



MAMMOGRAPHY AMENDMENTS

**House Bill 4529 as enrolled
Second Analysis (4-19-94)**

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

THE APPARENT PROBLEM:

Reportedly, when the regulation of mammography services was enacted through Public Act 56 of 1989, the fees set in the act for review of radiation machines by the Department of Public Health were deliberately set below those of the American College of Radiology, the major national private professional accreditation organization for radiation machines, operators, supervisors, and interpreters. This was done to encourage mammography facilities to be reviewed by this private professional organization rather than the DPH, thereby saving the state revenues. However, since enactment of the state mammography regulation, the ACR has raised its fees higher than those in the Public Health Code. Apparently the attorney general has said that the fees in the health code cannot be raised without enabling legislation, so legislation has been introduced that would continue to encourage review by the ACR rather than the DPH, and to address a number of other, technical issues.

THE CONTENT OF THE BILL:

The bill would amend the part of the Public Health Code that regulates mammography programs 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

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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, would delete the \$400 fee for each addition machine evaluation, and would 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;

MCL 333.13501 et al.

FISCAL IMPLICATIONS:

According to the Department of Health, there will be no costs to the department as a result of the bill and, at most, revenue of \$2,000 over three years (if the two facilities currently choosing state certification over ACR certification don't switch to ACR certification). (4-19-94)

ARGUMENTS:

For:

Reportedly, when the original mammography regulation legislation was enacted, 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, apparently the ACR has since raised its fees to levels higher than those in the act, which would raise costs to the state by encouraging at least some facilities to choose to be reviewed by the DPH rather than by the ACR. Since, reportedly, the attorney general has said that the fees set in the health code can't be raised through the rules process, in order to continue to encourage mammography facilities to be accredited through a private, professional accreditation body rather than by the DPH -- and thereby reducing state costs -- existing health code fees need to be raised to the level of the current fee schedule of the ACR.

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 devastating 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.

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 reportedly many radiation machines 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.