SENATE BILL NO. 136

March 12, 2025, Introduced by Senators ANTHONY, MCCANN, JOHNSON, BAYER, KLINEFELT, CHANG, GEISS, CAVANAGH, MCMORROW and SHINK and referred to Committee on Health Policy.

A bill to amend 1978 PA 368, entitled "Public health code,"

by amending sections 13501, 13521, 13522, and 13523 (MCL 333.13501, 333.13521, 333.13522, and 333.13523), sections 13501 and 13523 as amended by 1994 PA 100, section 13521 as amended by 2018 PA 544, and section 13522 as amended by 2023 PA 138; and to repeal acts and parts of acts.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

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 any of the following:
- (i) 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.
 - (ii) Interventional mammography.
- (d) "Mammography authorization" means authorization under section 13523 to use a radiation machine for mammography.
- (e) "Mammography interpreter" means an individual who meets the requirements set forth in section 13523(2)(g) and is responsible for evaluating and interpreting mammographic images.
- (d) $\frac{f}{f}$ "Person" means a person as **that term is** defined in section 1106 or a governmental entity.
- (e) "Radiation machine" means a machine, other than those exempted by department rule, that emits ionizing radiation.
- (f) (g)—"Radioactive material" means a solid, liquid, or gas material which that emits ionizing radiation spontaneously.
- (g) (h)—"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) (i)—"Registration" means registration of a source of ionizing radiation in writing with the department.
- 29 (i) (j) "Source of ionizing radiation" means a device or

material that emits ionizing radiation.

- (j) (k)—"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 licenses or specific licenses or registration, or exemption from licensing or registration, for radioactive materials and other sources of ionizing radiation. The rules must provide for the amendment, suspension, or revocation of licenses. In connection with those rules, subject to section 13527, 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 must 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 under this part, the department shall avoid requiring dual licensing, insofar as practical. Rules promulgated by the department may provide for the recognition of other state or federal licenses as the department

- considers desirable, subject to registration requirements 1 prescribed by the department. A person that, on the effective date 2 of an agreement under 1965 PA 54, MCL 3.801 to 3.802, possesses a 3 4 license issued by the federal government for a source of ionizing 5 radiation of the type for which the this state assumes regulatory 6 responsibility under the agreement, is considered to possess an 7 identical license issued under this part, which license expires 8 either 90 days after receipt of a written notice of termination from the department or on the date of expiration stated in the 9 10 federal license, whichever occurs first.
 - (2) The department may promulgate rules to establish a schedule of fees to be paid by applicants for licenses for radioactive materials and devices and equipment utilizing the radioactive materials.
- 15 (3) Except as otherwise provided in this subsection, the 16 department may promulgate rules to establish a schedule of fees to 17 be paid by an applicant for a license for other sources of ionizing 18 radiation and the renewal of the license, and by a person possessing sources of ionizing radiation that are subject to 19 20 registration. The registration or registration renewal fee for a radiation machine registered under this part is \$104.88 \$108.45 for 21 the first veterinary or dental x-ray or electron tube and \$58.19 22 23 \$60.17 for each additional veterinary or dental x-ray or electron tube annually, or \$174.88 \$180.83 annually per nonveterinary or 24 25 nondental x-ray or electron tube. The department shall not assess a fee for the amendment of a radiation machine registration 26 27 certificate. In addition, the department shall assess a fee of \$233.23 \$241.26 for each follow-up inspection due to noncompliance 28 29 during the same year. The department may accept a written

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1	certification from the licensee or registrant that the items of
2	noncompliance have been corrected instead of performing a follow-up
3	inspection. If the department does not inspect a source of ionizing
4	radiation for a period of 5 consecutive years, the licensee or
5	registrant of the source of ionizing radiation does not have to pay
6	further license or registration fees as to that source of ionizing
7	radiation until the first license or registration renewal date
8	following the time an inspection of the source of ionizing
9	radiation is made.
10	(4) A fee collected under this part must be deposited in the
11	state treasury and credited to the general fund of this state.
12	(5) Except as otherwise provided in subsection (6), the The
13	department shall assess the following nonrefundable fees in
14	connection with mammography authorization:inspection:
15	(a) Inspection, per radiation
16	machine \$ 233.23 241.26
17	(b) Reinspection for reinstatement of
18	mammography authorization, Follow-up inspection
19	due to noncompliance, per radiation
20	machine \$ 233.23 241.26
21	(c) Department evaluation of compliance with
22	section 13523(2)(a), per radiation
23	machine \$ 1,567.45
24	Each reevaluation of a radiation machine due
25	to failure during the previous evaluation,
26	relocation of the radiation machine, or similar
27	changes that could affect earlier evaluation
28	results \$ 671.65
29	(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.
- (6) $\frac{(7)}{(7)}$ Except as otherwise provided in subsections subsection (3), and (6), the department shall not waive a fee required under this section.
- (7) (8)—The department shall adjust on an annual basis the fees prescribed by subsections (3) and (5) by an amount determined by the state treasurer to reflect the cumulative annual percentage change in the Detroit Consumer Price Index, not to exceed 5%. As used in this subsection, "Detroit Consumer Price Index" means the most comprehensive index of consumer prices available for the Detroit Detroit-Warren-Dearborn area from the Bureau of Labor Statistics of the United States Department of Labor.
- Sec. 13523. (1) Beginning August 16, 1989, a 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, the personnel operating the radiation machine, and the facility in which the radiation machine is used meet all of the following standards:requirements established by the department by rule for radiation machines.
- (a) The radiation machine and the facility in which the radiation machine is used meet the criteria for the American college of radiology mammography accreditation program dated August, 1993 and published by the American college of radiology in

the documents entitled "overview, mammography accreditation
program, and ACR standards for the performance of screening
mammography", which documents and criteria are incorporated by
reference, excluding the physician interpreter and the
accreditation fee schedule. 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, the personnel operating the radiation machine,
and the facility in which the radiation machine is used meet those
criteria. If at any time the department determines that it will no
accept any evaluation reports issued by the American college of
radiology as evidence that a radiation machine, the personnel
operating the radiation machine, and the facility in which the
radiation machine is used meet those criteria, the department shall
promptly notify each person who has registered a radiation machine
used exclusively to perform mammography under this part and the
rules promulgated under this part.
(b) The radiation machine the film or other image recentor

- (b) The radiation machine, the film or other image receptor used in the radiation machine, and the facility in which the radiation machine is used meet the requirements set forth in department rules for radiation machines.
- $_{\mbox{\scriptsize (c)}}$ The radiation machine is specifically designed to perform mammography.
- (d) The facility in which the radiation machine is used 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.

(iii) Designates a physician or osteopathic physician licensed under article 15 to provide medical direction for the delivery of mammography services and to be responsible for the clinical aspects of the x-ray examinations and other procedures related to mammography. The physician designated under this subparagraph is responsible for conducting an on-site visit to each mammography station within the facility at least monthly for the purpose of providing professional feedback regarding clinical image quality and quality assurance procedures, for review of quality control documentation, and for ensuring that safe operating procedures are used in the delivery of mammographic services. If the physician designated under this subparagraph practices primarily outside of the facility, the physician shall keep a log of each on-site visit signed by the physician. The chief administrative officer of the facility or his or her designee may request to view the log at any time. The physician designated under this subparagraph shall meet the requirements of subdivision (g) (i) and (ii) or, until January 1, 1996, the requirements of subdivision (q) (ii) and (iii).

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

(f) Each individual who operates the radiation machine 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, and beginning 60 days after the rules required under section 13521(3) are promulgated, each individual

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who operates the radiation machine 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.

(g) The x-ray images of each mammographic examination performed with the radiation machine are interpreted by a mammography interpreter who is a physician or osteopathic physician licensed under article 15 and who meets the requirements of subparagraphs (i), (ii), (iii), (iv), and (v):

(i) Except as otherwise provided in this subparagraph, is certified in radiology or diagnostic radiology by the American board of radiology or the American osteopathic board of radiology, has been eligible for certification in radiology or diagnostic radiology for not more than 2 years, or is certified or determined to be qualified in radiology or diagnostic radiology by another professional organization approved by the radiation advisory board appointed under section 13531. Until the expiration of 2 years after the effective date of the amendatory act that added this subdivision, a physician or osteopathic physician licensed under article 15 who has been eligible for certification in radiology or diagnostic radiology for more than 2 years shall be considered to meet the requirement of this subparagraph.

(ii) Shall successfully complete or teach not less than 15 hours of continuing medical education every 3 years after the effective date of the amendatory act that added this subdivision in the technical aspects or clinical aspects, or both, of mammography in courses or programs approved by the individual's respective specialty organization and licensing board and has documentation of successful completion or teaching that is satisfactory to the

department.

 (iii) Shall have successfully completed not less than 2 months of formal training in reading mammograms with instruction in medical radiation physics, radiation effects, and radiation protection and has documentation of successful completion of the training that is satisfactory to the department. For purposes of this subparagraph, the department may accept time spent in a residency program that includes specific training in mammography if the individual has documentation of the residency program that is satisfactory to the department.

(iv) Interprets not less than 520 mammographic examinations each year.

(v) Maintains annual records concerning outcome data for correlation of positive mammograms to biopsies done, and the number of cancers detected.

(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, the personnel operating the radiation machine, and the facility in which the radiation machine is used meet the standards set forth in subsection (2) for approval for mammography. A temporary authorization granted under this subsection after February 16, 1991 is effective for no more than 12 months. The department may withdraw a temporary authorization before its expiration if the radiation machine, the personnel operating the radiation machine, or the facility in which the radiation machine is used 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 contingent upon the radiation machine, the
personnel operating the radiation machine, and the facility in
which the radiation machine is operated for which the mammography
authorization is issued meeting 1 of the following requirements:
(a) Maintaining continued accreditation by the American
college of radiology.

(b) Having an active accreditation application in process with the American college of radiology.

(c) Maintaining approval or being in the process of obtaining approval under a department evaluation process equivalent to that described in subdivisions (a) and (b).

(5) No later than 60 days after initial mammography authorization of a radiation machine under this section, the department shall inspect the radiation machine. 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 is 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

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- 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.
 - (2) To ensure compliance with the requirements described in this section, the department shall inspect a radiation machine at intervals that the department considers necessary or appropriate, including initiating a follow-up inspection of a radiation machine due to noncompliance.
 - (3) (11)—In addition to the penalties provided in section 13535 and the reinspection—fee required under section 13522(5) for a follow-up inspection due to noncompliance, 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.

- (4) (12)—The department may shall promulgate rules necessary to implement this section. after consultation with the radiation advisory board established under section 13531. In promulgating rules to implement this section, the department shall comply with both of the following:
- (a) The department shall incorporate by reference what the department determines to be the applicable standards for mammography, including, but not limited to, standards under the mammography quality standards act of 1992, Public Law 102-539, and any regulations promulgated under that act, that exist on the effective date of the amendatory act that added this sentence. If a standard described in this subdivision is revised after the effective date of the amendatory act that added this sentence, the department shall take notice of the revision and the department shall promulgate rules to incorporate the revision by reference.
- (b) The rules must specify the minimum training and performance standards for an individual using a radiation machine for mammography.
 - (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.

26 Enacting section 1. Sections 13524 and 13531 of the public 27 health code, 1978 PA 368, MCL 333.13524 and 333.13531, are 28 repealed.