

SUPPORTING STATEMENT

Part A

Medical Office Survey on Patient Safety Culture Database

May 19, 2025

Extension without change of a previously approved ICR,
OMB NO. 0935-0196

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:

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

Summary of Extension:

This Information Collection Request is for an extension, without change, of the Medical Office Survey on Patient Safety Culture Database, OMB Control Number 0935-0196, last approved on September 24th, 2021, and due to expire on September 30th, 2024. AHRQ is requesting a new expiration date, 3 years from approval of this ICR.

Background and Overview of 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 Surveys on Patient Safety Culture[®] (SOPS[®]) Medical Office Survey 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 January 2009 on the AHRQ website⁴.

The AHRQ SOPS Medical Office 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 SOPS Medical Office Database 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. 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.

This database has the following goals:

- 1) Promote improvements in the quality and safety of health care in medical office settings,
- 2) Present results from medical offices that voluntarily submit their data,
- 3) Provide data to medical offices to facilitate internal assessment and learning in the patient safety improvement process, and
- 4) 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) **Medical Office Eligibility and Registration Form** – The medical office point-of-contact (POC) completes several 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) **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 SOPS Medical Office Survey.
- 3) **Medical Office SOPS 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).
- 4) **Medical Office SOPS Data File(s) Specifications** – POCs upload their data file(s), using the medical office data file specifications (see Attachments D, E, and G), to ensure that users submit their data in a standardized way (e.g., variable names, order, coding, formatting). The number of submissions to the database is likely to vary from submission period to submission period 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 SOPS Medical Office Database Report that is made publicly available on the AHRQ website (see [Medical Office User Database Report](#))⁷;
- 2) Individual 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 SOPS Medical Office Survey data to the database. AHRQ's contractor, Westat, will then clean and aggregate 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 21 items measuring how often medical offices have problems exchanging information with other settings and other patient safety and quality issues and overall ratings on quality and patient safety. The report will also display these results by medical office characteristics (size of office, specialty, geographic region, etc.) and respondent characteristics (staff position and tenure).

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 for the population. We recommend that users review the database results with these caveats in mind.

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

Medical offices use the SOPS Medical Office, Database Reports, and Individual Feedback Reports 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 SOPS Medical Office 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 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 that administer the AHRQ SOPS Medical Office Survey may maintain a database of survey responses for their particular clients, or health systems may do so for their individual medical offices, AHRQ is the only entity that serves as a central U.S. repository for data on the SOPS Medical Office Survey and houses the largest known 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 2025 and September 2027.

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 July 31, 2024 and page 61427 for 60 days (see Attachment H).

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 15 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 SOPS Medical Office 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

Data will be kept private to the extent allowed by law. 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 feedback report is delivered to that person (See Attachment A). 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 SOPS Medical Office Survey data responses under the Data Use Agreement (DUA; see Attachment B). All medical office points-of-contact or representatives 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 30 individual medical offices each, will complete the database submission steps and forms. Each POC will submit the following:

1. Medical Office Eligibility and Registration Form – Estimated to take 3 minutes to complete.
2. Medical Office Site Information Form – Estimated to take 5 minutes to complete.
3. Medical Office SOPS Data Use Agreement – Estimated to take 3 minutes to complete.
4. Medical Office SOPS Data File(s) Submission – Estimated to take 1 hour to complete.

The total burden is estimated to be 306 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 \$19,761 annually.

Exhibit 1. Estimated annualized burden hours

Form Name	Number of respondents	Number of responses per POC	Hours per response	Total burden hours
1. Medical Office Eligibility and Registration Form	85	1	3/60	4
2. Medical Office Site Information Form	85	30	5/60	213
3. Medical Office SOPS Data Use Agreement	85	1	3/60	4
4. Medical Office SOPS Data File(s) Submission	85	1	1	85
Total	NA	NA	NA	306

Exhibit 2. Estimated annualized cost burden

Form Name	Total burden hours	Average hourly wage rate*	Total cost burden
1. Medical Office Eligibility and Registration Form	4	\$ 64.58	\$258
2. Medical Office Site Information Form	213	\$ 64.58	\$13,756
3. Medical Office SOPS Data Use Agreement	4	\$ 64.58	\$258
4. Medical Office SOPS Data File(s) Submission	85	\$ 64.58	\$5,489
Total	308	NA	\$19,761

* Mean hourly wage rate of \$64.58 for Medical and Health Services Managers (SOC code 11-9111) was obtained from the May 2023 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 to COMPLETE]

AHRQ Position	% Time	Annualized Cost
GS 15/5	3%	\$5,574.72
GS 14/5	3%	\$4,739.46
GS 13/5	3%	\$4,010.76
Total		\$14,324.94

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15. Changes in Hour Burden

The estimated number for each respondent participating in the SOPS Medical Office Database remains the same from the previous information collection request (ICR).

16. Time Schedule, Publication and Analysis Plans

Information for the SOPS Medical Office Database is collected by AHRQ through its contractor, Westat. Medical offices will be asked to voluntarily submit their SOPS Medical Office 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 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 SOPS Data Use Agreement
- Attachment C: Medical Office Site Information Form
- Attachment D: Data Submission Emails
- Attachment E: AHRQ Medical Office SOPS Survey Data File Specifications
- Attachment F: SOPS Technical Expert Panel (TEP) List
- Attachment G: Example Screenshots of Medical Office Survey on Patient Safety Culture
Data Submission Website Information Collection
- Attachment H: 60 Day Federal Register Notice

¹ Healthcare Research and Quality Act of 1999. Available at <https://www.ahrq.gov/policymakers/hrqa99a.html>. Last accessed 2/1/2024.

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 2/1/2024.

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 2/1/2024.

⁴ Medical Office Survey on Patient Safety Culture. Content last reviewed October 2023. Agency for Healthcare Research and Quality, Rockville, MD. <https://www.ahrq.gov/sops/surveys/medical-office/index.html>. Last accessed 2/1/2024.

⁵ Supplemental Items for the Medical Office SOPS. Content last reviewed May 2021. Agency for Healthcare Research and Quality, Rockville, MD. <https://www.ahrq.gov/sops/surveys/medical-office/supplemental-items/index.html> Last accessed 2/1/2024.

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 access 9/16/2024.

⁷ Medical Office User Database. Content last reviewed January 2024. Agency for Healthcare Research and Quality, Rockville, MD. Available at <https://www.ahrq.gov/sops/databases/medical-office/index.html> Last accessed 2/1/2024.