

HOUSE BILL NO. 6210

June 09, 2022, Introduced by Reps. Kahle, Steven Johnson, Tisdell, Martin, Beeler, Calley, Meerman, Bellino, Lightner, Clements, Eisen, Allor, Outman and Alexander and referred to the Committee on Oversight.

A bill to amend 1978 PA 368, entitled
"Public health code,"
by amending section 13523 (MCL 333.13523), as amended by 1994 PA
100.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

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

1 (2) The department shall authorize a radiation machine for use
2 for mammography if the radiation machine, the personnel operating
3 the radiation machine, and the facility in which the radiation
4 machine is used meet all of the following standards:

5 (a) The radiation machine and the facility in which the
6 radiation machine is used meet the criteria for the American
7 ~~college of radiology~~ **College of Radiology** mammography accreditation
8 program dated August, 1993 and published by the American ~~college of~~
9 ~~radiology~~ **College of Radiology** in the documents entitled "overview,
10 mammography accreditation program, and ACR standards for the
11 performance of screening mammography", which documents and criteria
12 are incorporated by reference, excluding the physician interpreter
13 and the accreditation fee schedule. The department shall make
14 copies of those criteria available to the public and may by rule
15 adopt modified criteria. The department may accept an evaluation
16 report issued by the American ~~college of radiology~~ **College of**
17 **Radiology** as evidence that a radiation machine, the personnel
18 operating the radiation machine, and the facility in which the
19 radiation machine is used meet those criteria. If at any time the
20 department determines that it will not accept any evaluation
21 reports issued by the American ~~college of radiology~~ **College of**
22 **Radiology** as evidence that a radiation machine, the personnel
23 operating the radiation machine, and the facility in which the
24 radiation machine is used meet those criteria, the department shall
25 promptly notify each person who has registered a radiation machine
26 used exclusively to perform mammography under this part and the
27 rules promulgated under this part.

28 (b) The radiation machine, the film or other image receptor
29 used in the radiation machine, and the facility in which the

1 radiation machine is used meet the requirements set forth in
2 department rules for radiation machines.

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

5 (d) The facility in which the radiation machine is used does
6 all of the following:

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

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

14 (iii) Designates a physician or osteopathic physician licensed
15 under article 15 to provide medical direction for the delivery of
16 mammography services and to be responsible for the clinical aspects
17 of the x-ray examinations and other procedures related to
18 mammography. The physician designated under this subparagraph is
19 responsible for conducting an on-site visit to each mammography
20 station within the facility at least monthly for the purpose of
21 providing professional feedback regarding clinical image quality
22 and quality assurance procedures, for review of quality control
23 documentation, and for ensuring that safe operating procedures are
24 used in the delivery of mammographic services. If the physician
25 designated under this subparagraph practices primarily outside of
26 the facility, the physician shall keep a log of each on-site visit
27 signed by the physician. The chief administrative officer of the
28 facility or his or her designee may request to view the log at any
29 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 (g) (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 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~~ **Board of Radiology** or the American ~~osteopathic board of radiology~~, **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,~~ **April 18, 1996**, a physician or osteopathic physician

1 licensed under article 15 who has been eligible for certification
2 in radiology or diagnostic radiology for more than 2 years ~~shall be~~
3 **is** considered to meet the requirement of this subparagraph.

4 (ii) Shall successfully complete or teach not less than 15
5 hours of continuing medical education every 3 years after ~~the~~
6 ~~effective date of the amendatory act that added this subdivision~~
7 **April 18, 1994**, in the technical aspects or clinical aspects, or
8 both, of mammography in courses or programs approved by the
9 individual's respective specialty organization and licensing board
10 and has documentation of successful completion or teaching that is
11 satisfactory to the department.

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

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

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

26 (3) The department may issue a nonrenewable temporary
27 authorization for a radiation machine for use for mammography if
28 additional time is needed to allow submission of evidence
29 satisfactory to the department that the radiation machine, the

1 personnel operating the radiation machine, and the facility in
2 which the radiation machine is used meet the standards set forth in
3 subsection (2) for approval for mammography. A temporary
4 authorization granted under this subsection after February 16, 1991
5 is effective for no more than 12 months. The department may
6 withdraw a temporary authorization before its expiration if the
7 radiation machine, the personnel operating the radiation machine,
8 or the facility in which the radiation machine is used does not
9 meet 1 or more of the standards set forth in subsection (2).

10 (4) To obtain authorization from the department to use a
11 radiation machine for mammography, the person who owns or leases
12 the radiation machine or an authorized agent of the person shall
13 apply to the department for mammography authorization on an
14 application form provided by the department and shall provide all
15 of the information required by the department as specified on the
16 application form. A person who owns or leases more than 1 radiation
17 machine used for mammography shall obtain authorization for each
18 radiation machine. The department shall process and respond to an
19 application within 30 days after the date of receipt of the
20 application. Upon determining to grant mammography authorization
21 for a radiation machine, the department shall issue a certificate
22 of registration specifying mammography authorization for each
23 authorized radiation machine. A mammography authorization is
24 effective for 3 years contingent upon the radiation machine, the
25 personnel operating the radiation machine, and the facility in
26 which the radiation machine is operated for which the mammography
27 authorization is issued meeting 1 of the following requirements:

28 (a) Maintaining continued accreditation by the American
29 ~~college of radiology.~~ **College of Radiology.**

1 (b) Having an active accreditation application in process with
2 the American ~~college of radiology~~. **College of Radiology**.

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

6 (5) No later than 60 days after initial mammography
7 authorization of a radiation machine under this section, the
8 department shall inspect the radiation machine. After that initial
9 inspection, the department shall annually inspect the radiation
10 machine and may inspect the radiation machine more frequently. The
11 department shall make reasonable efforts to coordinate the
12 inspections under this section with the department's other
13 inspections of the facility in which the radiation machine is
14 located.

15 (6) After each satisfactory inspection by the department, the
16 department shall issue a certificate of radiation machine
17 inspection or a similar document identifying the facility and
18 radiation machine inspected and providing a record of the date the
19 radiation machine was inspected. The facility shall post the
20 certificate or other document near the inspected radiation machine.

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

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

27 (9) Upon a finding that a deficiency in a radiation machine
28 used for mammography or a violation of this part or the rules
29 promulgated under this part seriously affects the health, safety,

1 and welfare of individuals upon whom the radiation machine is used
2 for mammography, the department may issue an emergency order
3 summarily withdrawing the mammography authorization of the
4 radiation machine. The department shall incorporate its findings in
5 the order and shall provide an opportunity for a hearing within 5
6 working days after issuance of the order. The order is effective
7 during the proceedings. **If the department summarily withdraws the**
8 **mammography authorization of a radiation machine under this**
9 **subsection, the department shall provide notice of the withdrawal**
10 **to all of the following within 24 hours:**

11 (a) **The senate majority leader and the speaker of the house of**
12 **representatives.**

13 (b) **Standing committees in the senate and house of**
14 **representatives that deal primarily with oversight.**

15 (c) **Any other standing committee in the senate and house of**
16 **representatives that the department considers necessary or**
17 **appropriate.**

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

1 mammography authorization.

2 (11) In addition to the penalties provided in section 13535
3 and the reinspection fee required under section 13522(5), if a
4 person violates subsection (1), the department may impose an
5 administrative fine against the owner of the radiation machine or,
6 if a lessee of the radiation machine has effective control of the
7 radiation machine, the lessee, of not more than \$500.00 for each
8 calendar week in which a mammography is performed in violation of
9 subsection (1). If a person continues to violate subsection (1) for
10 a period of 2 weeks after a fine is imposed under this subsection,
11 the department shall post a conspicuous notice on the unauthorized
12 radiation machine and at the entry to the facility where the
13 radiation machine is located warning the public that the facility
14 is performing mammography using a radiation machine that is a
15 substantial hazard to the public health.

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

19 (13) As used in this section:

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

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