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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: "Medical Office 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.

This proposed information collection was previously published in the Federal Register on November 28th, 2011 and allowed 60 days for public comment. No substantive comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by (insert date 30 days after date of publication).

ADDRESSES: Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395-6974 (attention: AHRQ's desk officer) or by email at OIRA_submission@omb.eop.gov (attention: AHRQ's desk officer).

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

Medical Office Survey on Patient Safety Culture Comparative Database

The Agency for Healthcare Research and Quality (AHRQ) requests that the Office of Management and Budget (OMB) approve, under the Paperwork Reduction Act of 1995, AHRQ's collection of information for the AHRQ Medical Office Survey on Patient Safety Culture (Medical Office SOPs) Comparative Database. The Medical Office SOPs Comparative Database consists of data from the AHRQ Medical Office Survey on Patient Safety Culture. Medical offices in the U.S. are asked to voluntarily submit data from the survey to AHRQ, through its contractor, Westat. The Medical Office SOPs Database is modeled after the Hospital SOPs Database [OMB NO. 0935-0162; approved 05/04/2010] that was originally developed by AHRQ

in 2006 in response to requests from hospitals interested in knowing how their patient safety culture survey results compare to those of other hospitals.

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 outpatient ambulatory health care, AHRQ developed and pilot tested the Medical Office Survey on Patient Safety Culture with OMB approval (OMB NO. 0935-0131; Approved July 5, 2007).

The survey is designed to enable medical offices to assess provider and staff opinions about patient safety issues, medical error, and error reporting and includes 52 items that measure 12 dimensions of patient safety culture. AHRQ released the survey to the public along with a Survey User's Guide and other toolkit materials in December 2008 on the AHRQ Web site (located at <http://www.AHRQ.gov/QUAL/patientsafetyculture/mosurvindex.htm>). Since its release, the survey has been voluntarily used by hundreds of medical offices in the U.S.

The Medical Office SOPS and the Comparative Database are supported by AHRQ to meet its goals of promoting improvements in the quality and safety of health care in medical office settings. The survey, toolkit materials, and preliminary comparative database results are all made available to the public along with technical assistance provided by AHRQ through its contractor at no charge to medical offices, to facilitate the use of these materials for medical office patient safety and quality improvement.

The goal of this project is to create the Medical Office SOPS Comparative Database. This database will 1) allow medical offices to compare their patient safety culture survey results with those of other medical offices; 2) provide data to medical offices to facilitate internal assessment and learning in the patient safety improvement process; and, 3) provide supplemental information to help medical offices identify their strengths and areas with potential for improvement in patient safety culture. De-identified data files will also be available to researchers conducting patient safety data analysis. The database will include 52 items that measure 12 areas, or composites, of 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 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 (a)(8).

Method of Collection

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

- 1) Eligibility Form - The purpose of this form is to determine the eligibility status and initiate the registration process for medical offices seeking to voluntarily submit their MO SOPS data to the MO SOPS Comparative Database. The medical office point of contact (POC) will complete the form. The POC is either an office manager, nurse manager, or a survey vendor who contracts with a medical office to collect their data. The POC may submit data on behalf of

multiple medical offices because many medical offices are part of a larger practice with multiple sites or part of a larger health system that includes many medical office sites.

2) Data Use Agreement - The purpose of this form is to obtain authorization from medical offices to use their voluntarily submitted MO SOPS data for analysis and reporting according to the terms specified in the Data Use Agreement (DUA). The medical office POC will complete the form.

3) Medical Office Information Form - The purpose of this form is to obtain basic information about the characteristics of the medical offices submitting their MO SOPS data to the MO SOPS Comparative Database (e.g., number of providers and staff, ownership, and type of specialty). The medical office POC will complete the form.

4) Data Submission - After the medical office POC has completed the Medical Office Eligibility Form, the Data Use Agreement and the Medical Office Information Form, they will submit their data from the MO SOPS to the MO SOPS Comparative Database.

Data from the AHRQ Medical Office Survey on Patient Safety Culture are used to produce three types of products: 1) A Medical Office SOPS Comparative Database Report that is produced periodically and made available to the public on the AHRQ Web site (see <http://www.AHRQ.gov/QUAL/mosurvey10/moresults10.htm>); 2) Medical Office Survey Feedback Reports that are confidential, customized reports produced for each medical office that submits data to the database; and, 3) Research data sets of staff-level and medical office-level de-identified data that enable researchers to conduct additional analyses.

Medical offices are asked to voluntarily submit their Medical Office SOPS data to the comparative database. The data are then edited to detect and correct errors and aggregated and used to produce a Comparative Database Report that displays averages, standard deviations, and percentile scores on the survey's 52 items and 12 patient safety culture dimensions, as well as displaying these results by medical office characteristics (size of office, specialty, geographic region, etc.) and staff characteristics (staff position).

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the medical office to participate in the Medical Office SOPS Comparative Database. The POC completes a number of data submission steps and forms, beginning with completion of the online Medical Office SOPS Database Eligibility Form and Data Use Agreement, which will be completed for 150 medical offices annually. The Medical Office Information Form will be completed for each medical office; since each POC represents an average of 10 medical offices, a total of 1,500 Information Forms will be completed annually, each requiring about 5 minutes to complete. The POC will submit data for all of the medical offices they represent which will take about 4 and ½ hours, including the amount of time POCs typically spend deciding whether to participate in the database, preparing their materials and data set for submission to the database, and performing the submission. The total annual burden hours are estimated to be 816.

Exhibit 1. Estimated annualized burden hours

Number of	Number of	Hours
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Form Name	respondents/ POCs	responses per POC	per response	Total burden hours
Eligibility Form	150	1	3/60	8
Data Use Agreement	150	1	3/60	8
Medical Office Information Form	150	10	5/60	125
Data Submission	150	1	4.5	675
Total	600	NA	NA	816

Medical offices administer the AHRQ Medical Office Survey on Patient Safety Culture on a periodic basis. Hospitals submitting to the Hospital SOPS Comparative Database administer the survey every 16 months on average. Similarly, the number of medical office submissions to the database is likely to vary each year because medical offices do not administer the survey and submit data every year. The 150 respondents/POCs shown in Exhibit 1 are based on an estimate.

Exhibit 2 shows the estimated annualized cost burden based on the respondents' time to submit their data. The cost burden is estimated to be \$34,779 annually.

Exhibit 2. Estimated annualized cost burden

Form Name	Number of respondents/ POCs	Total burden hours	Average hourly wage rate*	Total cost burden
Eligibility Form	150	8	\$42.62	\$341
Data Use Agreement	150	8	\$42.62	\$341
Medical Office Information Form	150	125	\$42.62	\$341
Data Submission	150	675	\$42.62	\$28,769
Total	600	816	NA	\$34,779

*Mean hourly wage rate of \$42.62 for Medical and Health Services Managers (SOC code 19111) was obtained from the May 2009 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 621100 - Offices of Physicians located at http://www.bls.gov/oes/2009/may/naic4_621100.htm.

Estimated Annual Cost to the Government

The estimated annualized cost to the government for developing, maintaining, and managing the database and analyzing the data and producing reports is shown below. The cost is estimated to be \$310,000 annually for 3 years. The total cost is estimated to be \$930,000.

Exhibit 3. Estimated Annualized Cost

Cost Component	Total Cost	Annualized Cost
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Project Development	\$59,715	\$19,905
Data Collection Activities	\$82,107	\$27,369
Data Processing and Analysis	\$111,963	\$37,321
Publication of Results	\$111,966	\$37,322
Project Management	\$7,464	\$2,488
Overhead	\$556,785	\$185,595
Total	\$930,000	\$310,000

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 healthcare research and healthcare 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.

Dated: January 20, 2012

Carolyn M. Clancy, M.D.
Director

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