Legislative Analysis

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RADIOLOGIC PERSONNEL AND MACHINES

House Bill 5116 as introduced
Sponsor: Rep. Rodney Wakeman
Committee: Health Policy
Complete to 1-27-22

Analysis available at
http://www.legislature.mi.gov

SUMMARY:

House Bill 5116 would amend the Public Health Code by adding Part 135A (Radiation Machine Control), which among other things would create several certifications for radiologic personnel. The bill also would amend existing Part 135 (Radiation Control). Several provisions of the new part, primarily those addressing radiation machines, are now contained in Part 135. The bill would remove some provisions currently in Part 135, including repealing four sections, and include many (but not all) of these provisions in the new Part 135A.

The bill would add several new definitions pertaining to ***radiography*** to the code and also move definitions from Part 135 (especially those related to mammography) to the new Part 135A.

> ***Radiography*** would mean the making of a film, digital image, or other record of an internal structure of the body by passing X-rays through the body to act on film or other image receptor. [In Part 135 the term is defined without reference to "digital image" and includes "gamma rays" in addition to X-rays; that definition would be retained in that part.]

The bill also would move or replicate several provisions in Part 135 into Part 135A, which would do all of the following:

- Carve out from the provisions certain electrical equipment, radiation machines, and non-ionizing radiation sources or devices. [Section 13556]
- Stipulate that the governor may enter into cooperative agreements regarding ionizing radiation/radiation machines. [Section 13561]
- Designate the Department of Labor and Economic Opportunity (LEO) as the radiation control agency/radiation machine control agency for the state. [Section 13565]
- Require LEO to issue an emergency order if it found that an emergency existed requiring immediate action to protect occupational or public health and safety. [Section 13566]
- Allow LEO to enter public or private property to determine compliance or violation with the radiation machine provisions. [Section 13567]
- Require LEO to promulgate rules providing for the registration of radiation machines and allow it to promulgate rules for the registration of non-ionizing radiation devices. [Section 13571]
- Require LEO to set a fee schedule for the registration of a radiation machine or non-ionizing radiation device. [Section 13572]

Additionally, the bill would repeal sections 13523 and 13524 of the code and largely replicate them in proposed sections 13573 and 13573a. Some of the key differences between the old and new sections are described below:

- Currently, a medical doctor (M.D.) or osteopathic doctor (D.O.) must be designated to provide medical direction for the delivery of mammography services. The bill specifies that the M.D. or D.O. would be the "lead interpreting physician."
- The bill would require a facility in which a radiation machine is used to submit to LEO evidence of a surety bond, secured trust fund, or other approved secured instrument or mechanism to ensure proper record retention if the facility closes.
- The bill would revise the requirements for an individual able to interpret the X-ray images of the mammographic examinations by doing the following:
    - Moving the determination of whether an alternate professional organization's determination or certificate makes a person qualified in radiology or diagnostic radiology from the Radiation Advisory Board (RAB) to LEO. [Note: The section that governs the RAB would also be repealed under the bill.]
    - Requiring three months instead of two months of formal training in reading mammograms.
    - Instead of the current requirement of interpretation of at least 520 mammographic examinations per year, requiring initial training of interpretation of at least 240 mammographic examinations in the six months before moving to independent interpretation, and interpretation or multi-reading of at least 960 during a 24-month period determined by the mammography facility.
- The bill would move the time period for inspection of the radiation machine from within 60 days of its initial mammography authorization to within 90 days.

The bill would require a facility in which a radiation machine is located to ensure that each individual, except for a licensed health professional, operating the radiation machine for screening or for diagnostic, interventional, or therapeutic purposes holds a certification from LEO to operate the machine. LEO could use interview or observation, or both, to ensure compliance with this requirement. Facilities would have to maintain records to demonstrate compliance.

New Certifications

Section 13575 would provide for the certification by LEO of **radiographers** and **radiation therapists**. Applicants for either certification would have to demonstrate to LEO that they meet the requirements for certification and registration in radiography or radiation therapy, respectively, from the American Registry of Radiologic Technologists (ARRT), or equivalent standards, in addition to any other requirements established by LEO for the certification of individuals operating radiation machines for human screening or for diagnostic, interventional, or therapeutic purposes.

Certified radiographers could operate radiography and fluoroscopy radiation machines. Certified radiation therapists could operate therapeutic radiation machines and computed tomography radiation machines for treatment planning purposes.

Section 13575 also would provide for the certification as **nuclear medicine technologists** of individuals who demonstrate to LEO that they meet the requirements for certification and

registration in nuclear medicine technology from ARRT or the Nuclear Medicine Technology Certification Board, or equivalent standards, in addition to any other requirements established by LEO for the certification of individuals operating radiation machines for human screening or for diagnostic, interventional, or therapeutic purposes.

Certified nuclear medicine technologists could operate radiation machines for the detection of radiation and computed tomography radiation machines for attenuated correction and anatomical localization.

Additionally, section 13575 would provide for the certification as **radiologist assistants** of individuals who hold a current certification as a radiographer and demonstrate to LEO that they meet the requirements for certification and registration as a radiologist assistant from ARRT or as a radiology practitioner assistant from the Certification Board of Radiology Practitioner Assistants, or equivalent standards, in addition to any other requirements established by LEO for the certification of individuals operating radiation machines for human screening or for diagnostic, interventional, or therapeutic purposes.

Certified radiologist assistants could operate radiography and fluoroscopy radiation machines. A radiologist assistant could not perform image interpretation, render a diagnosis, or prescribe a medication or therapy, but could perform activities in the areas of patient care, patient management, and radiography and fluoroscopy procedures under the supervision of a radiologist.

Finally, section 13575 would provide for certification to operate a computed tomography radiation machine for diagnostic purposes to individuals who demonstrate to LEO that they meet all of the following:

- Hold current certification from LEO as a radiographer, radiation therapist, nuclear medicine technologist, or radiologist assistant.
- Meet the requirements for certification and registration in computed tomography from ARRT or the Nuclear Medicine Technology Certification Board, or equivalent standards, as determined by LEO.
- Meet any other requirements established by LEO for the certification of individuals operating radiation machines for human screening or for diagnostic, interventional, or therapeutic purposes.

Section 13576 would provide that, to be granted certification by LEO as a **limited X-ray machine operator**, a person must meet the prerequisite qualifications, receive training, and demonstrate competence as follows:

- Complete at least 48 hours of didactic instruction in a formal program, approved by LEO, as described below.
- Achieve a passing score of 70% on the certification examination for the limited scope of practice in radiography developed by the American Registry of Radiologic Technologists and approved by LEO in at least one but no more than three of the limited scope categories of chest, extremities, skull/sinus, spine, or podiatric. [Note: A facility needing to perform examinations in addition to any three of these categories would have to employ a radiographer. A passing score on the basic chiropractic X-ray technology examination given through the American Chiropractic Registry of

Radiologic Technologists and approved by LEO would meet the requirements for limited scope spinal radiography.]

- Complete the clinical experience requirements described below. An individual who has been actively working as a medical X-ray operator for at least six months before the bill takes effect would be exempt from these experience requirements, but would have to document the didactic training requirements and examination requirements within three years after the bill's effective date.
- Obtain at least 15 hours, in any three-year period, of continuing education in the technical or clinical, or both, aspects and related subject of X-ray examinations in his or her scope of practice.
- Meet any other requirements established by LEO for the certification of individuals operating radiation machines for human screening or for diagnostic, interventional, or therapeutic purposes.

A limited X-ray machine operator would be limited in scope of practice to only examinations specified in section 13576 and to performing radiography without the use of contrast media or fluoroscopy.

An individual seeking certification as a limited X-ray machine operator would have to complete a minimum of 48 hours of didactic training in a formal training course. After successful completion, the individual would have to pass an examination appropriate to his or her scope of practice and complete the clinical experience requirements described below. The formal training course would be subject to LEO approval and would have to provide instruction in all of the following subjects:

- Radiation protection, including patient protection, personnel protection, and radiation exposure and monitoring.
- Equipment operation and maintenance, including radiographic unit components, principles of X-ray production, and recognition of malfunctions.
- Image production and evaluation, including selection of technique factors, film processing and quality assurance, and evaluation of radiographs.
- Patient care, including legal and professional responsibilities; patient education, safety, and comfort; prevention and control of infection; and patient monitoring.
- Radiographic procedure positioning.

An individual who completed this didactic training would also have to complete one month of clinical training, during which time the individual could perform the X-ray examinations allowed under the certification only under the direct supervision of the physician in charge or a radiographer. Such an individual would have to be trained in proper imaging procedures as listed below:

- Selection of appropriate radiographic image receptor size.
- Selection of appropriate technique factors.
- Use of correct source-to-image distance.
- Establishment of proper direction of central ray.
- Execution of proper patient position.
- Collimation of the X-ray beam as appropriate.
- Providing gonadal shielding if appropriate.
- Using correct radiographic image markers.

- Giving proper patient instruction.
- Placing patient information correctly on the radiographic image.
- Completing examination in a timely manner.
- Obtaining desired anatomy and positioning results on the radiographic image.
- Obtaining appropriate contrast and density on the radiographic image.
- Identifying visible motion or radiographic image artifacts and repeating exam if needed.

Violation and penalty

A person who violated the new Part 135A or a rule promulgated under the part or who failed to obtain or comply with a condition of registration or certification under the part would be guilty of a misdemeanor punishable by imprisonment for up to 180 days or a fine of up to $10,000, or both. Each day a violation continued would be a separate violation.

If, after thorough investigation, LEO judged that a person violated or was about to violate Part 135A or a rule or order promulgated or issued under it, the attorney general, at the request of LEO, would have to apply to the appropriate circuit court for an order enjoining the act or practice or for an order directing compliance with the statute, rule, or order.

Repealers

The bill would repeal four sections of the act. The provisions of sections 13523 and 13524 would largely be replicated in the new sections 13573 and 13573a, with the differences described above. Section 13527, regarding handheld dental X-ray systems,[1] which took effect in 2019, would not be replicated in Part 135A. Section 13531, regarding the Radiation Advisory Board, would likewise be repealed and not replicated.

MCL 333.13501 et seq.

FISCAL IMPACT:

House Bill 5116 could have significant fiscal implications for the Department of Labor and Economic Opportunity (LEO). The department raised concerns over revenue fluctuations resulting from changes to the fee structure and from additional costs LEO may incur. A more detailed fiscal analysis is in progress.

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■ This analysis was prepared by nonpartisan House Fiscal Agency staff for use by House members in their deliberations and does not constitute an official statement of legislative intent.

[1] 2018 PA 544 (House Bill 5647 of 2017-18) http://www.legislature.mi.gov/documents/2017-2018/billanalysis/House/pdf/2017-HLA-5647-89EF5F63.pdf