost burden is estimated to be $34,779 annually.

Exhibit 2. Estimated annualized cost burden

Form Name	Number of respondents/ POCs	Total burden hours	Average hourly wage rate*	Total cost burden
Eligibility Form	150	8	$42.62	$341
Data Use Agreement	150	8	$42.62	$341
Medical Office Information Form	150	125	$42.62	$5,328
Data Submission	150	675	$42.62	$28,769
Total	600	816	NA	$34,779

* Mean hourly wage rate of $42.62 for Medical and Health Services Managers (SOC code 19111) was obtained from the May 2009 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 621100 - Offices of Physicians located at http://www.bls.gov/oes/2009/may/naics4_621100.htm.

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 participating medical offices other than their time to submit data to the database. No additional equipment or software purchases are required for data submission.

14. Estimates of Annualized Cost to the Government

The estimated annualized cost to the government for developing, maintaining, and managing the database and analyzing the data and producing reports is shown below. The cost is estimated to be $310,000 annually. The total cost over the three years of this information collection request is $930,000.

Estimated Annualized Cost

Cost Component	Total Cost	Annualized Cost
Project Development	$59,715	$19,905
Data Collection Activities	$82,107	$27,369
Data Processing and Analysis	$111,963	$37,321
Publication of Results	$111,966	$37,322
Project Management	$7,464	$2,488
Overhead	$556,785	$185,595
Total	$930,000	$310,000

15. Changes in Hour Burden

This is a new collection of information.

16. Time Schedule, Publication and Analysis Plans

The estimated time to conduct data collection, data analysis, and report production activities is shown below:

1) Data submission (1 month)
2) Data cleaning, data analysis, and individual NH feedback report production (2.5 months)
3) MO SOPS Comparative Database Report production (1.5 month)
4) Publication of Comparative Database Report on AHRQ Web site (2 months)

Because the steps above for the MO SOPS Comparative Database are the same as for the already-established Hospital SOPS Comparative Database, detailed information on these steps is available in the most recent Hospital SOPS Comparative Database Report located on the AHRQ Web site at http://www.ahrq.gov/qual/hospsurvey11/hospsurv111.pdf. Specific information on data cleaning and calculations is on pages 77-81 of this document.

17. Exemption for Display of Expiration Date

AHRQ does not seek this exemption.

List of Attachments:

Attachment A:	Medical Office Survey on Patient Safety Culture questionnaire
Attachment B:	Medical Office SOPS Database Eligibility Form
Attachment C:	Medical Office SOPS Database Data Use Agreement
Attachment D:	Medical Office Information Form
Attachment E:	Sample Individual Medical Office Survey Feedback Report
Attachment F:	Federal Register Notice
Attachment G:	Medical Office Expert Review Panel Members
Attachment H:	Participant Lists for 2006, 2008, and 2010 Technical Expert Panel (TEP) Meetings for the AHRQ Surveys on Patient Safety Culture Comparative Databases
Attachment I:	E-mails Related to Data Submssion
Attachment J:	Example Screen Shots of Web Site Information Collection
Attachment K:	Medical Office SOPS Data Submission Specifications