Closed Facilities:

Strategies for Ensuring Patients' Access to Medical Records

If you think it unlikely the National Guard would be called in to safeguard patients' medical records, read on. This is what occurred in July of 1999, three months after Michigan's North Oakland Radiology declared bankruptcy and closed five clinics.

In April 1999, when patients learned that North Oakland Radiology planned to destroy over 200,000 medical records to avoid the cost of storage and distribution, the State Attorney General's Office stepped in. Attorneys for FDA and Blue Care Network joined the fray, fighting destruction of the records that were temporarily under the trusteeship of an attorney appointed by the U.S. Bankruptcy Court.

American Cancer Society staff and volunteers then entered the scene to begin moving the records to a court-designated site and to distribute files in response to the requests of anxious patients. Many of the critical requests were from mammography patients who needed their records for comparison with current records. Once the court approved a long-term storage and distribution plan, the National Guard stood ready to help transport the records for final safekeeping at Huron Valley-Sinai Hospital in Commerce, Michigan.

This second article on facility closings describes lessons learned from the Michigan case. It also details strategies to help closed facilities uphold their responsibility under the Mammography Quality Standards Act (MQSA) so that all mammography patients have access to these life-saving records.

Michigan Takes Action

"Typically, most facilities show greater responsibility toward patient records than was exhibited in Michigan's North Oakland Radiology case," observed Jim Camburn, a member of the National Mammography Quality Assurance Advisory Committee and Chief of Michigan's Radiation Safety Section, Department of Consumer & Industry Services. Nevertheless, this "worst-case scenario" was the hand dealt the State of Michigan, and deal with it they did, Camburn recounted.

To ensure that best practices are routinely employed in the wake of this event, the State of Michigan has modified the facility-closing procedures used by its radiation regulatory agency. For example, when a mammography facility informs it of an imminent closing, the State immediately requests information on its plan to store and distribute mammography records. In addition, frequent communication with the facilities about their obligations to ensure patient access to records is now standard operating procedure. Michigan reminds facilities of their responsibilities to patients (1) when they are first authorized by the State to perform mammography, (2) during their State-issued three-year

mammography authorization renewal, and (3) if they announce they will no longer perform mammography.

Camburn explained that 345 mammography facilities are now operating throughout Michigan. The State is aware of only 7 facilities since 1987 (2 percent of the current number in operation) having experienced major problems with record retention and distribution, and those problems occurred in the past 2-1/2 years. "However," Camburn continued, "most facilities still create a plan for distributing records in reaction to a planned, imminent, or actual closing."

To help facilities proactively devise distribution plans, Michigan is considering a new strategy. The State may require facilities to provide evidence that, if they close, adequate means are in place to ensure that records will be maintained and distributed to patients or their healthcare providers. According to Camburn, such evidence could include proof that a facility has:

- A surety bond adequate to cover the costs of maintaining and distributing its mammography records, or

- A written contract with an independent mammography facility of sound financial condition such that, if one closes, the other will assume control over and responsibility for all mammography records.

Other states are watching how Michigan proceeds with its efforts to safeguard records when facilities no longer perform mammography. Discussion now turns to strategies at the Federal level to guide closing or closed facilities.

FDA Provides Support and Guidance

To safeguard patients' records and help closing or closed facilities understand their obligations under MQSA, FDA follows a clear 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 a request for a plan describing how the facility will provide patients' access to their records. The letter provides the name and contact information for an FDA staff member who will answer questions and receive the plan.

- 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.

MQSA Policy Guidance expands on the above protocol by informing closing or closed facilities that they can store medical records in a hospital or an appropriate warehouse provided they have some method in place for releasing films. Policy Guidance also notes that under MQSA, facilities are not responsible for maintaining records for exams performed before October 1, 1994, although State and local regulations may require otherwise. Facilities are responsible for knowing and complying with these State and local laws.

What if a facility did not have the foresight to develop a records maintenance plan in the event of closure?

Dennis Swartz, FDA Radiological Health Expert, Central Region, Detroit District, commented that if a facility has no plan in place and is faced with imminent closure, FDA encourages it to advise referring physicians and patients that records may need to be transferred to their custody.

First to be notified are patients with "suspicious" or "probably benign" mammograms who had been flagged for follow-up.

To address the reality of our mobile society, Swartz noted that FDA also recommends that facilities place notices in newspapers to inform patients of a closing and its plans for record storage and distribution.

In some cases, Swartz reported, closing or closed facilities have voluntarily transferred records to other offices. "In one case," Swartz explained, "mammography records were made available to patients at a dental office because the dentist was part owner of a radiology practice. A sign was posted on the closed facility to inform patients where they could locate their medical records."

Recognizing that the vast majority of facilities fully intend to honor their obligations to ensure patients' access to records, FDA is most often called upon to guide closing or closed facilities. "We will always be available to listen to a plan for distribution of records and make suggestions that benefit patients' access to their records," concluded Swartz.