DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 94N–0335]

Medical Devices; Mammography Quality Standards Act of 1992; Inspection Fees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fees it will assess for inspections of mammography facilities during fiscal year 1995 (FY 95). The Mammography Quality Standards Act of 1992 (MQSA) requires FDA to assess and collect fees from mammography facilities to cover the costs of annual inspections required by the MQSA. This notice explains which facilities are subject to payment of inspection fees, provides information on the costs included in developing inspection fees, and provides information on the inspection, billing, and collection processes.

DATES: Effective October 1, 1994, for all inspections conducted under 42 U.S.C. 263b(g). Written comments by June 15, 1995.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm.1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: John L. McCrohan, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3332, fax 301–594–3306.

SUPPLEMENTARY INFORMATION:

I. Background

The MQSA amended Title III of the Public Health Services Act (the PHS Act) (42 U.S.C. 262 *et seq*.) by adding a new section 354 (42 U.S.C. 263b) to require uniform national quality standards for mammography facilities. The MQSA requires all mammography facilities, other than facilities of the Department of Veterans Affairs, to be accredited by an approved accreditation body and certified by the Secretary of Health and Human Services as meeting quality standards. Facilities must obtain a certificate by October 1, 1994, in order to continue to legally provide mammography services. See 58 FR 67558, December 21, 1993, ''Mammography Facilities—Requirements for Accrediting Bodies and Quality Standards and Certification Requirements,'' interim rules and 59 FR 49808, September 30, 1994, ''Quality Standards and Certification Requirements for Mammography Facilities,'' amending the interim rules. The MQSA requires FDA to establish a Federal certification and inspection program for mammography facilities; regulations and standards for accreditation bodies; and standards for equipment, personnel, quality assurance, and recordkeeping and reporting by mammography facilities.

The MQSA requires annual facility inspections to determine compliance with the quality standards. Section 354(r) of the PHS Act requires FDA to assess and collect fees for inspections of all mammography facilities, other than Governmental entities as determined by FDA, to cover the costs of inspections. FDA is providing notice of the fees to be assessed during FY 95 and additional information relating to those fees. Although the MQSA does not require FDA to solicit comments on fee assessment and collection, FDA is inviting comments from interested persons in order to have the benefit of additional views and information.

II. Inspections under the Mammography Quality Standards Act of 1992

Section 354(g)(1) of the PHS Act requires FDA, or a State operating under a delegation of authority from FDA, to conduct an annual inspection of each mammography facility. The purpose of the annual inspection is to determine facility compliance with quality standards established under the MQSA. The quality standards to be enforced during FY 95 were established by an interim rule published at 58 FR 67565, December 21, 1993, ''Quality Standards and Certification Requirements for Mammography Facilities,'' amended by an interim rule published at 59 FR 49808, September 30, 1994, ''Quality Standards and Certification Requirements for Mammography Facilities.'' Inspections will be conducted by inspectors who have met Federal training requirements and who are certified by FDA.

Under ordinary circumstances, inspections will be conducted during the regular business hours of the facility or at a mutually agreed time. FDA normally will provide 5 working days advance notice of each annual inspection. If a significant deficiency is identified during an inspection, FDA will provide information on necessary corrective action and in appropriate cases, will schedule a followup inspection after the facility has had a reasonable time to correct the deficiency. FDA normally will provide 5 working days advance notice of each followup inspection. FDA may make unannounced inspections or may provide shorter notice if prompt action is necessary to protect the public health (see 42 U.S.C. 263b(g)(4)).

III. Costs Included in FY 1995 Inspection Fees

Section 354(r) of the PHS Act requires FDA to assess and collect fees from persons who own or lease mammography facilities, or their agents, to cover the cost of annual and followup inspections conducted by FDA or a State acting under a delegation from FDA. Section 354(r) limits FDA's discretion in setting inspection fees in three ways: (1) Fees must be set so that, for a given fiscal year, the aggregate amount of fees collected will equal the aggregate costs of inspections conducted; (2) a facility's liability for fees must be reasonably based on the proportion of the inspection costs which relate to the facility; and (3) Governmental entities, as determined by FDA, are exempt from payment of fees.

FDA has determined that the following categories of costs are recoverable under section 354(r) of the PHS Act and has included them in the fees to be assessed in FY 95:

- Personnel costs of annual and followup inspections of mammography facilities, including administration and support.
- Purchase of equipment, development of instrument calibration procedures, calibration of instruments used in the inspections, and modification of training facilities and laboratories to support MQSA operations.
- Design, programming, and maintenance of data systems necessary to schedule and track inspections and to collect data during inspections.
- Training and certification of inspectors (both FDA and State inspectors).
- Costs of billing facilities for fees due for annual and followup inspections and collecting facility payments.
- Tracking, coordination, and direction of inspections.
- Overhead and support attributable to facility inspections.

FDA has calculated the fixed and variable amounts of these costs. Because facilities and most scientific equipment are durable and can be used for a period of years, it is not appropriate to recover the full costs of such expenditures in the year of purchase. To do so would result in the MQSA inspection fee varying widely from one year to the next. Instead, these costs will be

recovered over the useful life of the asset. FDA has used these data on fixed and variable costs to determine fees for two categories of inspection:

• Annual inspection of each mammography facility. The recoverable portions of all fixed costs of the inspection program and appropriate variable costs are recovered in the annual inspection fee. This fee will vary depending on how many mammography units are used by a facility. All mammography facilities, except Governmental entities, will be subject to this fee.

• Followup inspections. If the annual inspection of a facility identifies a deficiency that necessitates a followup inspection, that facility will be assessed an additional fee to recover the costs of that additional inspection. Only variable costs directly related to followup inspections are recovered. Governmental entities and all facilities that do not require a followup inspection are not subject to this fee.

IV. Inspection Fees to be Assessed During FY 95

After consulting with the National Mammography Quality Advisory Committee, FDA has determined that, for FY 95 (October 1, 1994 to September 30, 1995), a facility's inspection fees will be based on the number of mammography units used by the facility. Based on information submitted by States during contract negotiations and a 1993 survey by the National Cancer Institute, FDA estimates that there are 13,252 mammography units and 10,666 facilities subject to inspection in FY 1995. Most facilities (83 percent) have only a single mammography unit and fewer than 5 percent of facilities have more than two units.

FDA has determined that the following fees will be assessed for facility inspections conducted in fiscal year 1995:

Type of Inspection	Fee
Annual	$1,178 for the first unit, plus $152 for each additional unit.
Followup	$670 for each follow-up inspection.

The fee schedule is subject to change each fiscal year to ensure that the aggregate amount of fees collected during any fiscal year equals the aggregate amount of costs for such fiscal year for inspection of facilities

FDA reviewed and considered several methodologies for setting annual inspection fees for FY 95, including fee structures that would do one or more of the following: (1) Account for differences in facility size (the adopted methodology); (2) establish a flat fee that would not vary by facility size; (3) account for regional variations in inspection costs; (4) eliminate separate followup inspection fees by increasing the annual inspection fee. FDA decided to charge separately for annual and followup inspections because FDA believes it is more appropriate and equitable for the costs of followup inspections to be borne entirely by the facilities that require such inspections. In addition, this approach eliminated the need for FDA to attempt to estimate the number of followup inspections that will be conducted. FDA chose to use a uniform, national fee structure because, at this time, the agency lacks sufficient information to adopt any other approach.

For followup inspections, FDA considered a flat fee (the adopted methodology) and an hourly rate that would vary the fee by the length of the inspection. FDA has chosen to adopt a flat fee for followup inspections because this approach eliminates concerns about variations among inspectors and differential treatment of facilities.

The methodology adopted by FDA to determine inspection fees does not pass on the costs of inspecting Governmental entities to other facilities. The entire cost of inspecting Governmental entities will be borne by FDA and paid out of appropriated funds.

The agency invites comments on alternative methods of determining inspection fees under the MQSA and may consider altering its methodology in the future, after actual inspection experience provides more accurate data about differences among facilities and variations in costs by State, region, or other factors.

V. Facilities Subject to Payment of Inspection Fees

Under the MQSA, all certified mammography facilities except Governmental entities, as determined by FDA, are subject to payment of inspection fees (see 42 U.S.C. 263b(r)).

FDA has developed a definition that will be used to determine whether a facility qualifies as a ''Governmental entity'' for the purpose of determining whether a facility is exempt from payment of inspection fees under 42 U.S.C. 263b(r). A Governmental entity is a mammography facility subject to inspection under section 354(g)(1) of the Public Health Service Act (42 U.S.C. 263b(g)(1), that meets either of the following criteria: (1) Is operated by any Federal department, State, district, territory, possession, Federally-recognized Indian tribe, city, county, town, village, municipal corporation or similar political organization or subpart thereof, or (2) provides services under the Breast and Cervical Cancer Mortality Prevention Act of 1990, 42 U.S.C. 300k *et seq*., and at least 50 percent of the mammography screening examinations provided during the preceding 12 months were funded under that statute.

In making these determinations, FDA reviewed the legislative history of the Mammography Quality Standards Act of 1992. There is nothing in the legislative history to indicate that Congress intended the exemption for Governmental entities to be read expansively. Nor is there anything in the legislative history to suggest that Congress intended FDA to distinguish among mammography facilities with respect to this exemption for any particular policy reason, such as the type of organization operating the facility (e.g., facilities that qualify as a charitable organization under section 501(c)(3) of the Internal Revenue Code), location (e.g., rural facilities), or size (e.g., facilities that handle relatively few patients). Accordingly, FDA has interpreted the exemption provision in a manner that will recoup the costs of inspections from as many facilities as possible. This approach will reduce the likelihood that fiscal constraints will undermine the agency's ability to perform adequate inspections required by the law.

FDA determined that the definition of Governmental entity under the MQSA should include facilities that are highly dependent on funding provided under the Breast and Cervical Cancer Mortality Prevention Act of 1990 (BCCMPA) (see 42 U.S.C. 300k *et seq*.). That statute authorizes grants to States for programs to screen women for breast and cervical cancer as a preventive health measure (see 42 U.S.C. 300k). Low income women are given priority for screening services, including free services to any woman with income below the official poverty line (see 42 U.S.C. 300n). Advisory committee discussions raised concern that assessing an inspection fee on certain facilities receiving these grants would be at variance with, and could undermine, the initiative that Congress legislated through BCCMPA, and that the Department of Health and Human Services implemented, to provide mammography screening to under-served populations. In response to this concern, FDA decided to include in its definition of Governmental entity, those facilities with BCCMPA grants that provide at least 50 percent of their mammography screening services to the

population targeted by BCCMPA. FDA believes relatively few (less than 100) facilities will qualify as Governmental entities because of their dependence on BCCMPA grants. These facilities pursue the same public health objectives as the MQSA and are largely dependent on Federal payments. Assessing an inspection fee would do little more than shift the costs of one Federal program to another Federal program while subjecting the Federal government to the transaction costs involved with such transfers.

The agency invites comments on alternative ways to define Governmental entities under the MQSA and may consider altering its determination in the future, after actual inspection experience provides more accurate data about other types of facilities that might be included in the category which is exempt from inspection fees under 42 U.S.C. 263b(r).

Prior to the first annual inspection of a facility, FDA will contact the facility and provide an opportunity for the facility to attest that it qualifies as a Governmental entity. Facilities that FDA finds to be Governmental entities will not be billed for inspections.

VI. Billing and Collection Procedures

Within 30 days following inspection, FDA will mail a bill to the inspected facility (Governmental entities will not receive bills). The bill will set forth the type of inspection conducted (annual or followup), the fee to be paid, and the date payment is due (30 days after billing date). Inspection fees will be billed to and collected from the party that operates the facility. If the facility is owned or controlled by an entity other than the operator, it is up to the parties to establish, through contract or otherwise, how the costs of facility inspections will be allocated.

If full payment is not received by the due date, a second bill will be sent. At that time, interest will begin to accrue at the prevailing rate set by the Department of the Treasury (currently, the prevailing rate is 13 percent), a 6 percent late payment penalty will be assessed in accordance with 45 CFR 30.13, and a $20 administrative fee will be assessed for each 30-day period that a balance remains due. If payment is not received within 30 days of a third and final bill, FDA may initiate action to collect unpaid balances (with interest and penalties), including the use of collection agencies and reporting of delinquencies to commercial credit reporting agencies.

VII. Review and Appeals Procedures

FDA will review each declaration that a facility qualifies as a Governmental entity. If FDA disallows a facility's claim that it is a Governmental entity, a bill will be sent to the facility with payment due within 30 days.

If FDA determines that a facility is not a Governmental entity, but the facility believes it qualifies for exemption under the definition of Governmental entity set forth above, the facility may appeal FDA's determination by explaining and certifying the basis for its belief in a letter directed to the FDA Ombudsman, c/o Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045–6057, postmarked within 30 days of FDA's notice to the facility that the facility does not qualify as a Governmental entity. The FDA Ombudsman will review a facility's claim that it is a Governmental entity and will normally reach a decision within 60 days. If the Ombudsman determines that a facility does not qualify as a Governmental entity, the Ombudsman shall provide a statement of the grounds for that determination. The Ombudsman's decision will constitute the agency's final decision on the matter. During the time required for the Ombudsman's review, FDA's efforts to collect the fee will be suspended.

VIII. Request for Comments

Although MQSA does not require FDA to solicit comments on fee exemption, assessment and collection, FDA is inviting comments from interested persons in order to have the benefit of additional views and information. FDA may consider altering its methodology of defining Governmental entities, and assessing and collecting fees under MQSA in future years, after actual inspection experience provides more accurate data about differences among facilities and variations in costs by State, region, or other factors.

Interested persons may on or before June 15, 1995 submit to the Dockets Management Branch (address above) written comments regarding this notice. 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. Received comments and a full explanation of the costs included and the methodology employed in determining these fees are on file with the Dockets Management Branch (address above) and may be seen in that office between 9:00 a.m. and 4:00 p.m., Monday through Friday.

Dated: March 13, 1995.

William B. Schultz,

Deputy Commissoner for Policy.

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