

SUPPORTING STATEMENT

Part A

Nursing Home Survey on Patient Safety Culture Comparative Database

February 4, 2015

Agency of Healthcare Research and Quality (AHRQ)

Table of Contents

A. Justification.....	3
1. Circumstances that make the collection of information necessary.....	3
2. Purpose and Use of Information.....	5
3. Use of Improved Information Technology.....	6
4. Efforts to Identify Duplication.....	6
5. Involvement of Small Entities.....	6
6. Consequences if Information Collected Less Frequently.....	6
7. Special Circumstances.....	6
8. Federal Register Notice and Outside Consultations.....	6
9. Payments/Gifts to Respondents.....	7
10. Assurance of Confidentiality.....	7
11. Questions of a Sensitive Nature.....	8
12. Estimates of Annualized Burden Hours and Costs.....	8
13. Estimates of Annualized Respondent Capital and Maintenance Costs.....	9
14. Estimates of Annualized Cost to the Government.....	9
15. Changes in Hour Burden.....	10
16. Time Schedule, Publication and Analysis Plans.....	10
17. Exemption for Display of Expiration Date.....	10
List of Attachments:	11
Attachment A: Nursing Home Eligibility and Registration Form.....	11
Attachment B: Nursing Home Data Use Agreement.....	11
Attachment C: Nursing Home Site Information Form.....	11
Attachment F: SOPS Databases TEP List.....	11

A. Justification

1. Circumstances that make the collection of information necessary

AHRQ's mission. The mission of the Agency for Healthcare Research and Quality (AHRQ) set out in its authorizing legislation, The Healthcare Research and Quality Act of 1999 (see <http://www.ahrq.gov/hrqa99.pdf>), is to enhance the quality, appropriateness, and effectiveness of health services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical and health systems practices, including the prevention of diseases and other health conditions. AHRQ shall promote health care quality improvement by conducting and supporting:

1. research that develops and presents scientific evidence regarding all aspects of health care; and
2. the synthesis and dissemination of available scientific evidence for use by patients, consumers, practitioners, providers, purchasers, policy makers, and educators; and
3. initiatives to advance private and public efforts to improve health care quality.

Also, AHRQ shall conduct and support research and evaluations, and support demonstration projects, with respect to (A) the delivery of health care in inner-city areas, and in rural areas (including frontier areas); and (B) health care for priority populations, which shall include (1) low-income groups, (2) minority groups, (3) women, (4) children, (5) the elderly, and (6) individuals with special health care needs, including individuals with disabilities and individuals who need chronic care or end-of-life health care.

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 opinions about patient safety issues, medical error, and error reporting and includes 42 items that measure 12 dimensions 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 Web site (located at <http://www.ahrq.gov/professionals/quality-patient-safety/patientsafetyculture/nursing-home/index.html>).

The AHRQ Nursing Home SOPS Comparative Database consists of data from the AHRQ Nursing Home Survey on Patient Safety Culture. Nursing homes in the U.S. are asked to voluntarily submit data from the survey to AHRQ through its contractor, Westat. The Nursing Home SOPS database (OMB NO. 0935-0195, last approved on June 12, 2012) was developed by AHRQ in 2011 in response to requests from nursing homes interested in knowing how their

patient safety culture survey results compare to those of other nursing homes in their efforts to improve patient safety.

Rationale for the information collection. The Nursing Home SOPS and the Comparative 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 comparative database results are all made publicly available on AHRQ's Web site. 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 goal of this project is to renew the survey instrument of the Nursing Home SOPS Comparative Database. This database will:

- 1) Allow nursing homes to compare their patient safety culture survey results with those of other nursing homes,
- 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 determine the eligibility status and initiate the registration process for nursing homes seeking to voluntarily submit their NH SOPS data to the NH SOPS Comparative Database.
- 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 confidentiality assurances (see Attachment B).
- 3) Nursing Home Site Information Form – The purpose of the site information form (see Attachment C) is to obtain basic information about the characteristics of the nursing homes submitting their NH SOPS data to the NH SOPS Comparative Database (e.g., bed size, urbanicity, ownership, and geographic region). The nursing home POC completes the form.
- 4) Data Files Submission – 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 5 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 POCs then upload their data file(s), using the nursing home data file specifications (see Attachment E), to ensure that users submit standardized and consistent data in the way variables are named, coded, and formatted.

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).

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 Comparative Database Report that is produced periodically and made publicly available on the AHRQ Web site (see <http://www.ahrq.gov/professionals/quality-patient-safety/patientsafetyculture/nursing-home/2014/nhsurv14-ptl.pdf> for the 2014 report); 2) Individual Nursing Home Survey Feedback Reports that are confidential, customized reports produced for each nursing home that submits data to the database (the number of reports produced is based on the number of nursing homes submitting in any given calendar year); and 3) Research data sets of individual-level and nursing home-level de-identified data to enable researchers to conduct analyses.

Nursing homes are asked to voluntarily submit their Nursing Home SOPS survey data to the comparative database. The data are then cleaned and aggregated and used to produce a Comparative Database Report that displays averages, standard deviations, and percentile scores on the survey's 42 items and 12 patient safety culture dimensions, as well as displaying these results by nursing home characteristics (bed size, urbanicity, ownership, and Census Bureau Region, etc.) and respondent characteristics (work area/unit, staff position, and interaction with patients).

Data submitted by nursing homes are also used to give each nursing home its own customized survey feedback report that presents the nursing home's results compared to the latest comparative database results. If a nursing home submits data more than once, its survey feedback report also presents trend data, comparing its previous and most recent data.

Nursing homes use the Nursing Home SOPS, Comparative Database Reports and Individual Nursing Home Survey Feedback Reports for a number of purposes, to:

- Raise staff awareness about patient safety.
- Diagnose 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.
- Evaluate the cultural impact of patient safety initiatives and interventions.
- Compare patient safety culture survey results with other nursing homes in their efforts to improve patient safety and health care quality.

3. Use of Improved Information Technology

All information collection for the Nursing Home SOPS Comparative Database is done electronically, except the Data Use Agreement (DUA) that nursing homes sign in hard copy and fax or mail back. Registration, submission of nursing home information, and data upload is handled online through a secure Web site. Delivery of confidential nursing home survey feedback reports is also done electronically by having submitters enter a username and password and downloading their reports from a secure Web site. In the future, AHRQ may produce the Nursing Home SOPS Comparative Database Report as an online, interactive tool similar to the online interactive reporting system that the Consumer Assessment of Healthcare Providers and Systems (CAHPS) has recently developed for the CAHPS Database.

4. Efforts to Identify Duplication

While there are survey vendors that administer the AHRQ Nursing Home Survey on Patient Safety Culture and nursing home systems that may maintain a small database of data on the survey, AHRQ is the only entity that serves as a central U.S. repository for data on the survey and AHRQ houses the largest database of the survey's results.

5. Involvement of Small Entities

The collection of information associated with data submission does not unduly burden small businesses or small nursing homes. The information being requested has been held to the absolute minimum required for the intended uses. In addition, AHRQ has produced toolkit materials to make it easy for small and large nursing homes to administer the survey and analyze and report their results.

6. Consequences if Information Collected Less Frequently

Because nursing homes administer the AHRQ Nursing Home SOPS voluntarily, on their own schedule, most nursing homes would only submit their data once in any given calendar year (depending on their survey administration schedule), and greater frequency may not be immediately feasible. Nursing home data submission is available in April 2016.

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 March 23rd, 2015 for 60 days (See Attachment H:60-Day Federal Register Notice).

8.b. Outside Consultations

AHRQ has convened four external Technical Expert Panels (TEPs) to provide expertise and guidance to the development, functioning, and expansion of the SOPS Comparative Databases. The first TEP was convened on January 27, 2006 in Rockville, MD, and was comprised of 13 individuals who provided guidance on the strategy and plan for the initial hospital comparative database, including key components of the database: data submission process; data submission eligibility criteria; data submission timeline; calculation of comparative data; and access to and reporting format of comparative data.

The second TEP was convened on December 3, 2008 in Scottsdale, AZ, and was comprised of 14 individuals with experts for each of four different settings: hospital, medical office, nursing home, and international. The experts provided guidance on issues such as 1) number of years to include in the rolling comparative database; 2) minimum N of facilities to produce overall comparative data; 3) minimum number of respondents to produce facility-level comparative data; 4) trending criteria; 5) comparative database reports for submitters to the database; and 6) international user issues. The TEP also provided input on the development of new databases for the medical office and nursing home patient safety culture surveys recently developed by AHRQ.

The third TEP was convened in Baltimore, MD on April 19, 2010 and was comprised of 15 individuals with experts for each of five different settings: hospital, medical office, nursing home, international, and U.S. Department of Defense. The experts provided guidance on numerous issues, including the cycle for producing Hospital SOPS comparative database reports and developing processes for fulfilling requests from researchers for deidentified and identifiable research datasets.

The fourth TEP was convened virtually on October 21, 2013 and again on March 19, 2014 and was comprised of 16 individuals with experts for each of six different settings: hospital, medical office, nursing home, community pharmacy, international, and U.S. Department of Defense (see Attachment F). The experts provided guidance on the timing of the safety culture databases and Hospital SOPS version 2.0.

9. Payments/Gifts to Respondents

No payment or remuneration is provided to nursing homes for submitting data to the comparative database.

10. Assurance of Confidentiality

Individuals and organizations are assured of the confidentiality of their replies 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.

Confidentiality of the Point of Contact for a Nursing Home. The nursing home POC, 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 for use by the nursing home. In addition, the POC's contact information is important when any clarifications or corrections of the submitted

data set are required or followup is needed. However, the name of the nursing home POC and name of the nursing home is kept confidential and not reported. Only aggregated, de-identified results are displayed in any reports.

Confidentiality of the Survey Data Submitted by a Nursing Home. Nursing homes are assured of the confidentiality of their nursing home patient safety culture survey data through a Data Use Agreement (DUA) that they must sign that has been approved by AHRQ's general counsel (see Attachment B). The DUA states that their data will be handled in a secure manner using necessary administrative, technical and physical safeguards to limit access to it and maintain its confidentiality. In addition, the DUA states the data will be used for the purposes of the database, that only aggregated results will be reported, and that the nursing home is not 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 300 POCs, each representing an average of 5 individual nursing homes each, will complete the database submission steps and forms annually. Completing the eligibility and registration form will take about 3 minutes. Each POC will complete a data use agreement which takes about 3 minutes to complete. The Nursing Home Site Information Form is completed by all POCs for each of their nursing homes (300 x 5 = 1,500 forms in total) and is estimated to take 5 minutes to complete. The POC will submit data for all of the nursing homes he/she represents, which will take one hour on average. The total annual burden hours are estimated to be 455.

The 300 respondents/POCs shown in Exhibit 1 are based on an estimate of nursing homes submitting data in the coming years, with the following assumptions:

- 105 POCs for QIOs submitting on behalf of 10 nursing homes each
- 18 POCs for vendors outside of QIOs submitting on behalf of 10 nursing homes each
- 177 independent nursing homes submitting on their own behalf

Exhibit 2 shows the estimated annualized cost burden based on the respondents' time to submit their data. The cost burden is estimated to be \$20,839 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	300	1	3/60	15
Data Use Agreement	300	1	3/60	15
Nursing Home Site Information Form	300	5	5/60	125
Data Files Submission	300	1	1	300
Total	1,200	NA	NA	455

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	300	15	\$45.80	\$687
Data Use Agreement	300	15	\$45.80	\$687
Nursing Home Site Information Form	300	125	\$45.80	\$5,725
Data Files Submission	300	300	\$45.80	\$13,740
Total	1,200	455	NA	\$20,839

*The wage rate in Exhibit 2 is based on May 2013 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 http://www.bls.gov/oes/current/naics4_623100.htm and http://data.bls.gov/cgi-bin/print.pl/oes/current/naics2_62.htm. The hourly wage of \$45.80 is the weighted mean of \$47.97 (General and Operations Managers 11-1021; N = 88), \$40.07 (Medical and Health Services Managers 11-9111; N = 89), \$47.10 (General and Operations Managers 11-1021; N =105) and \$55.94 (Computer and Information Systems Managers 11-3021; N = 18).

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 \$180,000 annually. The cost of government oversight is estimated to be \$17,563 annually, and is included in the total annualized cost.

Exhibit 3. Estimated Annualized Cost

Cost Component	Annualized Cost
Database Development and Maintenance	\$30,000
Data Submission	\$50,000
Data Analysis & Reports	\$100,000
Total	\$180,000

Exhibit 4: Annual cost to AHRQ for project oversight

Project Officer – GS 15 Step 5 \$143,079	5%	\$7,154
Health Scientist Administrator GS 14 Grade 5 \$121,635	5%	\$6,081
Program Specialist GS 12 Grade 5 \$ 86564	5%	\$4,328
Total		\$ 17,563

Annual salaries based on 2015 OPM Pay Schedule for Washington/DC area:

<http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2015/DCB.pdf>

15. Changes in Hour Burden

The estimated hour burden for data file submission decreased from 5.5 hours in the previous information collection request (ICR) to 1 hour in this ICR. This decrease is due to efficiencies and improvements made in the data submission system. Even though the number of potential respondents increased since the last ICR, the total burden hours have decreased from 511 to 455, a decrease of 56 hours.

16. Time Schedule, Publication and Analysis Plans

Information for the Nursing Home SOPS database is collected by AHRQ through its contractor, Westat, beginning in 2016. Nursing homes are asked to voluntarily submit their Nursing Home SOPS survey data to the comparative database between April 1 and April 21. The data are then cleaned and aggregated and used to produce a Comparative Database Report that displays averages, standard deviations, and percentile scores on the survey's 42 items and 12 patient safety culture dimensions, as well as displaying these results by nursing home characteristics (bed size, urbanicity, ownership, and Census Bureau Region, etc.) and respondent characteristics (work area/unit, staff position, and interaction with patients). The report is posted on the AHRQ Web site during the last quarter of the year. Comparative Database Reports from 2011 and 2014 are available at <http://www.ahrq.gov/professionals/quality-patient-safety/patientsafetyculture/nursing-home/index.html>. Nursing homes are also provided with their own customized survey feedback report approximately two months after the close of data submission.

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: Nursing Home Data Use Agreement
- Attachment C: Nursing Home Site Information Form
- Attachment D: Nursing Home Data Submission Emails
- Attachment E: Nursing Home Survey Data File Specifications
- Attachment F: SOPS Databases TEP List
- Attachment G: Example Screen Shots of Nursing Home Survey on Patient Safety Culture
Data Submission Web Site Information Collection
- Attachment H: 60-Day Federal Register Notice