



**House
Legislative
Analysis
Section**

Washington Square Building, Suite 1025
Lansing, Michigan 48909
Phone: 517/373-6466

MAMMOGRAPHY REGULATION

House Bill 4074 as enrolled
Second Analysis (7-11-89)

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

THE APPARENT PROBLEM:

More than 5,000 women are diagnosed with breast cancer each year in Michigan (for example, in 1986, the figures were 5,095 women and 26 men), and more than 1,500 Michigan women die of breast cancer each year (the 1986 figures are 1,546 women and 12 men). Despite studies which show that a 30 percent reduction in deaths is possible through appropriate screening (that is, mammography combined with a physical examination), a Michigan survey suggests that less than one-third of the women who should be screened are currently getting annual mammograms and physical examinations. And although the risk of breast cancer increases with age, state and national surveys show that the likelihood of women getting appropriate screening actually decreases in the older age groups.

The effectiveness of using mammographies in breast cancer screening depends not only on the training of the physician who reads the mammogram, but also on the quality of the mammography machine and on the training of the person who operates the machine (the radiological technologist). Unfortunately, however, the quality of mammography machines and the training of the machine operators cannot be guaranteed at this time in Michigan.

All radiology (X-ray) machines are required to be registered with the Department of Public Health (DPH); as of January 1989, there were 391 registered facilities, using 448 machines to perform mammography. The Division of Radiological Health inspects mammography facilities, but due to staffing limitations the division is able to inspect mammography machines only every three to five years. And even when the department identifies problems during inspections of mammography facilities, it currently has authority only to order — but not enforce — recommended corrective actions. Inspections by the Division of Radiological Health have revealed significant problems with both mammography machines and with machine operators' techniques. In a 1988 survey of 96 mammography machines (21 percent of all of the machines in the state at that time), 52 of the machines — or 54 percent of the machines inspected — revealed significant problems in the areas of image quality and radiation levels. The American College of Radiology (ACR) recently initiated a voluntary accreditation program for mammography facilities, but by the end of January 1989, only 58 Michigan facilities (only half of the facilities which even applied for voluntary accreditation) had met ACR accreditation standards. And the ACR has found that in 64 percent of the facilities nationwide that failed to obtain accreditation failed to do so due to faulty technique used by the people operating the machines.

Although 23 states have radiological technologist licensing laws, Michigan currently has no specific requirements for accreditation, training, experience, or licensing of radiologic technologists, including those who perform mammography. (There is a voluntary national accreditation

program offered by the American Association of Radiological Technicians, but this program does not include specific training or credentials for mammography.) The Department of Public Health estimates that there are between 1,000 and 2,000 people performing mammography in Michigan, including not only trained radiological technologists but also staff in physicians' offices (including secretaries, receptionists, and nurses) and in unlicensed free-standing "mammography clinics."

Because breast cancer is a leading cause of death of women and because mammograms can significantly reduce the number of deaths from breast cancer, legislation has been proposed to educate the general public about the importance of appropriate breast cancer screening, require training for non-physician mammography machine operators, and allow the Department of Public Health to better regulate mammography machines.

THE CONTENT OF THE BILL:

The bill would amend the Public Health Code to establish education programs and a grant program to reduce breast cancer deaths, to prohibit the use of unauthorized mammography machines, to regulate (and establish fees for) mammography machines, and to require the Department of Public Health to promulgate rules specifying the minimum training and performance standards for people operating mammography machines.

Breast Cancer Program. The bill would create a Breast Cancer Mortality Reduction Program in the Department of Public Health (DPH). The program would include:

- education programs for health professionals to develop state-of-the-art skills in breast cancer screening, diagnosis, referral, treatment, and rehabilitation;
- programs to help the public understand the benefits of regular breast cancer screening; how to best use the medical care system for breast cancer screening, diagnosis, referral, treatment, and rehabilitation; and what the available options were for the treatment of breast cancer;
- an applied research and community demonstration grant program for local communities to demonstrate and evaluate methods to reduce illness and deaths from breast cancer and economical and effective ways of providing access to breast cancer screening, diagnosis, referral, treatment and rehabilitation services for those at higher than normal risk of breast cancer.

The DPH would be required to report every two years to the House and Senate committees dealing with public health. The report, which would evaluate the effectiveness of the Breast Cancer Mortality Reduction Program, would have to include information on the rate of illness and death from breast cancer in the state and the extent of participation in breast cancer screening.

H.B. 4074 (7-11-89)

Mammography machine operators. The bill would require the department to promulgate rules specifying the minimum training and performance standards for anyone (other than licensed physicians) using radiation machines for mammography.

Regulation of mammography machines. Beginning 60 days after the effective date of the bill, in order for someone to use a radiation machine for mammography, the machine would have to be registered with the DPH under its rules for registration of radiation machines and be specifically authorized under the bill for doing mammography. A mammography authorization would be effective for three years, and would be required for each radiation machine used for mammography.

Mammography radiation machine standards: The DPH would authorize a radiation machine for mammography if the machine met all of the following standards:

- it met the mammography accreditation standards set by the American College of Radiology (ACR);
- it met DPH requirements for radiation machines and was used according to DPH rules on patient radiation exposure and dose levels;
- it was specifically designed for mammography and was used only for mammography;
- it was used in a facility that met DPH requirements for radiation machines and that was evaluated annually by a qualified consulting radiation physicist (and that kept records of the annual consultations for at least seven years);
- it was operated only by a physician or by someone who could demonstrate to the DPH that he or she could meet the standards established by rule for operating mammography machines (until the department established these rules, the non-physician operator would have to be able to demonstrate that he or she was specifically trained in mammography).

Application for authorization. If an applicant for authorization of a mammography machine needed more than 60 days after the effective date of the bill to submit satisfactory evidence to the DPH that the machine met the bill's standards, the department could issue a nonrenewable temporary authorization. For the first 18 months after the bill's effective date, a temporary authorization would be effective for up to 12 months; after that it would be effective for no more than six months. In any case, the department could withdraw a temporary authorization at any time if the machine failed to meet one or more of the required standards.

The DPH would have to process and respond to an application for authorization within 30 days of receiving the application and would have to inspect a machine within 60 days of its initial authorization (except for the first year after the bill took effect, during which the department could take more than 60 days) and at least once a year thereafter. The department would have to make "reasonable efforts" to coordinate mammography machine inspections with any other inspections it did of the facility in which the machine was located.

The department would issue a "certificate of registration" for each authorized machine, and after each satisfactory inspection the department would issue a "certificate of radiation machine inspection" ("or a similar document") which identified the facility and machine inspected and which provided a record of when the machine had been inspected. The facility would have to post this information near the machine.

Loss of authorization and reinstatement. The department could withdraw authorization for a machine if the machine failed to meet one or more of the required standards, and would have to provide an opportunity for a hearing if it did withdraw an authorization. If necessary, the department could issue emergency orders summarily withdrawing mammography authorization and would have to hold a hearing within five working days after the order was issued. If the department withdrew authorization of a mammography machine, the machine could not be used for mammography.

An application for reinstatement of a machine from which authorization had been withdrawn would be made in the same way as an application for initial authorization. The DPH could not issue a reinstated certificate of mammography registration until it had received the reinspection fee, inspected the machine (within 60 days of receiving the application for reinstatement), and found that the machine met all of the required standards.

Penalties. Someone who used an unregistered and unauthorized radiation machine to do a mammography would be guilty of a misdemeanor punishable by a fine of up to \$2,000 and imprisonment for up to 180 days for each violation (though total fines for violations could not be more than \$10,000). In addition, the department could impose an administrative fine of up to \$500 a week for each week the machine were in violation of the bill. If a violation continued for more than two weeks, the department also would post a conspicuous notice (both on the unauthorized machine and at the entrance to where the machine was located) warning the public that the facility was doing mammography with a machine that was a substantial hazard to the public health.

Fees. The bill would establish the following fees for inspection and evaluation of mammography machines: \$100 per machine for each initial inspection, each annual inspection, and each reinspection for reinstatement of mammography authorization; and \$500 for the DPH to evaluate a machine for compliance with the American College of Radiology's criteria for its Mammography Accreditation Program (\$400 for each additional machine). The evaluation fee could be waived if an applicant submitted an evaluation report issued by the American College of Radiology that showed compliance with the college's Mammography Accreditation Program criteria.

MCL 333.13501 et al.

FISCAL IMPLICATIONS:

The Department of Public Health estimates that the Breast Cancer Program (which would include 4 FTE positions) would cost \$767,000, the community demonstration projects (grants for improving access for minority and other underserved women) would be \$1,000,000, and costs of the radiological program (which would include 4 FTE positions and cover the mammography machine registration, inspections, and enforcement provisions of the bill) would be \$233,000, for a total cost of \$2 million. In addition, there would be additional, indeterminate costs to the department to implement the minimum training and operating standards for mammography technicians. (3-21-89)

ARGUMENTS:

For:

Breast cancer is the leading cause of cancer death among Michigan women, and the American Cancer Society estimates that one in ten women will develop breast cancer

at some point in their lives. African American women have a higher death rate from breast cancer than white women, even though the disease occurs more frequently in white women. African American women tend to have their cancers discovered at later stages than white women, and have lower survival rates than white women of the same age and stage of diagnosis.

Breast cancer imposes enormous costs to individuals, their families, and the state, both in terms of suffering and in terms of economic loss. If each of the 1,500 Michigan women who die of breast cancer each year reached their full life expectancy, more than 29,000 years of potential life and nearly \$147,000 in future earnings would be saved every year.

Large, long-term studies have demonstrated that up to 30 percent of deaths due to breast cancer can be prevented through screening procedures that combine physical examinations and mammograms, and survival may approach 100 percent when breast cancers are detected before they reach one centimeter in size. Mammography is capable of detecting such cancers, yet a 1987 Michigan survey showed that less than one third of the women in the appropriate age groups followed the American Cancer Society (ACS) and National Cancer Institute guidelines for breast cancer screening, while a 1984 ACS study suggested that as few as eleven percent of physicians routinely advised their patients to follow the ACS screening guidelines.

The bill would encourage early detection of breast cancers through educating women about the importance of early detection through mammography and physical examinations and through providing for professional education to encourage physicians to perform breast examinations and refer women for routine mammography. It would further address the issue of breast cancer among minority and other underserved women by providing for community grants to help these women receive the services necessary for early detection and treatment of breast cancer.

For:

Encouraging women to get regular, appropriate screening for breast cancer will not help reduce the number of deaths from breast cancer if mammography equipment is deficient or if the machine operators are not skillful and well trained.

The Investigation and Compliance Section of the Division of Radiological Health did a survey of 96 mammography machines and facilities in 1988, with disturbing results. As many as 54 percent of the machines inspected were deficient, exhibiting significant problems with image quality or with radiation levels (this included both high radiation exposure at skin entrance as well as high patient mean glandular doses). This survey included hospitals, radiology offices, and medical offices. The bill would significantly improve regulatory control over mammography X-ray equipment and its use, require annual inspections (the department's current staff can only inspect the machines once every three to five years), and establish improved procedures for enforcing compliance with standards of safety and effectiveness.

Currently in Michigan there are no training, experience or proficiency requirements for non-physicians who perform mammography. And since the state does not regulate, through licensure or certification, mammography technologists, anyone can claim to be licensed or certified,

regardless of their training or background. To protect the public from unqualified technologists, the bill would set, through rules promulgated by the Department of Public Health, minimum training and operating standards for non-physician operators of mammography machines.

Against:

The inspection requirements of the bill could be unnecessarily burdensome on hospitals and could wind up increasing health care costs with no perceivable benefits. Hospitals routinely use people who have obtained training as radiological technologists through certified educational programs and who have passed national exams to become registered radiological technicians. Hospitals also routinely have the safety of their radiological equipment tested by qualified radiation physicists, and have a good safety track record. If there were to be minimum training and operating standards for mammography technologists, currently practicing technicians conceivably could demand higher compensation for the same job they are now doing, while the bill's inspection requirements could also add more costs for the hospitals. Hospitals have become deluged with inspections from one organization or another, and the unnecessary duplication of these inspections ends up simply adding to health care costs with no additional benefits. Supervision by radiologists of mammography technicians using dedicated mammography equipment (that is, radiology machines used only for mammography) should provide sufficient protection to patients, and the bill should at least specify that the proposed machine inspections not duplicate those already conducted for certification by the American College of Radiology.

Response: The bill would require the DPH to make "reasonable efforts" to coordinate its inspections, but that such inspections of mammography machines in hospitals is needed is evident from a survey conducted by the department in 1988. Of the 103 Michigan facilities that had voluntarily applied for accreditation by the American College of Radiology (ACR) by December, 1988 — those facilities, that is, that believed they were likely to receive accreditation — only 54 were approved, and it was the technique used by the radiological technologist (that is, the machine operator) that was identified as the cause of faulty image production by 61 percent of the facilities that failed to obtain accreditation. Clearly there is a wide variation among facilities in the quality of their mammography machines and in the ability of their mammography technicians, even among those facilities that consider themselves to be most qualified for ACR accreditation. Since properly calibrated equipment and skillful technicians are crucial to the safe and accurate delivery of mammograms, the bill clearly is needed for the protection of Michigan citizens.

Against:

Instead of singling out operators of mammography machines for some kind of minimum training and operating standards, the bill should address the larger issue of regulating all X-ray technologists. Surely citizens have a right to be assured that the technologist who X-rays their elbows or prostrates is as qualified to do so as the technologist who X-rays their breasts. People die from many kinds of cancers other than breast cancer, and the diagnostic equipment and operators should all be required to meet minimum standards.

Response: It is, indeed, desirable to assure patients that diagnostic X-ray equipment and technologists be minimally adequate, and legislation to regulate radiologic

technologists in general may soon be proposed. However, mammograms are the only X-rays that are routinely done in the absence of any suspicion of disease. Given the number of deaths due to breast cancer that could be prevented by appropriate screening, it would be penny wise but pound foolish to delay assuring that this vital preventative screening technology meets the purpose for which it is done. And since any exposure to X-rays is potentially damaging, it is imperative that this potentially life-saving use of X-rays be made as safe and effective as possible.