

REGULATION OF RADIATION MACHINES AND PERSONNEL

House Bill 4898 (Substitute H-1) First Analysis (10-24-03)

Sponsor: Rep. Larry Julian
Committee: Health Policy

THE APPARENT PROBLEM:

Currently, the laws governing the regulation of radioactive materials and x-ray machines are concentrated in Part 135 of the Public Health Code. However, Executive Orders 1996 – 1 and 1996 – 2 transferred the radiation program from the Department of Public Health to the Department of Environmental Quality (radioactive materials) and the Department of Consumer and Industry Services (radiation machines). For greater clarity and efficiency, it has been recommended that the statute be amended to reflect the two organizational frameworks currently in place.

In a related matter, several shortcomings in current law regarding radiation machines have been identified. With the exception of mammography machine operators, there are no minimal standards of training or education for radiation machine operators. The result is that persons operating radiation machines in dental offices, podiatrist offices, chiropractic offices, hospitals, etc., may have very different levels of skill and competency. An unskilled or incompetent operator can affect the quality of the film taken, which in turn can affect the speed or accuracy of a diagnosis. Also, severe burns can result when radiation therapy is performed by an undertrained technologist.

At least 36 other states have a program to license, register, or credential radiation machine operators who meet state or national training and educational standards. In addition, legislation currently before Congress would mandate the establishment of state licensing/credentialing programs; failure to do so would result in providers being denied Medicaid and Medicare reimbursement for x-ray procedures. Given the complexity and ever-changing advancements in x-ray technology and radiation therapy, and the health implications that can arise from procedures conducted by undertrained or incompetent technologists, many feel that it is essential to have reasonable, cost-effective, and

specialized training and educational standards for medical x-ray operators.

Further, current state laws are inadequate to protect patient records if an x-ray facility goes out of business. In 1999 at least four mammography facilities in the state closed, and another three closed in 2001. The result was that important patient records and mammography films were unavailable to patients or doctors. Since current films are compared to prior films to detect even minute changes, the lack of access to prior patient films resulted in some patients undergoing additional (and perhaps unnecessary) testing and biopsies, not to mention a delay in diagnosis and treatment. It has been recommended that the current laws be amended to require facilities to obtain a secured instrument so that mammography records and films would be protected and retained in the advent of a facility closure.

THE CONTENT OF THE BILL:

The bill would amend the Public Health Code to revise the regulations pertaining to radiation machines and to establish educational and training standards for personnel, other than licensed members of the healing arts, who use a radiation machine for human screening or for diagnostic or therapeutic purposes.

Sections 13523 and 13531 of the code would be repealed, although most of Section 13523 would be incorporated into the newly created Part 135A, entitled “Radiation Machine Control”. Several provisions relating to radiation machines and mammography currently contained in Part 135, Radiation Control, would be moved to the new part. In addition, the Radiation Advisory Board would be eliminated and replaced with the Ionizing Radiation Advisory Committee. Details of the significant changes follow.

Part 135, Radiation Control. Generally, the provisions relating to the regulation of radioactive materials would be unchanged. However, the bill would specify that Part 135 would be regulated by the Department of Environmental Quality and apply to radioactive material; references to ionizing radiation would be deleted. Provisions pertaining to sources or ionizing radiation, radiation machines, and mammography would be moved to Part 135A, Radiation Machine Control, which would be created by the bill. Further, the bill would make some editorial changes to update and clarify the provisions.

Part 135A, Radiation Machine Control. The Department of Consumer and Industry Services would be responsible for the regulation of Part 135A. Virtually all of Section 13523, which would be repealed by the bill, would be incorporated into this new part. Changes to provisions currently in Section 13523, but which would be moved into the new part, are as follows:

1) For departmental authorization to use a radiation machine for mammography, certain requirements must be met for both the facility and personnel operating the machine. The bill would:

- Clarify that a facility must designate a licensed allopathic physician (M.D.) or osteopathic physician (D.O.) as the lead interpreting physician.

- Require a facility to submit, as part of the application for authorization and subsequent renewals, evidence of a department-approved surety bond, secured trust fund, or other suitable secured instrument or mechanism that would insure proper patient mammography record and film handling and transfer in the advent of a facility closure. The facility would have to attest that the method chosen would completely cover all costs involved and would be adjusted accordingly, as needed.

- Require an interpreting physician to be certified in radiology by either the allopathic or osteopathic board of radiology, to have been eligible for certification in radiology or diagnostic radiology for not more than three years (instead of the current two years), or be certified or determined to be qualified by another professional organization approved by the department (instead of the Radiation Advisory Board). Also, the interpreting physician would have to complete not less than three months (instead of two) of formal training in reading mammograms. Further, the bill would add that the physician be required to have initial training that included documented interpretation of not less than 240

mammographic examinations in the six months immediately preceding the performance of independent interpretation. The current requirement to interpret not less than 520 mammographic examinations each year would be eliminated and replaced with a requirement that the interpreting physician must interpret or multi-read not less than 960 mammographic examinations during the 24 months immediately preceding the date of the mammography facility's annual inspection or the last day of the calendar quarter preceding that inspection, or any day in between those dates. The facility would have to choose one of those three dates to determine the 24-month period. Other requirements currently required by the health code for interpreting physicians would remain the same.

2) The bill would require the department to inspect a radiation machine used for mammography not later than 90 days (instead of 60) after the initial authorization and annually thereafter.

In addition, the bill would add the following changes to current provisions that would be moved to the new part:

- The bill would repeal the provision that created the Radiation Advisory Board and established its powers and duties. Instead, the director of the Department of Consumer and Industry Services (CIS) would have to appoint an Ionizing Radiation Committee. The committee would have to furnish the department with technical advice considered to be desirable or which the department may request on matters relating to the radiation machine control program.

- Fees for registration of a radiation machine or a non-ionizing radiation device and fees for inspection of radiation machines used for mammography would be adjusted to reflect current levels. (The fee levels were last adjusted in statute in 1992; however, the statute does allow the department to adjust the fees yearly for inflation based on the cumulative annual percentage change in the Detroit Consumer Price Index, but not to exceed five percent. Therefore, the fees listed in the bill reflect the fees charged by the department for fiscal year 2003-2004.)

- Currently, the code contains several exemptions from the prohibition on manufacturing, producing, transporting, transferring, disposing of, acquiring, owning, possessing, or using an unregistered radiation machine. The bill would keep the current exemptions (although the exemptions that apply to radiation machines would be moved into the new Part 135A), and would add an exemption for non-ionizing

radiation sources or devices, unless specifically addressed by departmental rule.

-The department would have to develop rules specifying the minimum training and performance standards for an individual using a radiation machine for human screening or for diagnostic or therapeutic purposes.

-The department could develop and conduct programs for evaluation and control of hazards associated with the use of non-ionizing radiation devices.

-Definitions for “mammography”, “mammography authorization”, and “mammography interpreter” would be deleted from Part 135 and placed in Part 135A. Many other terms would be defined in both Part 135 and Part 135A. The bill would add two new definitions to Part 135A. “Non-ionizing radiation” would mean sound waves; radar waves; microwaves; radio frequency fields; magnetic fields; and visible, infrared, or ultraviolet light. A “non-ionizing radiation device” would mean a machine or device that produced non-ionizing radiation in intensities or frequencies subject to regulation by departmental rule. The definition for “radiation machine” would be moved to Part 135A and amended to mean a machine or device that produced ionizing radiation in energies or intensities subject to regulation by departmental rule. The definition for “mammography system”, originally contained in one of the repealed sections, would be amended to mean the radiation machine used for mammography; automatic exposure control devices; imaging systems; image processor; darkroom; and viewboxes.

-A municipality or a department, agency, or official of a municipality could not license, regulate, or require the registration of a radiation machine or a non-ionizing radiation device.

Training standards for x-ray technicians. Facilities would be required to ensure that all individuals, except licensed members of the healing arts, who use radiation machines for human screening or for diagnostic or therapeutic purposes be adequately instructed in safe operating procedures. The bill would establish minimum standards for training and competency for limited scope x-ray operators, comprehensive scope x-ray operators, dental x-ray operators, and veterinary x-ray operators.

Limited scope operators. The scope of practice would be limited to only those procedures listed in the bill, e.g., certain x-ray examinations of the

extremities, spine, and chest. However, in an emergency and under the direct supervision of a physician, a limited scope operator could perform procedures not listed in the bill if determined necessary by the supervising physician. Operators would have to complete 48 hours of didactic instruction in a formal program that included subjects specified in the bill, successfully complete a department-approved certification examination developed by the American Registry of Radiologic Technologies (ARRT) in at least one but no more than three of the limited scope categories, complete one month of clinical training in proper imaging procedures as listed in the bill, and obtain at least 15 hours of continuing education in any three-year period in the technical and/or clinical aspects of x-ray examinations in their scope of practice. A person who had been actively working as a medical x-ray operator for at least six months before the bill’s effective date would not have to complete the clinical training, but would have to document completion of the didactic training requirements and the examination requirements within three years of the bill’s effective date.

Comprehensive scope operators. Comprehensive scope operators, who are not limited in scope of practice for performing medical x-rays, would have to meet prerequisite qualifications, receive training, and demonstrate competence as specified in the bill. This would include meeting the standards for issuance of a registration certificate as a registered technologist from the American Registry of Radiologic Technologists (ARRT) or other recognized nationally accreditation body. Meeting those standards would be prima facie evidence that an individual met the bill’s requirements.

Also, an individual whose scope of practice included specialties such as computed tomography or radiation therapy would have to meet the standards for issuance of advanced certification in that specialty from the ARRT. However, the bill would provide an exemption for a comprehensive scope operator under certain conditions. A facility that could demonstrate – based on the number, complexity, and variety of specialty procedures performed at that facility and any other facility under the same ownership within the preceding 12-month period – that a comprehensive scope operator could not possibly satisfy the comprehensive experience standards required to obtain an advanced certification in the specialty, could, if approved by the department, be exempt from meeting the standards for advanced certification. Documentation would have to be provided on a form prescribed by the department.

Operators would also have to complete 48 hours of didactic instruction in a formal program that included subjects specified in the bill and complete one month of clinical training in proper imaging procedures as listed in the bill.

Dental x-ray operators. With the exception of licensed dentists, dental x-ray operators would have to complete at least 36 hours of didactic instruction in a department-approved formal program in subjects required by the bill. Graduates of a department-approved dental hygiene or dental assisting program certified by the Commission on Dental Accreditation would be considered to have met the preceding requirements. Those operators who had been actively working as a dental x-ray operator for at least six months prior to the bill's effective date would have to document completion of the didactic training requirements within three years of the bill's effective date.

Veterinary x-ray operators. Unless under the direct supervision of a licensed veterinarian, a veterinary x-ray operator would have to complete at least 36 hours of didactic instruction in a department-approved formal program in the subjects required by the bill. Individuals who had been actively working as a veterinary x-ray operator for at least six months prior to the bill's effective date would have to document completion of the didactic training requirements within three years of the bill's effective date.

Penalties. Penalties for a violation of Part 135A or a rule promulgated under it, or failure to comply with a condition of registration, would be the same as the current penalties for a violation of Part 135. A violation would be a misdemeanor punishable by imprisonment for not more than 180 days, a fine of not more than \$10,000, or both. A court could fine a person not more than \$2,000 for each violation, and each day a violation continued would be considered a separate violation. Further, as with a violation or impending violation of Part 135, the attorney general, at the department's request, could apply to the appropriate circuit court for an order enjoining the act or practice or for an order directing compliance with Part 135A or any associated departmental rules or orders.

FISCAL IMPLICATIONS:

Though no official fiscal impact statement has been issued, a memo prepared by staff of the Radiation Safety Section within the Division of Health Facilities and Services, Department of Consumer and Industry Services, on Senate Bill 525 sheds some

light on the potential fiscal impact to the state. House Bill 4898 as introduced is almost identical to Senate Bill 525. According to the memo, the operator-training portion of the legislation would have an impact on the inspection and compliance aspects of the radiation safety program.

Although no additional inspection planning or travel was expected to be required as a result of the legislation, inspection and follow-up times would be likely to increase in order to ensure proper operator credentials. Verifying the credentials of x-ray technologists who have not already received national certification could involve reviewing a number of educational records, training records, and continuing education documents. According to the memo, this could significantly increase inspection time, as could any necessary follow-up to verify compliance. For those non-mammography x-ray facilities in the state that do not have registered technologists, inspection time could increase by an estimated 30 minutes for each inspection. Since this category represents about 8800 x-ray facilities, one additional full-time inspector (FTE) could be needed to implement the legislation. (6-30-03)

ARGUMENTS:

For:

The bill represents good public policy for several reasons.

- The bill would separate regulation of radiation machines from regulation of radioactive materials. This is consistent with executive orders issued in the mid-1990s that placed oversight of radioactive materials with the Department of Environmental Quality and the regulation of radiation machines with the Department of Consumer and Industry Services.
- The minimum standards for training, education, and competency for x-ray operators would mirror federal requirements. Apparently, federal law as far back as the 1980s called for states to establish minimum standards. However, there are no penalties for noncompliance. Michigan is one of about 11 states that has not yet complied.
- Proposed federal legislation would require each state to adopt some type of licensure/registration/credentialing regulatory structure and would establish penalties for noncompliance. H.R. 1214, also known as the "Consumer Assurance of Radiologic Excellence Act" or C.A.R.E., would prohibit Medicare and Medicaid

payments for radiologic services performed by providers in noncompliant states.

- The bill would increase public safety. Radiation therapy, as well as other procedures, performed by undertrained or incompetent operators can cause burns if radiation levels are not monitored closely. Reportedly, some burns have been so severe as to necessitate limb amputation. Also, undertrained or incompetent operators take films of poor quality. A poor quality film is hard to read or may not reveal a fracture or disease condition. According to health professionals, a poor quality film can lead to errors and delays in diagnoses. With some progressive diseases, such as cancer, a delay in diagnosis also delays proper treatment, which in turn negatively impacts a patient's prognosis and outcome. Apparently, because there are no statutory minimum levels of education and competency for operating non-mammography radiation equipment, a physician or hospital could literally hire someone off the streets today and after brief instruction, authorize that person to operate an x-ray machine or perform radiation therapy on a patient tomorrow. Taking a good quality film involves more than just knowing which button to push on the machine. Advancing complexity in x-ray machine and imaging materials technology and procedures has made it essential for operators to receive the specialized training and education needed to perform their duties safely and well. A recent study of data collected from Pennsylvania hospitals revealed that lower education levels of nurses resulted in higher patient deaths. As the educational level of nurses increased (for example, more nurses with four-year nursing degrees instead of two- or three-year degrees), patient death rates dropped. It is reasonable, therefore, to assume that greater education and training in any health profession would translate into better patient outcomes. Michigan needs to join the majority of the states that have standards for all radiation machine operators.

- The bill would provide more consistency with federal mammography standards. According to the Radiation Safety Section of the Bureau of Health Systems within CIS, there are technical inconsistencies between current state law and the federal Mammography Quality Standards Act due to federal updates in 1999. These need to be corrected.

- The proposed federal legislation (C.A.R.E.) would also cover sources of non-ionizing radiation such as lasers and indoor tanning devices. Regulation of non-ionizing radiation sources is recommended by the national Conference of Radiation Control

Program Directors. The growing use of devices using non-ionizing radiation, such as lasers and indoor tanning devices, creates an additional arena for radiation safety challenges. The bill would give CIS the authority to develop and implement departmental rules to regulate sources of non-ionizing radiation in case the proposed federal law were enacted and also to meet radiation safety concerns.

- At least seven mammography facilities have closed in Michigan over the past four years. The result was that important patient records and mammography films were unavailable to patients or their doctors. Though extensive public intervention prevented some of these facilities from destroying the records, the records were unavailable for an extended period of time. Since an important part of breast cancer detection is done by comparison of recent films to past films, some patients were forced to undergo additional, and in some cases unnecessary, testing and biopsies. The bill would create a mechanism by which patient records would be protected and kept accessible if a mammography facility went out of business.

Against:

Part of the impetus behind the bill is to be in compliance with federal law; however, the federal law in question is still pending committee action in Congress. Since proposed laws are always open to amendments, it would seem prudent to wait to see the final form that the federal law takes, rather than to structure a bill now to meet standards or conditions that could change.

POSITIONS:

The Michigan Society of Radiologic Technologists supports the bill. (10-15-03)

The Michigan Radiological Society is neutral on the bill. (10-15-03)

The Michigan Health & Hospital Association (MHA) is neutral on the bill. (10-15-03)

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