PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, AND SETTING) INCLUSION AND EXCLUSION CRITERIA

Category	Inclusion criteria	Exclusion criteria
Population	*Primary:* Individuals receiving acute medical care *Secondary:* Healthcare workers using or caring for devices used in patient care	Individuals receiving ambulatory care.
Interventions	*Primary interest:* Devices/items that are intended to prevent infection or are used for general bedside care, including but not limited to PPE, drapes, linens, laryngoscopes, blood pressure cuffs, pulse oximeters. *Secondary interest:* Other devices/items used during hospital care, including but not limited to: surgical devices, other scopes. Regulatory status: All devices/items must be either • FDA approved as reusable, and reprocessed per specifications. OR • Designated as single-use, FDA authorized for reprocessing, and reprocessed per specifications.	Devices/items with minimal or no pathogen transmission risk. Devices/items primarily used in an ambulatory or non-acute-care setting. Devices/items that have been reprocessed under emergency use authorization only. Implantable devices other than catheters.
Comparators	Devices/items that are approved as single-use and are discarded after one use	Single-use devices/items for which no reusable or authorized reprocessed alternatives are available in the US.
Outcomes	*Health outcomes* (Patient-level or aggregated patient data) Outcomes include but are not limited to: HAI, SSI, or pathogen transmission (including MDRO; Sepsis; ICU stay related to HAI; Length of stay; Mortality; Adverse effects; Healthcare worker infection or injury. *Economic outcomes* (Hospital/health system perspective) Outcomes include but are not limited to: Procurement cost; Cost per procedure/use; Costs for: reprocessing, transportation, storage, functionality testing, maintenance, repair, disposal, replacement; Supply chain implications. *Environmental outcomes* *a. Environmental impact* (Global, national, or regional perspective). Outcomes include but are not limited to: Greenhouse gas emissions; Air pollution; Water use; Water contamination; Energy use; Chemical use and toxicity; Recycling volume; Landfill use; Carcinogenic exposure; Climate change; Raw material extraction and processing. *b. Environmental health* (Population health perspective). Outcomes include but are not limited to: Respiratory illness; Cardiovascular disease; Cancer risk; Infectious disease outbreaks.	Quality of reprocessing. Usability by healthcare workers or patients. Device/item preferences of healthcare workers or patients. Device/item availability. Bacterial colonization of device/item.
Timing	Any	NA.
Setting	Acute care hospitals in countries rated ''very high'' on the 2021 Human Development Index (as defined by the United Nations Development Programme)*.	Non-hospital settings. Other countries.
Publication type	English language For primary interest interventions (devices/items used to prevent infections or for general bedside care): SRs, randomized controlled trials, nonrandomized controlled studies. For secondary interest interventions (other devices/items used for hospital care): SRs.	Non-English-language, abstracts, case reports, non-comparative studies, narrative reviews, commentaries, guidelines.

FDA: Food and Drug Administration; HAI: Healthcare-associated infection; ICU: Intensive care unit; MDRO: Multi-drug resistant organism; NA: Not applicable; PPE: Personal protective equipment; SR: Systematic review; SSI: Surgical site infection; US: United States.

*Human development index. United Nations Development Programme. Accessed April 16, 2024. *https://hdr.undp.org/data-center/human-development-index#/indicies/HDI.*

Mamatha Pancholi,

Deputy Director.

[FR Doc. 2024–17935 Filed 8–12–24; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the extension without change of the currently approved information collection ''Surveys on Patient Safety Culture (SOPS) Ambulatory Surgery Center (ASC) Survey Database, (OMB No. 0935–0242).''

DATES: Comments on this notice must be received by October 15, 2024.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at *REPORTSCLEARANCEOFFICER@ahrq.hhs.gov.*

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at *REPORTSCLEARANCEOFFICER@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

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

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®) Ambulatory Surgery Centers (ASC) Survey with OMB approval (OMB NO. 0935–0216; approved October 31, 2013).

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.

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.

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 SOPS–ASC database:

(1) Presents results from ASCs that voluntarily submit their data;

(2) Provides data to ASCs to facilitate internal assessment and learning in the patient safety improvement process; and

(3) Provides 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) 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. 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, 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) 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 confidentiality assurances.

(4) SOPS ASC Survey 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.

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).

Method of Collection

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).

Estimated Annual Respondent Burden

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. 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. 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

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form name	Number of respondents/ POCs	Number of responses per POC	Hours per response	Total burden hours
Total	NA	NA	NA	86

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Total burden hours	Average hourly wage rate *	Total cost burden
1. 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*).

Request for Comments

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3520, comments on AHRQ's information collection are requested with regard to any of the following: (a) whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: August 8, 2024.

Marquita Cullom,

Associate Director.

[FR Doc. 2024–18003 Filed 8–12–24; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10239]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by October 7, 2024.

ADDRESSES: When commenting, please reference the document identifier or Office of Management and Budget (OMB) control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *https://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement