When Facilities No Longer Perform Mammography:

Ensuring Patients' Access to Medical Records

When a facility closes, or otherwise ceases to perform mammography, its responsibility to provide patients' access to their medical records remains.

This is the first of two articles that examine facility closings and the implications for patients' access to their medical records. The term "closings" as used in this article refers to facilities that are no longer in operation, as well as those that although still open, no longer perform mammography. The information below outlines facilities' responsibilities under both scenarios and the steps FDA takes if it appears a facility is not fulfilling this responsibility.

The second article will discuss "best practices" in facility closings—how FDA and facilities have identified creative solutions to ensure this critical access to records.

Safeguarding Patients' Access to Medical Records

The Mammography Quality Standards Act (MQSA) requires facilities, regardless of their operational status, to meet federal standards for retaining patients' mammography films. (For more information about mammography patients' rights, see *Mammography Today: Questions and Answers for Patients on Being Informed Consumers*.)

Although most facilities understand their responsibilities, FDA sometimes learns that a facility is no longer performing mammography when a concerned patient calls the Facility Hotline to report difficulty getting her records. FDA also receives reports on facility closings from the accreditation bodies and the States. Presenting FDA's response in these situations is a helpful reminder to facilities of their responsibilities and the actions FDA will take to protect mammography patients.

Under MQSA, a facility must:

- Keep films and reports in a medical record for no less than 5 years, or no less than 10 years if a patient has had no other mammograms at that facility; however, this period could be even longer if mandated by State or local law.

- Transfer a patient's medical record to her, the mammography facility where she will receive future care, or to her referring physician or health care provider.

- Grant a request for permanent or temporary transfer of a medical record made by the patient or by someone acting on her behalf.

- Limit any fee charged to a patient for transferring her medical record to the documented costs of this service.

To safeguard patients' records and to help a facility understand its responsibilities if it has closed its doors to mammography, FDA implements the following protocol:

- Identifies the individual listed as the responsible party at the facility.

- Sends a letter to that individual, outlining the facility's responsibilities under MQSA, sanctions to be imposed if those responsibilities are not fulfilled, and FDA's request for a plan describing how the facility will provide patients access to their mammography medical records.

- Reviews the facility's plan for ensuring patients' access to their medical records.

- Approves this plan, which it confirms in a follow-up letter to the facility. If a facility fails to meet its responsibilities, however, FDA institutes proceedings against the facility (discussed below).

MQSA Policy Guidance expands on how a facility can ensure that patients have access to their medical records. Facilities no longer performing mammography can store the medical records in a hospital or in an appropriate warehouse. Facilities also must ensure that some method for releasing the films is in place. Policy Guidance notes that under MQSA, facilities are not responsible for maintaining records for exams performed before October 1, 1994 (when the rule became effective), although State and local regulations may require otherwise. The facility is responsible for knowing and complying with any such State and local laws.

Working With Facilities to Ensure Patients' Access to Records

In working to help a facility comply with its responsibilities under MQSA, FDA provides in its letter to a facility the name of a contact to answer questions and receive the facility's plan for providing patients' access to medical records. FDA directs the facility to respond within 10 days to its request for this plan, which must include the name and address of the establishment where patients' records are located, and the name and phone number of a person patients can contact to obtain their mammography medical records. Please note any letters to facilities in the States of Iowa and Illinois will be sent by those two States, instead of FDA, since they are certifying agencies. Likewise, any responses from facilities in Iowa or Illinois should be directed to those States.

The letter FDA sends to facilities about their responsibilities also describes sanctions to be imposed if a facility fails to comply with transferring a patient's medical record. These sanctions could include civil penalties up to $10,000 per violation, or per day of violation, and/or revocation of certification, even if the facility has already closed. The

latter sanction would prevent a facility's owner/operator from opening a new facility for two years and could result in an order to stop performing mammography at any other facilities it owns and operates.

Commenting on the need to intervene when a facility no longer performs mammography and patients cannot get their records, FDA's Division of Mammography Quality and Radiation Programs Deputy Director Helen Barr, M.D., stressed that this scenario was the exception. "Only a small percentage of facilities stop performing mammography each year, and only a few of those require us to follow the protocol outlined here." Dr. Barr concluded, "Our job is to ensure the safety of a woman's mammography experience, which includes having ready access to her medical record. Most facilities understand that and share this goal."

If a facility is anticipating closing its doors to mammography, it should devise a plan for storing patients' mammography medical records that allows patients access to them. This proactive strategy will uphold the facility's responsibility under MQSA and avoid the need for FDA to implement the protocol described above.

In our next article, we will discuss best practices in facility closings, detailing FDA's role in working with facilities and partnering organizations, when needed, to responsibly plan for storage and distribution of medical records.

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