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Senate Bill 879 (Substitute S-3 as passed by the Senate)
Sponsor: Senator Dave Hildenbrand
Committee: Health Policy

(as enrolled)

Date Completed: 6-23-14

RATIONALE

A mammogram, or x-ray picture of the breast, can detect tumors and other indications of the presence of cancer. According to the National Cancer Institute, mammography is one of the most effective means of early breast cancer detection, reducing the number of deaths due to the disease. On occasion, however, a mammogram appears normal even though cancer is present. Reportedly, false-negative results are caused primarily by high breast density--the ratio of fibroglandular tissue to fatty tissue in the breast. On a mammogram, cancer and dense tissue both appear as white areas, making it difficult to distinguish between them. As a result, cancer might not be detected in people with dense breasts until the disease has progressed significantly, necessitating more drastic treatment and reducing the likelihood of survival. Also, people with dense breasts may have a slightly elevated risk of breast cancer.

For some women with dense breast tissue, it might be appropriate to undergo additional screening beyond mammography. Other methods, such as magnetic resonance imaging (MRI) and ultrasound technology, may detect cancer that is missed on a mammogram. Many women, however, are not aware of their own breast density or the concerns associated with dense tissue, although Federal regulations require that patients be given a summary of the results of a mammogram. It has been suggested that, if a mammogram demonstrates dense breast tissue, the summary should include a notice to that effect and encourage the patient to consult a health care provider regarding her personal breast cancer risk and need for advanced screening.

CONTENT

The bill would amend the Public Health Code to do the following:

- **Require a person who provided mammography services to give certain information to a patient whose mammogram demonstrated dense breast tissue.**
- **Authorize the Department of Community Health (DCH) to update the definition of "dense breast tissue" by order, if necessary.**

The bill would take effect on June 1, 2015.

Under regulations established pursuant to Federal law, a facility that performs a mammogram must ensure that a written report of the results of a mammography examination, signed by the interpreting physician, is prepared. The report must be given to the patient's physicians, or, if such a physician is not available or if there is no such physician, directly to the patient. Additionally, a summary of the report in terms easily understood by a lay person must be sent directly to the patient.

Under the bill, if a patient's mammogram demonstrated dense breast tissue, in the summary sent directly to the patient, a person who provided mammography services in Michigan would have to give the patient notification that included the following information:

Your mammogram shows that your breast tissue is dense. Dense breast tissue is very common and is not abnormal. However, dense breast tissue can make it harder to find cancer through a mammogram. Also, dense breast tissue may increase your risk for breast cancer. This information about the result of your mammogram is given to you to raise your awareness. Use this information to discuss with your health care provider whether other supplemental tests in addition to your mammogram may be appropriate for you, based on your individual risk. A report of your results was sent to your ordering physician. If you are self-referred, a report of your results was sent to you in addition to this summary.

The bill would define "dense breast tissue" as heterogeneously or extremely dense breast tissue as defined in nationally recognized guidelines or systems for breast imaging reporting of mammography screening, including the Breast Imaging Reporting and Data System (BI-RADS) established by the American College of Radiology. After the bill's effective date, if new terms were defined in revised guidelines or systems for breast imaging reporting of mammography screening, and the DCH determined that the new terms were more appropriate for the purposes of the information required to be provided under the bill, the DCH, by order, could update the definition of "dense breast tissue" to use those new terms. Upon issuance, the DCH would have to forward the order to the Legislature.

Proposed MCL 333.13524

ARGUMENTS

(Please note: The arguments contained in this analysis originate from sources outside the Senate Fiscal Agency. The Senate Fiscal Agency neither supports nor opposes legislation.)

Supporting Argument

The notice required by the bill would enable women to be informed participants in their own health care. While information about breast density is included in a mammogram report sent to a patient's referring physician, it frequently is not included in the summary sent directly to the patient. In some cases, the patient is notified that she has dense breast tissue, but is not informed of its significance: that it might increase the risk of cancer and that it can make detecting cancer difficult through mammography alone. It should be standard practice to give women this information so they can have educated discussions with their doctors about their breast cancer risk and appropriate screening and diagnostic procedures for their individual circumstances.

A breast cancer diagnosis and the necessary treatment can be devastating. Dense breast tissue can delay diagnosis, sometimes by several years, allowing undetected cancer to metastasize. Generally, these circumstances require an aggressive combination of interventions, including chemotherapy, surgery, radiation, and lifelong need for medication. People may be unable to work due to their illness or the effects of treatment, and may be affected psychologically by hair loss, mastectomy, and the prospect of death. Some of this physical and emotional suffering, as well as the burdensome costs of cancer treatment, can be avoided through early detection, which the bill's required notice could facilitate.

Just as it is important for people to know their blood pressure and cholesterol levels and take that information into account when making lifestyle and medical decisions, it is important for women to understand their overall lifetime breast cancer risk, including their breast density. The addition of one paragraph to a patient's mammogram summary would be a simple but significant way to educate people and enable them to be effective advocates for themselves. This knowledge would facilitate patients' communication with health care providers about risk levels and the need for supplemental screening. Ultimately, the required disclosure could lead to better health outcomes, including saved lives, and lower costs.

Opposing Argument

The bill would set an unwise precedent by codifying medical best practice rather than allowing doctors to determine how best to communicate important health information to their patients.

Also, advances in the practice of medicine eventually could make the required notice obsolete. Improved digital mammography has led to higher cancer detection rates and fewer false-positive results, and one day it could surpass MRI and ultrasound technology in terms of effectiveness. It would be imprudent to prescribe statutory disclosure language for a particular screening method when the future direction of technological evolution is unknown.

Additionally, the role of breast density in an individual's overall lifetime cancer risk is a matter of debate. Some in the medical community believe that, while dense breast tissue can increase a person's risk, other factors, such as family history and alcohol use, generally are more important. The bill's required notice regarding breast density specifically could lead patients to focus on that particular factor over the others. It might be more effective to inform a patient when a mammogram is performed of all of the risk factors, as well as lifestyle changes that could reduce her risk.

Furthermore, measurement of breast density depends on the interpretation of the person reading the mammogram and may vary between radiologists. The required notice could emphasize any inconsistency, potentially confusing or worrying patients and creating a false impression that mammography is not reliable.

Also, there is a tradeoff associated with some of the supplemental screening methods--while they might be effective in identifying cancer that a mammogram fails to detect, they also have a higher rate of false-positive results. This can lead to unnecessary biopsies, which are costly, carry a risk of infection, and increase anxiety for patients. Furthermore, enhanced screening procedures often are not covered by insurance, meaning individuals must pay for them out of pocket. In light of these potential outcomes, additional screening might be advisable only for women with the highest breast cancer risk, such as those who have multiple risk factors.

Response: The bill would not mandate additional screening, but simply would require that mammography patients be given information to make decisions with their health care providers regarding follow-up care. Physicians already routinely evaluate their patients' individual risks and make judgments about the best course of care, so the bill's required notice should not have a significant effect on the way doctors practice.

Although advanced screening methods might lead to other medical procedures, health care expenses, and anxiety that later turn out to be unnecessary, the negative implications of a delayed cancer diagnosis are far worse. Despite the potential drawbacks associated with the bill's required notice, many women would prefer to be well-informed about their own bodies and personal breast cancer risk, than to have a possibly false sense of security provided by a mammogram that appears normal.

Legislative Analyst: Julie Cassidy

FISCAL IMPACT

The bill would result in very minor costs to the Department of Community Health to update information and forward the changes to the Legislature.

Fiscal Analyst: Steve Angelotti

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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.