Appeal Options Available to Mammography Facilities Concerning Adverse Accreditation Decisions, Suspension/Revocation of Certificates, or Patient and Physician Notification Orders

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Draft Guidance for Mammography Facilities and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

Document issued on July 21, 2020.

You should submit comments and suggestions regarding this draft document within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions about this document, contact the CDRH Ombudsman's Office at 301-796-5699 or CDRHOmbudsman@FDA.HHS.GOV.

When final, this guidance will supersede section 4.5 of the Center for Devices and Radiological Health (CDRH) Appeals Processes guidance document issued on July 2, 2019.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Preface

Additional Copies

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please use the document number 19004 to identify the guidance you are requesting.

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

This guidance document describes the processes available to mammography facilities to request additional review of an adverse appeals decision on a facility's accreditation, and/or a suspension or revocation of certificate, and/or a patient and physician notification (PPN) order. This guidance, when final, will supersede section 4.5 of the Center for Devices and Radiological Health (CDRH) Appeals Processes guidance document dated July 2, 2019.[1] The remainder of the July 2, 2019 CDRH Appeals guidance, with exception of technical edits for consistency with the newly amended section 4.5, will not be substantively changed and will remain in effect.

[1] Available on FDA's website at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/center-devices-and-radiological-health-cdrh-appeals-processes.

A mammography facility that is in disagreement with an accreditation body's adverse accreditation or reaccreditation decision that precludes certification or recertification is entitled to appeal the decision directly to the accreditation body. If a satisfactory resolution cannot be reached with the accreditation body, the facility may request reconsideration (further appeal) of the adverse appeals decision by the Director of FDA's Division of Mammography Quality Standards (DMQS). If a facility is further dissatisfied with FDA's reconsideration decision, it may request a formal hearing before the Departmental Appeals Board, Department of Health and Human Services, as well as further review of the hearing officer's decision.

A mammography facility that wishes to challenge a suspension or revocation of an FDA certificate issued under the authority of the Mammography Quality Standards Act (MQSA) may request an informal (regulatory) hearing before the FDA as described below. The FDA has approved certain States as State Certification Agencies – or States as Certifiers (SACs) – which are responsible for certifying facilities within the state to perform mammography.[2] In these instances, for mammography facilities that wish to challenge the suspension or revocation of a certificate issued by a SAC under the authority of the MQSA, FDA recommends presenting such challenge to their respective SAC. This document provides general information about each process, as well as guidance on how to submit related requests to DMQS.

A mammography facility that wishes to appeal a PPN order may request supervisory review (appeal) of the order under 21 CFR 10.75. The appeal should be submitted to the next level supervisor of the official who signed the PPN order.

FDA's guidance documents, including this draft guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

The Mammography Quality Standards Act (MQSA) (42 U.S.C. § 263b) requires that, before a mammography facility can perform mammography, it must be certified. For a facility to be certified, it must meet certain requirements including: be accredited by an FDA-approved private nonprofit or state accreditation body; undergo periodic review of its clinical images by its accreditation body; have an annual survey by a medical physicist; meet federally developed quality standards for personnel qualifications, equipment, radiation dose, quality assurance programs, and recordkeeping and reporting; and undergo periodic inspection [by FDA or its designee] to assure it meets the federally developed quality standards.

[2] For more information on SACs, see FDA's website at https://www.fda.gov/radiation-emitting-products/mqsa-insights/states-certifiers-who-they-are-and-what-they-do

III. Appealing an Adverse Accreditation Decision with the Accreditation Body

Under the MQSA, facilities[3] offering mammography services must meet certain national quality standards and be certified by FDA or a SAC approved by the FDA following accreditation by an accreditation body.[4] A list of FDA-approved accreditation bodies can be found at the following link MQSA: Accreditation Bodies.[5] In accordance with 21 CFR 900.7(b), when an accreditation body denies an accreditation or reaccreditation (i.e., revocation of accreditation) to a facility, the accreditation body shall notify the facility in writing and explain the bases for its decision. The notification shall also describe the appeals process available from the accreditation body to the facility to contest the decision (21 CFR 900.4(a)(6)). Facilities must avail themselves of the accreditation body's appeals process before requesting reconsideration from FDA (21 CFR 900.15(c)).

Following revocation of accreditation, and during the 60-day period in which the facility may appeal the adverse accreditation decision to FDA under 21 CFR 900.15, the agency may conduct an investigation into the reasons for revocation and determine that the facility's certificate is no longer in effect. A facility whose certificate is no longer in effect may not practice mammography (21 CFR 900.13(a)). Likewise, the mammography facility is not permitted to provide mammography services while an adverse accreditation decision is being appealed to FDA (see 21 CFR 900.15(d)(6)). Alternatively, the agency may take whatever other action or combination of actions that will best protect the public health, including the establishment and implementation of a corrective plan of action that will permit the certificate to continue in effect while the facility seeks reaccreditation (21 CFR 900.13(a)).

IV. Request for Reconsideration of Adverse Appeals Decision by the Accreditation Body

A request for reconsideration by FDA of an adverse appeals decision by the accreditation body in accordance with 21 CFR 900.15 is available to mammography facilities that have exhausted the appeals process offered by the accreditation body and are precluded from certification or recertification by the FDA. Any such request for reconsideration must be submitted to FDA within 60 days of the accreditation body's adverse appeals decision (see 21 CFR 900.15(d)(3)(i)). Under 900.13(a), FDA may determine the facility's certificate is no longer in effect during this 60-day time period. Facilities that were instead issued a certificate by a SAC should follow the appeals process for requesting reconsideration offered by their certifying agency (see 21 CFR 900.22(e)).

Request for reconsideration by facilities certified by the FDA should be directed to:

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[3] See 42 U.S.C. § 263b(a)(3).

[4] See 42 U.S.C. § 263b(a)(1) & (e)(1)(A).

[5] Available at https://www.fda.gov/radiation-emitting-products/facility-certification-and-inspection-mqsa/mqsa-accreditation-bodies

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Division of Mammography Quality Standards
Attention: Program Management Branch
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Included with a reconsideration request must be the accreditation body's original denial of accreditation, all information submitted by the facility to the accreditation body relevant to the appeal, a copy of the accreditation body's adverse appeals decision, and a statement detailing the bases for the facility's disagreement with the accreditation body's decision (see 21 CFR 900.15(d)(3)(ii)).

Facilities that are requesting reconsideration of the accreditation body's interpretation of images should provide a rationale for the basis of their dispute, including instances of gross discrepancy, along with the images submitted to the accreditation body in a format that is readily accessible by FDA. Facilities that have questions about whether their images may be readily accessible by FDA should contact DMQS. If a point of contact from DMQS has not been provided in prior correspondance with FDA, mammography facilities should contact the MQSA hotline (https://www.fda.gov/radiation-emitting-products/mammography-quality-standards-act-and-program/contact-mqsa-program).

Requests for reconsideration of the adverse appeals decision by an accreditation body are an opportunity for facilities to have FDA review the adverse decision made by the accreditation body and ensure that the accreditation body followed its FDA approved procedures and policies. To ensure a timely review, FDA recommends that facilities submit in their request for reconsideration only the images reviewed by the accreditation body and relied upon in making their adverse appeals decision or alternatively, if providing new information facilities should provide a justification for why that new information should be considered. Generally, FDA does not intend to consider images from prior patient exams, DBT images, or additional reviews that were not initially submitted to the accreditation body to be relevant to the request for reconsideration absent justification provided by the facility that the evidence is relevant and material to the matters at issue.

Within 60 days after receipt of a reconsideration request, the Director of DMQS intends to issue a decision and notify the facility in writing of the decision and the facility's options as a consequence of the decision. A facility that is dissatisfied with the Division's decision following reconsideration is entitled to a formal hearing before the Departmental Appeals Board, Department of Health and Human Services (21 CFR 900.15(d)(4); see 42 CFR part 498, subpart D). The mammography facility is not permitted to provide mammography services while the adverse accreditation appeals decision is being further appealed to FDA or during any time period that FDA determines the certificate is no longer in effect (see 21 CFR 900.13(a); 900.15(d)(6)). If the facility's certificate is no longer in effect during any proceedings under 21 CFR 900.15, following those proceedings, FDA may place the certificate back into effect or

leave the certificate no longer in effect for a period of time during which any further FDA or facility actions, or combination of actions, are implemented.

V. Request for Regulatory Hearing Before the Food and Drug Administration (21 CFR Part 16)

A mammography facility that is unable to become certified or recertified by the FDA because it has been denied accreditation or reaccreditation (i.e., revocation of accreditation) by an accreditation body and wishes to appeal the accreditation body's decision should follow the process described in Section III of this document (and subsequently Section IV of this document if applicable).

Under 21 CFR 900.14(a), FDA may suspend or revoke a facility's MQSA certificate under certain circumstances after providing the owner or operator of the facility with notice and opportunity for a regulatory hearing under 21 CFR part 16. In most cases a suspension would precede a revocation (see 21 CFR 900.14(d)). To suspend or revoke an MQSA certificate under 21 CFR 900.14(a), the Agency would send the owner or operator of the facility a notice of opportunity for regulatory hearing and a proposal to suspend or revoke the certificate (see 21 CFR 16.22(a)). The proposal would set forth the ground(s) for suspension or revocation and specify the amount of time within which the facility could request a hearing on the ground(s) for the proposed suspension or revocation (see 21 CFR 16.22). Under 21 CFR 16.26(a), however, a request for a Part 16 hearing may be denied if the request fails to justify a hearing by demonstrating a genuine and substantial issue of fact. Only after providing opportunity for a regulatory hearing may FDA then suspend or revoke a certificate 21 CFR 900.14(a).

Under 21 CFR 900.14(b), FDA may immediately suspend a facility's MQSA certificate under certain circumstances before holding a regulatory hearing. FDA does so by issuing a notice of suspension setting forth one or more of the grounds in 21 CFR 900.14 and a determination that: (1) failure to comply with the required standards presents a serious risk to human health; (2) the refusal to permit inspection makes immediate suspension necessary; and/or (3) there is reason to believe that the violative acts were intentional or otherwise rise to a level that presents a threat to the public. The notice would provide instructions for requesting a hearing, including specifying the amount of time within which the facility could request a hearing. The Agency must provide the facility with an opportunity for a hearing no later than 60 days from the effective date of the suspension (21 CFR 900.14(c)). Under 21 CFR 16.26(a), however, a request for a Part 16 hearing may be denied if the request fails to justify a hearing by demonstrating a genuine and substantial issue of fact. Any suspension goes into immediate effect upon receipt of the notice of suspension and remains in effect until the Agency makes a determination that the allegations of violations or misconduct were not substantiated, violations of required standards have been corrected to the Agency's satisfaction, or the facility's certificate is revoked in accordance with 21 CFR 900.14(d) (see 21 CFR 900.14(c)(2)). Following a suspension under 21 CFR 900.14(b), FDA may revoke the facility's certificate if a determination is made that the facility is unwilling or unable to correct violations that were the basis for suspension or the facility has engaged in fraudulent activity to obtain or continue certification (21 CFR 900.14(d)).

When FDA provides a notice of opportunity for hearing under either of these suspension or revocation methods, the notice will designate an FDA employee in the Office of the Commissioner through whom the facility may request a Part 16 hearing. A facility may request a hearing by mail, telegram, telex, personal delivery, or any other mode of written communication (see 21 CFR 16.22(b)). For mammography facilities that wish to challenge the suspension or revocation of a certificate that was instead issued by a SAC under the authority of the MQSA, FDA recommends presenting such challenge to their respective SAC under its FDA-approved process (see 42 U.S.C. 263b(q)(1)(A); 21 CFR 900.21(b)(3)(iii)(C); 900.22(d)).

A notice of opportunity for hearing will not operate to delay or stay any other administrative action (see 21 CFR 16.22(d)). The facility is not permitted to provide mammography services during the time period when a certificate is suspended or revoked (see 21 CFR 900.11(a) and (c)).

VI. Appealing a Patient and Physician Notification (PPN) Order

In accordance with 21 CFR 900.12(j)(2), if FDA or a SAC determines the quality of mammography performed by a facility, whether or not certified under 21 CFR 900.11, is so inconsistent with the quality standards as to present a significant risk to individual or public health, the certifying agency has the authority to require the facility to notify patients who received mammograms and their referring physicians of the deficiencies, potential harm, appropriate remedial measures and other relevant information required by the FDA. In accordance with 21 CFR 10.75, a facility receiving such a Patient and Physician Notification (PPN) order can appeal the order to the next level supervisor of the official who signed the PPN order.[6] A request for supervisory review (appeal) must be addressed to the next organizational level or higher above the individual who made the decision; marked "Appeal: Request for Supervisory Review" in the subject line of the electronic request; and sent to the CDRH Ombudsman at CDRHOmbudsman@fda.hhs.gov (see 21 CFR 800.75(b)(2)). The request for supervisory review should be received by the FDA within 30 days of the issuance date of the PPN order to ensure the appeal can be reviewed in a timely manner and prior to the deadlines provided in the PPN order. Any appeal received after 60 days of the date the PPN order was issued will be denied as untimely, unless CDRH, for good cause, permits the request to be filed after 60 days (see 21 CFR 800.75(b)(2)). A request for supervisory review under section 10.75 does not delay or stay the actions required by the PPN order (see 21 CFR 10.35).

[6] See also FDA's guidances, "Center for Devices and Radiological Health (CDRH) Appeals Processes," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/center-devices-and-radiological-health-cdrh-appeals-processes, and "Center for Devices and Radiological Health (CDRH) Appeals Processes: Questions and Answers About 517A," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/center-devices-and-radiological-health-cdrh-appeals-processes-questions-and-answers-about-517a.

FDA's decision to require a facility to conduct a PPN is often based on findings made by the accreditation body during the AMR review. If a facility submits both an appeal of the adverse accreditation decision to FDA (under 21 CFR 900.15) and a request for supervisory review of the PPN order (in accordance with 21 CFR 10.75), then generally FDA will not issue a decision for the 10.75 appeal of the PPN order until a decision on the 900.15 appeal has been issued to the facility.

Facilities that wish to appeal a PPN order that was instead issued by their certifying agency should follow the appeals processes offered by their respective SAC under its FDA-approved process (see 42 U.S.C. 263b(h)(2); 21 CFR 900.21(b)(3)(iii)(N); 900.22(g)).

VII. Additional Information

Copies of regulations discussed in this document are available from the U.S. Government Printing Office. They may also be found and downloaded by accessing the CFR on the Internet at www.ecfr.gov and searching CFR titles and volumes.[7]

You may also contact the CDRH Ombudsman's Office at 301-796-5699 or CDRHOmbudsman@FDA.HHS.GOV with questions regarding the policies and procedures discussed in this document.

[7] Available at https://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR