

guidance document may also be seen on FDA's web site at "www.FDA.gov".

Dated: August 21, 1998.

**William K. Hubbard,**

*Associate Commissioner for Policy  
Coordination.*

[FR Doc. 98-23026 Filed 8-24-98; 3:45 pm]

BILLING CODE 4160-01-F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 98D-0697]

#### **Compliance Guidance: The Mammography Quality Standards Act Final Regulations Draft; Availability**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance document entitled "Compliance Guidance: The Mammography Quality Standards Act Final Regulations." This draft guidance document is not final nor is it in effect at this time. The final regulations implementing the Mammography Quality Standards Act of 1992 (the MQSA) will become effective April 28, 1999, and will replace the interim regulations which, under the MQSA, currently regulate mammography facilities. The draft guidance document is intended to assist facilities and their personnel to meet the MQSA final regulations.

**DATES:** Written comments must be received by November 25, 1998.

**ADDRESSES:** Submit written requests for single copies on a 3.5" diskette of the draft guidance document entitled "Compliance Guidance: The Mammography Quality Standards Act Final Regulations" to the Division of Small Manufacturers Assistance (HFZ-220),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 See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

Submit written comments on this draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the

docket number found in brackets in the heading of this document.

#### **FOR FURTHER INFORMATION CONTACT:**

Walid G. Mourad, 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. After October 1, 1994, the MQSA required all mammography facilities, except facilities of the U.S. Department of Veterans Affairs, to 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. On October 28, 1997, FDA published the MQSA final regulations in the **Federal Register**. The final regulations will become effective April 28, 1999, and will replace the interim regulations (58 FR 67558 and 58 FR 67565) which, under the MQSA, currently regulate mammography facilities. Development of the guidance began in August 1997 and is based in part on discussions with, and input from, the National Mammography Quality Assurance Advisory Committee.

##### **II. Significance of Guidance**

This draft guidance document represents the agency's current thinking on the final regulations implementing the MQSA. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This draft guidance document is issued as a Level 1 guidance consistent with GGP's.

##### **III. Electronic Access**

In order to receive the "Compliance Guidance: The Mammography Quality Standards Act Final Regulations" via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (1259)

followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance document may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Web. Updated on a regular basis, the CDRH home page includes the "Compliance Guidance: The Mammography Quality Standards Act Final Regulations", device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>. The "Compliance Guidance: The Mammography Quality Standards Act Final Regulations" will be available at <http://www.fda.gov/cdrh/dmqrp.html>.

##### **IV. Comments**

Interested persons may, on or before November 25, 1998, submit to the Dockets Management Branch (address above) written comments regarding this draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 7, 1998.

**D.B. Burlington,**

*Director, Center for Devices and Radiological Health.*

[FR Doc. 98-23030 Filed 8-26-98; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

[Document Identifier: HCFA-R-254]

#### **Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)**

**AGENCY:** Health Care Financing Administration.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

We are, however, requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. Due to an unanticipated event and the fact that this collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR, Part 1320, we are requesting an emergency review.

With the creation of the Medicare+Choice program, as required by the Balanced Budget Act of 1997 (Pub. L. 105-33), Medicare beneficiaries' health care options were expanded to include coordinated care plans such as Health Maintenance Organizations, Preferred Provider Organizations, Provider-sponsored Organizations, as well as Private Fee-for-Service Plans and Medical Savings Accounts. While the new options bring more flexibility for health care decisions for people with Medicare, they also necessitate the need for a carefully planned, extensive education campaign to assure that Medicare beneficiaries have understanding of the new health plan choices offered by Medicare and how to use HCFA-developed information tools that will be available through an annual publication, a toll-free number and the World Wide Web.

The purpose of this submission is to request approval of a baseline and follow-up survey of beneficiaries in six communities where we are conducting case studies to examine how all of our activities related to the education campaign are working. The baseline

survey will be conducted in September and the follow-up survey will be done this winter after all of the material related to the education campaign for this year has been mailed to beneficiaries. Examples of the types of questions that will be asked of beneficiaries include their satisfaction with the availability and usefulness of Medicare information when they need it, where they obtain information for particular Medicare-related decisions, their use of the Handbook and other information sources, their awareness of some of the major messages HCFA is trying to convey in the campaign and the demographics of the respondents.

HCFA is requesting OMB review and approval of this collection within 6 working days of publication of this notice in the **Federal Register**, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below by 5 working days of the publication of this notice. During this 180-day period, we will publish a separate **Federal Register** notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements. We will submit the requirements for OMB review and an extension of this emergency approval.

*Type of Information Request:* New Collection.

*Title of Information Collection:* National Medicare Education Program Community Survey of Medicare Beneficiaries.

*Form Number:* HCFA-R-254 (OMB approval #: 0938-NEW).

*Use:* The primary purpose of the baseline and follow-up survey is to collect information on beneficiary satisfaction with the availability and usefulness of Medicare information when they need it, where beneficiaries obtain information for particular Medicare-related decisions, beneficiary use of the Handbook and other information sources, and their awareness of the major messages HCFA is trying to convey in the campaign. This information will be used in conjunction with other information collected in these six communities through focus groups and interviews to identify problems and make recommendations for ways of improving HCFA's education campaign in future years.

*Frequency:* On occasion.

*Affected Public:* Individuals or Households.

*Number of Respondents:* 4,800.

*Total Annual Responses:* 4,800.

*Total Annual Hours Requested:* 1,200 hours.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's WEB SITE ADDRESS at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address and phone number, to [Paperwork@hcfa.gov](mailto:Paperwork@hcfa.gov), or call the Reports Clearance Office on (410) 786-1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and record keeping requirements must be mailed and/or faxed to the designees referenced below within 5 working days of the publication of this notice in the **Federal Register**:

Health Care Financing Administration,  
Office of Information Services,  
Security and Standards Group,  
Division of HCFA Enterprise  
Standards, Room N2-14-26, 7500  
Security Boulevard, Baltimore, MD  
21244-1850. Fax Number: (410) 786-  
0262 Attn: John Rudolph HCFA-R-  
254 and,

Office of Information and Regulatory  
Affairs, Office of Management and  
Budget, Room 10235, New Executive  
Office Building, Washington, DC  
20503, Fax Number: (202) 395-6974  
or (202) 395-5167 Attn: Allison  
Herron Eydt, HCFA Desk Officer.

Dated: August 20, 1998.

**John Parmigiani,**

*Acting HCFA Reports Clearance Officer,  
HCFA, Office of Information Services,  
Security and Standards Group, Division of  
HCFA Enterprise Standards.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

[Document Identifier: HCFA-R-0253]

### Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Health Care Financing Administration.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send