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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: "Pretest of the Ambulatory Surgery/Procedure Survey on Patient Safety Culture Questionnaire (Ambulatory Surgery SOPS)." 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

Pretest of the Ambulatory Surgery/Procedure Survey on Patient Safety Culture Questionnaire (Ambulatory Surgery SOPS)

One setting which has demonstrated tremendous growth both in the volume and complexity of procedures being performed is ambulatory surgical and procedure centers (ASCs). ASCs are defined by the Centers for Medicare & Medicaid Services (CMS) as distinct entities that operate exclusively to provide surgical services to patients who do not require hospitalization and are not expected to need to

stay in a surgical facility longer than 24 hours (42 C.F.R. §416.2). Many of the services performed in these facilities extend beyond procedures traditionally thought of as surgery, including endoscopy, and injections to treat chronic pain. Currently, there are over 5,300 Medicare-certified ASCs in the U.S., which represents a greater than 54% increase since 2001. In 2007, Medicare paid for more than 6 million surgeries performed in these facilities at a cost of nearly \$3 billion. Recent CMS audits suggest infection control deficiencies in these facilities are widespread. For example, preliminary data from 2011 found that 51 percent of ASCs surveyed had an infection control deficiency; 11 percent were considered very serious deficiencies. These findings are only slightly lower than 2010 audits and a 2008 sample of ASCs in three states.

Given the widespread impact of ASCs on patient safety, the new Ambulatory Surgery/Procedure Survey on Patient Safety Culture (Ambulatory Surgery SOPS) will measure ASC staff perceptions about what is important in their organization and what attitudes and behaviors related to patient safety culture are supported, rewarded, and expected. The survey will help ASCs to identify and discuss strengths and weaknesses of patient safety culture within their individual facilities. 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 ASCs that practice all types of surgical procedures including those that require incisions and less invasive or non-surgical procedures such as gastrointestinal procedures or pain management injections.

This research has the following goals:

- 1) Develop, cognitively test and modify as necessary the Ambulatory Surgery/Procedure Survey on Patient Safety Culture Questionnaire (Ambulatory Surgery SOPS); and
- 2) Pretest and modify the questionnaire as necessary; and
- 3) Make the final questionnaire publicly available.

This study is being conducted by AHRQ through its contractor, Health Research & Educational Trust (HRET), and subcontractor, 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 projects' goals the following activities-and data collections will be implemented:

- 1) Cognitive interviews. One round of cognitive interviews on the Ambulatory Surgery SOPS will be conducted by telephone with 15 respondents from ASCs. The purpose of these interviews is to understand the cognitive processes the respondent engages in when answering a question on the survey and to refine the survey's items and composites. These interviews will be conducted with a mix of

physicians, management, nurses, surgical technicians, and administrative staff throughout the U.S. from ASCs with varying characteristics (e.g., size, geographic location, and type of ownership).

2) Pretest for the Ambulatory Surgery SOPS. The draft questionnaire will be pretested with physicians and staff from 40 ASCs. The purpose of the pretest is to collect data for an assessment of the reliability and construct validity of the survey items and composites, allowing for their further refinement. A site-level point of contact (POC) will be recruited in each ASC to manage the data collection at that organization (compile sample information, distribute surveys, promote survey response, etc.).

3) Dissemination activities. The final questionnaire will be made publicly available through the AHRQ website. 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 Ambulatory Surgery SOPS. Psychometric analysis will be conducted on the pretest 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 ambulatory surgery 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.

The final survey instrument will be made available to the public for use in ASCs to assess their safety culture from the perspectives of their staff. The survey can be used by ASCs to identify areas for patient safety culture improvement. Researchers are also likely to use the survey to assess the impact of ASC's patient safety culture improvement initiatives such as the implementation of a surgical safety checklist. This survey is an expansion of AHRQ's suite of surveys on patient safety culture, which are available on the AHRQ Web site at (<http://www.ahrq.gov/professionals/quality-patient-safety/surveys/index.html>). Those surveys have been used by thousands of hospitals, nursing homes, medical offices, and pharmacies across the U.S. to assess patient safety culture. The Ambulatory Surgery SOPS contains new and revised questions and composites that more accurately apply to the ambulatory surgery setting.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondents' time to participate in this research. Cognitive interviews will be conducted with 15 ASC staff (approximately three physicians, six nurses, two medical technicians, two administrative managers, and two administrative assistants) and will take about one hour and 30 minutes to complete. The Ambulatory Surgery SOPS will be completed by 529 ASC staff from 40 facilities (about 13 per facility). Each survey will require approximately 15 minutes to complete. A site-level POC will spend approximately 6 hours administering the Ambulatory Surgery SOPS. The total burden is estimated to be 395 hours annually.

Exhibit 2 shows the estimated annualized cost burden associated with the respondents' time to participate in this research. The total cost burden is estimated to be \$16,173 annually.

Exhibit 1. Estimated annualized burden hours

Form Name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Cognitive interviews	15	1	1.5	23
Pretest for the Ambulatory Surgery SOPS	529	1	15/60	132
POC Administration of the survey	40	1	6	240
Total	584	na	na	395

Exhibit 2. Estimated annualized cost burden

Form Name	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
Cognitive interviews	15	23	\$46.52\ a\	\$1,070
Pretest for the Ambulatory Surgery SOPS	529	132	\$46.04\ b\	\$6,077
POC Administration of the survey	40	240	\$37.61\ c\	\$9,026
Total	584	395	na	\$16,173

\ a\ Based on the weighted average wages for 1 Anesthesiologist (29-1061, \$108.35), 2 Surgeons (29-1067, \$106.48), 2 Administrative Services Managers (11-3011, \$37.61), 6 Registered Nurses (29-1141, \$34.23), 2 Medical and Clinical Laboratory Technicians (29-2030, \$28.90), 1 Licensed Practical or Licensed Vocational Nurse (29-2061, \$21.17), and 1 Office and Administrative Support Workers, All Other (43-9199, \$16.92).

\ b\ Based on the weighted average wages for 150 Registered Nurses, 85 Office and Administrative Support Workers, 85 Medical and Clinical Laboratory Technicians, 70 Surgeons, 50 Licensed Practical/Vocational Nurses, 49 Anesthesiologists, and 40 Administrative Services Managers.

\c\ Based on the on the average wages for 1 Administrative Services Managers.

*\ National Occupational Employment and Wage Estimates in the United States, May 2012, "U.S. Department of Labor, Bureau of Labor Statistics" (available at http://www.bls.gov/oes/current/naics4_621400.htm [for outpatient care setting])

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.

Dated: June 25, 2013

Carolyn M. Clancy,

Director

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