

SENATE BILL NO. 1042

October 16, 2024, Introduced by Senators ANTHONY, GEISS, POLEHANKI, CHANG, KLINEFELT and CAVANAGH and referred to the 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:

- 1 Sec. 13501. (1) As used in this part:
- 2 (a) "General license" means a license, effective pursuant to
- 3 rules promulgated by the department without the filing of an

1 application, to transfer, acquire, own, possess, or use quantities
2 of, or devices or equipment utilizing, radioactive material.

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

6 (c) "Mammography" means ~~radiography~~ **any of the following:**

7 **(i) Radiography** of the breast for the purpose of enabling a
8 physician to determine the presence, size, location, and extent of
9 cancerous or potentially cancerous tissue in the breast.

10 **(ii) Interventional mammography.**

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

13 ~~(e) "Mammography interpreter" means an individual who meets~~
14 ~~the requirements set forth in section 13523(2)(g) and is~~
15 ~~responsible for evaluating and interpreting mammographic images.~~

16 ~~(d) (f)~~ "Person" means a person as **that term is** defined in
17 section 1106 or a governmental entity.

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

20 ~~(f) (g)~~ "Radioactive material" means a solid, liquid, or gas
21 material ~~which~~ **that** emits ionizing radiation spontaneously.

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

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

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

29 ~~(j) (k)~~ "Specific license" means a license issued to use,

1 manufacture, produce, transfer, receive, acquire, own, or possess
2 quantities of, or devices or equipment utilizing, radioactive
3 material.

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

6 Sec. 13521. (1) The department shall promulgate rules
7 providing for general **licenses** or specific licenses or
8 registration, or exemption from licensing or registration, for
9 radioactive materials and other sources of ionizing radiation. The
10 rules must provide for **the** amendment, suspension, or revocation of
11 licenses. In connection with those rules, subject to section 13527,
12 the department may promulgate rules to establish requirements for
13 record keeping, permissible levels of exposure, notification and
14 reports of accidents, protective measures, technical qualifications
15 of personnel, handling, transportation, storage, waste disposal,
16 posting and labeling of hazardous sources and areas, surveys, and
17 monitoring.

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

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

24 Sec. 13522. (1) In promulgating rules under this part, the
25 department shall avoid requiring dual licensing, insofar as
26 practical. Rules promulgated by the department may provide for the
27 recognition of other state or federal licenses as the department
28 considers desirable, subject to registration requirements
29 prescribed by the department. A person that, on the effective date

1 of an agreement under 1965 PA 54, MCL 3.801 to 3.802, possesses a
2 license issued by the federal government for a source of ionizing
3 radiation of the type for which ~~the~~**this** state assumes regulatory
4 responsibility under the agreement, is considered to possess an
5 identical license issued under this part, which license expires
6 either 90 days after receipt of a written notice of termination
7 from the department or on the date of expiration stated in the
8 federal license, whichever occurs first.

9 (2) The department may promulgate rules to establish a
10 schedule of fees to be paid by applicants for licenses for
11 radioactive materials and devices and equipment utilizing the
12 radioactive materials.

13 (3) Except as otherwise provided in this subsection, the
14 department may promulgate rules to establish a schedule of fees to
15 be paid by an applicant for a license for other sources of ionizing
16 radiation and the renewal of the license, and by a person
17 possessing sources of ionizing radiation that are subject to
18 registration. The registration or registration renewal fee for a
19 radiation machine registered under this part is ~~\$104.88~~**\$108.45** for
20 the first veterinary or dental x-ray or electron tube and ~~\$58.19~~
21 **\$60.17** for each additional veterinary or dental x-ray or electron
22 tube annually, or ~~\$174.88~~**\$180.83** annually per nonveterinary or
23 nondental x-ray or electron tube. The department shall not assess a
24 fee for the amendment of a radiation machine registration
25 certificate. In addition, the department shall assess a fee of
26 ~~\$233.23~~**\$241.26** for each follow-up inspection due to noncompliance
27 during the same year. The department may accept a written
28 certification from the licensee or registrant that the items of
29 noncompliance have been corrected instead of performing a follow-up

1 inspection. If the department does not inspect a source of ionizing
2 radiation for a period of 5 consecutive years, the licensee or
3 registrant of the source of ionizing radiation does not have to pay
4 further license or registration fees as to that source of ionizing
5 radiation until the first license or registration renewal date
6 following the time an inspection of the source of ionizing
7 radiation is made.

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

10 (5) ~~Except as otherwise provided in subsection (6), the~~ **The**
11 department shall assess the following nonrefundable fees in
12 connection with mammography authorization: **inspection:**

13 (a) Inspection, per radiation
14 machine..... \$ 233.23**241.26**

15 (b) ~~Reinspection for reinstatement of~~
16 ~~mammography authorization,~~ **Follow-up inspection**
17 **due to noncompliance,** per radiation
18 machine..... \$ 233.23**241.26**

19 (c) ~~Department evaluation of compliance with~~
20 ~~section 13523(2) (a),~~ per radiation
21 machine..... \$ 1,567.45

22 ~~Each reevaluation of a radiation machine due~~
23 ~~to failure during the previous evaluation,~~
24 ~~relocation of the radiation machine, or similar~~
25 ~~changes that could affect earlier evaluation~~
26 ~~results.....~~ \$ 671.65

27 (6) ~~If an applicant for mammography authorization submits an~~
28 ~~evaluation report issued by the American College of Radiology that~~
29 ~~evidences compliance with section 13523(2) (a), the department shall~~

1 ~~waive the fee under subsection (5) for department evaluation of~~
 2 ~~compliance with that provision.~~

3 (6) ~~(7)~~ Except as otherwise provided in ~~subsections~~ **subsection**
 4 (3), and ~~(6)~~, the department shall not waive a fee required under
 5 this section.

6 (7) ~~(8)~~ The department shall adjust on an annual basis the
 7 fees prescribed by subsections (3) and (5) by an amount determined
 8 by the state treasurer to reflect the cumulative annual percentage
 9 change in the Detroit Consumer Price Index, not to exceed 5%. As
 10 used in this subsection, "Detroit Consumer Price Index" means the
 11 most comprehensive index of consumer prices available for the
 12 Detroit area from the Bureau of Labor Statistics of the United
 13 States Department of Labor.

14 Sec. 13523. (1) ~~Beginning August 16, 1989, a~~ **A** person shall
 15 not use a radiation machine to perform mammography unless the
 16 radiation machine is registered with the department under
 17 department rules for registration of radiation machines and ~~is~~
 18 ~~specifically authorized under this section for use for mammography.~~

19 ~~(2) The department shall authorize a radiation machine for use~~
 20 ~~for mammography if the radiation machine, the personnel operating~~
 21 ~~the radiation machine, and the facility in which the radiation~~
 22 ~~machine is used meet all of the following standards:~~ **requirements**
 23 **established by the department by rule for radiation machines.**

24 ~~(a) The radiation machine and the facility in which the~~
 25 ~~radiation machine is used meet the criteria for the American~~
 26 ~~college of radiology mammography accreditation program dated~~
 27 ~~August, 1993 and published by the American college of radiology in~~
 28 ~~the documents entitled "overview, mammography accreditation~~
 29 ~~program, and ACR standards for the performance of screening~~

1 ~~mammography", which documents and criteria are incorporated by~~
2 ~~reference, excluding the physician interpreter and the~~
3 ~~accreditation fee schedule. The department shall make copies of~~
4 ~~those criteria available to the public and may by rule adopt~~
5 ~~modified criteria. The department may accept an evaluation report~~
6 ~~issued by the American college of radiology as evidence that a~~
7 ~~radiation machine, the personnel operating the radiation machine,~~
8 ~~and the facility in which the radiation machine is used meet those~~
9 ~~criteria. If at any time the department determines that it will not~~
10 ~~accept any evaluation reports issued by the American college of~~
11 ~~radiology as evidence that a radiation machine, the personnel~~
12 ~~operating the radiation machine, and the facility in which the~~
13 ~~radiation machine is used meet those criteria, the department shall~~
14 ~~promptly notify each person who has registered a radiation machine~~
15 ~~used exclusively to perform mammography under this part and the~~
16 ~~rules promulgated under this part.~~

17 ~~(b) The radiation machine, the film or other image receptor~~
18 ~~used in the radiation machine, and the facility in which the~~
19 ~~radiation machine is used meet the requirements set forth in~~
20 ~~department rules for radiation machines.~~

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

23 ~~(d) The facility in which the radiation machine is used does~~
24 ~~all of the following:~~

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

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

3 ~~(iii) Designates a physician or osteopathic physician licensed~~
4 ~~under article 15 to provide medical direction for the delivery of~~
5 ~~mammography services and to be responsible for the clinical aspects~~
6 ~~of the x-ray examinations and other procedures related to~~
7 ~~mammography. The physician designated under this subparagraph is~~
8 ~~responsible for conducting an on site visit to each mammography~~
9 ~~station within the facility at least monthly for the purpose of~~
10 ~~providing professional feedback regarding clinical image quality~~
11 ~~and quality assurance procedures, for review of quality control~~
12 ~~documentation, and for ensuring that safe operating procedures are~~
13 ~~used in the delivery of mammographic services. If the physician~~
14 ~~designated under this subparagraph practices primarily outside of~~
15 ~~the facility, the physician shall keep a log of each on-site visit~~
16 ~~signed by the physician. The chief administrative officer of the~~
17 ~~facility or his or her designee may request to view the log at any~~
18 ~~time. The physician designated under this subparagraph shall meet~~
19 ~~the requirements of subdivision (g) (i) and (ii) or, until January 1,~~
20 ~~1996, the requirements of subdivision (g) (ii) and (iii).~~

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

23 ~~(f) Each individual who operates the radiation machine can~~
24 ~~demonstrate to the department that he or she is specifically~~
25 ~~trained in mammography or an individual who is a physician or an~~
26 ~~osteopathic physician, and beginning 60 days after the rules~~
27 ~~required under section 13521(3) are promulgated, each individual~~
28 ~~who operates the radiation machine can demonstrate to the~~
29 ~~department that he or she meets the standards required by those~~

1 ~~rules or an individual who is a physician or an osteopathic~~
2 ~~physician.~~

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

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

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

29 ~~(iii) Shall have successfully completed not less than 2 months~~

1 ~~of formal training in reading mammograms with instruction in~~
2 ~~medical radiation physics, radiation effects, and radiation~~
3 ~~protection and has documentation of successful completion of the~~
4 ~~training that is satisfactory to the department. For purposes of~~
5 ~~this subparagraph, the department may accept time spent in a~~
6 ~~residency program that includes specific training in mammography if~~
7 ~~the individual has documentation of the residency program that is~~
8 ~~satisfactory to the department.~~

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

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

14 ~~(3) The department may issue a nonrenewable temporary~~
15 ~~authorization for a radiation machine for use for mammography if~~
16 ~~additional time is needed to allow submission of evidence~~
17 ~~satisfactory to the department that the radiation machine, the~~
18 ~~personnel operating the radiation machine, and the facility in~~
19 ~~which the radiation machine is used meet the standards set forth in~~
20 ~~subsection (2) for approval for mammography. A temporary~~
21 ~~authorization granted under this subsection after February 16, 1991~~
22 ~~is effective for no more than 12 months. The department may~~
23 ~~withdraw a temporary authorization before its expiration if the~~
24 ~~radiation machine, the personnel operating the radiation machine,~~
25 ~~or the facility in which the radiation machine is used does not~~
26 ~~meet 1 or more of the standards set forth in subsection (2).~~

27 ~~(4) To obtain authorization from the department to use a~~
28 ~~radiation machine for mammography, the person who owns or leases~~
29 ~~the radiation machine or an authorized agent of the person shall~~

1 ~~apply to the department for mammography authorization on an~~
2 ~~application form provided by the department and shall provide all~~
3 ~~of the information required by the department as specified on the~~
4 ~~application form. A person who owns or leases more than 1 radiation~~
5 ~~machine used for mammography shall obtain authorization for each~~
6 ~~radiation machine. The department shall process and respond to an~~
7 ~~application within 30 days after the date of receipt of the~~
8 ~~application. Upon determining to grant mammography authorization~~
9 ~~for a radiation machine, the department shall issue a certificate~~
10 ~~of registration specifying mammography authorization for each~~
11 ~~authorized radiation machine. A mammography authorization is~~
12 ~~effective for 3 years contingent upon the radiation machine, the~~
13 ~~personnel operating the radiation machine, and the facility in~~
14 ~~which the radiation machine is operated for which the mammography~~
15 ~~authorization is issued meeting 1 of the following requirements:~~

16 ~~(a) Maintaining continued accreditation by the American~~
17 ~~college of radiology.~~

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

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

23 ~~(5) No later than 60 days after initial mammography~~
24 ~~authorization of a radiation machine under this section, the~~
25 ~~department shall inspect the radiation machine. After that initial~~
26 ~~inspection, the department shall annually inspect the radiation~~
27 ~~machine and may inspect the radiation machine more frequently. The~~
28 ~~department shall make reasonable efforts to coordinate the~~
29 ~~inspections under this section with the department's other~~

1 ~~inspections of the facility in which the radiation machine is~~
2 ~~located.~~

3 ~~(6) After each satisfactory inspection by the department, the~~
4 ~~department shall issue a certificate of radiation machine~~
5 ~~inspection or a similar document identifying the facility and~~
6 ~~radiation machine inspected and providing a record of the date the~~
7 ~~radiation machine was inspected. The facility shall post the~~
8 ~~certificate or other document near the inspected radiation machine.~~

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

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

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

25 ~~(10) If the department withdraws the mammography authorization~~
26 ~~of a radiation machine, the radiation machine shall not be used for~~
27 ~~mammography. An application for reinstatement of a mammography~~
28 ~~authorization shall be filed and processed in the same manner as an~~
29 ~~application for mammography authorization under subsection (4),~~

1 ~~except that the department shall not issue a reinstated certificate~~
 2 ~~of mammography registration until the department receives the~~
 3 ~~reinspection fee required under section 13522(5), inspects the~~
 4 ~~radiation machine, and determines that it meets the standards set~~
 5 ~~forth in subsection (2). The department shall conduct an inspection~~
 6 ~~required under this subsection no later than 60 days after~~
 7 ~~receiving a proper application for reinstatement of a mammography~~
 8 ~~authorization.~~

9 **(2) To ensure compliance with the requirements described in**
 10 **this section, the department shall inspect a radiation machine at**
 11 **intervals that the department considers necessary or appropriate,**
 12 **including initiating a follow-up inspection of a radiation machine**
 13 **due to noncompliance.**

14 **(3)** ~~(11)~~ In addition to the penalties provided in section
 15 13535 and the ~~reinspection fee~~ required under section 13522(5) **for**
 16 **a follow-up inspection due to noncompliance,** if a person violates
 17 subsection (1), the department may impose an administrative fine
 18 against the owner of the radiation machine or, if a lessee of the
 19 radiation machine has effective control of the radiation machine,
 20 the lessee, of not more than \$500.00 for each calendar week in
 21 which a mammography is performed in violation of subsection (1). If
 22 a person continues to violate subsection (1) for a period of 2
 23 weeks after a fine is imposed under this subsection, the department
 24 shall post a conspicuous notice on the ~~unauthorized~~ radiation
 25 machine and at the entry to the facility where the radiation
 26 machine is located warning the public that the facility is
 27 performing mammography using a radiation machine that is a
 28 substantial hazard to the public health.

29 **(4)** ~~(12)~~ The department ~~may~~ **shall** promulgate rules necessary

1 to implement this section. ~~after consultation with the radiation~~
2 ~~advisory board established under section 13531.~~ **In promulgating**
3 **rules to implement this section, the department shall comply with**
4 **both of the following:**

5 (a) The department shall incorporate by reference what the
6 department determines to be the applicable standards for
7 mammography, including, but not limited to, standards under the
8 mammography quality standards act of 1992, Public Law 102-539, and
9 any regulations promulgated under that act, that exist on the
10 effective date of the amendatory act that added this sentence. If a
11 standard described in this subdivision is revised after the
12 effective date of the amendatory act that added this sentence, the
13 department shall take notice of the revision and the department
14 shall promulgate rules to incorporate the revision by reference.

15 (b) The rules must specify the minimum training and
16 performance standards for an individual using a radiation machine
17 for mammography.

18 ~~(13) As used in this section:~~

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

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

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