

CHAPTER 138

H.B. No. 63

AN ACT

relating to the regulation of mammography devices and the practice of mammography.

Be it enacted by the Legislature of the State of Texas:

SECTION 1. Chapter 401, Health and Safety Code, is amended by adding Subchapter L to read as follows:

SUBCHAPTER L. CERTIFICATION OF MAMMOGRAPHY SYSTEMS

Sec. 401.421. *DEFINITIONS. In this subchapter:*

- (1) "Certification" means an authorization for the use of a mammography system.
- (2) "Mammography" means the use of radiation to produce an image of the breast on film, paper, or digital display that may be used to detect the presence of pathological conditions of the breast.
- (3) "Mammography system" includes the following:
 - (A) an x-ray unit used as a source of radiation in producing images of breast tissue
 - (B) an imaging system used for the formation of a latent image of breast tissue
 - (C) an imaging processing device for changing a latent image of breast tissue to a visual image that can be used for diagnostic purposes;
 - (D) a viewing device used for the visual evaluation of an image of breast tissue if the image is produced in interpreting visual data captured on an image receptor;
 - (E) a medical radiological technologist who performs a mammography; and
 - (F) a physician who engages in, and who meets the requirements adopted by board rule relating to, the reading, evaluation, and interpretation of mammograms.

Sec. 401.422. *CERTIFICATION REQUIRED. (a) A person may not perform mammography unless the mammography system used has been issued a certification under this subchapter.*

(b) A certification under Subsection (a) is required in addition to any license, registration, or other requirement under this chapter.

Sec. 401.423. *POWERS AND DUTIES OF BOARD. (a) The board shall:*

- (1) prescribe application forms for original and renewal certifications;
- (2) adopt rules for the administration of this subchapter; and
- (3) take other action necessary to enforce this subchapter.

(b) The board shall apply under the Mammography Quality Standards Act of 1992 (42 U.S.C. Section 354) to carry out the certification program requirements and to implement the standards established by the United States Secretary of Health under that Act in this state. If the United States Secretary of Health grants the board's application, the board shall assume those responsibilities.

Sec. 401.424. **MAMMOGRAPHY CERTIFICATION STANDARDS.** (a) To receive a mammography certification under this subchapter, the mammography system must, at a minimum:

(1) meet criteria at least as stringent as the American College of Radiology mammography accreditation program;

(2) be specifically designed and used for the performance of mammography;

(3) be operated by an individual certified as a medical radiologic technologist under Chapter 1096, Acts of the 70th Legislature, Regular Session, 1987 (Article 4512m, Vernon's Texas Civil Statutes), who has successfully completed special training in mammography; and

(4) be used in a facility that:

(A) meets, at minimum, the requirements for certification of the Mammography Quality Standards Act of 1992 (42 U.S.C. Section 354);

(B) has a licensed medical physicist specialized in radiology under Chapter 235, Acts of the 72nd Legislature, Regular Session, 1991 (Article 4512n, Vernon's Texas Civil Statutes), who at least annually provides on-site consultation to the facility, including a complete evaluation of the entire mammography system to ensure compliance with this subchapter;

(C) maintains records of the consultations required under Paragraph (B) for not less than seven years after the date the consultation was performed;

(D) establishes a quality control program that meets requirements that are at least as stringent as those of the American College of Radiology mammography accreditation program; and

(E) maintains and makes available to a patient of the facility original mammograms performed at the facility until the earlier of:

(i) the fifth anniversary of the mammography;

(ii) if an additional mammogram of the same patient is not performed by the facility, the 10th anniversary of the mammography; or

(iii) at the request of the patient, the patient's medical records are forwarded to another medical institution.

(b) To protect the public health, the board by rule may adopt more stringent or additional requirements for:

(1) the certification of mammography systems; and

(2) the retention of original mammograms.

(c) To protect the public health, the board by rule shall adopt qualifications for a physician who reads, evaluates, and interprets a mammogram that are no less stringent than the standards of the American College of Radiology.

(d) The board shall make available to the public copies of the criteria of the American College of Radiology mammography accreditation program or the modified criteria adopted by board rule.

(e) Notwithstanding any other provision of this chapter, the standards imposed for certification under this chapter may not be less stringent than the standards imposed on a facility under the Mammography Quality Standards Act of 1992 (42 U.S.C. Section 354).

Sec. 401.425. **ALTERNATIVE CERTIFICATION; EXEMPTIONS.** (a) The department shall issue a certification under this subchapter for a mammography system for which the department is provided proof of accreditation by the American College of Radiology or another recognized organization that has standards no less stringent than the standards of the American College of Radiology.

(b) A mammography system issued a certification under this section is exempt from the certification standards established by or under Section 401.424 and the inspection requirements established by or under Section 401.430.

(c) If the board finds that application of this section would make the requirements of this chapter less stringent than the standards applicable under the Mammography Quality

Standards Act of 1992 (42 U.S.C. Section 354), the board may not issue a certification under this section.

Sec. 401.426. APPLICATION FOR CERTIFICATION. (a) A person who owns, leases, or uses or the agent of a person who owns, leases, or uses a mammography system must file a written application for certification under Section 401.424 or Section 401.425 on a form prescribed by the board.

(b) The department may require, at any time after an application is filed, further information from the applicant and conduct inspections necessary to determine whether the application for certification should be granted or denied.

Sec. 401.427. CERTIFICATION RENEWAL. (a) A certification is valid for one year and may be renewed annually on payment of the required renewal fee.

(b) The board by rule may adopt a system under which certifications under this subchapter expire on various dates during the year.

(c) If a certification holder fails to renew the certification by the required date, the certification holder may renew the certification on payment of the renewal fee and a late fee set by the board. If the certification is not renewed before the 181st day after the date on which the certification expired, the certification holder must apply for an original certification under this subchapter.

(d) A mammography system may not be used after the expiration date of the certification unless the holder of the expired certification has made a timely and sufficient application for renewal of the certification as provided under Section 18, Administrative Procedure and Texas Register Act (Article 6252-13a, Vernon's Texas Civil Statutes), and a final determination of the application by the board has not been made.

Sec. 401.428. DENIAL, SUSPENSION, REVOCATION, OR REINSTATEMENT OF CERTIFICATION. (a) The department may deny, suspend, revoke, or reinstate a certification.

(b) The board shall adopt rules establishing the grounds for denial, suspension, revocation, or reinstatement of a certification and establishing procedures for disciplinary actions.

(c) Proceedings relating to the suspension or revocation of a certification issued under this subchapter are subject to the Administrative Procedure and Texas Register Act (Article 6252-13a, Vernon's Texas Civil Statutes).

(d) A person whose certification has been revoked may apply for a new certification on the expiration of one year after the date the certification was revoked.

Sec. 401.429. CERTIFICATION FOR MULTIPLE MAMMOGRAPHY SYSTEMS. (a) An applicant for certification under Section 401.426 must obtain a separate certification for each mammography system that is owned, leased, or used by the applicant.

(b) Certification of multiple mammography systems by a single applicant may be recorded on a single certification document. If multiple mammography systems are recorded on a single certification document, each specific machine certified, if any, must be identified on the certification document by referring to the machine's manufacturer, model number, and serial number.

Sec. 401.430. INSPECTIONS. (a) The department shall inspect each mammography system that receives a certification under this subchapter not later than the 60th day after the date the certification is issued.

(b) The department shall inspect, at least once annually, each mammography system that receives a certification.

(c) To protect the public health, the department may conduct more frequent inspections than required under this section.

(d) The department shall make reasonable attempts to coordinate inspections under this section with other inspections required under this chapter for the facility where the mammography system is used.

(e) After each satisfactory inspection, the department shall issue a certificate of inspection for each mammography system inspected. The certificate of inspection must be posted at a

conspicuous place on or near the place where the mammography system is used. The certificate of inspection shall:

- (1) specifically identify the mammography system inspected;
 - (2) state the name and address of the facility where the mammography system was used at the time of the inspection; and
 - (3) state the date of the inspection.
- (f) A notice of a mammography system's failure to satisfy department standards shall be posted:
- (1) on the mammography system at a conspicuous place if the system is a machine; or
 - (2) near the place where the mammography system practices if the system is an individual.
- (g) To protect the public health, the board may adopt rules concerning the grounds for posting a failure notice and the placement and size of the failure notice, and for patient notification, as appropriate.
- Sec. 401.431. *TRANSITION.* (a) A mammography system is not required to have a certification under this subchapter until July 1, 1994.
- (b) Section 401.422 takes effect July 1, 1994.
 - (c) The board shall adopt rules under this subchapter not later than January 1, 1994.
 - (d) This section expires January 1, 1996.

SECTION 2. The importance of this legislation and the crowded condition of the calendars in both houses create an emergency and an imperative public necessity that the constitutional rule requiring bills to be read on three several days in each house be suspended, and this rule is hereby suspended, and that this Act take effect and be in force from and after its passage, and it is so enacted.

Passed by the House on March 18, 1993, by a non-record vote; the House concurred in Senate amendments to H.B. No. 63 on April 29, 1993, by a non-record vote; passed by the Senate, with amendments, on April 26, 1993: Yeas 31, Nays 0.

Approved May 11, 1993.

Effective Aug. 30, 1993, 90 days after date of adjournment.