

SUPPORTING STATEMENT

Part A

**Surveys on Patient Safety Culture® (SOPS®)
Ambulatory Surgery Center (ASC) Survey Database**

Version: October 2, 2024

Extension without change of a previously approved ICR
(OMB NO. 0935-0242)

Agency for Healthcare Research and Quality (AHRQ)

Table of contents

A. Justification	3
1. Circumstances that make the collection of information necessary.....	3
2. Purpose and Use of Information.....	5
3. Use of Improved Information Technology.....	6
4. Efforts to Identify Duplication.....	6
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.....	6
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.....	8
15. Changes in Hour Burden.....	9
16. Time Schedule, Publication and Analysis Plans.....	9
17. Exemption for Display of Expiration Date.....	9

A. Justification

1. Circumstances That Make the Collection of Information Necessary

About AHRQ:

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 <https://www.ahrq.gov/policymakers/hrqa99a.html>), 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.

Summary of this Information Collection Request (ICR):

This ICR is for the extension without change for the Surveys on Patient Safety Culture® (SOPS®) Ambulatory Surgery Center (ASC) Survey Database. AHRQ requests that the Office of Management and Budget (OMB) approve the extension, under the Paperwork Reduction Act of 1995, AHRQ's collection of information for the AHRQ SOPS ASC Database; OMB NO. 0935-0242, last approved on October 7, 2021.

Project Overview:

Background on the Survey on Patient Safety Culture Ambulatory Surgery Center (SOPS ASC).

In 1999, the Institute of Medicine called for healthcare 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 healthcare, AHRQ developed and pilot tested the Surveys on Patient Safety Culture® (SOPS®) ASC Survey with OMB approval (OMB NO. 0935-0216; approved October 31, 2013).

Ambulatory surgery centers (ASCs) are a fast-growing healthcare setting, demonstrating tremendous growth both in the volume and complexity of procedures being performed. ASCs provide surgical services to patients who are not expected to need an inpatient stay following surgery.¹ The Centers for Medicare and Medicaid Services (CMS) defines ASCs as distinct entities that operate exclusively to provide surgical services to patients who do not require hospitalization and are not expected to need to stay in a surgical facility longer than 24 hours.²

The SOPS ASC is designed to enable ASCs to assess provider and staff perspectives about patient safety issues, medical error, and error reporting. The survey includes 27 items that measure 8 composites of patient safety culture. In addition to the composite items, the survey includes one item measuring how often ASCs document near-misses; one item asking whether the respondent is in the room during surgeries, procedures, or treatments; and three items about communication before and after surgeries, procedures, or treatments. The survey also includes an overall rating item on patient safety, two items about respondent characteristics, and a section for open-ended comments. AHRQ made the survey publicly available along with a Survey User's Guide and other toolkit materials in May 2015 on the AHRQ website.³

The AHRQ SOPS ASC Database consists of data from the AHRQ ASC Survey on Patient Safety Culture. Ambulatory surgery centers in the U.S. can voluntarily submit data from the survey to AHRQ, through its contractor, Westat. The SOPS ASC Database (OMB NO. 0935-0242; last approved on October 7, 2021; expiration date October 31, 2024) was developed by AHRQ in 2019 in response to requests from ASCs interested in tracking their own survey results. Organizations submitting data receive a feedback report, as well as a report of the aggregated, de-identified findings of the other ASCs submitting data. These reports are used to assist ASC staff in their efforts to improve patient safety culture in their organizations.

Rationale for the information collection. The SOPS ASC Survey and the SOPS ASC Database support AHRQ's goals of promoting improvements in the quality and safety of healthcare in ASCs. 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 ASCs, to facilitate the use of these materials for ASC patient safety and quality improvement.

The goals of the SOPS ASC database are:

1. Present results from ASCs that voluntarily submit their data;
2. Provide data to ASCs to facilitate internal assessment and learning in the patient safety improvement process; and
3. Provide supplemental information to help ASCs identify their strengths and areas with potential for improvement in patient safety culture.

To achieve these goals, the following activities and data collections will be implemented:

1. **ASC Eligibility and Registration Form** – The point-of-contact (POC), often the manager of the ASC, completes a number of data submission steps and forms, beginning with completion of an online Eligibility and Registration Form (see **Attachment A**). The purpose of this form is to collect basic demographic information about the ASC and initiate the registration process.
2. **ASC Site Information** – The purpose of the site information form (see **Attachment C**), completed by the ASC POC, is to collect background characteristics of the ASC. This information will be used to analyze data collected with the SOPS ASC Survey.

3. **ASC SOPS Data Use Agreement** – The purpose of the data use agreement, completed by the ASC manager, is to state how data submitted by ASCs will be used and provides privacy assurances (see **Attachment B**).
4. **Data File(s) Submission** – POCs upload their data file(s), using the SOPS ASC Survey data file specifications 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 ASCs do not administer the survey and submit data every year. Data submission is typically handled by one POC who is either an ASC administrative manager or a survey vendor who contracts with an ASC to collect and submit its data (see **Attachments D, E, and G**).

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) and (2).

2. Purpose and Use of Information

Survey data from the AHRQ Ambulatory Surgery Center Survey on Patient Safety Culture are used to produce three types of products:

1. A SOPS ASC Database Report that will be made publicly available on the AHRQ website (see [ASC Database Report](#)).⁴
2. Individual Feedback Reports that are customized for each ASC that submits data to the database; and
3. Research data sets of individual-level and ASC-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 ASC-level.

ASCs will be invited to voluntarily submit their SOPS ASC 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 items and patient safety culture composite measures. The report also will display results by ASC characteristics (e.g., number of operating/procedure rooms and geographic region) and respondent characteristics (e.g., staff position and hours worked per week).

The Database Report includes a section on data limitations, emphasizing that the report does not reflect a representative sampling of the U.S. ASC population. Because participating ASCs will choose to voluntarily submit their data into the database and therefore are not a random or national sample of ASCs, 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 ASC that submits data receives a customized feedback report that presents their results alongside the aggregated results from other participating ASCs.

ASCs use the SOPS ASC Survey, 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 ASC;
- Identify strengths and areas for patient safety culture improvement;
- Examine trends in patient safety culture change over time; and
- Evaluate the cultural impact of patient safety initiatives and intervention.

3. Use of Improved Information Technology

All information collection for the SOPS ASC Database is done electronically, except the Data Use Agreement (DUA), which ASCs will print, sign, and return (either via fax, by scanning and emailing or uploading to a secure website, or by mailing back). Registration, submission of ASC information, and data upload is handled online through a secure website. Customized feedback reports will be delivered electronically (the person submitting the data will enter a username and password and will have access to a secure website from which to download their reports).

4. Efforts to Identify Duplication

While survey vendors that administer the AHRQ SOPS ASC Survey may maintain a database of survey responses for their particular clients and ASC chains may have responses for their individual facilities, AHRQ is the only entity that serves as a central U.S. repository for data on the SOPS ASC 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 ASC staff respondents. The data requested of ASCs represents the absolute minimum information required for the intended uses and the data submission process does not unduly burden small ASCs or other businesses.

6. Consequences if Information Collected Less Frequently

Because ASCs administer the survey voluntarily, on their own schedule, most ASCs 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. ASC data submission will be available in June 2025 and June 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), notice was published in the Federal Register on August 13, 2024, and page 65914 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**), including an ASC representative. The TEP will provide guidance as needed on the administration of the SOPS ASC Database.

9. Payments/Gifts to Respondents

No payment or remuneration is provided to ASCs 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 an ASC. The ASC point-of-contact, who submits data on behalf of an ASC, is asked to provide his/her name, phone number, and email address during the data submission process to ensure that the ASC's individual 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 ASC point-of-contact and name of the ASC is kept private and not reported. Only aggregated, de-identified results are displayed in any reports.

Privacy of the Survey Data Submitted by an ASC. ASCs are assured of the privacy of their SOPS ASC Survey data responses under the Data Use Agreement (DUA; see **Attachment B**). All ASC 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 ASC 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

Exhibit 1 shows the estimated annualized burden hours for the respondents' time to participate in the database. The total burden is estimated to be 86 hours.

1. **ASC Eligibility and Registration Form** – Completed once by 60 ASC POCs. The form takes about 3 minutes to complete.

2. **ASC Site Information** – Completed an average of 4 times by the 60 ASC POCs. The form takes 5 minutes to complete.
3. **Data Use Agreement** – Completed once by 60 ASC POCs. The form takes about 3 minutes to complete.
4. **SOPS ASC Survey Data File(s) Submission** – Each of the 60 POCs will submit their SOPS ASC Survey data. The data submission requires an hour on average to complete.

Exhibit 2 shows the estimated annualized cost burden based on the respondents' time to submit their data. The cost burden is estimated to be \$4,386 annually.

Exhibit 1. Estimated annualized burden hours

Form Name	Number of Respondents/POCs	Number of responses per POC	Hours per response	Total burden hours
1. ASC Eligibility and Registration Form	60	1	3/60	3
2. ASC Site Information	60	4	5/60	20
3. Data Use Agreement	60	1	3/60	3
4. SOPS ASC Survey Data Files Submission	60	1	1	60
Total	NA	NA	NA	86

Exhibit 2. Estimated annualized cost burden

Form Name	Total burden hours	Average hourly wage rate*	Total cost burden
1. ASC Eligibility and Registration Form	3	\$50.99	\$153
2. ASC Site Information	20	\$50.99	\$1,020
3. Data Use Agreement	3	\$50.99	\$153
4. SOPS ASC Survey Data Files Submission	60	\$50.99	\$3,060
Total	86	NA	\$4,386

*Based on the mean hourly wage for 60 ASC Administrative Services Managers (11-3010; \$50.99) obtained from the May 2023 National Industry-Specific Occupational Employment and Wage Estimates: NAICS 621400 – Outpatient Care Centers (located at https://www.bls.gov/oes/current/naics4_621400.htm#11-00000).

13. Estimates of Annualized Respondent Capital and Maintenance Costs

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 \$200,000 each data submission year.

Exhibit 3. Estimated Annualized Cost

Cost Component	Annualized Cost
Database Development and Maintenance	\$75,000
Data Submission	\$50,000
Data Analysis & Reports	\$75,000
Total	\$200,000

Exhibit 4. Federal Government Personnel Cost

Activity	Federal Personnel	Hourly Rate	Estimated Hours	Cost
Data Collection Oversight	GS14/5	\$56.80	82	\$4,657.6
Review of Results	GS15/5	\$ 66.82	79	\$5,278.78
Total				\$9,936.38

https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2024/GS_h.pdf

15. Changes in Hour Burden

The estimated number of POCs decreased from 100 in the previous information request (ICR) to 60 in this ICR. This updated estimate is based upon the actual number of POCs from the 2023 SOPS ASC data submission. As a result of fewer POCs submitting data, the total burden hours have decreased from 121 to 88.

16. Time Schedule, Publication and Analysis Plans

Information for the SOPS ASC Database is collected by AHRQ through its contractor, Westat. ASCs will be asked to voluntarily submit their SOPS ASC Survey data to the database approximately every other year in June. The data are then cleaned and aggregated to produce a Database Report that is posted on the AHRQ website. ASCs are also automatically provided with their own customized feedback report.

17. Exemption for Display of Expiration Date

AHRQ does not seek this exemption.

List of Attachments:

Attachment A: ASC Eligibility and Registration Form

Attachment B: Data Use Agreement
Attachment C: ASC Site Information
Attachment D: Data Submission Emails
Attachment E: Survey Data File Specifications
Attachment F: SOPS Technical Expert Panel (TEP) List
Attachment G: Example Screenshots of SOPS ACS Data Submission Website
Attachment H: 60 Day Federal Register Notice

¹ SOPS® Frequently Asked Questions. Content last reviewed January 2024. Agency for Healthcare Research and Quality, Rockville, MD. <https://www.ahrq.gov/sops/about/faq.html>. Last accessed 2/1/2024.

² See 42 C.F.R. §416.2. <https://www.govinfo.gov/app/details/CFR-2022-title42-vol3/CFR-2022-title42-vol3-sec416-2>. Last accessed 10/2/2024.

³ Ambulatory Surgery Center Survey on Patient Safety Culture. Content last reviewed October 2024. Agency for Healthcare Research and Quality, Rockville, MD. <https://www.ahrq.gov/sops/surveys/asc/index.html>. Last accessed 2/1/2024.

⁴ SOPS Ambulatory Surgery Center Database. Content last reviewed October 2024. Agency for Healthcare Research and Quality, Rockville, MD. Available at <https://www.ahrq.gov/sops/databases/asc/index.html>. Last accessed 2/1/2024.