

Centers for Disease Control & Prevention, Attn: Lynn Armstrong, FOIA Officer, 1600 Clifton Road, NE, MS D54, Atlanta, GA 30333. The materials should be available approximately 15 working days after the meeting.

Dated: February 17, 2000.

David Satcher,

Assistant Secretary for Health and Surgeon General.

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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: (AHRQ), formerly known as the Agency for Health Care Policy and Research (AHCPR), HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request the Office of Management and Budget (OMB) to allow the proposed information collection project; "Development and Implementation of National Guideline Clearinghouse Evaluation (NGC)". In accordance with the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)), AHRQ invites the public to comment on this proposed information collection.

DATE: Comments on this notice must be received by April 25, 2000.

ADDRESSES: Written comments should be submitted to: Cynthia McMichael, Reports Clearance Officer, AHRQ, 2101 East Jefferson Street, Suite 500, Rockville, MD 20852-4908.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval of the proposed information collection. All comments will become a matter of public record.

In accordance with the above cited legislation, comments on the AHRQ information collection proposal are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of functions of the Agency, including whether the information will have practical utility; (b) the accuracy of the Agency's estimate of the burden (including hours and costs) of the proposed collection 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 on respondents, including the use of automated collection techniques or other forms of information technology.

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:

Cynthia D. McMichael, AHRQ Reports Clearance Officer, (301) 594-3132.

SUPPLEMENTARY INFORMATION:

Proposed Project

Development and Implementation of National Guideline Clearinghouse Evaluation (NGC)

The NGC already reaches many individuals indicating its great potential to affect medical practice. In the nine months since it became available to the public, the NGC site has processed over 5 million requests for guideline information, with an average user visit lasting seven minutes. Over the last six months, the "hit volume" (e.g., connection to the Internet site) has been fairly constant with approximately 36,000 per day. The majority of users are within the United States, but the site is also utilized globally, indicating the potential for far reaching effects. As the NGC audience continues to grow and the field of best practices develops, the Web site will only be effective if it keeps pace with the needs of its users. A small study conducted by the American Medical Association (AMA) to gauge NGC awareness and satisfaction with the site among their members provides the only data to date on how the NGC is currently perceived by users. Although its conclusions were limited by a small sample size of physician respondents (e.g., n=44), the AMA survey suggested that several functions of the NGC could be improved. These findings support the need for a further, more comprehensive evaluation of the site's quality and usefulness in order for AHRQ to meet users' needs and to promote implementation of guidelines by health care professionals. The results of this type of evaluation will assist AHRQ and others to understand what user's want and need to utilize clinical guidelines in the provision of care. The timeliness and need for this evaluation effort is further underscored by the concurrent development of a customer satisfaction survey by the NGC Web site developer pursuant to its original contract in accordance with widely accepted

management practices. This electronic survey, is being designed to capture NGC audience satisfaction with the interface and format of the Web site, which will complement this proposed evaluation of the content, quality, and usefulness of information.

The NGC is intended to serve the needs of a diverse population of users. Not only are the user groups different, their expectations and uses of the NGC are unique. Moreover, no single sampling or data collection technique is efficient to capture the needed information from these groups. A survey that attempted to capture the perspectives of all groups would be long, complicated, and burdensome. Therefore, we propose using a three-tiered data collection scheme designed to get distinct types of information in a manner most useful to helping evaluate how well the Web site is serving its intended populations. The three proposed approaches are survey questionnaire, focus group discussions, and unstructured, informational discussions.

Each will be applied to a subset of all users, as appropriate, to capture their unique opinions and best complement the overall data collection effort.

Data Confidentiality Provisions

Although no information on race, income, sexual behavior and attitudes, religious beliefs, or other matters commonly considered private will be requested, the contractor responsible for conducting the study will perform in accordance with the requirements of the Agency's confidentiality statute, 42 USC 299c-3(c), to protect respondents' privacy and the confidentiality of data collected. All results will be reported without attributing responses to any individual source. Information gained for the purposes of this data collection will only be used for the purposes of this project.

Data Products

The evaluation goals will be achieved through three types of data collection: (1) Written survey questionnaires, (2) focus groups, and (3) discussions with individuals working in health care who contribute to guideline development and use. Assignments of data collection modes to target audience groups are designed to reach the maximum number of respondents and the broadest range of groups. Participation will be minimally burdensome and is voluntary. Both qualitative and quantitative data will be collected to characterize the experiences and needs of users in a manner most likely to facilitate improvement activities by AHRQ.

The project will benefit AHRQ, the medical community, policy makers, health service researchers, and ultimately patients in the following ways:

- AHRQ will be able to monitor how their current format and content are serving their intended audiences;
- AHRQ will be able to assess how the Clearinghouse is affecting future development of guidelines and their implementation in clinical practices;
- AHRQ will be able to use the evaluation results to refine the site, thereby making it more useful for the medical community and other professionals who use guidelines in care management;

• Individual clinicians will be better able to obtain timely guidance about the management of complex clinical problems;

- Federal, State, and private purchasers will be able to encourage contracted or prospective plans and providers to adopt clinical practices that are consistent with the best available standards of care; and,
- Public policy experts will be better able to obtain unbiased, evidence-based guidelines and information for decisionmaking and policy purposes.

Method of Collection

Electronic mail will be used to transmit the written survey responses.

The written survey will also be linked to the NGC Website. Users can complete the survey on-line, and their responses will be automatically submitted. By using e-mail and the Web link to target our audience we are ensuring that our respondents are Web-based users. This approach significantly reduces the burden to non-Web users who would be unable to contribute information useful to this data collection. Additionally, this use of information technology minimizes the burden on the targeted respondents by improving the ease in which they can submit their survey responses.

ESTIMATED ANNUAL RESPONDENT BURDEN

Annual number of respondents	Estimated time per respondent (in hours)	Estimated total annual burden hours	Estimated annual cost to the Government
1,3595	408	\$249,993

The survey instrument is short and poses minimal burden on the time of respondents. Estimates of time required to complete the survey during the pilot phase range from 7 to 20 minutes. The annual hour burden calculation assumes each survey will last 15 minutes, therefore the total of annualized hourly costs to participants is estimated to be \$30,040.

Dated: February 16, 2000.

John M. Eisenberg,

Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-0302]

Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document 2; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document 2." The guidance document is intended to assist facilities and their personnel to meet the

Mammography Quality Standards Act of 1992 (the MQSA) final regulations. The final regulations implementing the MQSA became effective April 28, 1999, replacing the interim regulations.

DATES: Submit written comments concerning this guidance at any time.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the guidance document entitled "Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document 2" to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments on "Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document 2" to the contact person listed below.

FOR FURTHER INFORMATION CONTACT: Charles A. Finder, Center for Devices and Radiological Health (HFZ-240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-594-3332.

SUPPLEMENTARY INFORMATION:

I. Background

The MQSA was passed on October 27, 1992, to establish national quality

standards for mammography. The MQSA required that to provide mammography services legally after October 1, 1994, all facilities, except facilities of the U.S. Department of Veterans Affairs, must be accredited by an approved accreditation body and certified by the Secretary of Health and Human Services (the Secretary). The authority to approve accreditation bodies and to certify facilities was delegated by the Secretary to FDA. In the **Federal Register** of October 28, 1997, FDA published the MQSA final regulations. The final regulations became effective April 28, 1999, and replaced the interim regulations (58 FR 67558 and 58 FR 67565, December 21, 1993) which, under the MQSA, previously regulated mammography facilities. The document addresses new questions that FDA has received since the publication of "Compliance Guidance: The Mammography Quality Standards Act Final Regulations" on August 27, 1998.

The guidance document was published as a draft proposal for public comment on March 19, 1999 (64 FR 13589). It was discussed with the National Mammography Quality Assurance Advisory Committee in November 1998 and a working group of the Conference of Radiation Control Program Directors in May 1999. The document has been modified from the original draft proposal to address public comments. While there are many clarifying changes in the document,