SUPPORTING STATEMENT

Part A

Collection of Information for
Agency for Healthcare Research and Quality's (AHRQ)
Pharmacy Survey on Patient Safety Culture Comparative Database

Version November 6, 2013

Agency for 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/policymakers/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.

In addition, the Agency 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 health statistics, surveys, database development, and epidemiology [Section 902, (a) (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) Comparative 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 knowing how their patient safety culture survey results compare to those of other similar health care organizations.

Rationale for the information collection. The Pharmacy SOPS survey and the Pharmacy SOPS Comparative 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 comparative 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.

The goal of this project is to create the Pharmacy SOPS Comparative Database. This database will:

1) allow pharmacies to compare their patient safety culture survey results with those of other pharmacies,
2) provide data to pharmacies to facilitate internal assessment and learning in the patient safety improvement process, and
3) provide supplemental information to help pharmacies identify their strengths and areas with potential for improvement in patient safety culture.

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

1) **Registration Form** -- The point-of-contact (POC), the pharmacy manager or a participating organization, completes a number of data submission steps and forms, beginning with completion of an online 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) **Pharmacy Background Characteristics Form** – The purpose of this form (see Attachment B), completed by the pharmacy manager or a participating organization, is to collect background characteristics of the pharmacy. This information will be used to analyze data collected with the Pharmacy SOPS survey.

3) **Data Use Agreement** – The purpose of the data use agreement, completed by the pharmacy manager or a participating organization, is to state how data submitted by pharmacies will be used and provides confidentiality assurances (see Attachment C).

4) **Data Files Submission** – 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 participating organization. POCs will submit data on behalf of 10 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. Following the steps described in Supporting Statement Part B, Section 2 – Information Collection Procedures, the POC will complete a registration form (see Attachment A). After registering, if registrants are deemed eligible to submit data, an automated email is sent to authenticate the account and update the user password (see Attachment D). Next the POC will enter pharmacy information (see Attachment B) and upload their survey questionnaire (see Attachment J, Figure 1) and submit a data use agreement (see Attachment C). POCs then upload their data file(s) (see Attachment J, Figure 2), using the 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.

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 Comparative Database Report that is made publicly available on the AHRQ Web site, 2) Individual Pharmacy Survey Feedback Reports that are confidential, customized reports produced 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 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 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).

Data submitted by pharmacies are also used to give each pharmacy its own customized survey feedback report that presents the pharmacy's results compared to the latest comparative database results. 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, Comparative 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.
- Compare patient safety culture survey results with other pharmacies in their efforts to improve patient safety and quality.

3. Use of Improved Information Technology

All information collection for the Pharmacy SOPS Comparative Database is done electronically, except the Data Use Agreement (DUA) that pharmacies sign in hard copy and fax or mail back. Registration, submission of pharmacy information, and data upload is handled online through a secure Web site. Delivery of confidential 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. In the future, AHRQ may produce the Pharmacy SOPS Comparative Database Report as an online, interactive tool similar to the online interactive reporting system that CAHPS has recently developed for the CAHPS Database.

4. Efforts to Identify Duplication

While there are participating organizations 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 AHRQ Pharmacy SOPS voluntarily, on their own schedule, most pharmacies 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. Pharmacy data submission will be available in September 2014 and October 2017.

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 December 6, 2013 for 60 days (see Attachment H). One comment was received (see Attachment I).

8.b. Outside Consultations

AHRQ has convened three 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 on April 19, 2010 in Baltimore, MD, 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.

AHRQ plans to convene a fourth TEP virtually on October 21, 2013 with membership including representatives from all previous settings and adding members for the pharmacy setting (see Attachment F).

9. Payments/Gifts to Respondents

No payment or remuneration is provided to pharmacies 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 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 confidential and not reported. Only aggregated, de-identified results are displayed in any reports.

Confidentiality of the Survey Data Submitted by a Pharmacy. Pharmacies are assured of the confidentiality 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 C). 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 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 respondent's time to participate in the database. An estimated 150 POCs, each representing an average of 10 individual pharmacies each, will complete the database submission steps and forms annually. Completing the registration form will take about 5 minutes. The Pharmacy Background Characteristics Form is completed by all POCs for each of their pharmacies (150 x 10 = 1,500 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 296 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 $14,392 annually.

Exhibit 1. Estimated annualized burden hours

Form Name	Number of respondents/ POCs	Number of responses per POC	Hours per response	Total burden hours
Registration Form	150	1	5/60	13
Pharmacy Background Characteristics Form	150	10	5/60	125
Data Use Agreement	150	1	3/60	8
Data Files Submission	150	1	1	150

Total	600	NA	NA	296

Exhibit 2. Estimated annualized cost burden

Form Name	Number of respondents/ POCs	Total burden hours	Average hourly wage rate*	Total cost burden
Registration Form	150	13	$48.62	$632
Pharmacy Background Characteristics Form	150	125	$48.62	$6,078
Data Use Agreement	150	8	$48.62	$389
Data Files Submission	150	150	$48.62	$7,293
Total	600	296	NA	$14,392

*Mean hourly wage rate of $48.62 for General and Operations Managers (SOC code 11-1021) was obtained from the May 2012 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 and Exhibit 4 shows the estimated annualized cost to the government for the contractor and government personnel 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 annually.

Exhibit 3. Estimated Annualized Cost for the Contractor

Cost Component	Annualized Cost
Database Development and Maintenance	$40,000
Data Submission	$60,000
Data Analysis & Reports	$100,000
Total	$200,000

Exhibit 4: Estimated annualized cost to AHRQ for project oversight

Project Officer GS 15 Step 5 $ 141,660	5%	$ 7,083
Subject Matter Expert (3) GS 15 Step 5 $ 141,660	5%	$ 21,099
Health Scientist ~~Admisnitrator~~Administrator GS 13 Step 5 $ 101,914	5%	$ 5,095
Program ~~Specialsit~~Specialist GS 12 Step 5 $ 85,703	5%	$ 4,285
Total		$ 37,562

Annual salaries based on 2014 OPM Pay Schedule for Washington/DC area: http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2014/DCB.pdf

15. Changes in Hour Burden

This is a new collection of information.

16. Time Schedule, Publication and Analysis Plans

Information for the Pharmacy SOPS database is collected by AHRQ through its contractor, Westat, beginning in 2014. Pharmacies are asked to voluntarily submit their Pharmacy SOPS survey data to the comparative database between September 15 and November 1. The data are then cleaned and aggregated and used to produce a Comparative Database Report that is published in a limited number of hard copies and also posted on the AHRQ web site during the first quarter of each year. Pharmacies are also 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 SOPS Registration Form
Attachment B:	Pharmacy Background Characteristics Form
Attachment C:	Pharmacy SOPS Database Data Use Agreement
Attachment D:	Pharmacy SOPS Data Submission Emails
Attachment E:	Pharmacy SOPS Survey Data File Specifications
Attachment F:	SOPS Databases TEP List
Attachment G:	2012 Preliminary Comparative Results: Pharmacy Survey on Patient Safety Culture
Attachment H:	Federal Register Notice
Attachment I:	Public Comment
Attachment J:	Example Screen Shots of Pharmacy Survey on Patient Safety Culture Data Submission Web Site Information Collection