SUPPORTING STATEMENT

Part A

Nursing Home Survey on Patient Safety Culture Comparative Database

September 20, 2024

Extension without change of a previously approved ICR,
OMB NO. 0935-0195

Agency of Healthcare Research and Quality (AHRQ)

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A. Justification

1. Circumstances That Make the Collection of Information Necessary

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.[1] 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 healthcare and on systems for the delivery of such care, including activities with respect to health statistics, surveys, database development, and epidemiology."[2]

Furthermore, AHRQ shall conduct and support research "to provide objective clinical information to healthcare practitioners and other providers of healthcare goods or services; identify the causes of preventable healthcare errors and patient injury in healthcare delivery; develop, demonstrate, and evaluate strategies for reducing errors and improving patient safety; and disseminate such effective strategies throughout the healthcare industry".[3]

Summary of Extension:
This Information Collection Request is for an extension, without change, of the Nursing Home Survey on Patient Safety Culture Comparative, OMB NO. 0935-0195, last approved on October 26, 2021, and due to expire on October 31, 2024. AHRQ is requesting a new expiration date, 3 years from approval of the ICR.

Background and Overview of the Nursing Home Survey on Patient Safety Culture (Nursing Home SOPS):
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®) Nursing Home Survey with OMB approval (OMB NO. 0935-0132; Approved July 5, 2007).

The survey is designed to enable nursing homes to assess provider and staff perspectives about patient safety issues, medical error, and error reporting and includes 42 items that measure 12 composites of patient safety culture. AHRQ made the survey publicly available along with a Survey User's Guide and other toolkit materials in November 2008 on the AHRQ website[4].

The AHRQ SOPS Nursing Home Database consists of data from the AHRQ Nursing Home Survey on Patient Safety Culture and may include reportable, non-required supplemental items[5]. Nursing homes in the U.S. can voluntarily submit data from the survey to AHRQ through its contractor, Westat. The SOPS Nursing Home Database (OMB NO. 0935-0195, last approved on October 26, 2021) was developed by AHRQ in 2011 in response to requests from nursing homes interested in viewing their organizations' patient safety culture survey results. Organizations

submitting data receive a feedback report, as well as a report on the aggregated, de-identified findings of the other nursing homes submitting data. These reports are used to assist nursing home staff in their efforts to improve patient safety culture in their organizations. Technical assistance is provided by AHRQ through its contractor at no charge to nursing homes, to facilitate the use of these materials for nursing home patient safety and quality improvement.

The survey and database have the following goals:

1) Promote improvements in the quality and safety of healthcare in nursing home settings,
2) Present results from nursing homes that voluntarily submit their data,
3) Provide data to nursing homes to facilitate internal assessment and learning in the patient safety improvement process, and
4) Provide supplemental information to help nursing homes 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) **Nursing Home Eligibility and Registration Form** – The nursing home (or parent organization) point–of-contact (POC) completes a number of data submission steps and forms, beginning with the completion of an online Eligibility and Registration Form (see **Attachment A**). The purpose of this form is to collect basic demographic information about the nursing home and initiate the registration process.

2) **SOPS Nursing Home Database Data Use Agreement** – The purpose of the data use agreement, completed by the nursing home POC, is to state how data submitted by nursing homes will be used and provides privacy assurances (see **Attachment B**).

3) **Nursing Home Site Information** – The purpose of the site information form (see **Attachment C**), completed by the nursing home POC, is to collect background characteristics of the nursing home. This information will be used to analyze data collected with the SOPS Nursing Home Survey.

4) **Nursing Home SOPS Data File Submission** – POCs upload their data file(s) using the data file specifications (see **Attachments D, E and G**), 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 nursing homes do not administer the survey and submit data every database year. Data submission is typically handled by one POC who is either a corporate level healthcare manager for a Quality Improvement Organization (QIO), a survey vendor who contracts with a nursing home to collect their data, or a nursing home Director of Nursing or nurse manager. POCs submit data on behalf of 1 nursing home, on average, because many nursing homes are part of a QIO or larger nursing home or health system that includes many nursing home sites, or the POC is a vendor that is submitting data for multiple nursing homes.

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.[6]

2. Purpose and Use of Information

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

1. A SOPS Nursing Home User Database Report that is made publicly available on the AHRQ website (see [Nursing Home User Database Report](#))[7];
2. Individual Feedback Reports that are customized for each nursing home that submits data to the database; and
3. Research data sets of individual-level and nursing home-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 nursing home-level.

Nursing homes will be invited to voluntarily submit their SOPS Nursing Home Survey data to 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 items and patient safety culture composite measures. The report will also display results by nursing home characteristics (e.g., bed size, ownership, and region) and respondent characteristics (e.g., work area/unit, staff position, interaction with residents, shift worked most often, and tenure in nursing home).

The Database Report includes a section on data limitations, emphasizing that the report does not reflect a representative sampling of the U.S. nursing home population. Because participating nursing homes will choose to voluntarily submit their data into the database and therefore are not a random or national sample of nursing homes, estimates based on this self-selected group might be biased estimates for the population. We recommend that users review the database results with these caveats in mind.

Each nursing home that submits data receives a customized feedback report that presents their results alongside the aggregate results from other participating nursing homes.

Nursing homes use the SOPS Nursing Home Survey, Database Reports and Individual Feedback Reports to:

- Raise staff awareness about patient safety;
- Elucidate and assess the current status of patient safety culture in their nursing home;
- 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 interventions;

3. Use of Improved Information Technology

All information collection for the SOPS Nursing Home Database is done electronically, except the Data Use Agreement (DUA), which nursing homes 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 nursing home 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 for access to a secure website from which to download their reports).

4. Efforts to Identify Duplication

While survey vendors that administer the AHRQ SOPS Nursing Home Survey may maintain a database of survey responses for their particular clients, and nursing home systems may do so for their individual facilities, AHRQ is the only entity that serves as a central U.S. repository for data on the SOPS Nursing Home Survey and houses the largest known database of the survey's results.

5. Involvement of Small Entities

AHRQ designed the data collection instrument and procedures to minimize burden on individual nursing home staff respondents. The data requested of nursing homes represents the absolute minimum information required for the intended uses and the data submission process does not unduly burden small nursing homes or other businesses.

6. Consequences if Information Collected Less Frequently

Because nursing homes administer the survey voluntarily, on their own schedule, most nursing homes 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. Nursing home data submission will be available in October 2024 and October 2026.

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

As required by 5 CFR 1320.8(d), a notice was published in the Federal Register on August 9, 2024, on page 65350 for 60 days (See **Attachment H**).

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 most SOPS TEP is comprised of 15 members from various parts of the health sector covered by the patient safety culture surveys (see **Attachment F**), including nursing home representatives. The TEP will provide guidance as needed on the administration of the SOPS Nursing Home Database.

9. Payments/Gifts to Respondents

No payment or remuneration is provided to nursing homes 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 a Nursing Home. The nursing home point-of-contact, who submits data on behalf of a nursing home, is asked to provide his/her name, phone number and email address during the data submission process to ensure that the nursing home's individual survey feedback report is delivered to that person. Such information is critical if any clarifications or corrections of the submitted data set are necessary. However, the name of the nursing home POC and name of the nursing home is kept private and not reported. Only aggregated, de-identified results are displayed in any reports.

Privacy of the Survey Data Submitted by a Nursing Home. Nursing homes are assured of the privacy of their SOPS Nursing Home Survey data under the Data Use Agreement (DUA; see Attachment B). All nursing home points-of-contact or representatives 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 nursing home 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 50 POCs, each representing an average of 1 individual nursing home each, will complete the database submission steps and forms. Each POC will submit the following:

1. Eligibility and registration form (completion is estimated to take about 3 minutes).
2. Data Use Agreement (completion is estimated to take about 3 minutes).
3. Nursing Home Site Information Form (completion is estimated to take about 5 minutes).
4. Survey data submission will take an average of one hour.

The total annual burden hours are estimated to be 60 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 $2,903 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. Nursing Home Eligibility and Registration Form	50	1	3/60	3
2. SOPS Nursing Home Database Data Use Agreement	50	1	3/60	3
3. Nursing Home Site Information Form	50	1	5/60	4
4. Nursing Home SOPS Data File Submission	50	1	1	50
Total	NA	NA	NA	60

Exhibit 2. Estimated annualized cost burden

Form Name	Total burden hours	Average hourly wage rate*	Total cost burden
1. Nursing Home Eligibility and Registration Forms	3	$48.43	$145
2. SOPS Nursing Home Database Data Use Agreement	3	$48.43	$145
3. Nursing Home Site Information Form	4	$48.43	$194
4. Nursing Home SOPS Data File Submission	50	$48.43	$2,422
Total	61	NA	$2, 907

* Mean hourly wage rate of $64.64 for Medical and Health Services Managers (SOC code 11-9111) was obtained from the May 2023 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 623000 – Nursing and Residential Care Facilities located at https://www.bls.gov/oes/current/naics3_623000.htm.

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

Cost Component	Annualized Cost
Database Development and Maintenance	30,000
Data Submission	50,000
Data Analysis & Reports	120,000
Total	200,000

Exhibit 4: Annual cost to AHRQ for project oversight

AHRQ Position	% Time	Annualized Cost
GS15/5	3%	$5,574.72
GS14/5	3%	$4,739.46
GS13/5	3%	$4,010.76
Total		$14,324.94

https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2024/DCB.pdf

15. Changes in Hour Burden

The estimated number of POCs decreased from 60 in the previous information collection request (ICR) to 50 in this ICR. This updated estimate is based upon the actual number of POCs in the 2022 SOPS Nursing Home data submission. As a result of fewer POCs submitting data, the total burden hours decreased from 91 to 60.

16. Time Schedule, Publication and Analysis Plans

Information for the SOPS Nursing Home database is collected by AHRQ through its contractor, Westat. Nursing homes will be asked to voluntarily submit their SOPS Nursing Home Survey data to the database every other fall. The data are then cleaned and aggregated and used to produce a Database Report that is posted on the AHRQ website. Nursing homes are also provided with their own individual feedback report.

17. Exemption for Display of Expiration Date

AHRQ does not seek this exemption.

List of Attachments:

Attachment A: Nursing Home Eligibility and Registration Form
Attachment B: SOPS Nursing Home Database Data Use Agreement
Attachment C: Nursing Home Site Information Form
Attachment D: Nursing Home SOPS Data File Submission
Attachment E: Nursing Home Survey Data File Specifications
Attachment F: SOPS Databases Technical Expert Panel (TEP) List
Attachment G: Example Screenshots of Nursing Home Survey on Patient Safety Culture Data
                 Submission Website Information Collection
Attachment H: 60 Day Federal Register Notice

[1] Healthcare Research and Quality Act of 1999. Available at https://www.ahrq.gov/policymakers/hrqa99a.html. Last accessed 2/1/2024.

[2] 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 2/1/2024.

[3] See Section 912, (b) (2) (A) (ii) (I) 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 2/1/2024.

[4] Nursing Home Survey on Patient Safety Culture. Content last reviewed March 2023. Agency for Healthcare Research and Quality, Rockville, MD. https://www.ahrq.gov/sops/surveys/nursing-home/index.html. Last accessed 2/1/2024.

[5] Workplace Safety Supplemental Item Set for Nursing Home SOPS. Content last reviewed November 2023. Agency for Healthcare Research and Quality, Rockville, MD. https://www.ahrq.gov/sops/surveys/nursing-home/supplemental-items/workplace-safety.html. Last accessed 2/1/2024/

[6] 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 2/1/2024..

[7] SOPS Nursing Home Database. Content last reviewed September 2023. Agency for Healthcare Research and Quality, Rockville, MD. https://www.ahrq.gov/sops/databases/nursing-home/index.html. Last accessed 2/1/2024.