SUPPORTING STATEMENT

Part A

Medical Office Survey on Patient Safety Culture Comparative Database

July 1, 2015

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.

Background on the Medical Office Survey on Patient Safety Culture (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 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 survey is designed to enable medical offices to assess provider and staff opinions about patient safety issues, medical error, and error reporting. The survey includes 38 items that measure 10 composites of patient safety culture. In addition to the composite items, 14 items measure how often medical offices have problems exchanging information with other settings and other patient safety and quality issues. AHRQ made the survey publicly available 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/professionals/quality-patient-safety/patientsafetyculture/medical-office/index.html). Since its release, the survey has been voluntarily used by hundreds of medical offices in the U.S.

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 (OMB NO. 0935-0196, last approved on June 12, 2012) was developed by AHRQ in 2011 in response to requests from medical offices interested in knowing how their patient safety culture survey results compare to those of other medical offices in their efforts to improve patient safety.

Rationale for the information collection. The Medical Office SOPS and the Comparative Database support AHRQ's goals of promoting improvements in the quality and safety of health care in medical office 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 medical offices, to facilitate the use of these materials for medical office patient safety and quality improvement.

The goal of this project is to renew the survey instrument of 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.

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

1) **Eligibility and Registration Form** – The medical office 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 medical offices seeking to voluntarily submit their MO SOPS data to the MO SOPS Comparative Database.

2) **Data Use Agreement** – The purpose of the data use agreement, completed by the medical office POC, is to state how data submitted by medical offices will be used and provides confidentiality assurances (see Attachment B).

3) **Medical Office Site Information Form** – The purpose of the site information form (see Attachment C) 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 completes the form.

4) **Data Files Submission** – The number of submissions to the database is likely to vary each year because medical offices do not administer the survey and submit data every year. Data submission is typically handled by one POC who is either an office manager, nurse manager, or a survey vendor who contracts with a medical office to collect their data. POCs submit data on behalf of 10 medical offices, on average, because many medical offices are part of a health system that includes many medical office sites, or the POC is a vendor that is

submitting data for multiple medical offices. Following the steps described in Supporting Statement Part B, Section 2 – Information Collection Procedures, the POC completes an eligibility and registration form (see Attachment A). After registering, if registrants are deemed eligible to submit data, an automated email is sent to authenticate the account and update the user password (see Attachment D, Email #2). Next the POC enters medical office information (see Attachment C) and uploads their survey questionnaire and submits a data use agreement (see Attachment B). POCs then upload their data file(s), using the medical office data file specifications (see Attachment E), to ensure that users submit standardized and consistent data in the way variables are named, coded, and formatted.

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 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 publicly available on the AHRQ Web site (see http://www.ahrq.gov/professionals/quality-patient-safety/patientsafetyculture/medical-office/2014/index.html); 2) Individual Medical Office Survey Feedback Reports that are confidential, customized reports produced for each medical office that submits data to the database (the number of reports produced is based on the number of medical offices submitting each year); and 3) Research data sets of individual-level and medical office-level de-identified data to enable researchers to conduct analyses.

Medical offices are asked to voluntarily submit their Medical Office 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 38 items that measure 10 composites of patient safety culture, and 14 items measuring how often medical offices have problems exchanging information with other settings and other patient safety and quality issues. The report also displays these results by medical office characteristics (size of office, specialty, geographic region, etc.) and respondent characteristics (staff position).

Data submitted by medical offices are used to give each medical office its own customized survey feedback report that presents the medical office's results compared to the latest comparative database results.

Medical offices use the Medical Office SOPS, Comparative Database Reports and Individual Medical Office 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 medical office.
- Identify strengths and areas for improvement in patient safety culture.
- 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 collection 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 is 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 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 medical offices to administer the survey and analyze and report their results.

6. Consequences if Information Collected Less Frequently

Because medical offices administer the AHRQ Medical Office SOPS voluntarily, on their own schedule, most medical offices would only submit their data once in any given calendar year (depending on their survey administration schedule), and greater frequency may not be immediately feasible. Medical office data submission will be available in October 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), a notice was published in the Federal Register on March 23rd, 2015 for 60 days.

8.b. Outside Consultations

AHRQ has convened four 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 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 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.

The fourth TEP was convened virtually on October 21, 2013 and again on March 19, 2014 and was comprised of 16 individuals with experts 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 the timing of the safety culture databases and Hospital SOPS version 2.0.

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 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 Medical Office. The medical office POC, who submits data on behalf of a medical office, is asked to provide his/her name, phone number, and email address during the data submission process to ensure that the medical office's individual survey feedback report is delivered to that person for use by the medical office. 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 medical office POC and name of the medical office is 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 their medical office 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 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 respondents' time to participate in the database. An estimated 150 POCs, each representing an average of 10 individual medical offices each, will complete the database submission steps and forms annually. Completing the registration form will take about 3 minutes. The Medical Office Information Form is completed by all POCs for each of their medical offices (150 x 10 = 1,500 forms in total) and is estimated to take 5 minutes to complete. Each POC will complete a data use agreement which takes 3 minutes to complete and submitting the data will take an hour on average. The total burden is estimated to be 291 hours.

Exhibit 2 shows the estimated annualized cost burden based on the respondents' time to submit their data. The cost burden is estimated to be $13,968 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	150	1	3/60	8
Data Use Agreement	150	1	3/60	8
Medical Office Information Form	150	10	5/60	125
Data Files Submission	150	1	1	150
Total	600	NA	NA	291

Exhibit 2. Estimated annualized cost burden

Form Name	Number of respondents/ POCs	Total burden hours	Average hourly wage rate*	Total cost burden
Registration Form	150	8	$48.00	$384
Data Use Agreement	150	8	$48.00	$384
Medical Office Information Form	150	125	$48.00	$6,000
Data Files Submission	150	150	$48.00	$7,200
Total	600	291	NA	$13,968

* Mean hourly wage rate of $48.00 for Medical and Health Services Managers (SOC code 11-9111) was obtained from the May 2013 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 621100 - Offices of Physicians located at http://www.bls.gov/oes/2013/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 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 annually.

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

Team Lead – GS 15 Step 5 143,079	5%	$7,153
Subject Matter Expert- GS 15 Step 5	5%	$7,153
Health Scientist Administrator GS 13 Grade 5 $ 102,932	5%	$5,147
Program Specialist GS 12 Grade 5 $ 86,564	5%	$4,328
Total		$ 23,781

Annual salaries based on 2015 OPM Pay Schedule for Washington/DC area:
Pay & Leave : Salaries & Wages - OPM.gov

Note that these oversight costs are included in "Overhead" in Exhibit 3.

15. Changes in Hour Burden

The estimated hour burden for data file submission decreased from 4.5 hours in the previous information collection request (ICR) to 1 hour in this ICR. As a result, the total burden hours have decreased from 816 to 291, a decrease of 525 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 Medical Office SOPS database has been collected by AHRQ through its contractor, Westat, beginning in 2013. Medical offices are asked to voluntarily submit their

Medical Office SOPS survey data to the comparative database approximately every other year between October 1 and 21. The data are then cleaned and aggregated and used to produce a Comparative Database Report that is posted on the AHRQ web site. Medical offices 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:	Medical Office Eligibility and Registration Form
Attachment B:	Medical Office Data Use Agreement
Attachment C:	Medical Office Site Information Form
Attachment D:	Medical Office Data Submission Emails
Attachment E:	Medical Office Survey Data File Specifications
Attachment F:	SOPS Databases TEP List
Attachment G:	Example Screen Shots of Medical Office Survey on Patient Safety Culture Data Submission Web Site Information Collection