

## 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: "Eisenberg Center Voluntary Customer Survey Generic Clearance for the Agency for Healthcare Research and Quality." In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3520, AHRQ invites the public to comment on this proposed information collection.

**DATES:** Comments on this notice must be received by July 19, 2010.

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

#### SUPPLEMENTARY INFORMATION:

##### Proposed Project

*Eisenberg Center Voluntary Customer Survey Generic Clearance for the Agency for Healthcare Research and Quality*

The Agency for Healthcare Research and Quality (AHRQ) requests that the Office of Management and Budget (OMB) renew, under the Paperwork Reduction Act of 1995, AHRQ's Generic Clearance to collect information from users of work products and services initiated by the John M. Eisenberg Clinical Decisions and Communications Science Center (Eisenberg Center).

AHRQ is the lead agency charged with supporting research designed to improve the quality of healthcare, reduce its cost, improve patient safety, decrease medical errors, and broaden access to essential services. See 42 U.S.C. 299. AHRQ's Eisenberg Center is

an innovative effort aimed at improving communication of findings to a variety of audiences ("customers"), including consumers, clinicians, and health care policy makers. The Eisenberg Center compiles research results into a variety of useful formats for customer stakeholders. The Eisenberg Center also conducts its own program of research into effective communication of research findings in order to improve the usability and rapid incorporation of findings into medical practice. The Eisenberg Center is one of three components of AHRQ's Effective Health Care Program, see 42 U.S.C. 299b–7. For the period 2005 until September 2008, the Eisenberg Center was operated through a contractual arrangement with the Oregon Health and Science University (OHSU), Department of Medicine, located in Portland, Oregon. In September 2008, the contract for operation of the Eisenberg Center was awarded to Baylor College of Medicine (BCM), located in Houston Texas.

The collections proposed under this clearance include activities to assist in the development of materials to be disseminated through the Eisenberg Center and to provide feedback to AHRQ on the extent to which these products meet customer needs. These materials include Summary Guides that summarize and translate the findings of comparative effectiveness reviews (CER) and research reports for purposes of summarizing research findings for various decision-making audiences, such as consumers, clinicians, or policymakers. The guides are designed to help these decision makers use research evidence to maximize the benefits of health care, minimize harm, and optimize the use of health care resources. In addition, each year of the project the Eisenberg Center will develop one computerized, interactive decision aid for those clinical problems identified from selected CERs. The intent is for the decision aid to increase the patient/consumer's knowledge of the health condition, options, and risk/benefits, lead to greater assurance in making a decision, increase the congruence between values and choices, and enhance involvement in the decision making process. Information collections conducted under this generic clearance are not required by regulation and will not be used to regulate or sanction customers. Surveys will be entirely voluntary, and information provided by respondents will be combined and summarized so that no individually identifiable information will be released. The Eisenberg Center will produce from 17

to a maximum of 33 Summary Guides per audience (*i.e.*, clinician, policymaker, consumer) per year, depending on the information needed for each product with each audience.

In accordance with OMB guidelines for generic clearances for voluntary customer surveys and Executive Order 12862, AHRQ has established an independent review process to assure the development, implementation, and analysis of high quality customer surveys within AHRQ. Specifically, AHRQ understands that each activity conducted must be submitted to OMB with a supporting statement and accompanying instruments. Information collection may not proceed until approved by OMB.

#### Method of Collection

Information collections conducted under this clearance will be collected via the following methods:

- *Focus Groups.* Focus groups may include clinical professionals, patients or other health care consumers, or health policy makers. They will be used to provide input regarding the needs for products and for the development of Decision Aids and Summary Guides. Focus groups may also be used to test draft products to determine if intended information and messages are being delivered through products that are produced and disseminated through the Eisenberg Center.

- *In-person or Telephone Interviews.* Interviews will be conducted with individuals from one or more of the three groups identified above. The purpose of these interviews is to (1) to provide input regarding the development of Decision Aids and Summary Guides, (2) to determine if intended information and messages are being delivered effectively through products that are produced and disseminated through the Eisenberg Center, and (3) to engage the subject in cognitive testing to (a) determine if changes in topical knowledge levels can be identified following exposure to Eisenberg Center informational or instructional products, and (b) identify strengths and weaknesses in products and services for purposes of making improvements that are practical and feasible.

- *Customer Satisfaction Survey for the Decision Aids.* Baseline survey data will be collected on both clinician and patient characteristics, characteristics of the health care condition, and selected outcome measures such as knowledge and decisional self-efficacy. Following delivery of the decision aid, a user survey will be completed to explore subjects' impressions of the tool,

including ease of use, clarity of presentation, length, balance of information, rating of interactive features, and overall satisfaction. Both clinicians and patients/consumers will be surveyed. For patients, the customer satisfaction survey will include decisional outcome measures (e.g., decisional conflict, desire for involvement in decision-making), measures of attitudes and self-efficacy, and indicators of choice intention or actual choice made. If the aid is evaluated within a clinical context, measures of physician-patient interaction will also be considered. Additionally, clinicians may be interviewed about the impact of the aid on clinical flow.

- **Customer Satisfaction Surveys for the Summary Guides.** These surveys will be offered to health care professionals, consumers, and policy makers that use the online Summary Guides. Respondents will report via Likert-type or numerical response scales how specific informational or educational products or materials influenced health care or clinical practice behaviors.

- **Follow-up CME Surveys.** Continuing Medical Education (CME) credit will be offered to physicians who wish to participate in online activities developed around the Summary Guides for clinicians. Three months after completing the educational activity, physicians will be asked to complete a follow-up survey to assess realized changes in clinical practice, barriers to making change, and self-assessed impacts on patient care.

- **Solicited Topic Nominations.** Visitors to the Web site will have the opportunity to provide information about suggested topics that might be addressed through the research and dissemination efforts of the EHC program.

- **Web site Registration.** Visitors to the Web site will be able to register personal contact information (e.g., name, e-mail address) if wishing to receive updated information and materials as they become available.

- **Glossary Feedback Survey.** Visitors to the Web site who access the health care glossary will be asked to suggest missing terms and provide additional comments on definitions or usage sentences, if desired.

This information will be used to develop, improve and/or maintain high quality products and services to lay and health professional publics.

#### Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden for the respondents time to participate in this research. These estimates assume a maximum of 33 Summary Guides per year and separate Guides for clinicians, policy makers and consumers and are thus slight overestimates.

Focus groups will be used for needs assessment and will be conducted with clinicians and consumers for development of the Summary Guides, and additionally with policymakers for those Guides in which policy recommendations are applicable. Focus groups will be conducted with no more than 1,056 persons per year and will last about 1½ hours.

Once the Summary Guides are developed they will be subjected to in-person or telephone interviews for purposes of usability and product testing with clinicians, policy makers and consumers. In-person telephone interviews will be conducted twice with about 1,386 persons annually and will take about 66 minutes on average. Two rounds of interviews will be conducted with all consumer representatives during product development, with a second round of interviews conducted occasionally with clinicians and policy makers, as needed.

Customer satisfaction surveys for the Summary Guides will be conducted with approximately 6,600 representatives from the audience to be targeted by the Summary Guides annually (i.e., clinician, policymaker or consumer) and will take 5 minutes to complete.

Customer satisfaction surveys will also be administered to approximately 50 clinicians and 500 patients in evaluating the Decision Aid. These surveys will take about 10 minutes to complete, and will be administered before and after implementation of the Decision Aid in the study populations.

Clinicians that have completed CME accrediting requirements and are requesting CME credit will be asked to complete the follow-up CME Survey three months following completion of the online activity. This data collection will be completed with about 1,320 clinicians annually and will require 5 minutes to complete.

Approximately 2,500 solicited topic nomination forms will be completed annually by healthcare professional and consumer visitors to the Web site and will require about 5 minutes to complete. Web site Registration will be completed by all persons wanting to stay up-to-date with the latest information from the Eisenberg Center, about 6,000 annually, and requires about 5 minutes to complete. The Glossary Feedback Survey will be completed by about 200 persons annually that access the glossary and takes 5 minutes to complete. The total burden hours are estimated to be 6,203.

Exhibit 2 shows the estimated annualized cost burden associated with the respondents time to participate in this research. The cost burden is estimated to be \$290,227 annually.

#### Exhibit 1. Estimated Annualized Burden Hours

Type of data collection	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Focus Groups .....	1,056	1	1.5	1,584
In-person/Telephone Interviews .....	1,386	2	1.1	3,050
Customer Satisfaction Surveys for the Decision Aid .....	550	2	10/60	184
Customer Satisfaction Surveys for the Summary Guides .....	6,600	1	5/60	550
Follow-up CME Surveys .....	1,320	1	5/60	110
Solicited Topic Nominations .....	2,500	1	5/60	208
Web site Registration .....	6,000	1	5/60	500
Glossary Feedback Survey .....	200	1	5/60	17
<b>Total .....</b>	<b>19,612</b>	<b>(<sup>1</sup>)</b>	<b>(<sup>1</sup>)</b>	<b>6,203</b>

<sup>1</sup> Not applicable.

**Exhibit 2. Estimated Annualized Cost Burden**

Type of data collection	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
Focus Groups .....	1,056	1,584	\$48.98	\$77,584
In-person/Telephone Interviews .....	1,386	3,050	46.82	142,801
Customer Satisfaction Surveys for the Decision Aid .....	550	184	25.53	4,698
Customer Satisfaction Surveys for the Summary Guides .....	6,600	550	39.55	21,753
Follow-up CME Surveys .....	1,320	110	77.64	8,540
Solicited Topic Nominations .....	2,500	208	48.07	9,999
Web site Registration .....	6,000	500	48.07	24,035
Glossary Feedback Survey .....	200	17	48.07	817
<b>Total .....</b>	<b>19,612</b>	<b>6,203</b>	<b>(<sup>1</sup>)</b>	<b>290,227</b>

<sup>1</sup> Not applicable.

\*Based upon the mean and weighted mean wages for clinicians (29–1062 family and general practitioners), policy makers (11–0000 management occupations, 11–3041 compensation & benefits managers, 13–1072 compensation, benefits & job analysis specialists, 11–9111 medical and health service managers, 13–2053 insurance underwriters and 15–2011 actuaries) and consumers (00–0000 all occupations). Focus groups include 528 clinicians (\$77.64/hr) and 528 consumers (\$20.32/hr); in-person/telephone interviews includes 528 clinicians, 330 policy makers (\$39.91/hr) and 528 consumers; customer satisfaction surveys for the decision aid includes 50 clinicians and 500 consumers; customer satisfaction surveys for the summary guides includes 1,650 clinicians, 1,650 policy makers and 3,300 consumers; follow-up CME surveys includes 1,320 clinicians; solicited topic nominations include 1,125 clinicians, 250 policy makers and 1,125 consumers; Web site registration includes 2,700 clinicians, 600 policy makers and 2,700 consumers; glossary feedback survey includes 90 clinicians, 20 policy makers and 90 consumers, National Compensation Survey: Occupational wages in the United States May 2008, “U.S. Department of Labor, Bureau of Labor Statistics.”

**Estimated Annual Costs to the Federal Government**

The maximum cost to the Federal Government is estimated to be

\$1,439,003 annually. Exhibit 3 shows the total and annualized cost by the major cost components.

**Exhibit 3. Estimated Total and Annualized Cost**

Cost component	Total cost	Annualized cost
Project Development .....	\$1,019,970	\$339,990
Data Collection Activities .....	735,405	245,135
Data Processing and Analysis .....	1,889,505	629,835
Project Management .....	557,380	185,793
Overhead .....	114,750	38,250
<b>Total .....</b>	<b>4,317,010</b>	<b>1,439,003</b>

**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 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: May 10, 2010.

**Carolyn M. Clancy,**

*Director.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA-2010-D-0226]

**Draft Guidance for Industry, Third Parties and Food and Drug Administration Staff; Medical Device ISO 13485:2003 Voluntary Audit Report Submission Program; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled “Medical Device ISO 13485:2003 Voluntary Audit Report Submission Program.” This draft guidance is intended to provide information on the implementation of a section of the Food and Drug Administration Amendments Act of 2007 (FDAAA), which amends a section of the Federal Food, Drug, and Cosmetic Act (the act). This guidance document describes how FDA's Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER) are implementing this provision of the law. This draft guidance is not final nor is it in effect at this time.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit