

No. 1992-93

AN ACT

SB 1393

Providing for licensure of screening mammography service providers; prescribing powers and duties of the Department of Health; establishing radiation machine and facility inspection procedures; providing for licensure revocation and nonrenewal; and imposing penalties.

The General Assembly finds as follows:

(1) Breast cancer is the most common cancer and the second-leading cause of cancer deaths in the United States.

(2) There were approximately 10,300 new cases of breast cancer in this Commonwealth in 1991 and 2,600 breast cancer deaths.

(3) One of every ten women can expect to develop breast cancer in her lifetime.

(4) Early detection of breast cancer is the most effective means to reduce breast cancer mortality.

(5) Periodic screening mammography, in conjunction with good health care and monthly self-examination, can reduce a woman's risk of dying from breast cancer by 30%.

(6) A mammogram is among the radiographic images most difficult to read thus requiring adherence to strict quality standards to insure optimal clarity.

(7) If a mammogram image quality is poor or the interpretation is faulty, the interpreter may miss cancerous lesions which could delay treatment and result in avoidable mastectomy or death.

TABLE OF CONTENTS

Section 1.	Short title.
Section 2.	Definitions.
Section 3.	Authorization by department.
Section 4.	Application.
Section 5.	Inspections.
Section 6.	Reasons for limitation, suspension, revocation or nonrenewal of license.
Section 7.	Right to enter and inspect.
Section 8.	Provider violations.
Section 9.	Departmental orders.
Section 10.	Actions against unlicensed health care providers.
Section 11.	Actions against violations of law, rules and regulations.
Section 12.	Injunction or restraining order when appeal is pending.
Section 13.	Fees.
Section 14.	Regulations.
Section 15.	Effective date.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. Short title.

This act shall be known and may be cited as the Mammography Quality Assurance Act.

Section 2. Definitions.

The following words and phrases when used in this act shall have the meanings given to them in this section unless the context clearly indicates otherwise:

“Department.” The Department of Health of the Commonwealth.

“Mammography system.” The radiation machine used for mammography; automatic exposure control devices; films, screens and cassettes; image processors; darkrooms and viewboxes.

“Provider.” An individual, organization, facility, institution or part thereof which provides screening mammography services.

“Qualified radiation physicist.” An individual certified by an accrediting organization recognized by the Department of Health in radiological physics or diagnostic radiological physics.

“Radiation machine.” Any device that emits ionizing radiation.

“Radiation technologist.” As defined in regulations promulgated under section 4163 of the Omnibus Budget Reconciliation Act of 1990 (Public Law 101-508, 104 Stat. 1388).

“Screening mammography facility.” An individual, organization, facility, institution or part thereof staffed and equipped to provide screening mammography services.

“Screening mammography service.” A radiologic procedure furnished to an asymptomatic woman for the purpose of early detection of breast cancer. The term includes a physician’s interpretation of the results of the procedure.

Section 3. Authorization by department.

(a) General rule.—A person shall not use a radiation machine to perform mammography unless the radiation machine is specifically authorized by the department under this act for use for mammography.

(b) Standards.—No person shall maintain or operate a screening mammography service without first obtaining a license to operate such a service, except that a provider of screening mammography services approved by the department under section 4163 of the Omnibus Budget Reconciliation Act of 1990 (Public Law 101-508, 104 Stat. 1388) is exempt from the provisions of this act. Such license shall be based on meeting the following requirements:

(1) The radiation machine meets the criteria established by regulations promulgated under section 4163 of the Omnibus Budget Reconciliation Act of 1990. The Department of Health may contract with the Department of Environmental Resources to determine whether the radiation machine meets the required criteria.

(2) The radiation machine is specifically designed to perform mammography.

(3) The provider of screening mammography services does all of the following:

(i) Establishes a quality control program, including inspections by a qualified radiation physicist, that meets the criteria established by regulations promulgated under section 4163 of the Omnibus Budget Reconciliation Act of 1990.

(ii) Retains and makes available to patients original mammograms as required by regulations promulgated under section 4163 of the Omnibus Budget Reconciliation Act of 1990.

(4) A radiation technologist who meets the criteria established by regulations promulgated under section 4163 of the Omnibus Budget Reconciliation Act of 1990 operates the radiation machine.

(5) The interpreting physician meets the criteria established by regulations promulgated under section 4163 of the Omnibus Budget Reconciliation Act of 1990.

Section 4. Application.

(a) General rule.—To obtain a license to operate screening mammography services, the provider of screening mammography services shall apply to the department on an application form provided by the department and shall provide all of the information required by the department as specified on the application form.

(b) Multiple machines.—A provider of screening mammography services who owns or leases more than one radiation machine used for mammography shall notify the department of each radiation machine.

(c) Expansion of screening mammography service.—Application for expansion of a previously licensed facility shall be made on forms furnished by the department.

(d) Issuance of license.—

(1) The department shall issue a license upon determining that the applicant has met the following criteria:

(i) The screening mammography service provider is a responsible person.

(ii) The location to be used as a screening mammography facility is adequately constructed, equipped, maintained and operated to safely and efficiently render the services offered.

(iii) The screening mammography facility provides or, in the case of a facility not in existence on the effective date of this act, will provide safe and efficient services which are adequate for the care, treatment and comfort of the patients of the facility.

(iv) There is or, in the case of a facility not in existence on the effective date of this act, will be substantial compliance with this act and any rules and regulations adopted by the department under this act.

(2) In lieu of meeting the criteria under paragraph (1), if the screening mammography service provider submits to the department annual documentation of full compliance with the accreditation program recognized

by the department, the department shall issue a license which specifies the number of authorized radiation machines.

(3) Each license issued by the department shall specify the number of authorized radiation machines located at a given screening mammography facility. A screening mammography facility license is effective for three years. The facility shall post its license in a prominent location.

Section 5. Inspections.

(a) Initial inspection.—No license to operate a screening mammography facility shall be issued until the department has inspected the facility, including each radiation machine. Previously existing providers of mammography services may continue in operation until the department conducts the initial inspection. The department shall conduct such initial inspection no later than 60 days following the effective date of this act.

(b) Subsequent inspection.—After the initial inspection, the department shall annually inspect the screening mammography facility and may inspect the radiation machine more frequently. The department shall make reasonable efforts to coordinate the inspections under this section with the department's other inspections of the facility in which the radiation machine is located.

(c) Inspection certificate.—After each inspection by the department which finds the screening mammography facility in full compliance with the requirements of this act, the department shall issue a certificate of radiation machine inspection or a similar document identifying the facility and radiation machine inspected and providing a record of the date the radiation machine was inspected. The facility shall post the certificate or other document near the inspected radiation machine.

Section 6. Reasons for limitation, suspension, revocation or nonrenewal of license.

The department may refuse to renew a license or may suspend or revoke or limit a license for all or any portion of a screening mammography facility for the following reasons:

(1) A serious violation of this act or of licensure regulations issued under this act. For the purpose of this paragraph, a serious violation is one which poses a significant threat to the health of patients.

(2) Failure of a licensee to submit a reasonable timetable to correct deficiencies.

(3) The existence of a cyclical pattern of deficiencies over a period of two or more years.

(4) Failure to correct deficiencies in accordance with a timetable submitted by the applicant and agreed upon by the department.

(5) Fraud or deceit in obtaining or attempting to obtain a license.

(6) Lending, borrowing or using the license of another or in any way knowingly aiding or abetting the improper granting of a license.

(7) Incompetence, negligence or misconduct in operating a screening mammography facility or in providing services to or treatment of patients.

(8) A serious violation of the laws relating to medical assistance or Medicare reimbursement.

Section 7. Right to enter and inspect.

For the purpose of determining the suitability of the applicants and of the premises or for determining the adequacy of the care and treatment provided or the continuing conformity of the licensees to this act and to applicable Federal, State and local regulations, any authorized agent of the department may enter, visit and inspect the building, grounds, equipment and supplies of any screening mammography facility licensed or requiring a license under this act and shall have full and free access to the records of the facility and to the patients and employees therein and their records and shall have full opportunity to interview the patients and employees. Upon entering a screening mammography facility, the inspectors shall properly identify themselves to the individual on the premises then in charge of the facility.

Section 8. Provider violations.

(a) Notice of violations.—Whenever the department shall, upon inspection, investigation or complaint, find a violation of this act or regulations adopted by the department under this act or under Federal law, it shall give written notice thereof specifying the violation found to the screening mammography facility. The notice shall require the screening mammography service provider to take action or to submit a plan of correction which shall bring the screening mammography facility into compliance with applicable law or regulation within a specified time. The plan of correction must be submitted within ten days of receipt of the written notice.

(b) Appointment of temporary management.—When the screening mammography service provider has failed to bring the facility into compliance within the time specified by the department or when the facility has demonstrated that it is unwilling or unable to achieve compliance, such as would convince a reasonable person that any correction of violations would be unlikely to be maintained, the department may petition the Commonwealth Court or the court of common pleas of the county in which the facility is located to appoint temporary management designated as qualified by the department to assume operation of the facility at the facility's expense to assure the health and safety of the facility patients until improvements are made to bring the facility into compliance with the laws and regulations for licensure or until there is an orderly closure of the facility. In the alternative, the department may proceed in accordance with the other provisions of this act.

Section 9. Departmental orders.

Orders of the department from which no appeal is taken to the State Health Facility Hearing Board and orders of the board from which no timely appeal is taken to the Commonwealth Court are final orders and may be enforced in court.

Section 10. Actions against unlicensed health care providers.

(a) Actions in equity.—Whenever a license is required under this act to maintain or operate a screening mammography facility, the department may maintain an action in the name of the Commonwealth for an injunction or other process restraining or prohibiting any person from establishing, conducting or operating any unlicensed screening mammography facility.

(b) **Permanent injunction.**—Should a person who is refused a license or the renewal of a license to operate or conduct a screening mammography facility or whose license to operate or conduct a screening mammography facility is limited, suspended or revoked fail to appeal or should such appeal be decided finally favorably to the department, then the court shall issue a permanent injunction upon proof that the person is operating or conducting a screening mammography facility without a license as required by this act.

Section 11. Actions against violations of law, rules and regulations.

(a) **Actions brought by department.**—Whenever any person, regardless of whether such person is a licensee, has violated any of the provisions of this act or the regulations issued under this act, the department may maintain an action in the name of the Commonwealth for an injunction or other process restraining or prohibiting such person from engaging in such activity.

(b) **Civil penalty.**—Any person, regardless of whether such person is a licensee, who has committed a violation of this act or any regulation under this act, including failure to correct a licensure violation within the time specified in a deficiency citation, may be assessed a civil penalty by an order of the department of up to \$500 for each deficiency for each day that each deficiency continues. Civil penalties shall be collected from the date the facility receives notice of the violation until the department confirms correction of the violation.

(c) **Facility closure for threat to health or safety.**—Whenever the department determines that deficiencies pose an immediate and serious threat to the health or safety of the patients served by a screening mammography facility, the department may direct the closure of the facility and the transfer of patients and their records to other licensed or certified screening mammography facilities.

Section 12. Injunction or restraining order when appeal is pending.

Whenever the department shall have refused to grant or renew a license or shall have limited, suspended or revoked a license required by this act to operate or conduct a screening mammography facility or shall have ordered the person to refrain from conduct violating the rules and regulations of the department, and the person, deeming himself aggrieved by such refusal or limitation or suspension or revocation or order, shall have appealed from the action of the department to the State Health Facility Hearing Board or from the order of the board to the Commonwealth Court, the court may, during pendency of such appeal, issue a restraining order or injunction upon a showing that the continued operation of the screening mammography facility adversely affects the well-being, safety or interest of the patients or the screening mammography facility, or the court may authorize continued operation of the facility or make such other order, pending final disposition of the case, as justice and equity require.

Section 13. Fees.

The department may publish as final regulations an initial fee schedule for licensure of screening mammography facilities and inspections of radiation machines. Any alteration of that fee schedule shall be pursuant to the act of June 25, 1982 (P.L.633, No.181), known as the Regulatory Review Act. The

fees shall be paid to the department for deposit into the State Treasury of the Commonwealth. The fees assessed by the department shall approximate, to the extent possible, the costs required to implement this act.

Section 14. Regulations.

The department may promulgate rules and regulations to administer and enforce this act.

Section 15. Effective date.

This act shall take effect in 60 days.

APPROVED—The 9th day of July, A. D. 1992.

ROBERT P. CASEY