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BILL ANALYSIS

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Senate Bill 136 (as enacted)
Sponsor: Senator Sarah Anthony
Committee: Health Policy

PUBLIC ACT 63 of 2025

Date Completed: 1-13-26

CONTENT

The bill amends Part 135 (Radiation Control) of the Public Health Code to do the following:

- **Delete statutory requirements governing authorization to use radiation machines to perform a mammography and instead require the Department of Labor and Economic Opportunity (LEO) to promulgate rules regarding the authorized use of radiation machines for that purpose.**
- **Require promulgated rules to incorporate standards under the Mammography Quality Standards Act (MQSA) and prescribe minimum training and performance standards for an individual using a radiation machine for mammography.**
- **Increase fees related to the inspection, registration, and evaluation of radiation machines.**
- **Repeal Section 13524 and Section 13531 of the Code, which respectively prescribe requirements for notifying an individual who demonstrates dense breast tissue in a mammography and establishes the Radiation Advisory Board.**

The bill will take effect March 24, 2026.

Generally, Part 135 governs licensure and operation of medical radiation and radiation machinery used for mammography, the practice of x-ray imaging breast tissue to detect cancers and other diseases. The Radiation Safety Section (RSS) of LEO administers Part 135.

"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. The bill includes interventional mammography in the definition.

The bill defines "radiation machine" as a machine, other than those exempted by LEO rule, that emits ionizing radiation.

Deletion of Statutory Requirements and Application of LEO Rules

Currently, a person may not use a radiation machine to perform mammography unless the radiation machine is registered with LEO by rules for registration of radiation machines and is specifically authorized for use for mammography. The Code requires LEO to 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 the following standards:

-- The criteria for the American College of Radiology Mammography Accreditation Program entitled "Overview, Mammography Accreditation Program, and ACR Standards for the Performance of Screening Mammography".
-- Rules promulgated.

-- The radiation machine is specifically designed to perform mammography.
-- The facility in which the radiation machine is used receives annual, on-site consultation from a qualified radiation physicist, maintains records of the on-site consultation and its findings for at least seven years, and designates a physician to provide medical direction for the delivery of mammography services and to be clinically responsible for x-ray examinations and other mammography-related services.
-- The radiation machine is used according to rules on patient radiation exposure and radiation dose levels.
-- Each individual operating the machine demonstrates specific training in mammography.
-- The x-ray images of the radiation machine are interpreted by a mammography interpreter who is a physician and who meets certain requirements related to mammography.

To obtain authorization from LEO to use a radiation machine for mammography, the person who owns or leases the radiation machine or an authorized agent of the person must apply to LEO for mammography authorization and provide all the information required by LEO as specified on the application form. A person who owns or leases more than one radiation machine used for mammography must obtain authorization for each radiation machine. The Department must process and respond to an application within 30 days and upon determining to grant mammography authorization for a radiation machine must issue a certificate of registration. A mammography authorization is effective for three years.

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 LEO that the machine and personnel meet statutory requirements, and LEO may withdraw a temporary authorization before its expiration if the machine and personnel do not meet statutory requirements.

Upon finding that a deficiency in a radiation machine used for mammography or a violation of Part 135 or its rules seriously affects the health, safety, and welfare of individuals upon whom the radiation machine is used for mammography, LEO may issue an emergency order summarily withdrawing the mammography authorization of the radiation machine. If LEO withdraws the authorization of a radiation machine, the radiation machine must not be used for mammography and another application for the machine must be submitted.

The bill deletes all the above provisions. Instead, a person must not use a radiation machine to perform mammography unless the radiation machine is registered with LEO under promulgated rules for registration of radiation machines and the radiation machine, the personnel operating the radiation machine, and the facility in which the radiation machine is used meets requirements established by LEO by rule for radiation machines.

In addition, to ensure compliance with the requirements above, the bill requires LEO to inspect a radiation machine at intervals that LEO considers necessary or appropriate, including initiating a follow-up inspection of a radiation machine due to noncompliance.

Rulemaking Requirements

Currently, the Code requires LEO to promulgate rules after consultation with the Radiation Advisory Board, which the bill deletes. Instead, under the bill, LEO must comply with the following in rule promulgation:

-- The Department must incorporate by reference what it determined to be the applicable standards for mammography, including standards under the MQSA and any regulations promulgated thereunder that existed on the bill's effective date; if a standard under MQSA

is revised, LEO will have to take notice of the revision and promulgate rules to incorporate the revision by reference.

-- The rules must specify the minimum training and performance standards for an individual using a radiation machine for mammography.

Departmental Fees for Radiation Machine Registration

The Code prescribes the fees described below for radiation machine registration and inspection. The bill increases these fees as follows:

What the Fee Is For	Current Fee Amount	New Fee Amount
The annual registration or registration renewal fee for a machine registered under Part 135 for the first veterinary or dental x-ray or electron tube.	$104.88	$108.45
The annual registration or registration renewal fee for a machine registered under Part 135 for each additional veterinary or dental x-ray or electron tube.	$58.19	$60.17
The annual registration or registration renewal fee for a machine registered under Part 135 for nonveterinary or nondental x-ray or electron tube.	$174.88	$180.83
The inspection of radiation machines used for mammography and for reinspection due to non-compliance, per radiation machine.	$233.23	$241.26

The bill also deletes fees for evaluation, and reevaluation due to non-compliance, of a mammography radiation machine's compliance with standards prescribed in Section 13523(2)(a), which is a Section that the bill deletes.

Repealed Sections

Generally, Section 13524 of the Code prescribes notification requirements that a person who provides mammography services must provide to a patient whose mammogram demonstrates dense breast tissue. Section 13531 establishes the Radiation Advisory Board and requires the Board to provide LEO with technical advice on the use of radiation machines. The bill repeals Sections 13524 and 13531.

MCL 333.13501 et al.

BRIEF RATIONALE

During September 2023, the United States Food and Drug Administration updated the MQSA, which is the Federal law that governs mammography facilities. The updates changed the information collected in a mammography report and the notification provided to a patient about dense breast tissue.[1] Some people believe that the updated Federal standards improve early detection of breast cancer by informing women of irregular breast density sooner, and that Michigan's standards should align with the Federal standards to improve early detection of breast cancer.

[1] United States Food and Drug Administration, "Important Information: Final Rule to Amend the Mammography Quality Standards Act (MQSA)", September 2024.

BACKGROUND

The RSS is responsible for all nonfederal, nontribal radiation machine and facility regulation in Michigan.[2] The RSS serves to reduce unnecessary exposure to ionizing radiation from x-ray machines and other radiation machines. The RSS is also responsible for the annual registration of Michigan's 10,000 x-ray facilities with over 29,000 x-ray machines and the inspection of any new mammography machine within 60 days of initial use or authorization. The MQSA became law on October 27, 1992. The MQSA was enacted to ensure access to quality mammography for the detection of breast cancer in its earliest, most treatable stages.[3] A mammography facility must be MQSA-certified as providing quality mammography services.

PREVIOUS LEGISLATION

(This section does not provide a comprehensive account of previous legislative efforts on this subject matter.)

Senate Bill 136 is a reintroduction of Senate Bill 1042 of the 2023-2024 Legislative Session. Senate Bill 1042 passed the Senate and was discharged from the House Committee on Health Policy but received no further action.

Legislative Analyst: Alex Krabill

FISCAL IMPACT

The bill will have no fiscal impact on State or local government.

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[2] Michigan Department of Labor and Economic Opportunity, "*About Radiation Safety Section*", 2024.
[3] United States Food and Drug Administration, "*Mammography Quality Standards Act and Program*", 2024.

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This analysis was prepared by nonpartisan Senate staff for use by the Senate in its deliberations and does not constitute an official statement of legislative intent.