

by small businesses that have merged with or been acquired by another business. This information is used by the SBA, Congress, Federal agencies and the general public for various reasons such as determining if agencies are meeting statutory goals, set-aside determinations, and market research.

### B. Annual Reporting Burden

An upward adjustment is being made to the estimated annual reporting burden since the last notice regarding an extension for this clearance published on May 4, 2015 in the **Federal Register** at 80 FR 25293. Based on fiscal year 2017 re-representation modification data from the Federal Procurement Data System (FPDS), the number of annual respondents has increased from 1,700 to 2,200.

*Respondents: 2,200.*

*Responses per Respondent: 1.*

*Total Number of Responses: 2,200.*

*Hours per Response: 0.5.*

*Total Burden Hours: 1,100.*

### C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the FAR, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

#### *Obtaining Copies of Proposals:*

Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW, Washington, DC 20405, telephone 202-501-4755.

Please cite OMB Control No. 9000-0163, Small Business Size Re-representation, in all correspondence.

Dated: March 7, 2018.

**Lorin S. Curit,**

*Director, Federal Acquisition Policy Division,  
Office of Governmentwide Acquisition Policy,  
Office of Acquisition Policy, Office of  
Governmentwide Policy.*

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**BILLING CODE 6820-EP-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 proposed information collection project “*Ambulatory Surgery Center Survey on Patient Safety Culture Database.*”

**DATES:** Comments on this notice must be received by May 14, 2018.

**ADDRESSES:** Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at [doris.lefkowitz@AHRQ.hhs.gov](mailto:doris.lefkowitz@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 [doris.lefkowitz@AHRQ.hhs.gov](mailto:doris.lefkowitz@AHRQ.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### Proposed Project

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

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501-3521, the Agency for Healthcare Research and Quality (AHRQ) invites the public to comment on this proposed information collection. Ambulatory surgery centers (ASCs) are a fast-growing health care 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. 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.

*How AHRQ's Mission and Directives Relate to ASCs.* As described in its 1999 reauthorizing legislation, Congress directed 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. 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.” 42 U.S.C. 299a(a)(8).

Shortly after Congress enacted this legislation, the Institute of Medicine (IOM) published “*To Err is Human,*” a seminal report on medical errors that connected the dots between errors and workplace culture. In it, the IOM called for health care organizations to develop a “culture of safety” such that staffing and system processes are aligned to improve the reliability and safety of patient care. This appeal for safety culture improvements directly relates to AHRQ’s legislative directive and mission (*i.e.*, “to produce evidence to make health care safer, higher quality, more accessible, equitable, and affordable, and to work within the U.S. Department of Health and Human Services and with other partners to make sure that the evidence is understood and used”). Given its legislatively mandated role, AHRQ is uniquely positioned to support data collection and analyses that will help fuel ASC patient safety culture improvements.

The expanding volume and scope of ASC services, the growing attention of federal regulators on patient safety within ASCs, and the resultant implications for public health has prompted AHRQ to present this application to the Office of Management and Budget (OMB). In this request, AHRQ seeks OMB approval to expand its Surveys on Patient Safety Culture™ (SOPS™) program by creating an ASC SOPS Database to capture and report on ASC SOPS data voluntarily submitted by ASCs that have administered the ASC SOPS. This is the newest database for the SOPS program and would be modeled after four other SOPS databases developed by AHRQ: Hospital SOPS [OMB NO. 0935-0162; last approved 10/18/2016]; Medical Office SOPS [OMB NO. 0935-0196; last approved 08/25/15]; Nursing Home SOPS [OMB NO. 0935-0195; last approved 09/30/15]; and Community Pharmacy SOPS [OMB NO. 0935-0218; last approved 06/26/17].

*Background on ASC SOPS.* This section provides context for this request to the OMB regarding the need for AHRQ's requested database. Factors include the continued ASC growth trajectory and increasing public attention on the quality of ASC care—particularly as it relates to patient safety culture.

*Rapid ASC Growth.* Medicare-certified ASCs have experienced impressive growth in the last 35 years—up from 239 facilities in 1983 to 5,316 in 2010. In recent years, Medicare ASCs have seen continued growth in both their number and scope, as illustrated by the annual average growth rate of 1.1 percent between 2010 to 2014. In 2015, CMS spent \$4.1 billion for 3.4 million fee-for-service Medicare beneficiaries to receive care across 5,500 Medicare-certified ASCs. Research suggests that transitioning eligible surgical procedures from inpatient to ASC settings may yield significant and sustained Medicare cost savings.

*Federal Attention on ASC Care Quality and Safety Culture.* Concern about the quality of ASC care is not new. Following a 2008 Hepatitis C outbreak in Nevada blamed on poor ASC infection control practices, HHS's Office of the Secretary oversaw a \$10 million program for state survey agencies to improve healthcare-associated infection reduction in ASCs. The Centers for Disease Control's National Healthcare Safety Network subsequently expanded its surgical site infection (SSI) surveillance efforts to enable ASC data submission to accommodate state SSI reporting mandates. Through the Affordable Care Act of 2010, Congress also pursued ASC performance improvement by directing the HHS Secretary to implement an ASC-focused Medicare value-based purchasing program.

The relationship between patient safety culture and the quality of ASC care has attracted more recent attention from policymakers and regulators. On the national level, the Joint Commission in early 2017 within its ASC accreditation manual established a new chapter on patient safety systems improvement, which includes strategies for “motivating staff to uphold a fair and just safety culture.” CMS, meanwhile, published in November 2017 its Final Rule outlining the ASC Quality Reporting Program, which ties quality and patient safety performance to reimbursement.

*ASC SOPS Pilot.* AHRQ developed and pilot tested the ASC SOPS with OMB approval (OMB No. 0935-0216; approved 10/31/2013). The survey is designed to enable any ASC, regardless

of type of procedures it performs, to assess its staff's perceptions about patient safety and quality assurance issues, including what safety-related attitudes and behaviors are supported, rewarded, and expected. It includes 27 items that measure 8 composites of patient safety culture, as well as five individual items on near-miss documentation, overall rating on patient safety and communication in the procedure/surgery room. The pilot test was conducted in early 2014 in ASC facilities: (1) Where patients have surgeries, procedures, and treatments and are not expected to need an inpatient stay, and (2) that have been certified and approved to participate in the CMS ASC program. Twenty-five percent of the pilot sites were affiliated with a hospital and 75% were not hospital-affiliated. Participants included 1,800 staff members from 59 ASCs—or approximately one percent of the total number of ASCs at that time.

AHRQ made the survey publicly available along with a Survey User's Guide, the pilot study results, and related toolkit materials on the *AHRQ Ambulatory Surgery Center Survey on Patient Safety Culture Web page* in April 2015. The AHRQ ASC SOPS Database will consist of data from the AHRQ ASC patient safety culture survey. ASCs in the U.S. will be asked to voluntarily submit data from the survey to AHRQ.

*Rationale for the information collection.* AHRQ sponsored the development of the ASC SOPS as a new survey in the suite of AHRQ Surveys on Patient Safety Culture. The database will support AHRQ's goals of promoting improvements in the quality and safety of health care in ASC settings. Like the survey and other toolkit materials, the database results will be 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. Technical assistance will also be provided to support ASC data submission.

The goal of this project is to create the ASC SOPS Database. This database will:

- (1) Present results from ASCs that voluntarily submit their data;
- (2) Present trend data for ASCs that have submitted their data more than once;
- (3) Provide data to ASCs to facilitate internal assessment and learning in the patient safety improvement process; and
- (4) Provide supplemental information to help ASCs identify their strengths and areas with potential for improvement in patient safety culture.

This study is being conducted by AHRQ through its contractor, Westat, pursuant to AHRQ's statutory authority to conduct and support research on health care and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of health care services and with respect to health statistics, surveys, and database development. 42 U.S.C. 299a(a)(1) and (8).

#### Method of Collection

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

(1) *Eligibility and Registration Form*—The pointofcontact (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 level specifications, completed by the ASC manager, is to collect background characteristics of the ASC. This information will be used to analyze data collected with the ASC SOPS 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 privacy assurances.

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

With the approval and addition of the ASC SOPS Database, data from the database will be used to produce three types of products:

- (1) An ASC SOPS Database Report that will be made publicly available on the AHRQ website (see, for example, another project in the SOPS suite, the Hospital User Database Report);
- (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 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, 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 33 items and 8 patient safety culture dimensions. In addition, the report will also display results by respondent characteristics (e.g., staff position, tenure, and hours worked per week).

The Database Report will include 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 submit their data voluntarily 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. These limitations will be noted in the database report. We will recommend that users review the

database results with these caveats in mind.

Each ASC that submits its data will receive a customized survey feedback report that presents their results alongside the aggregated results from other participating ASCs. If an ASC submits data more than once, its survey feedback report will also present trend data.

ASC users of the ASCs SOPS Survey, Database Reports, and Individual ASC Survey Feedback Reports can use these documents to:

- Raise staff awareness about patient safety;
- Diagnose and assess the current status of patient safety culture in their own 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.

**Estimated Annual Respondent Burden**

Exhibit 1 shows the estimated annualized burden hours for the

respondents' time to participate in the database. Given that this will be the first call for voluntary data submission, participation is initially expected to be modest. 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 \$5,472.83.

**EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS**

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
<b>Total .....</b>	<b>NA</b>	<b>NA</b>	<b>NA</b>	<b>121</b>

**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	\$45.23	\$361.84
Data Use Agreement .....	100	5	45.23	226.15
ASC Site Information .....	100	8	45.23	361.84
Data Files Submission .....	100	100	45.23	4,523.00
<b>Total .....</b>	<b>NA</b>	<b>121</b>	<b>45.23</b>	<b>5,472.83</b>

\* Based on the mean hourly wage for 100 ASC Administrative Services Managers (11-3011; \$45.23) obtained from the May 2016 National Industry-Specific Occupational Employment and Wage Estimates: NAICS 621400—Outpatient Care Centers (located at [http://www.bls.gov/oes/current/naics4\\_621400.htm#11-0000](http://www.bls.gov/oes/current/naics4_621400.htm#11-0000)).

**Request for Comments**

In accordance with the Paperwork Reduction Act, 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.

Karen J. Migdail,

Chief of Staff.

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BILLING CODE 4160-90-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[30Day-18-17AVB]

#### Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled “Leveraging the Emerging Field of Disaster Citizen Science to Enhance Community Resilience and Improve Disaster Response” to the Office of Management and Budget (OMB) for review and approval. CDC previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on September 19, 2017 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and

instruments, call (404) 639-7570 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov). Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

#### Proposed Project

Leveraging the Emerging Field of Disaster Citizen Science to Enhance Community Resilience and Improve Disaster Response—New—Office of Public Health Preparedness and Response (OPHPR), Centers for Disease Control and Prevention (CDC).

#### Background and Brief Description

The information collection for which approval is sought is in accordance with OPHPR’s mission to safeguard health and save lives by providing a platform for public health preparedness and emergency response. As part of its role, OPHPR is empowered to fund applied research to improve the ability of CDC and its partners, including but not limited to state and local health departments, emergency management organizations, and health care entities, to effectively prepare for and respond to public health emergencies and disasters.

Citizen science is defined as research activities (*e.g.*, data collection, analysis, and reporting) performed by members of the general public without any particular training in science. Citizen science is growing in popularity, fueled in part by growing use of smartphones and other personal devices in the population. Although citizen collection and use of data during disasters has increased exponentially in recent years and there is great policy interest in the phenomenon, there has been no robust research to date on the use of, barriers to, and impact of citizen science in disasters. Local health departments (LHDs) lack tools to respond to and coordinate with citizen science activities within communities. Furthermore, citizen science organizations lack information on how to organize their activities for ultimate impact.

This is an exploratory study and is the first of its kind to explore the growing phenomenon of disaster citizen science. Disaster citizen science is a rapidly growing field that is the focus of policy interest, but currently devoid of research. While interviews will be hypothesis generating and provide rich data on the experiences with citizen science to date across all stakeholders active in this enterprise, the nationally-

representative survey data will allow us to generalize findings to the full population of LHDs in the U.S.

CDC requests approval of a new information collection to learn about how the emerging field of disaster citizen science can enhance community resilience for a period of 1 year. This (mixed methods) information collection using interviews and a cross-sectional survey aims to: (1) Explore the potential of disaster citizen science for increasing community resilience, enhancing participation in preparedness and response activities, and improving preparedness efforts; and (2) provide evidence to inform the development of educational and instructional tools for communities and health departments to navigate the emerging field of disaster citizen science and promote collaborations. Insights from this information collection will be used to inform the development of guidance and toolkits for LHDs and community groups so that they can align their efforts and strengthen the benefits and positive impacts of citizen science activities. For interviews, the information collection will target citizen scientists and end users of citizen science data.

This information collection will be implemented in collaboration with a contractor and will target citizen scientists and their partners (*e.g.*, academics who work with citizen scientists on research projects) and LHDs in a position to use citizen science data to inform public health decision-making. For interviews, researchers will sample for maximum variation, seeking to obtain variation on U.S. region, type and sophistication of citizen science project, type of disaster encountered, and previous experience with disaster citizen science.

The project aims to conduct 35–55 facilitated, semi-structured, individual and group interviews, each lasting approximately 60 minutes, to cover topics including benefits and uses of citizen science, barriers to and facilitators of citizen science, and strengths and limitations of citizen science activities and resources.

Researchers will identify potential interview participants through literature reviews and snowball sampling in a phased approach starting with citizen science and LHD organizations.

The project will sample for maximum variation in order to capture the full range of citizen scientist and health department experiences on this topic. For the survey, the project aims to obtain a nationally representative sample of 600 local health officials and will apply survey weights to ensure that