

SUBJECT: Certification of mammography systems

COMMITTEE: Public Health — committee substitute recommended

VOTE: 5 ayes — Berlanga, Hirschi, Glaze, Janek, Maxey
0 nays
3 absent — Coleman, Davila, Delisi

WITNESSES: For — Cindy Antolik, American Cancer Society
Against — None
On — Ruth McBurney, Texas Department of Health

DIGEST: CSHB 1534 would authorize the Texas Department of Health to become the accreditation body to carry out certification requirements established by the federal government for mammography systems. It also would add to existing certification requirements the requirement that mammography system operators are individuals who meet, at a minimum, federal requirements for personnel who perform mammography.

If a facility's mammography system failed to meet the department's standards, and the failure was a severity level I violation, the facility would have to notify each patient on whom the facility performed a mammography during the 30 days preceding the date the facility received notice of the failure. Notification would have to:

- inform the patient that the mammography failed to meet department standards;
- recommend the patient have another mammogram at another facility; and
- list three mammogram facilities closest to the original testing facility.

The department could also require a facility to render the above notification if the facility failed to meet other certification standards.

System certification would be valid for three years instead of one year. The

board of health would be authorized to establish annual fees and late fees for certificate holders in amounts reasonable and necessary to administer certification. The board could revoke the certification of an entity that did not pay the annual fee and late fee before the required date. Department inspections upon system certification would be limited to newly certified systems that have not been fully certified under federal standards.

The bill would take effect September 1, 1997.

**SUPPORTERS
SAY:**

CSHB 1534 would update state law to conform to new federal requirements, and enact notification requirements to protect the public from fraudulent or negligent mammography facility operators.

Last session the Legislature enacted HB 63 by Hamric, which established a system of regulating mammography devices and the practice of mammography and authorized the Texas Department of Health to administer the regulations. At the same time, the federal government also was considering certification and other requirements for mammography systems. CSHB 1534 would simply update and conform Texas law to the new federal standards and bring all systems up to similar standards.

Notification by substandard mammography facility operators to former patients would properly place the responsibility on those facilities to contact women whose lives they might have jeopardized by improperly performed mammographies and would help ensure that women obtain needed retesting. In doing so, CSHB 1534 would place the cost of notification on the violating facilities, which would help retain state funding for further inspection and enforcement activities, including monitoring notification procedures by the violating facilities.

Mammograms are an essential component in the early detection of breast cancer, which can help save the lives of thousands of Texas women each year. Severity Level I violations refer to the most severe violations of mammography standards, and include repeated failure to meet imaging standards and interpretation of results by unqualified individuals.

OPPONENTS SAY: Notification to women who received treatment at a substandard facility is a public health responsibility, not a private operator's responsibility, and should be performed by the Texas Department of Health. If the facility could not be trusted to perform quality mammograms, it should not be entrusted with the responsibility of accurately informing the public of their violations and the locations of alternative facilities.

NOTES: The committee substitute added requirements that the failure be a Severity Level I violation before a facility would be required to notify former patients and that the department require a facility to notify former patients of the facility's failure to meet other certification standards.