

SUPPORTING STATEMENT

Part A

Nursing Home Survey on Patient Safety Culture Database

April 28, 2021

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 health care 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 health care practitioners and other providers of health care goods or services; identify the causes of preventable health care errors and patient injury in health care delivery; develop, demonstrate, and evaluate strategies for reducing errors and improving patient safety; and disseminate such effective strategies throughout the health care industry”.³

Background on the Nursing Home Survey on Patient Safety Culture (Nursing Home SOPS). 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 Nursing Home Survey on Patient Safety Culture 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 website⁴.

The AHRQ Nursing Home SOPS Database consists of data from the AHRQ Nursing Home Survey on Patient Safety Culture. Nursing homes in the U.S. can voluntarily submit data from the survey to AHRQ through its contractor, Westat. The Nursing Home SOPS Database (OMB NO. 0935-0195, last approved on November 5, 2018) was developed by AHRQ in 2011 in response to requests from nursing homes interested in viewing their organizations' patient safety culture survey results. Those 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.

Rationale for the information collection. The Nursing Home SOPS and Nursing Home SOPS Database support AHRQ's goals of promoting improvements in the quality and safety of health care in nursing home 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 nursing homes, to facilitate the use of these materials for nursing home patient safety and quality improvement.

Request for information collection approval. 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 Nursing Home SOPS Database; OMB NO. 0935-0195, last approved on November 5, 2018.

This database will:

- 1) Present results from nursing homes that voluntarily submit their data,
- 2) Provide data to nursing homes to facilitate internal assessment and learning in the patient safety improvement process, and
- 3) 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) **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) **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 Form** – 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 Nursing Home SOPS survey.
- 4) **Data File(s) Submission** – POCs upload their data file(s) using the data file specifications (see Attachment E), 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 nursing homes do not administer the survey and submit data every year. Data submission is typically handled by one POC who is either a corporate level health care 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 4 nursing homes, 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 effectiveness, efficiency, and quality of healthcare services and procedures⁵.

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 Nursing Home SOPS User Database Report that is made publicly available on the AHRQ website (see [Nursing Home User Database Report](#))⁶;
- 2) Individual Nursing Home Survey Feedback Reports are individualized reports produced 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 Nursing Home SOPS survey data to the database. The data are then cleaned and aggregated and used to produce a Database Report in PDF format that displays averages, standard deviations, and percentile scores on the survey's 42 items and 12 patient safety culture composites, as well as displaying these results by nursing home characteristics (bed size, ownership, and region) and respondent characteristics (work area/unit, staff position, interaction with residents, shift worked most often, and tenure in nursing home).

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

Nursing homes use the Nursing Home SOPS Database Reports and Individual Nursing Home Survey Feedback Reports for a number of purposes, 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.
- Evaluate trends in patient safety culture change over time.
- Evaluate the cultural impact of patient safety initiatives and interventions.

3. Use of Improved Information Technology

All information collection for the Nursing Home SOPS Database is done electronically, except the Data Use Agreement (DUA) that nursing homes 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. Individualized nursing home survey feedback reports are 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 and nursing home systems that administer the AHRQ Nursing Home SOPS may maintain a small database of survey responses for their particular clients (survey vendors) or their individual facility (nursing homes), AHRQ is the only entity that serves as a central U.S. repository for Nursing Home SOPS data and houses the largest 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 others 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 is available in September 2022.

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

In accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104-13) and Office of Management and Budget (OMB) regulations at 5 CFR Part 1320 (60 FR 44978, August 29, 1995), ACF published a notice in the Federal Register announcing the agency's intention to request an OMB review of this information collection activity. This notice was published on June 23, 2021, Volume 86, Number 118, page 32931, and provided a sixty-day period for public comment. A copy of this notice is attached as Attachment H. During the notice and comment period, the government received no requests for information or substantive comments.

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 recent TEP was comprised of 18 individuals from various parts of the health sector covered by the patient safety culture surveys (see Attachment F). With representation from nursing home experts, they TEP will provide guidance as needed on the administration of the Nursing Home SOPS 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 Nursing Home SOPS survey data under the Data Use Agreement (DUA) (see Attachment B). All respondents 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 40 POCs, each representing an average of 3 individual nursing homes 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).
- Nursing Home Site Information Form (completion is estimated to take about 5 minutes).
- Survey data submission will take an average of one hour.

The total annual burden hours are estimated to be 61 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 \$2,833 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	40	1	3/60	2
Data Use Agreement	40	1	3/60	2
Nursing Home Site Information Form	40	5	5/60	17
Data Files Submission	40	1	1	40
Total	NA	NA	NA	61

Exhibit 2. Estimated annualized cost burden

Form Name	Number of respondents/ POCs	Total burden hours	Average hourly wage rate*	Total cost burden
Eligibility/Registration Forms	40	2	\$46.45	\$93
Data Use Agreement	40	2	\$46.45	\$93
Nursing Home Site Information Form	40	17	\$46.45	\$790
Data Files Submission	40	40	\$46.45	\$1,858
Total	NA	61	NA	\$2,833

*The wage rate in Exhibit 2 is based on May 2019 National Industry-Specific Occupational Employment and Wage Estimates, Bureau of Labor Statistics, U.S. Dept. of Labor. Mean hourly wages for nursing home POCs are located at https://www.bls.gov/oes/current/naics3_623000.htm. The hourly wage of \$46.45 is the weighted mean of \$47.32 (General and Operations Managers 11-1021; N = 26) and \$44.82 (Medical and Health Services Managers 11-9111; N = 14).

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 complying with 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
GS-15, Step-5	3%	\$8,167
GS-14, Step -5	5%	\$6,943
GS-13, Step- 5	3%	\$5,875
Total		\$20,985

<https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/21Tables/html/DCB.aspx>

15. Changes in Hour Burden

The estimated number of POCs decreased from 60 in the previous information collection request (ICR) to 40 in this ICR. This updated estimate is based upon the actual number of POCs in the 2019 Nursing Home SOPS data submission. As a result of fewer POCs submitting data, the total burden hours decreased from 91 to 61.

16. Time Schedule, Publication and Analysis Plans

Information for the Nursing Home SOPS database is collected by AHRQ through its contractor, Westat, beginning in 2013. Nursing homes are invited to voluntarily submit their Nursing Home SOPS survey data to the database approximately every other year between September 1 and September 21. 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 survey feedback report.

17. Exemption for Display of Expiration Date

AHRQ does not seek this exemption.

List of Attachments:

- Attachment A: Eligibility and Registration Form
- Attachment B: Data Use Agreement
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- Attachment G: Example Screenshots of Nursing Home Survey on Patient Safety Culture Data Submission Website Information Collection
- Attachment H: Federal Register Notice

¹ Healthcare Research and Quality Act of 1999. Available at <https://www.ahrq.gov/policymakers/hrqa99a.html>. Last accessed 2/1/2021.

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 2/1/2021.

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 2/1/2021.

⁴ Nursing Home Survey on Patient Safety Culture. Content last reviewed October 2020. Agency for Healthcare Research and Quality, Rockville, MD. <https://www.ahrq.gov/sops/surveys/nursing-home/index.html>. Last accessed 2/1/2021

⁵ See 42 U.S.C. 299a(a)(1). Available at <http://uscode.house.gov/view.xhtml?req=Child+Support&f=treesort&fq=true&num=584>. Last accessed 2/1/2021.

⁶ SOPS Nursing Home Database. Content last reviewed November 2019. Agency for Healthcare Research and Quality, Rockville, MD. <https://www.ahrq.gov/sops/databases/nursing-home/index.html>. Last accessed 2/1/2021.