This revised analysis replaces the analysis dated 4-19-94.

House
Legislative
Analysis
Section

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MAMMOGRAPHY AMENDMENTS

House Bill 4529 as enrolled
Revised Second Analysis (9-13-94)

Sponsor: Rep. Maxine Berman
House Committee: Public Health
Senate Committee: Health Policy

THE APPARENT PROBLEM:

After numerous studies showed that early diagnosis and treatment of breast cancer could increase a woman's chances of surviving this deadly disease, the legislature enacted Public Act 56 of 1989, which requires the state to educate the public about the importance of early screening for breast cancer, requires training for non-physician mammography machine operators, and allows the Department of Public Health to regulate mammography machines. Under the act, the department also is required to promulgate rules specifying the minimum training and performance standards for anyone using radiation machines for mammography. Unfortunately, once these provisions became law questions arose about whether the law specifically authorized the department to promulgate rules governing standards for physician "supervisors" and certain other radiological technicians involved in reviewing mammography tests, known as "interpreters." The standards which the department planned to adopt were developed by the American College of Radiology (ACR), the major national private professional accreditation organization for radiation machines, operators, supervisors, and interpreters, and most states currently apply these standards to those who wish to work in this capacity with mammography programs. Then in 1993, the attorney general recommended (apparently in an informal opinion) that it would be more appropriate to establish minimum training and performance standards for such medical professionals by statute rather than by rule.

In a related matter, the 1989 amendments established fees that a facility must pay to have one or more mammography radiation machines it uses for testing reviewed by the Department of Public Health for purposes of accredition, assuming the facility chooses not to be accredited by the ACR. (The fee is $500 for the first machine tested, and drops to $400 per machine for each additional one.) The state fee was set above the fee established by the ACR apparently to encourage mammography facilities to have their equipment reviewed by this private professional organization rather than the DPH, which in turn would save the state time and money. However, since 1989 the ACR has raised its fee above the state accreditation fee, which, in 1993, apparently prompted at least two facilities to have their equipment accredited by DPH rather than the ACR. In order to encourage all facilities to have their machines ACR-accredited, the department has requested raising the state accreditation fee charged per machine to a level at or above that charged by the ACR.

THE CONTENT OF THE BILL:

The bill would amend the part of the Public Health Code that regulates mammography programs (MCL 333.13501 et al.) to require that mammography machines, staff, and facilities meet American College of Radiology (ACR) standards and to require that mammograms be read by specially certified licensed physicians.

Radiation machines. Currently, the Department of Public Health must authorize a radiation machine for mammography if it meets the following standards:

* the machine meets the criteria, adopted by reference, of the American College of Radiology mammography accreditation program adopted in June, 1987, and amended in September, 1988;

* the machine, the film (or other image) receptor used in the machine, and the facility in which the machine is used meet the department's requirements as set forth in rules and is used according to department rules on patient radiation exposure and dose levels;

* the machine is specifically designed for mammography;

* the machine is used exclusively for mammography;

* the facility in which the machine is used (1) at least annually has a qualified radiation physicist provide on-site consultation to the facility and (2) keeps records of these consultations for at least seven years; and

* the machine is used by a physician or by someone who can demonstrate that he or she meets the standards required by departmental rules.

The bill would change some of these standards (adding ACR requirements for people operating the machines and the facilities in which the machines were located, and requiring facilities to have a medical director of mammography services), drop one of them (the requirement that the machine be used exclusively for mammography), and add a new standard requiring that the X-ray images of each mammographic examination be interpreted by a mammography interpreter who was a licensed physician who met certain requirements.

Instead of authorizing a radiation machine for mammography if the machine met certain standards, the bill would say that the department would authorize a radiation machine for mammography if the machine, the people operating the machine, and the facility in which the machine was used met certain standards. The revised standards would require:

* that not only radiation machines but the facility in which they were used met ACR standards dated August, 1993 (instead of June, 1987, and September, 1988) and published by the ACR in a document entitled "Overview, Mammography Accreditation Program, and ACR Standards for the Performance of Screening Mammography";

* that the facility in which a radiation machine was used not only have annual consultations by radiation physicists and keep seven-year records, but also that the facility designate a licensed physician (M.D. or D.O.) both to provide medical direction for delivering mammographic services and to be responsible for the clinical aspects of the X-ray examinations and other procedures related to mammography.

Medical director of mammography services. Until January 1, 1996, the physician designated to provide medical direction for mammographic services would have to meet the following two requirements:

(1) successfully complete or teach -- and satisfactorily document so doing -- at least 15 hours of continuing medical education (every three years after the bill took effect) in approved (by his or her specialty organization and board) technical or clinical aspects of mammography; and

(2) successfully complete (and satisfactorily document the successful completion of) at least two months of formal training in reading mammograms, with instruction in medical radiation physics, radiation effects, and radiation protection. (The DPH could accept time spent in a residency program that included specific training in mammography if the physician had satisfactory documentation.)

After January 1, 1996, the designated physician would have to meet the continuing medical education requirement as well as the following:

(a) be certified in radiology or diagnostic radiology by the American Board of Radiology or the American Osteopathic Board of Radiology;

(b) have been eligible for certification for not more than two years; or

(c) be certified or determined to be qualified in radiology by some other professional organization approved by the state Radiation Advisory Board.

The medical director of mammography services would be responsible for monthly on-site inspections of each "mammography station," for reviewing quality control documentation, and for ensuring that safe operating procedures were used in delivering mammographic services. If the designated physician practiced primarily outside of the facility, he or she would have to keep a signed log of each on-site visit. The facility's chief administrative officer (or his or her designee) could request to view the log at any time.

Mammography interpreters. Currently, the health code requires that radiation machines be operated only by physicians or by people who meet the standards required by departmental rules. There are no current requirements regarding the

interpretation of mammograms.

The bill would require that the X-ray images of each mammographic examination be interpreted by a "mammography interpreter" who was a licensed physician who met the following requirements:

(1) was certified in radiology or diagnostic radiology by the American Board of Radiology or the American Osteopathic Board of Radiology, had been eligible for certification for not more than two years, or was certified or determined to be qualified in radiology or diagnostic radiology by another approved professional organization (however, for two years after the bill took effect, a physician who had been eligible for certification in radiology or diagnostic radiology for more than two years would be considered to meet these requirements);

(2) successfully completed or taught -- and satisfactorily documented so doing -- at least 15 hours of continuing medical education (every three years after the bill took effect) in approved (by his or her specialty organization and board) technical or clinical aspects of mammography;

(3) successfully completed (and satisfactorily documented) at least two months of formal training in reading mammograms, with instruction in medical radiation physics, radiation effects, and radiation protection. (The DPH could accept time spent in a residency program that included specific training in mammography if the physician had satisfactory documentation);

(4) interpreted at least 520 mammographic examinations each year; and

(5) kept annual records regarding outcome data for correlation of positive mammograms to biopsies done, and the number of cancers detected.

Fees. The bill would raise the fees for department evaluations of radiation machines from the current $500 to a proposed $700, delete the $400 fee for each additional machine evaluation, and add a $300 re-evaluation fee (for re-evaluation due to failure during the previous evaluation, relocation, or similar changes that could affect earlier evaluation results).

Temporary authorization for machines. The bill would increase from six to twelve months the length of a temporary authorization for radiation machines used for mammography.

FISCAL IMPLICATIONS:

The Department of Public Health says the bill would not increase costs to the department but could result in increased revenue to it of, at most, $2,000 over three years (assuming the two facilities currently choosing state certification over ACR certification don't switch to ACR certification). (4-19-94)

ARGUMENTS:

For:

Although the majority of mammography facilities in Michigan reportedly are ACR-accredited, some nonaccredited facilities may not use qualified radiologists for supervision or interpretation of mammography and mammograms, and, therefore, would not meet national standards. Since the early detection of breast cancer is one of the best ways to combat this potentially fatal disease, it is imperative that the technique of the mammogram operator and the equipment used in taking mammograms be functioning at optimal levels, and that physicians responsible for mammography supervision and interpretation have and maintain qualifications at least as stringent as those of the major professional accreditation organization, the American College of Radiology. The bill would ensure that those hired to do this specialized type of work were well-trained and had the necessary skills and understanding to use mammography radiation equipment properly.

For:

When the original mammography regulation legislation was enacted in 1989, the fees were deliberately set to be higher than those charged by the American College of Radiology (ACR) in order to encourage facilities to seek accreditation from the ACR instead of through the Department of Public Health. However, in 1993 the ACR raised its fees to levels higher than those in the act, which has encouraged some facilities to choose to be reviewed by DPH rather than by ACR, resulting in increased costs--albeit minimal--to the state. When legislation was introduced to address the issue of qualification of radiologists, a DPH official suggested that the bill include an amendment to raise the accreditation fee charged by the department to a level at or above that charged by the ACR in order to encourage facilities to use the ACR accreditation program. Under the bill, facilities with multiple mammography testing machines, particularly, would save money by being ACR-accredited as the fee for

each machine tested after the first would be $100 less per machine than if they were accredited by the state.

Response:

Setting the state accreditation fee at a specific dollar amount likely will result in the legislature later having to return to raise it to keep pace with changes made by ACR to its fees. To avoid this, it would be wiser to statutorily tie the state fee to the ACR fee so that it would automatically move with it.

For:

Deleting the requirement that radiation machines used for mammography be used exclusively for mammography would allow these machines to be used for other, appropriate purposes, such as locating foreign bodies in hands or feet. Originally, the requirement was included in the 1989 act regulating mammography because many radiation machines reportedly were being inappropriately used for mammography. However, because radiation machines used for mammography now must meet nationally-recognized standards, this provision is no longer needed to ensure that high quality equipment is used for mammography in Michigan.