

SUPPORTING STATEMENT

Part A

Medical Office Survey on Patient Safety Culture Database

September 8, 2021

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

A. Justification

1. Circumstances that make the collection of information necessary

AHRQ’s mission. As described in its 1999 reauthorizing legislation, Congress directed the Agency for Healthcare Research and Quality (AHRQ) to enhance the quality, appropriateness, and effectiveness of health services, as well as access to such services, by establishing a broad base of scientific research and promoting clinical and health systems practice improvements.¹ The legislation also directed AHRQ to “conduct and support research, evaluations, and training, support demonstration projects, research networks, and multidisciplinary centers, provide technical assistance, and disseminate information on health care and on systems for the delivery of such care, including activities with respect to health statistics, surveys, database development, and epidemiology.”²

Furthermore, AHRQ shall conduct and support research “to provide objective clinical information to health care practitioners and other providers of health care goods or services; identify the causes of preventable health care errors and patient injury in health care delivery; develop, demonstrate, and evaluate strategies for reducing errors and improving patient safety; and disseminate such effective strategies throughout the health care industry”.³

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 perspectives 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 staff perceptions how often medical offices have problems exchanging information with other settings as well as 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 website⁴.

The AHRQ Medical Office SOPS Database consists of data from the AHRQ Medical Office Survey on Patient Safety Culture and may include reportable, non-required supplemental items⁵. Medical offices in the U.S. can voluntarily submit data from the survey to AHRQ, through its contractor, Westat. The Medical Office SOPS Database (OMB NO. 0935-0196, last approved on September 10, 2018) was developed by AHRQ in 2011 in response to requests from medical offices interested in tracking their own survey results. Those organizations submitting data receive a feedback report, as well as a report of the aggregated, de-identified findings of the other medical offices submitting data. These reports are used to assist medical office staff in their efforts to improve patient safety culture in their organizations.

Rationale for the information collection. The Medical Office SOPS and the Medical Office SOPS 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 database results are all made publicly available on AHRQ's website. 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.

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 Medical Office SOPS Database; OMB NO. 0935-0196, last approved on September 10, 2018.

This database will:

- 1) Present results from medical offices that voluntarily submit their data,
- 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 collect basic demographic information about the medical office and initiate the registration process.
- 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 privacy assurances (see Attachment B).
- 3) **Medical Office Site Information Form** – The purpose of the site information form (see Attachment C) also completed by the medical office POC, is to collect background characteristics of the medical office. This information will be used to analyze data collected with Medical Office SOPS survey.
- 4) **Data Files Submission** – POCs 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. 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 or a survey vendor who contracts with a medical office to collect their data. POCs submit data on behalf of 20 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.

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.⁶

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 Database Report that is made publicly available on the AHRQ website (see [Medical Office User Database Report](#))⁷;
- 2) Individual Medical Office Survey Feedback Reports that are customized for each medical office that submits data to the database; and
- 3) Research data sets of individual-level and medical office-level de-identified data to enable researchers to conduct analyses. All data released in a data set are de-identified at the individual-level and the medical office-level.

Medical offices will be invited to voluntarily submit their Medical Office SOPS survey data to the database. AHRQ's contractor, Westat, then cleans and aggregates the data to produce a PDF-formatted Database Report displaying averages, standard deviations, and percentile scores on the survey's 38 items and 10 patient safety culture 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).

The Database Report includes a section on data limitations, emphasizing that the report does not reflect a representative sampling of the U.S. medical office population. Because participating medical offices will choose to voluntarily submit their data into the database and therefore are not a random or national sample of medical offices, estimates based on this self-selected group might be biased estimates. We recommend that users review the database results with these caveats in mind.

Each medical office that submits its data receives a customized survey feedback report that presents their results alongside the aggregated results from other participating medical offices.

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

- Raise staff awareness about patient safety;
- Elucidate and assess the current status of patient safety culture in their medical office;
- Identify strengths and areas for patient safety culture improvement;
- Evaluate trends in patient safety culture change over time;
- Evaluate the cultural impact of patient safety initiatives and interventions.

3. Use of Improved Information Technology

All information collection for the Medical Office SOPS Database is done electronically, except the Data Use Agreement (DUA) that medical offices print, sign and return (either via fax, by scanning and emailing or uploading to a secure website, or by mailing back). Registration, submission of medical office information, and data upload is handled online through a secure

website. Customized medical office survey feedback reports are delivered electronically (the person submitting the data will enter a username and password for access to a secure website from which to download their reports).

4. Efforts to Identify Duplication

While survey vendors and medical office systems that administer the AHRQ Medical Office SOPS may maintain a database of survey responses for their particular clients (survey vendors) or their individual facility (medical offices), AHRQ is the only entity that serves as a central U.S. repository for data on the Medical Office SOPS survey and houses the largest database of the survey's results.

5. Involvement of Small Entities

AHRQ designed the data collection instruments and procedures to minimize burden on individual medical office staff respondents. The data requested of medical offices represents the absolute minimum information required for the intended uses and the data submission process does not unduly burden small medical offices or other businesses.

6. Consequences if Information Collected Less Frequently

Because medical offices administer the survey voluntarily, on their own schedule, most medical offices would only submit their data once every two years (depending on their survey administration schedule), and greater frequency may not be immediately feasible. Less frequent data collection would inhibit timely response to developing interventions designed to enhance patient safety culture. Medical office data submission will be available in September 2021.

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

In accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104-13) and Office of Management and Budget (OMB) regulations at 5 CFR Part 1320 (60 FR 44978, August 29, 1995), ACF published a notice in the Federal Register announcing the agency's intention to request an OMB review of this information collection activity. This notice was published on May 3, 2021, Volume 86, Number 83, page 23369, and provided a sixty-day period for public comment. A copy of this notice is attached as Attachment H. During the notice and comment period, the government received no requests for information or substantive comments.

8.b. Outside Consultations

AHRQ periodically convenes an external Technical Expert Panel (TEP) to provide expertise and guidance to the development, functioning, and expansion of the SOPS Databases. The SOPS TEP is comprised of 18 members from various parts of the health sector covered by the patient safety culture surveys (see Attachment F). With representation from medical office experts, the TEP will provide guidance as needed on the administration of the Medical Office SOPS Database.

9. Payments/Gifts to Respondents

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

10. Assurance of Confidentiality

Individuals and organizations are assured limitation on use of certain information 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.

Privacy of the Point-of-Contact for a Medical Office. The medical office point-of-contact, 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. Such contact information is critical if any clarifications or corrections of the submitted data set are necessary. However, the name of the medical office POC and name of the medical office is kept private and not reported. Only aggregated, de-identified results are displayed in any reports.

Privacy of the Survey Data Submitted by a Medical Office. Medical offices are assured of the privacy of their Medical Office SOPS survey data responses under the Data Use Agreement (DUA; see Attachment B). All respondents must sign the DUA. Reviewed by HHS's general counsel, the DUA states that all submitted data will be handled in a secure manner using necessary administrative, technical and physical safeguards to limit access to it and maintain its privacy. In addition, the DUA outlines that survey response 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 85 POCs, each representing an average of 20 individual medical offices each, will complete the database submission steps and forms. Each POC will submit the following:

- Eligibility and registration form (completion is estimated to take about 3 minutes).
- Data Use Agreement (completion is estimated to take about 3 minutes).
- Medical Office Information Form (completion is estimated to take about 5 minutes).
- Survey data submission will take an average of one hour.

The total burden is estimated to be 341.5 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 \$17,854 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	85	1	3/60	4.25
Data Use Agreement	85	1	3/60	4.25
Medical Office Information Form	85	35	5/60	248
Data Files Submission	85	1	1	85
Total	NA	NA	NA	341.5

Exhibit 2. Estimated annualized cost burden

Form Name	Number of respondents/ POCs	Total burden hours	Average hourly wage rate*	Total cost burden
Registration Form	85	4.25	\$ 52.58	\$222
Data Use Agreement	85	4.25	\$ 52.58	\$222
Medical Office Information Form	85	248	\$ 52.58	\$12,965
Data Files Submission	85	85	\$ 52.58	\$4,444
Total	NA	341.5	NA	\$17,854

* Mean hourly wage rate of \$52.28 for Medical and Health Services Managers (SOC code 11-9111) was obtained from the May 2019 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 621100 - Offices of Physicians located at https://www.bls.gov/oes/current/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 participating in 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 \$220,000 each data submission year.

Exhibit 3. Estimated Annualized Cost

Cost Component	Annualized Cost
Database Development and Maintenance	\$60,000
Data Submission	\$30,000
Data Analysis & Reports	\$130,000
Total	\$220,000

Exhibit 4: Estimated Annual cost to AHRQ for project oversight

AHRQ Position		% Time	Annualized Cost
Health Science Administrator	GS-15/5	5%	\$8,167
Social Science Analyst	GS-14/5	5%	\$6,143
Health Science Administrator	GS-13/5	5%	\$5,875
Total			\$20,985

<https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/21Tables/html/DCB.aspx>

15. Changes in Hour Burden

The estimated number of POCs increased from 70 in the previous information collection request (ICR) to 85 in this ICR. As a result of more POCs submitting data for fewer sites, the total burden hours have increased slightly from 283 to 341.5.

16. Time Schedule, Publication and Analysis Plans

Information for the Medical Office SOPS Database is collected by AHRQ through its contractor, Westat, beginning in 2013. Medical offices are invited to voluntarily submit their Medical Office SOPS survey data to the database approximately every other year in September. The data are then cleaned and aggregated and used to produce a Database Report that is posted on the AHRQ website. Medical offices are also automatically provided with their own individual survey feedback report.

17. Exemption for Display of Expiration Date

AHRQ does not seek this exemption.

List of Attachments:

- Attachment A: Eligibility and Registration Form
- Attachment B: Data Use Agreement
- Attachment C: Site Information Form
- Attachment D: Data Submission Emails
- Attachment E: Data File Specifications
- Attachment F: SOPS Databases TEP List
- Attachment G: Example Screen Shots of Medical Office Survey on Patient Safety Culture Data Submission Website Information Collection
- Attachment H: Federal Register Notice

¹ Healthcare Research and Quality Act of 1999. Available at <https://www.ahrq.gov/policymakers/hrqa99a.html>. Last accessed 12/28/2020.

² See Section 902, (a) (8) of the Healthcare Research and Quality Act of 1999. Available at <https://www.ahrq.gov/policymakers/hrqa99a.html>. Last accessed 12/28/2020.

³ See Section 912, (b) (2) (A) (ii) (I) and (iii) (II) and (c) (1) (2) and (3) of the Healthcare Research and Quality Act of 1999. Available at <http://www.ahrq.gov/policymakers/hrqa99b.html>. Last accessed 12/28/2020.

⁴ Medical Office Survey on Patient Safety Culture. Content last reviewed March 2020. Agency for Healthcare Research and Quality, Rockville, MD. <https://www.ahrq.gov/sops/databases/medical-office/index.html> Last accessed 12/28/2020.

⁵ Supplemental Items for the SOPS Medical Office Survey. Content last reviewed March 2020. Agency for Healthcare Research and Quality, Rockville, MD. <https://www.ahrq.gov/sops/surveys/medical-office/supplemental-items/index.html> Last accessed 1/6/2021

⁶ See 42 U.S.C. 299a(a)(1) (2), and (8). Available at <http://uscode.house.gov/view.xhtml?req=Child+Support&f=treesort&fq=true&num=584>. Last accessed 1/6/2021.

⁷ Medical Office User Database Reports. Content last reviewed March 2020. Agency for Healthcare Research and Quality, Rockville, MD. Available at <https://www.ahrq.gov/sops/databases/medical-office/index.html> Last accessed 1/6/2021