

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: "National Study of the Hospital Adverse Event Reporting Follow-Up Survey." In accordance with the Paperwork Reduction Act of 1995, 44 U.S.C. 3506(j)(2)(A), AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on July 24th, 2008 and allowed 60 days for public comment. No comments were received. The purpose of this notice is to allow an additional 30 days for public comment. Changes were made to this 30 day notice to account for the electronic patient records review which were not accounted for in the 60 day notice.

DATES: Comments on this notice must be received by December 1, 2008.

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 e-mail 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 e-mail at doris.lefkowitz@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION:**Proposed Project**

"National Study of the Hospital Adverse Event Reporting Follow-Up Survey"

This proposed information collection will conduct a survey similar to a previous AHRQ baseline survey conducted in 2005, which examined and characterized adverse event reporting in the Nation's hospitals (Farley DO, Haviland A, Champagne S, Jain AK, Battles JB, Munier WB, Loeb JM. Adverse Event Reporting Practices by U.S. Hospitals: Results of a National Survey, under review for publication). The follow-up survey will allow AHRQ to examine how hospitals' use of adverse event reporting systems has changed over time. The baseline survey was completed by 1,652 hospital risk managers selected from a nationally representative sample frame. The follow-up survey will consist of a random sample of 1,200 of the respondents to the baseline survey. We anticipate an 85% response rate for the follow-up survey, resulting in 1,020 completed questionnaires.

Similar to the baseline survey, the follow-up survey will ascertain whether hospitals collect information on adverse events, and how the information is stored. Information will also be collected regarding the hospital's case definition of a reportable event, whether information on the severity of the adverse event is collected, who might report this information and whether they can report to a system which is confidential and/or anonymous. The questionnaire also asks about the uses of the data that are collected, and whether information is used for purposes including analytic uses, personnel action, and improvement interventions. Finally, the questionnaire asks about the other sources of information that are useful to hospitals for patient safety-related interventions.

This project is being conducted pursuant to AHRQ's statutory mandates to (1) promote health care quality improvement by conducting and supporting research that develops and presents scientific evidence regarding

all aspects of health care, including methods for measuring quality and strategies for improving quality (42 U.S.C. 299(b)(1)(F)) and (2) conduct and support research on health care and on systems for the delivery of such care, including activities with respect to quality measurement and improvement (42 U.S.C. 299a(a)(2)). In addition, Congress has, in report language, directed AHRQ to provide a report detailing the results of its efforts to reduce medical errors. See Report for the Departments of Labor, Health and Human Services, and Education, and related agencies Appropriation Bill for Fiscal Year 2002, S. Rep. 107-84, at 11 (2001).

This project is being funded by AHRQ and conducted by the RAND Corporation as part of a contract under which RAND serves as the Patient Safety Evaluation Center for AHRQ's patient safety initiative.

Method of Collection

The baseline survey and data collection procedures have been previously conducted and reviewed (under OMB Number 0935-0125, Expiration Date 07/31/2008). The follow-up survey will include an initial mailed survey with two waves of mailed follow-ups as needed, and a Computer-Assisted Telephone Interviewing (CATI) survey follow-up for the remaining non-responders. The survey will be completed by one Risk Manager per hospital.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondents' time to participate in this information collection. The questionnaire is expected to require 25 minutes to complete, resulting in a total burden of 425 hours.

Exhibit 2 shows the estimated annualized cost burden for the respondents, which is estimated to be \$11,518. The respondents will not incur any other costs beyond those associated with their time to participate.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Risk manager questionnaire	1,020	1	25/60	425
Total	1,020	(¹)	(¹)	425

¹ Not applicable.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate ¹	Total cost burden
Risk manager questionnaire	1,020	425	\$27.10	\$11,518
Total	1,020	425	(²)	\$11,518

¹ Based upon the mean of the average wages, National Compensation Survey: Occupational wages in the United States 2006, "U.S. Department of Labor, Bureau of Labor Statistics."

² Not applicable.

Estimated Annual Costs to the Federal Government

The Agency is supporting the conduct of this survey and analysis of survey data as part of a contract with the RAND Corporation under which RAND serves as the Patient Safety Evaluation Center for AHRQ's patient safety initiative. The estimated cost for this work is \$240,000, including \$190,000 for data collection activities and \$50,000 to design the study, analyze the data and report the findings.

Request for Comments

In accordance with the above-cited Paperwork Reduction Act legislation, 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, quality improvement and 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: September 19, 2008.

Carolyn M. Clancy,
Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Ethics Subcommittee, Advisory Committee to the Director (ACD), Centers for Disease Control and Prevention (CDC)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), CDC announces the following meeting for the aforementioned subcommittee:

Name: Ethics Subcommittee, Advisory Committee to the Director (ACD), CDC.

Time and Date: 12-2 p.m., October 9, 2008.

Place: This meeting will be held by conference call. The call in number is (866) 919-3560 and enter passcode: 4168828.

Status: Open to the public. The public is welcome to participate during the public comment period which is tentatively scheduled from 1:30 p.m.-1:45 p.m.

Purpose: The Ethics Subcommittee will provide counsel to the ACD, CDC, regarding a broad range of public health ethics questions and issues arising from programs, scientists and practitioners.

Matters to be Discussed: Agenda items will include review of ethics guidance for public health emergency preparedness and response.

Contact Person for More Information: Drue Barrett, PhD, Designated Federal Official, Ethics Subcommittee, CDC, 1600 Clifton Road, NE., M/S D-50, Atlanta, Georgia 30333. Telephone 404-639-4690, e-mail: d Barrett@cdc.gov.

The Ethics Subcommittee determines that subcommittee business requires its consideration of this matter on less than 15 days notice to the public and that no earlier notice of this meeting was possible. At the Ethics Subcommittee's September 25, 2008 meeting, the subcommittee discussed this matter and determined that additional consideration is necessary prior to submitting the report to the ACD, CDC. The ACD, CDC is scheduled to meet late October.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: September 26, 2008.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1419-N]

Medicare Program; Request for Nominations for the Program Advisory and Oversight Committee for the Competitive Acquisition of Durable Medical Equipment and Other Items

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice solicits nominations for individuals to serve on the Program Advisory and Oversight Committee (PAOC) that will advise the Secretary of Health and Human Services on the competitive acquisition of durable medical equipment and certain other items and services under the Medicare program. Section 1847(c) of the Social Security Act requires the Secretary of the Department of Health and Human Services (Secretary) to establish the PAOC. In addition, section 1847(c)(4) exempts the PAOC from the Federal Advisory Committee Act, 5 U.S.C., appendix 2.

DATES: Nominations will be considered if we receive all of the required information no later than 5 p.m., November 3, 2008.

ADDRESSES: Mail or deliver nominations to the following address: Division of DMEPOS Policy, Mail stop C5-08-17, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore MD, 21244-1850. Attention: Ralph Goldberg or Gina Longus. Nominations may also be e-mailed to ralph.goldberg@cms.hhs.gov or gina.longus@cms.hhs.gov.