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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: "A Prototype Consumer Reporting System For Patient Safety Events." 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 September 11\th\, 2012 and allowed 60 days for public comment. AHRQ received 45 substantive comments and 64 personal stories from members of the public. These comments and personal stories raised 37 issues in the wording of the intake form, two issues with wording in other supporting documentation to the intake form, and 69 design issues that we categorized into 18 types of design concerns. To address these comments substantial revisions were made to the data collection tools and supporting documentation. 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).

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

A Prototype Consumer Reporting System For Patient Safety Events

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 a Prototype Consumer Reporting System for Patient Safety Events. This project aims to design and test a system for collecting information from patients about health care safety events following standard definitions and formats. When complete, project findings will be available for use by local providers that wish to create or enhance their own local consumer reporting systems.

There is a growing body of evidence that many adverse medical events go unreported in current systems (Weissman et al., 2008). One important reason for this reporting gap is that most reporting systems do not presently accept or elicit reports from patients and their families (RTI 2010). AHRQ recognizes that the unique perspective of health care consumers could reveal important information that is not reported by health care providers. Patient reports could complement and enhance reports from providers and thus produce a more complete and accurate understanding of the prevalence and characteristics of medical adverse events (RTI, 2010).

In an effort to realize untapped potential of health care consumers to provide important information about patient safety events, AHRQ has funded the development of a prototype Consumer Reporting System for Patient Safety (CRSPS), designed to collect information from patients about medical errors that resulted or nearly resulted in harm or injury. The purpose of this project is to test the prototype for its ability to record data from consumers about patient safety events defined as an incident or near miss by the AHRQ Common Formats (AHRQ, 2010, details at: www.pso.ahrq.gov/formats/commonfmt.htm).

Currently there is no mechanism for consumers to report information about patient safety events defined as incidents or near misses by the AHRQ Common Formats, which were designed for use by providers of care. Such information is necessary for research on how to improve the quality of health care, promote patient safety, and reduce medical errors. There is a need to collect information about patient safety events from consumers and match these consumer reports to the information collected by providers, because the two sources may differ and, even when reporting on the same event, may provide complementary information. Examining data from both sources allows the project to determine to what extent patients are able to contribute to more complete and/or more detailed information.

This research has the following goals:

1. To develop and design a prototype system to collect information about patient safety events

2. To develop and test web and telephone modes of a prototype questionnaire

3. To develop and test protocols for a follow-up survey of health care providers

This demonstration project is being conducted by AHRQ through its contractor, RAND Corporation, with Brigham and Women's Hospital, Dana Farber Cancer Institute, and ECRI Institute, 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 and with respect to quality measurement and improvement. 42 U.S.C. 299a(a)(1) and (2).

Method of Collection

To achieve the goal of this project the following data collection efforts will be implemented:

1. Safety event intake form and follow up. The safety event intake form asks about a medical error or mistake, harm or injury as well as near misses. Patients, consumers, family members and other caregivers voluntarily report safety events through a web-site or by telephone. The questions ask what happened, details of the event, when, where, whether there was harm, the type of harm, contributing factors, disclosure, and whether the patient reported the event and to whom. Information is also collected regarding whether the respondent is willing to have CRSPS staff follow up to clarify information. If a respondent consents, CRSPS staff will follow up by phone and ask questions about any information that was not clear in the initial report and annotate the report with this information.

2. Health care provider follow up. For the subset of consumers that consent, patient safety officers at health care provider organizations who maintain the adverse event reporting system will contribute supplemental information about the consumer-reported incident which occurred at their facility. CRSPS staff will contact the health care organization to share the consumer report with the patient safety officer or other appointed liaison. The liaison will determine if the consumer-reported incident matches an event in the provider's Incident Reporting System, and if so, provide additional information.

Data collected will be analyzed to produce estimates and basic descriptive statistics on the quantity and type of consumer-reported patient safety events, examine the variability of responses to questions, examine the mode of data collection by event types, and conduct correlations, cross tabulations of responses and other statistical analysis.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for respondents' time to participate in this information collection based on the expected number of respondents, 840 to the intake form and 84 to the provider follow up. The number of respondents is based on the size of the selected community, estimates of health care utilization, rates of adverse events, and response rates in similar investigations. The intake form is expected to maximally require 25 minutes via the web or telephone including the optional 10 minutes of follow-up questions, resulting in a total burden of 490 hours. The health care provider follow up is expected to take 20 minutes and only occurs for the estimated 10% of patients

consenting; this form carries a total burden of 28 hours. The total burden is 518 hours annually.

Exhibit 1. Estimated annualized burden hours

Form Name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Safety event intake form and follow up	840	1	35/60	490
Health care provider follow up	84	1	20/60	28
Total	924	NA	NA	518

Exhibit 2 shows the estimated annualized cost burden for patients, $10,652, and for the health care organization, $885, for a total annualized cost burden of $11,537. Respondents will not incur any other costs beyond those associated with their time to participate.

Exhibit 2. Estimated annualized cost burden

Form Name	Number of respondents	Total burden hours	Average hourly wage rate	Total cost burden
Safety event intake form and follow up	840	490	$21.74*	$10,652
Health care provider follow up	84	28	$31.61**	$885
Total	924	518	NA	$11,537

*Based upon the mean of the average wages, National Compensation Survey: Occupational wages in the United States, May 2011, U.S. Department of Labor, Bureau of Labor Statistics. http://www.bls.gov/oes/current/oes_nat.htm#00-0000

** Based upon the mean of the average wages, National Compensation Survey: Occupational wages in the United States, May 2011: Occupational Health and Safety Specialists (General Medical and Surgical Hospitals). U.S. Department of Labor, Bureau of Labor Statistics. http://www.bls.gov/oes/current/oes299011.htm

Estimated Annual Cost to the Government

AHRQ is supporting the conduct of this project as part of a contract with the RAND Corporation and the ECRI Institute. The estimated cost for this work is $899,827.

Exhibit 3. Estimated Annualized Cost

Cost Component	Total Cost	Annualized Cost
Intake Form Development	$364,375	$242,917
System Development	$413,860	$275,907
Project Management	$35,325	$23,550
Overhead	$86,267	$57,511
Total	$899,827	$599,885

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: May 30, 2013

Carolyn M. Clancy,
Director

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