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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities:

Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: *Pharmacy Survey on Patient Safety Culture Comparative Database.*” In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501-3521, AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by (INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION).

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at doris.lefkowitz@AHRQ.hhs.gov.

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by email at doris.lefkowitz@AHRQ.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

Pharmacy Survey on Patient Safety Culture Comparative Database

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.

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) Comparative Database; OMB NO. 0935-0218, last approved on June 12, 2014.

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.

This study is being conducted by AHRQ through its contractor, Westat, pursuant to AHRQ's statutory authority to conduct and support research 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 health care services; quality measure and development, and database development. 42 U.S.C. 299a(a)(1), (2), and 8.

Method of Collection

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

- 1) Pharmacy Eligibility and Registration Form – The pointofcontact (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. 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 confidentiality assurances.
- 3) Pharmacy Site Information Form – The purpose of this form, 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 or hospital pharmacy data file specifications, 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 its 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.

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 (see <http://www.ahrq.gov/professionals/quality-patient->

safety/patientsafetyculture/pharmacy/pharm-reports.html), 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.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondents' time to participate in the database. An estimated 100 POCs from community pharmacies and 50 POCs from hospital 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 (150 x 3 = 450 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 209 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 \$11,222 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	150	1	5/60	13
Data Use Agreement	150	1	3/60	8
Pharmacy Site Information Form	150	3	5/60	38
Data Files Submission	150	1	1	150
Total	NA	NA	NA	209

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	150	13	\$53.69	\$698
Data Use Agreement	150	8	\$53.69	\$430
Pharmacy Site Information Form	150	38	\$53.69	\$2,040
Data Files Submission	150	150	\$53.69	\$8,054
Total	NA	209	NA	\$11,222

*Based on the weighted average hourly wage in community pharmacies for 100 General and Operations Managers (11-1021; \$49.26) and 50 General and Operations Managers (11-1021; \$62.56) obtained from the May 2015 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) and NAICS 622000 - Hospitals (located at http://www.bls.gov/oes/current/naics3_622000.htm)

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) whether the proposed

collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Sharon B. Arnold,
Deputy Director

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