

Act No. 56
Public Acts of 1989
Approved by the Governor
June 15, 1989
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**STATE OF MICHIGAN
85TH LEGISLATURE
REGULAR SESSION OF 1989**

Introduced by Reps. Berman, Hertel, Rocca, DeMars, Dolan, Brown, Emerson, Munsell, Stabenow, Jondahl, Johnson, Krause, Saunders, Emmons, Crandall, Gire, Runco, Gubow and Kilpatrick

ENROLLED HOUSE BILL No. 4074

AN ACT to amend sections 13501, 13521, and 13522 of Act No. 368 of the Public Acts of 1978, entitled as amended "An act to protect and promote the public health; to codify, revise, consolidate, classify, and add to the laws relating to public health; to provide for the prevention and control of diseases and disabilities; to provide for the classification, administration, regulation, financing, and maintenance of personal, environmental, and other health services and activities; to create or continue, and prescribe the powers and duties of, departments, boards, commissions, councils, committees, task forces, and other agencies; to prescribe the powers and duties of governmental entities and officials; to regulate occupations, facilities, and agencies affecting the public health; to regulate health maintenance organizations and certain third party administrators and insurers; to promote the efficient and economical delivery of health care services, to provide for the appropriate utilization of health care facilities and services, and to provide for the closure of hospitals or consolidation of hospitals or services; to provide for the collection and use of data and information; to provide for the transfer of property; to provide certain immunity from liability; to regulate and prohibit the sale and offering for sale of drug paraphernalia under certain circumstances; to provide for penalties and remedies; to repeal certain acts and parts of acts; to repeal certain parts of this act; and to repeal certain parts of this act on specific dates," section 13522 as amended by Act No. 403 of the Public Acts of 1982, being sections 333.13501, 333.13521, and 333.13522 of the Michigan Compiled Laws; and to add part 95 and section 13523.

The People of the State of Michigan enact:

Section 1. Sections 13501, 13521, and 13522 of Act No. 368 of the Public Acts of 1978, section 13522 as amended by Act No. 403 of the Public Acts of 1982, being sections 333.13501, 333.13521, and 333.13522 of the Michigan Compiled Laws, are amended and part 95 and section 13523 are added to read as follows:

PART 95. BREAST CANCER PROGRAM

Sec. 9501. The breast cancer mortality reduction program is created in the department. The program shall include, but is not limited to, all of the following:

(a) Professional education programs for health professionals to develop state-of-the-art skills in cancer screening, diagnosis, referral, treatment, and rehabilitation.

(b) Public education programs to assist the public in understanding all of the following:

(i) The benefits of regular breast cancer screening.

(ii) How to make the best use of the medical care system for cancer screening, diagnosis, referral, treatment, and rehabilitation.

(iii) The available options for treatment of cancer.

(c) An applied research and community demonstration grant program that provides grants to local communities to demonstrate and evaluate 1 or more of the following:

- (i) Methods to reduce cancer morbidity and mortality.
- (ii) Economical and effective methods of providing access to breast cancer screening, diagnosis, referral, treatment, and rehabilitation services for populations with higher than expected rates of breast cancer morbidity or mortality.

Sec. 9503. The department shall biennially submit a report to the senate and house committees with jurisdiction over matters pertaining to public health. The report shall evaluate the effectiveness of the breast cancer mortality reduction program. The report shall include, but is not limited to, data describing the rate of breast cancer morbidity and mortality in this state and the extent of participation in breast cancer screening.

Sec. 13501. (1) As used in this part:

(a) "General license" means a license, effective pursuant to rules promulgated by the department without the filing of an application, to transfer, acquire, own, possess, or use quantities of, or devices or equipment utilizing, radioactive material.

(b) "Ionizing radiation" means gamma rays and x rays, alpha particles, beta particles, high speed electrons, neutrons, protons, high speed ions, and other high speed nuclear particles.

(c) "Mammography" means radiography of the breast for the purpose of enabling a physician to determine the presence, size, location, and extent of cancerous or potentially cancerous tissue in the breast.

(d) "Mammography authorization" means authorization under section 13523 to use a radiation machine for mammography.

(e) "Person" means a person as defined in section 1106 or a governmental entity.

(f) "Radioactive material" means a solid, liquid, or gas material which emits ionizing radiation spontaneously.

(g) "Radiography" means the making of a film or other record of an internal structure of the body by passing x rays or gamma rays through the body to act on film or other image receptor.

(h) "Registration" means registration of a source of ionizing radiation in writing with the department.

(i) "Source of ionizing radiation" means a device or material that emits ionizing radiation.

(j) "Specific license" means a license issued to use, manufacture, produce, transfer, receive, acquire, own, or possess quantities of, or devices or equipment utilizing, radioactive material.

(2) In addition, article 1 contains general definitions and principles of construction applicable to all articles in this code.

Sec. 13521. (1) The department shall promulgate rules providing for general or specific licenses or registration, or exemption from licensing or registration, for radioactive materials and other sources of ionizing radiation. The rules shall provide for amendment, suspension, or revocation of licenses. In connection with those rules, the department may promulgate rules to establish requirements for record keeping, permissible levels of exposure, notification and reports of accidents, protective measures, technical qualifications of personnel, handling, transportation, storage, waste disposal, posting and labeling of hazardous sources and areas, surveys, and monitoring.

(2) The rules shall not limit the intentional exposure of patients to radiation for the purpose of lawful therapy or research conducted by licensed health professionals.

(3) The department shall promulgate rules specifying the minimum training and performance standards for an individual using a radiation machine for mammography as set forth in section 13523.

Sec. 13522. (1) In promulgating rules pursuant to this part, the department shall avoid requiring dual licensing, insofar as practical. Rules promulgated by the department may provide for recognition of other state or federal licenses as the department considers desirable, subject to registration requirements prescribed by the department. A person who, on the effective date of an agreement under Act No. 54 of the Public Acts of 1965, being sections 3.801 to 3.802 of the Michigan Compiled Laws, possesses a license issued by the federal government for a source of ionizing radiation of the type for which the state assumes regulatory responsibility under the agreement, shall be considered to possess an identical license issued pursuant to this part which license shall expire either 90 days after receipt of a written notice of termination from the department, or on the date of expiration stated in the federal license, whichever occurs first.

(2) The department shall promulgate rules to establish a schedule of fees to be paid by applicants for specific licenses for radioactive materials and devices and equipment utilizing the materials.

(3) The department shall promulgate rules to establish a schedule of fees to be paid by an applicant for a specific license for other sources of ionizing radiation and the renewal of the specific license, and by a person possessing sources of ionizing radiation which are subject to registration, except that the registration or registration renewal fee for a radiation machine registered under this part is \$30.00 for the first veterinary or dental x-ray or electron tube and \$15.00 for each additional veterinary or dental x-ray or electron tube annually, or \$50.00 annually per nonveterinary or nondental x-ray or electron tube plus a fee of \$100.00 for each followup inspection due to noncompliance during the same year. The department may accept a written certification from the licensee or registrant that the items of noncompliance have been corrected instead of a followup inspection. If the department does not inspect a source of ionizing radiation for a period of 5 consecutive years, the licensee or registrant of the source of ionizing radiation shall be excused from payment of further license or registration fees as to that source of ionizing radiation until the first license or registration renewal date following the time an inspection of the source of ionizing radiation is made.

(4) A fee collected under this part shall be deposited in the state treasury and credited to the general fund of this state.

(5) Except as otherwise provided in subsection (6), the department shall assess the following nonrefundable fees in connection with mammography authorization:

- (a) Initial inspection, per radiation machine.....\$ 100.00
- (b) Annual inspection, per radiation machine\$ 100.00
- (c) Reinspection for reinstatement of mammography authorization, per radiation machine\$ 100.00
- (d) Department evaluation of compliance with section 13523(2)(a), first radiation machine.....\$ 500.00
Each additional radiation machine\$ 400.00.

(6) If an applicant for mammography authorization submits an evaluation report issued by the American college of radiology that evidences compliance with section 13523(2)(a), the department shall waive the fee under subsection (5) for department evaluation of compliance with that provision.

Sec. 13523. (1) Beginning 60 days after the effective date of this section, a person shall not use a radiation machine to perform mammography unless the radiation machine is registered with the department under department rules for registration of radiation machines and is specifically authorized under this section for use for mammography.

(2) The department shall authorize a radiation machine for use for mammography if the radiation machine meets all of the following standards:

(a) The radiation machine meets the criteria for the American college of radiology mammography accreditation program as adopted in June, 1987 and amended in September, 1988 and published by the American college of radiology, which criteria are incorporated by reference. The department shall make copies of those criteria available to the public and may by rule adopt modified criteria. The department may accept an evaluation report issued by the American college of radiology as evidence that a radiation machine meets those criteria. If at any time the department determines that it will not accept any evaluation reports issued by the American college of radiology as evidence that a radiation machine meets those criteria, the department shall promptly notify each person who has registered a radiation machine under this part and the rules promulgated under this part.

(b) The radiation machine, the film or other image receptor used in the radiation machine, and the facility where the radiation machine is used meet the requirements set forth in department rules for radiation machines.

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

(d) The radiation machine is used exclusively to perform mammography.

(e) The radiation machine is used in a facility that does all of the following:

(i) At least annually has a qualified radiation physicist provide on-site consultation to the facility, including, but not limited to, a complete evaluation of the entire mammography system to ensure compliance with this part and the rules promulgated under this part.

(ii) Maintains for at least 7 years records of the consultation required in subparagraph (i) and the findings of the consultation.

(f) The radiation machine is used according to department rules on patient radiation exposure and radiation dose levels.

(g) The radiation machine is operated only by an individual who can demonstrate to the department that he or she is specifically trained in mammography or an individual who is a physician or an osteopathic physician. Beginning 60 days after the rules required under section 13521(3) are promulgated, the radiation machine is

operated only by an individual who can demonstrate to the department that he or she meets the standards required by those rules or an individual who is a physician or an osteopathic physician. If the department promulgates emergency rules covering the subject matter described in section 13521(3), then for a period beginning 60 days after those emergency rules are promulgated and ending on the day that those emergency rules cease to be in effect, the radiation machine is operated only by an individual who can demonstrate to the department that he or she meets the standards required by those emergency rules or an individual who is a physician or an osteopathic physician.

(3) The department may issue a nonrenewable temporary authorization for a radiation machine for use for mammography if additional time is needed to allow submission of evidence satisfactory to the department that the radiation machine meets the standards set forth in subsection (2) for approval for mammography. A temporary authorization granted under this subsection during the first 18 months after the effective date of this section shall be effective for no more than 12 months. A temporary authorization granted under this subsection after 18 months after the effective date of this section shall be effective for no more than 6 months. The department may withdraw a temporary authorization prior to its expiration if the radiation machine does not meet 1 or more of the standards set forth in subsection (2).

(4) To obtain authorization from the department to use a radiation machine for mammography, the person who owns or leases the radiation machine or an authorized agent of the person shall apply to the department for mammography authorization 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. A person who owns or leases more than 1 radiation machine used for mammography shall obtain authorization for each radiation machine. The department shall process and respond to an application within 30 days after the date of receipt of the application. Upon determining to grant mammography authorization for a radiation machine, the department shall issue a certificate of registration specifying mammography authorization for each authorized radiation machine. A mammography authorization is effective for 3 years.

(5) No later than 60 days after initial mammography authorization of a radiation machine under this section, the department shall inspect the radiation machine, except that for a period not to exceed 1 year after the effective date of this section, the department may conduct that initial inspection later than 60 days after initial mammography authorization under this section. After that initial inspection, the department shall annually inspect the radiation machine 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.

(6) After each satisfactory inspection by the department, 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.

(7) The department may withdraw the mammography authorization for a radiation machine if it does not meet 1 or more of the standards set forth in subsection (2).

(8) The department shall provide an opportunity for a hearing in connection with a denial or withdrawal of mammography authorization.

(9) Upon a finding that a deficiency in a radiation machine used for mammography or a violation of this part or the rules promulgated under this part seriously affects the health, safety, and welfare of individuals upon whom the radiation machine is used for mammography, the department may issue an emergency order summarily withdrawing the mammography authorization of the radiation machine. The department shall incorporate its findings in the order and shall provide an opportunity for a hearing within 5 working days after issuance of the order. The order shall be effective during the proceedings.

(10) If the department withdraws the mammography authorization of a radiation machine, the radiation machine shall not be used for mammography. An application for reinstatement of a mammography authorization shall be filed and processed in the same manner as an application for mammography authorization under subsection (4), except that the department shall not issue a reinstated certificate of mammography registration until the department receives the reinspection fee required under section 13522(5), inspects the radiation machine, and determines that it meets the standards set forth in subsection (2). The department shall conduct an inspection required under this subsection no later than 60 days after receiving a proper application for reinstatement of a mammography authorization.

(11) In addition to the penalties provided in section 13535 and the reinspection fee required under section 13522(5), if a person violates subsection (1), the department may impose an administrative fine against the owner of the radiation machine or, if a lessee of the radiation machine has effective control of the radiation machine, the lessee, of not more than \$500.00 for each calendar week in which a mammography is performed in violation of subsection (1). If a person continues to violate subsection (1) for a period of 2 weeks after a fine is imposed under this subsection, the department shall post a conspicuous notice on the unauthorized radiation

machine and at the entry to the facility where the radiation machine is located warning the public that the facility is performing mammography using a radiation machine that is a substantial hazard to the public health.

(12) The department may promulgate rules necessary to implement this section after consultation with the radiation advisory board established under section 13531.

(13) As used in this section:

(a) "Radiation machine" means a machine, other than those exempted by department rule, that emits ionizing radiation.

(b) "Mammography system" means the radiation machine used for mammography; automatic exposure control devices; films, screens, and cassettes; image processor; darkroom; and viewboxes.

This act is ordered to take immediate effect.

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Clerk of the House of Representatives.

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Secretary of the Senate.

Approved

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Governor.