

# **SUPPORTING STATEMENT**

## **Part A**

### **Ambulatory Surgery Center Survey on Patient Safety Culture Database**

**March 1, 2021**

Agency of Healthcare Research and Quality (AHRQ)

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## A. Justification

### **1. Circumstances that make the collection of information necessary**

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.<sup>1</sup> 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.<sup>2</sup>

**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.<sup>3</sup> 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.”<sup>4</sup>

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”.<sup>5</sup>

**Background on the Ambulatory Surgery Center Survey on Patient Safety Culture (ASC 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 ASC Survey on Patient Safety Culture with OMB approval (OMB NO. 0935-0216; approved October 31, 2013).

The survey 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.

The AHRQ ASC SOPS 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 ASC SOPS Database (OMB NO. 0935-0242; Approved September 10, 2018) 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 ASC SOPS and the ASC SOPS Database support AHRQ's goals of promoting improvements in the quality and safety of health care 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.

**Rationale 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 ASC SOPS Database; OMB NO. 0935-0242; Approved September 10, 2018.

This database will:

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

1. **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. **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).
3. **ASC Site Information** -- The purpose of the site level specifications (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 ASC SOPS survey.

4. **Data Files Submission** –POCs upload their data file(s), using ASC survey 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 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.

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.<sup>6</sup>

## **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) An ASC SOPS Database Report that will be made publicly available on the AHRQ website (see [ASC Database Report](#));<sup>7</sup>
- 2) Individual ASC Survey 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 ASC SOPS survey data into 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 items and patient safety culture composite measures. The report also displays results these 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. We recommend that users review the database results with these caveats in mind.

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

ASCs use the ASC SOPS Survey, Database Reports, and Individual ASC 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 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 ASC SOPS 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 ASC survey 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 ASC SOPS may maintain a database of survey responses for their particular clients (survey vendors) or their individual facility (ASCs), AHRQ is the only entity that serves as a central U.S. repository for data on the ASC 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 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 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 25, 2021, Volume 86, Number 99, page 28111, 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), including an ASC representative. The TEP will provide guidance as needed on the administration of the ASC SOPS Database.

### **9. Payments/Gifts to Respondents**

No payment or remuneration is provided to ASCs 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 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 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 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 ASC 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 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. An estimated 100 ASC managers (i.e., POCs from ASCs) will complete the database submission steps and forms. Each POC will submit the following:

- Eligibility and registration form (completion is estimated to take about 5 minutes).
- Data use agreement (completion is estimated to take about 3 minutes).
- ASC Site 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 121 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 \$5,804.37

**Exhibit 1. Estimated annualized burden hours**

Attachment A: Eligibility and Registration Form  
Attachment B: Data Use Agreement  
Attachment C: Site Information Form  
Attachment D: Data Submission Emails

Form Name	Number of Respondents/POCs	Number of responses per POC	Hours per response	Total burden hours
Eligibility and Registration Form	100	1	5/60	8
Data Use Agreement	100	1	3/60	5
ASC Site Information Form	100	1	5/60	8
Data Files Submission	100	1	1	100
Total	NA	NA	NA	121

**Exhibit 2. Estimated annualized cost burden**

Form Name	Number of Respondents/POCs	Total burden hours	Average hourly wage rate*	Total cost burden
Eligibility and Registration Form	100	8	\$47.97	\$383.76
Data Use Agreement	100	5	\$47.97	\$239.85
ASC Site Information	100	8	\$47.97	\$383.76
Data Files Submission	100	100	\$47.97	\$4,797.00
Total	NA	121	NA	\$5,804.37

\*Based on the mean hourly wage for 100 ASC Administrative Services Managers (11-3010; \$47.97) obtained from the May 2019 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](https://www.bls.gov/oes/current/naics4_621400.htm#11-00000)).

**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 \$200,000 each data submission year.

**Exhibit 3. Estimated Annualized Cost**



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

**Exhibit 4: Estimated Annual cost to AHRQ for project oversight**

<b>AHRQ Position</b>		<b>% Time</b>	<b>Annualized Cost</b>
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 hour burden for each respondent participating in the ASC SOPS Database remains the same from the previous information collection request (ICR).

**16. Time Schedule, Publication and Analysis Plans**

Information for the ASC SOPS Database is collected by AHRQ through its contractor, Westat. ASCs will be asked to voluntarily submit their ASCs SOPS 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 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: Databases TEP List
- Attachment G: Example Screen Shots of ASC Survey on Patient Safety Culture Data Submission Website Information Collection
- Attachment H: Federal Register Notice

- <sup>1</sup> Frequently Asked Questions: Surveys on Patient Safety Culture. Content last reviewed March 2020. Agency for Healthcare Research and Quality, Rockville, MD. <https://www.ahrq.gov/sops/about/faq.html>. Last accessed 1/11/2021.
- <sup>2</sup> See 42 C.F.R. §416.2. See <https://www.gpo.gov/fdsys/granule/CFR-2010-title42-vol3/CFR-2010-title42-vol3-sec416-2>. Last accessed 1/11/2021.
- <sup>3</sup> Healthcare Research and Quality Act of 1999. Available at <https://www.ahrq.gov/policymakers/hrqa99a.html>. Last accessed 1/11/2021.
- <sup>4</sup> 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 1/11/2021.
- <sup>5</sup> 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 1/11/2021.
- <sup>6</sup> 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 1/11/2021.
- <sup>7</sup> Hospital User Database Reports. Content last reviewed November 2017. Agency for Healthcare Research and Quality, Rockville, MD. Available at <https://www.ahrq.gov/sops/databases/hospital/index.html>. Last accessed 1/11/2021.