

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN—Continued

Form name	Number of respondents	Total burden hours	Average hourly wage rate	Total cost burden
Team Checkup Tool (Attachment J) (<i>1 checklist conducted monthly per facility during 18 months of intervention for LTC cohort, 300 facilities total</i>)	100	306	*51.53	15,768.18
Electronic Health Record (EHR) Extracts				
Initial data pull (Attachment P)—(once at baseline for ICU and non-ICU cohorts, 800 units total)	267	2,403	— 35.17	84,513.51
Initial data pull (Attachment Q)—(once at baseline for Surgical cohort, 300 settings total)	100	50	— 35.17	1,758.50
Initial data pull (Attachment R)—(once at baseline for LTC cohort, 300 facilities total)	100	500	— 35.17	17,585.00
Quarterly data (Attachments P and Q)—(<i>quarterly during 18 months of intervention for ICU, non-ICU, and Surgical cohorts, 1,100 units total</i>)	367	1,101	— 35.17	38,722.17
Monthly data (Attachment R)—(<i>monthly per facility during 18 months of intervention for LTC cohort, 100 facilities total</i>)	100	900	— 35.17	31,653.00
Total	13,535	13,151	596,597.83

* This is an average of the average hourly wage rate for physician, nurse, nurse practitioner, physician's assistant, and nurse's aide from the May 2019 National Occupational Employment and Wage Estimates, United States, U.S. Bureau of Labor Statistics (https://www.bls.gov/oes/current/oes_nat.htm#00-0000).

— This is an average of the average hourly wage rate for nurse and IT specialist from the May 2019 National Occupational Employment and Wage Estimates, United States, U.S. Bureau of Labor Statistics (https://www.bls.gov/oes/current/oes_nat.htm#00-0000).

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: April 27, 2021.

Marquita Cullom,
Associate Director.

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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 renewal of the information collection project "Medical Office Survey on Patient Safety Culture Database."

DATES: Comments on this notice must be received by July 2, 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:

Proposed Project**Medical Office Survey on Patient Safety Culture Database**

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 Medical Office Survey on Patient Safety Culture with OMB approval (OMB NO.0935-0131; Approved July 5, 2007).

The survey is designed to enable medical offices to assess provider and staff perspectives about patient safety issues, medical error, and error reporting. The survey includes 38 items that measure 10 composites of patient safety culture. In addition to the composite items, 14 items measure staff perceptions how often medical offices have problems exchanging information with other settings as well as other patient safety and quality issues. AHRQ made the survey publicly available along with a Survey User's Guide and other toolkit materials in December 2008 on the AHRQ website.

The AHRQ Medical Office SOPS Database consists of data from the AHRQ Medical Office Survey on Patient Safety Culture and may include reportable, non-required supplemental items. Medical offices in the U.S. can voluntarily submit data from the survey to AHRQ, through its contractor, Westat.

The Medical Office SOPS Database (OMB NO. 0935–0196, last approved on September 10, 2018) was developed by AHRQ in 2011 in response to requests from medical offices interested in tracking their own survey results. Those organizations submitting data receive a feedback report, as well as a report of the aggregated, de-identified findings of the other medical offices submitting data. These reports are used to assist medical office staff in their efforts to improve patient safety culture in their organizations.

Rationale for the information collection. The Medical Office SOPS and the Medical Office SOPS Database support AHRQ’s goals of promoting improvements in the quality and safety of health care in medical office settings. 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 medical offices, to facilitate the use of these materials for medical office patient safety and quality improvement.

Request for information collection approval. AHRQ requests that OMB reapprove, under the Paperwork Reduction Act, 44 U.S.C. 3501–3521, AHRQ’s collection of information for the AHRQ Medical Office SOPS Database; OMB NO. 0935–0196, last approved on September 10, 2018.

This database:

- (1) Presents results from medical offices that voluntarily submit their data,
- (2) Provides data to medical offices to facilitate internal assessment and learning in the patient safety improvement process, and
- (3) Provides supplemental information to help medical offices 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

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

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

(1) *Eligibility and Registration Form*—The medical office point-of-contact (POC) completes a number of data submission steps and forms, beginning with the completion of an online Eligibility and Registration Form. The purpose of this form is to collect basic demographic information about the medical office and initiate the registration process.

(2) *Data Use Agreement*—The purpose of the data use agreement, completed by the medical office POC, is to state how data submitted by medical offices will be used and provides privacy assurances.

(3) *Medical Office Site Information Form*—The purpose of the site information form also completed by the medical office POC, is to collect background characteristics of the medical office. This information will be used to analyze data collected with Medical Office SOPS survey.

(4) *Data Files Submission*—POCs upload their data file(s), using the medical office 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 medical offices do not administer the survey and submit data every year. Data submission is typically handled by one POC who is either an office manager or a survey vendor who contracts with a medical office to collect their data. POCs submit data on behalf of 20

medical offices, on average, because many medical offices are part of a health system that includes many medical office sites, or the POC is a vendor that is submitting data for multiple medical offices.

Survey data from the AHRQ Medical Office Survey on Patient Safety Culture are used to produce three types of products:

- (1) A Medical Office SOPS Database Report that is made publicly available on the AHRQ website; and
- (2) Individual Medical Office Survey Feedback Reports that are customized for each medical office that submits data to the database; and
- (3) Research data sets of individual-level and medical office-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 medical office-level.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondents’ time to participate in the database. An estimated 85 POCs, each representing an average of 20 individual medical offices each, will complete the database submission steps and forms. Each POC will submit the following:

- Eligibility and registration form (completion is estimated to take about 3 minutes).
- Data Use Agreement (completion is estimated to take about 3 minutes).
- Medical Office 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 341.5 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 \$17,854 annually.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents/ POCs	Number of responses per POC	Hours per response	Total burden hours
Eligibility/Registration Form	85	1	3/60	4.25
Data Use Agreement	85	1	3/60	4.25
Medical Office Information Form	85	35	5/60	248
Data Files Submission	85	1	1	85
Total	NA	NA	NA	341.5

EXHIBIT 2—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents/ POCs	Total burden hours	Average hourly wage rate *	Total cost burden
Registration Form	85	4.25	\$52.28	\$222
Data Use Agreement	85	4.25	52.28	222
Medical Office Information Form	85	248	52.28	12,965
Data Files Submission	85	85	52.28	4,444
Total	NA	341.5	NA	17,854

* Mean hourly wage rate of \$52.28 for Medical and Health Services Managers (SOC code 11-9111) was obtained from the May 2019 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 621100—Offices of Physicians located at https://www.bls.gov/oes/current/naics4_621100.htm.

Request for Comments

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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: April 27, 2021.

Marquita Cullom,
Associate Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Patient Safety Organizations: Voluntary Relinquishment for the Sigma PSO, LLC

AGENCY: Agency for Healthcare Research and Quality (AHRQ), Department of Health and Human Services (HHS).

ACTION: Notice of Delisting.

SUMMARY: The Patient Safety and Quality Improvement Final Rule

(Patient Safety Rule) authorizes AHRQ, on behalf of the Secretary of HHS, to list as a patient safety organization (PSO) an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be "delisted" by the Secretary if it is found to no longer meet the requirements of the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when a PSO's listing expires. AHRQ accepted a notification of proposed voluntary relinquishment from the Sigma PSO, LLC, PSO number P0190, of its status as a PSO, and has delisted the PSO accordingly.

DATES: The delisting was effective at 12:00 Midnight ET (2400) on April 1, 2021.

ADDRESSES: The directories for both listed and delisted PSOs are ongoing and reviewed weekly by AHRQ. Both directories can be accessed electronically at the following HHS website: <http://www.pso.ahrq.gov/listed>.

FOR FURTHER INFORMATION CONTACT:

Cathryn Bach, Center for Quality Improvement and Patient Safety, AHRQ, 5600 Fishers Lane, MS 06N100B, Rockville, MD 20857; Telephone (toll free): (866) 403-3697; Telephone (local): (301) 427-1111; TTY (toll free): (866) 438-7231; TTY (local): (301) 427-1130; Email: psa@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION:

Background

The Patient Safety Act, 42 U.S.C. 299b-21 to 299b-26, and the related Patient Safety Rule, 42 CFR part 3, published in the **Federal Register** on November 21, 2008 (73 FR 70732-70814), establish a framework by which individuals and entities that meet the definition of provider in the Patient Safety Rule may voluntarily report information to PSOs listed by AHRQ, on a privileged and confidential basis, for

the aggregation and analysis of patient safety events.

The Patient Safety Act authorizes the listing of PSOs, which are entities or component organizations whose mission and primary activity are to conduct activities to improve patient safety and the quality of health care delivery.

HHS issued the Patient Safety Rule to implement the Patient Safety Act. AHRQ administers the provisions of the Patient Safety Act and Patient Safety Rule relating to the listing and operation of PSOs. The Patient Safety Rule authorizes AHRQ to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be "delisted" if it is found to no longer meet the requirements of the Patient Safety Act and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when a PSO's listing expires. Section 3.108(d) of the Patient Safety Rule requires AHRQ to provide public notice when it removes an organization from the list of PSOs.

AHRQ has accepted a notification of proposed voluntary relinquishment from the Sigma PSO, LLC to voluntarily relinquish its status as a PSO. Accordingly, the Sigma PSO, LLC, P0190, was delisted effective at 12:00 Midnight ET (2400) on April 1, 2021.

Sigma PSO, LLC has patient safety work product (PSWP) in its possession. The PSO will meet the requirements of section 3.108(c)(2)(i) of the Patient Safety Rule regarding notification to providers that have reported to the PSO and of section 3.108(c)(2)(ii) regarding disposition of PSWP consistent with section 3.108(b)(3). According to section 3.108(b)(3) of the Patient Safety Rule, the PSO has 90 days from the effective date of delisting and revocation to complete the disposition of PSWP that is currently in the PSO's possession.

More information on PSOs can be obtained through AHRQ's PSO website at <http://www.pso.ahrq.gov>.