SUPPORTING STATEMENT

Part A

Pharmacy Survey on Patient Safety Culture Database

June 13, 2017

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. 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, 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 the quality, effectiveness, efficiency, appropriateness and value of heatlchare services; quality measure and development, and database development [Section 902, (a)(1),(2), and (8) (http://www.ahrq.gov/policymakers/hrqa99a.html)].

Furthermore, AHRQ shall conduct and support research to provide objective clinical information to pharmacists; improve the quality of health care through the prevention of adverse effects of drugs and the consequences of such effects; 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 [Section 912, (b) (2) (A) (ii) (II) and (iii) (II) and (c) (1) (2) and (3) (http://www.ahrq.gov/policymakers/hrqa99b.html).

Background on the Pharmacy 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 Pharmacy Survey on Patient Safety Culture with OMB approval (OMB NO. 0935-0183; Approved 08/12/2011). The survey is designed to enable pharmacies to assess staff opinions about patient and medication safety and quality-assurance issues, and includes 36 items that measure 11 dimensions of patient safety culture. AHRQ made the survey publicly available along with a Survey User's Guide and other toolkit materials in October 2012 on the AHRQ Web site.

The AHRQ Pharmacy Survey on Patient Safety Culture (Pharmacy SOPS) Database consists of data from the AHRQ Pharmacy Survey on Patient Safety Culture. Pharmacies in the U.S. are asked to voluntarily submit data from the survey to AHRQ, through its contractor, Westat. The Pharmacy SOPS Database is modeled after three other SOPS databases: Hospital SOPS [OMB NO. 0935-0162; Approved 05/04/2010]; Medical Office SOPS [OMB NO. 0935-0196; Approved 06/12/12]; and Nursing Home SOPS [OMB NO. 0935-0195; Approved 06/12/12] that were originally developed by AHRQ in response to requests from hospitals, medical offices, and nursing homes interested in viewing other organizations' patient safety culture survey results.

Rationale for the information collection. The Pharmacy SOPS survey and the Pharmacy SOPS Database will support AHRQ's goals of promoting improvements in the quality and safety of health care in pharmacy 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 pharmacies, to facilitate the use of these materials for pharmacy 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 Pharmacy Survey on Patient Safety Culture (Pharmacy SOPS) Database; OMB NO. 0935-0218, last approved on June 12, 2014.

This database will:

1) present results from pharmacies that voluntarily submit their data,
2) presents trend data, comparing its previous and most recent data, for pharmacies that have submitted their data more than once,
3) provide data to pharmacies to facilitate internal assessment and learning in the patient safety improvement process, and
4) provide supplemental information to help pharmacies 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) **Pharmacy Eligibility and Registration Form –** The point-of-contact (POC), often the pharmacy manager of a participating organization, completes a number of data submission steps and forms, beginning with completion of an online Eligibility and Registration Form (see Attachment A). The purpose of this form is to collect basic demographic information about the pharmacy and initiate the registration process.

2) **Data Use Agreement –** The purpose of the data use agreement, completed by the pharmacy POC, is to state how data submitted by pharmacies will be used and provides privacy assurances (see Attachment B).

3) **Pharmacy Site Information Form –** The purpose of this form (see Attachment C), completed by the pharmacy POC, is to collect background characteristics of the pharmacy. This information will be used to analyze data collected with the Pharmacy SOPS survey.

4) **Data Files Submission** –POCs upload their data file(s), using the community pharmacy 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 pharmacies do not administer the survey and submit data every year. Data submission is typically handled by one POC who is either a pharmacy manager or a survey vendor who contracts with a pharmacy to collect and submit their data. POCs submit data on behalf of 3 pharmacies, on average, because many pharmacies are part of a multi-pharmacy system, or the POC is a vendor that is submitting data for multiple pharmacies.

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 and with respect to quality measurement and improvement. 42 U.S.C. 299a(a)(1) and (2).

2. Purpose and Use of Information

Survey data from the AHRQ Pharmacy Survey on Patient Safety Culture are used to produce three types of products: 1) A Pharmacy SOPS Database Report that is made publicly available on the AHRQ Web site (see http://www.ahrq.gov/professionals/quality-patient-safety/patientsafetyculture/pharmacy/pharm-reports.html), 2) Individual Pharmacy Survey Feedback Reports that are customized for each pharmacy that submits data to the database (the number of reports produced is based on the number of pharmacies submitting each year); and 3) Research data sets of individual-level and pharmacy-level de-identified data to enable researchers to conduct analyses.

Pharmacies are asked to voluntarily submit their Pharmacy 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 36 items and 11 patient safety culture dimensions, as well as displaying these results by pharmacy characteristics (pharmacy type, number of locations, average number of prescriptions dispensed per week, etc.) and respondent characteristics (staff position, tenure, and hours worked per week).

The Database Report includes a section on Data Limitations in the first chapter highlighting that the results are not representative of the population of U.S. community pharmacies. Community pharmacies voluntarily submit their data to the database. Since the voluntary organizations are not a random sample of the community pharmacy population, and only a small percentage of all community pharmacies may choose to participate, the submitting pharmacies are not representative of all community pharmacies in the U.S. Estimates based on this self-selected group may produce biased estimates of the population and it is not possible to compute estimates of precision from such a self-selected group. The first Pharmacy SOPS Database in 2015 represented less than 0.5% of pharmacies in the U.S. Therefore, we recommend reviewing the database results with these caveats in mind.

As a result of participation, each submitting pharmacy receives its own customized survey feedback report that presents the pharmacy's results and the aggregated results from the other participating organizations. If a pharmacy submits data more than once, its survey feedback report also presents trend data, comparing its previous and most recent data.

Pharmacies use the Pharmacy SOPS Survey, Database Reports and Individual Pharmacy 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 pharmacy.
- 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.

3. Use of Improved Information Technology

All information collection for the Pharmacy SOPS Database is done electronically, except the Data Use Agreement (DUA) that pharmacies sign in hard copy and fax, scan and email, scan and upload to a secure Web site, or mail back. Registration, submission of pharmacy information, and data upload is handled online through a secure web site. Delivery of customized pharmacy survey feedback reports is also done electronically by having submitters enter a username and password and downloading their reports from a secure web site.

4. Efforts to Identify Duplication

While there are survey vendors that administer the AHRQ Pharmacy Survey on Patient Safety Culture and pharmacy 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 pharmacies. 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 pharmacies to administer the survey and analyze and report their results.

6. Consequences if Information Collected Less Frequently

Because pharmacies administer the survey voluntarily, on their own schedule, most pharmacies would only submit their data once every two years (depending on their survey administration schedule), and greater frequency may not be immediately feasible. Pharmacy data submission is expected to occur every two years.

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), notice was published in the Federal Register on November 18th, 2016 for 60 days (Attachment I).

8.b. Outside Consultations

AHRQ has convened five external Technical Expert Panels (TEPs) to provide expertise and guidance to the development, functioning, and expansion of the SOPS 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 database, including key components of the database: data submission process; data submission eligibility criteria; data submission timeline; calculation of aggregate data; and access to and reporting format of the database report.

The second TEP was convened on December 3, 2008 in Scottsdale, AZ and was comprised of 14 individuals with expertise 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 database; 2) minimum N of facilities to produce overall aggregate data; 3) minimum number of respondents to produce facility-level aggregate data; 4) trending criteria; 5) customized feedback 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 on April 19, 2010 in Baltimore, MD and was comprised of 15 individuals with expertise 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 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 expertise for each of six different settings: hospital, medical office, nursing home, community pharmacy, international, and U.S. Department of Defense. The experts provided guidance on the timing of the safety culture databases and Hospital SOPS version 2.0.

The fifth TEP was convened virtually on August 6, 2015 and was comprised of 19 individuals with expertise for each of six different settings: hospital, medical office, nursing home, community pharmacy, international and U.S. Department of Defense (see Attachment G). The experts provided guidance on Hospital SOPS version 2.0 and the Health Information Technology Supplemental Item Set.

9. Payments/Gifts to Respondents

No payment or remuneration is provided to pharmacies 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 Pharmacy. The pharmacy point-of-contact, who submits data on behalf of a pharmacy, is asked to provide his/her name, phone number and email address during the data submission process to ensure that the pharmacy's individual survey feedback report is delivered to that person for use by the pharmacy. In addition, the point-of-contact's contact information is important when any clarifications or corrections of the submitted data set are required and follow up is needed. However, the name of the pharmacy point-of-contact and name of the pharmacy is kept private and not reported. Only aggregated, de-identified results are displayed in any reports.

Privacy of the Survey Data Submitted by a Pharmacy. Pharmacies are assured of the privacy of their pharmacy 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 privacy. 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 pharmacy 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 100 POCs from community pharmacies, each representing an average of 3 individual pharmacies, will complete the database submission steps and forms. Completing the eligibility and registration form will take about 5 minutes. The Pharmacy Site Information Form is completed by all POCs for each of their pharmacies (100 x 3 = 300 forms in total) and is estimated to take 5 minutes to complete. Each POC will complete a data use agreement which takes 3 minutes to complete and submitting the data will take an hour on average. The total burden is estimated to be 138 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 $13,856 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 and Registration Form	100	1	5/60	8
Data Use Agreement	100	1	3/60	5
Pharmacy Site Information Form	100	3	5/60	25
Data Files Submission	100	1	1	100
Total	NA	NA	NA	138

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	$50.20	$402
Data Use Agreement	100	5	$50.20	$251
Pharmacy Site Information Form	100	25	$50.20	$1,255
Data Files Submission	100	100	$50.20	$5,020
Total	NA	138	NA	$6,928

*Based on the average hourly wage in community pharmacies for 100 General and Operations Managers (11-1021; $50.20) obtained from the May 2016 National Industry-Specific Occupational Employment and Wage Estimates: NAICS 446110 - Pharmacies and Drug Stores (located at http://www.bls.gov/oes/current/naics5_446110.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 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 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	$100,000
Total	$180,000

Exhibit 4: Estimated Annual cost to AHRQ for project oversight

AHRQ Position	% Time	Annualized Cost
Health Scientist Administrator/SME-GS 15 Step 5	5%	$ 7,466
Health Scientist Administrator GS 13 Step 5	5%	$ 5,371
Total		$ 12,837

https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2017/DCB.pdf

15. Changes in Hour Burden

The estimated number of responses per POC decreased from 10 responses in the previous information collection request (ICR) to 3 responses in this ICR. As a result, the total burden hours have decreased from 296 to 138, a decrease of 158 responses. This updated estimate is based upon the actual number of responses submitted by POCs in the 2015 Pharmacy SOPS data submission.

16. Time Schedule, Publication and Analysis Plans

Information for the Pharmacy SOPS database is collected by AHRQ through its contractor, Westat, since 2015. Pharmacies are asked to voluntarily submit their Pharmacy SOPS survey data to the database approximately every other year between September 15 and November 1. The data are then cleaned and aggregated and used to produce a Database Report that is posted on the AHRQ web site. Pharmacies are also automatically provided with their own customized survey feedback report.

17. Exemption for Display of Expiration Date

AHRQ does not seek this exemption.

List of Attachments:

Attachment A: Pharmacy Eligibility and Registration Form
Attachment B: Pharmacy Database Data Use Agreement
Attachment C: Pharmacy Site Information Form
Attachment D: Pharmacy Data Submission Emails
Attachment E: Community Pharmacy Survey Data File Specifications
Attachment F: SOPS Databases TEP List
Attachment G: Example Screen Shots of Pharmacy SOPS Data Submission Web Site
Attachment H: 60-Day Federal Register Notice