

Dated: March 8, 2011.

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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: "Pilot Test of the Proposed Pharmacy Survey on Patient Safety Culture." In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501-3521, A1-IRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by May 10, 2011.

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

SUPPLEMENTARY INFORMATION:

Proposed Project

Pilot Test of the Proposed Pharmacy Survey on Patient Safety Culture

As the baby boomer population ages, the general U.S. population continues to grow, and as drug therapies for the treatment of chronic diseases become more efficacious, the expected increase in the number of prescriptions and demand for pharmaceutical products is likely to increase the potential for medication errors in community/retail pharmacies. In 2007, there were about 56,000 community/retail pharmacies,

including about 22,000 traditional chain pharmacy companies, nearly 17,000 independent drug stores, about 9,300 supermarket pharmacies, and about 7,700 mass merchant pharmacies. Numerous reports substantiate the presence of medication errors in pharmacies. For example, one national observational study of prescription dispensing accuracy and safety in 50 pharmacies in the U.S. found a rate of about 4 errors per day in a pharmacy filling 250 prescriptions daily. This error rate translates to an estimated 51.5 million errors occurring during the filling of 3 billion prescriptions each year.

Given the widespread impact of pharmacies on patient safety, the new Pharmacy Survey on Patient Safety Culture (Pharmacy SOPS) will measure pharmacy staff perceptions about what is important in their organization and what attitudes and behaviors related to patient safety are supported, rewarded, and expected. The survey will help community/retail pharmacies to identify and discuss strengths and weaknesses of patient safety culture within their individual pharmacies. They can then use that knowledge to develop appropriate action plans to improve their practices and their culture of patient safety. This survey is designed for use in community/retail pharmacies, which includes chain drugstores (e.g., Walgreens and CVS), supermarket pharmacies, independently owned pharmacies, and mass merchant pharmacies (e.g., Wal-Mart, Costco, Target), not for use in hospital pharmacies.

This research has the following goals:

- (1) Cognitively test and modify as necessary the Pharmacy Survey on Patient Safety Culture Questionnaire;
- (2) Pretest and modify the questionnaire as necessary;
- (3) Make the final questionnaire available to the public.

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).

Method of Collection

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

- (1) *Cognitive interviews*—Two rounds of interviews will be conducted by

telephone with 10 respondents each. The purpose of these interviews is to refine the questionnaire's items and composites. Each round will be conducted with a mix of pharmacists and non-pharmacist staff working in community/retail pharmacies throughout the U.S. The same interview guide will be used for each round.

(2) *Pretest*—The draft questionnaire will be pretested with all pharmacy staff in approximately 60 community/retail pharmacies. The purpose of the pretest is to collect data for an assessment of the reliability and construct validity of the survey's items and composites, allowing for their further refinement.

(3) *Pharmacy background questionnaire*—This questionnaire will be completed by the pharmacy manager in each of the 60 pretest sites to provide background characteristics of the pharmacy, such as pharmacy type (independently owned or chain), type of chain (traditional drugstore, supermarkets, mass merchant), average number of prescriptions filled weekly, average number of hours the pharmacy is open on weekdays, etc.

(4) *Dissemination activities*—The final questionnaire will be made available to the public through the AHRQ Web site. This activity does not impose a burden on the public and is therefore not included in the burden estimates in Exhibit 1.

The information collected will be used to test and improve the draft survey items in the Pharmacy Survey on Patient Safety Culture Questionnaire. Psychometric analysis will be conducted on the pilot data to examine item nonresponse, item response variability, factor structure, reliability, and construct validity of the items included in the survey. Because the survey items are being developed to measure specific aspects of patient safety culture in the pharmacy setting, the factor structure of the survey items will be evaluated through multilevel confirmatory factor analysis. On the basis of the data analyses, items or factors may be dropped.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the pharmacies' time to participate in this research. Cognitive interviews will be conducted with staff at 20 pharmacies (approximately 10 pharmacists and 10 nonpharmacist staff) and will take about one hour and 30 minutes to complete. 627 staff from 60 pharmacies will participate in the pretest (an average of 10.45 staff from each pharmacy). The pretest questionnaire (the Pharmacy Survey on Patient Safety Culture)

requires 15 minutes to complete. The pharmacy background questionnaire will be completed by the manager at each of the 60 pharmacies participating in the pretest and takes 10 minutes to

complete. The total annualized burden is estimated to be 197 hours. Exhibit 2 shows the estimated annualized cost burden associated with the pharmacies' time to participate in

this research. The total cost burden is estimated to be \$4,948 annually.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

| Form name/activity | Number of pharmacies | Number of responses per pharmacy | Hours per response | Total burden hours |
|---|----------------------|----------------------------------|--------------------|--------------------|
| Cognitive interviews | 20 | 1 | 1.5 | 30 |
| Pretest | 60 | 10.45 | 15/60 | 157 |
| Pharmacy background questionnaire | 60 | 1 | 10/60 | 10 |
| Total | 140 | na | na | 197 |

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

| Form name/activity | Number of pharmacies | Total burden hours | Average hourly wage rate* | Total cost burden |
|---|----------------------|--------------------|---------------------------|-------------------|
| Cognitive interviews | 20 | 30 | \$32.28 | \$968 |
| Pretest | 60 | 157 | 22.08 | 3,467 |
| Pharmacy background questionnaire | 60 | 10 | 51.27 | 513 |
| Total | 140 | 197 | na | 4,948 |

*Based upon the mean of the average hourly wages for Pharmacists (29–1051; \$51.27), Pharmacy Technicians (29–2052; \$13.92), and Pharmacy Aides (31–9095; \$10.74), National Compensation Survey: Occupational wages in the United States May 2009, “U.S. Department of Labor, Bureau of Labor Statistics.” The hourly wage for the cognitive interviews is a weighted average for 10 pharmacists, 8 pharmacy technicians and 2 pharmacy aides; the hourly wage for the pretest is a weighted average for 157 pharmacists, 235 pharmacy technicians and 235 pharmacy aides.

Estimated Annual Costs to the Federal Government

Exhibit 3 shows the estimated total and annualized cost for this project.

Although data collection will last for less than one year, the entire project will take about 3 years. The total cost for this project is approximately \$320,818.

EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST

| Cost component | Total cost | Annualized cost |
|------------------------------------|----------------|-----------------|
| Project Development | \$65,340 | \$21,780 |
| Data Collection Activities | 62,831 | 20,944 |
| Data Processing and Analysis | 11,004 | 3,368 |
| Publication of Results | 15,767 | 5,256 |
| Project Management | 7,496 | 2,498 |
| Overhead | 158,380 | 5,293 |
| Total | 320,818 | 106,939 |

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: March 2, 2011.

Carolyn M. Clancy,
Director.

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