

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, Health and Human Services (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) reapprove the proposed information collection project “*Ambulatory Surgery Center Survey on Patient Safety Culture Database*.”

DATES: Comments on this notice must be received by July 26, 2021.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at 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.

SUPPLEMENTARY INFORMATION: 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 Ambulatory Surgery Center (ASC) Survey on Patient Safety (SOPS) Database; OMB NO. 0935-0242; Approved September 10, 2018.

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 (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 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.

This 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.

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 healthcare 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 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. 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.

3. ASC Site Information—The purpose of the site level specifications, 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, 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.

Estimated Annual Respondent Burden

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

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).

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: May 19, 2021.

Marquita Cullom,

Associate Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–P–2048]

Determination That MANGANESE SULFATE, Injectable, Equivalent 0.1 Milligram Manganese/Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that MANGANESE SULFATE, injectable, equivalent (Eq) 0.1 milligram (mg) manganese/milliliter (mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for MANGANESE SULFATE, injectable, Eq 0.1 mg manganese/mL, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Sungjoon Chi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6216, Silver Spring, MD 20993–0002, 240–402–9674, Sungjoon.Chi@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which

authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the “listed drug,” which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the “Approved Drug Products With Therapeutic Equivalence Evaluations,” which is known generally as the “Orange Book.” Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the