

Department of Legislative Services
Maryland General Assembly
2013 Session

FISCAL AND POLICY NOTE
Revised

House Bill 312

(Delegate Pena-Melnyk, *et al.*)

Health and Government Operations

Finance

Mammograms - Dense Breast Tissue - Notification

This bill requires a center where mammography testing is performed to include, in a screening results letter that is sent to the patient as required by federal law, a specified notice. However, this requirement does not apply if the federal Mammography Quality Standards Act of 1992 or regulations adopted under the Act require a notice regarding breast density to be included in the screening results letter that is sent to a patient. Furthermore, the bill may not be construed to (1) require a notice that is inconsistent with the Act or (2) create a standard of care, obligation, or duty that provides a basis for a cause of action.

Fiscal Summary

State Effect: The bill is not expected to materially affect State operations or finances.

Local Effect: The bill does not directly affect local government operations or finances.

Small Business Effect: Minimal.

Analysis

Bill Summary: “Dense breast tissue” means heterogeneously dense or extremely dense tissue as defined in nationally recognized guidelines or systems for breast imaging reporting of mammography screening, including the breast imaging reporting and data system of the American College of Radiology (ACR).

The notice required by the bill must state as follows:

This notice contains the results of your recent mammogram, including information about breast density.

If your mammogram shows that your breast tissue is dense, you should know that dense breast tissue is a common finding and is not abnormal, with about half of women having dense or highly dense breasts. However, dense breast tissue can make it harder to find cancer on a mammogram and may also be associated with an increased risk of cancer.

This information about the result of your mammogram is given to you to raise your awareness and to inform your conversations with your physician. Together, you can decide which screening options are right for you based on your mammogram results, individual risk factors, or physical examination. A report of your results was sent to your physician.

If the Department of Health and Mental Hygiene (DHMH) finds significant differences between the content of this notice and current medical evidence on breast density, DHMH may adopt regulations changing the content of the notice.

Current Law: “Mammogram” means a radiographic image produced through mammography. “Mammography testing” means the imaging of the breast with ionizing radiation. A person may not, subject to civil penalty, perform mammography testing unless (1) the individual performing the testing is qualified under the Health Occupations Article and (2) the center where the testing is performed has obtained specified accreditation and certification.

Background: Breast cancer occurs in both women and men, although male breast cancer is rare. The National Institutes of Health advise that, over the course of a lifetime, one in eight women will be diagnosed with breast cancer. According to the National Cancer Institute, there will be more than 234,000 new cases of – and over 40,000 deaths from – breast cancer in the United States in 2013.

Breasts are made up of a combination of fibrous and glandular tissue and fatty tissue. Breasts are considered dense if they have a high proportion of fibrous or glandular tissue but little fat. According to ACR, there are four categories of mammographic density; ACR estimates that, in the United States, 10% of women have almost entirely fatty breasts and 10% of women have extremely dense breasts, while 80% of women are classified into one of two middle categories (“heterogeneously dense breasts” and “scattered areas of fibroglandular density in breasts”).

A recent study published in the *Journal of the National Cancer Institute* found that high breast density is a strong risk factor for developing breast cancer but does not affect a breast cancer patient's risk of death. ACR advises that high breast density makes it more difficult for doctors to spot cancer on mammograms because dense tissue appears white on a mammogram – as do tumors (whether benign or cancerous). ACR further advises that ultrasound and magnetic resonance imaging (MRI) may help identify breast cancers that cannot be detected on a mammogram; however, both MRI and ultrasound also show more findings that are not cancer, which may result in added testing and unnecessary biopsies.

Several states (California, Connecticut, New York, Texas, and Virginia) have passed laws requiring patients to be informed if their mammograms demonstrate dense breast tissue. In addition, federal legislation requiring such a disclosure to be made was recently introduced in the U.S. House of Representatives.

Additional Information

Prior Introductions: None.

Cross File: SB 334 (Senator Jones-Rodwell, *et al.*) - Finance.

Information Source(s): American College of Radiology, National Institutes of Health, National Cancer Institute, *New York Times*, Department of Health and Mental Hygiene, Department of Legislative Services

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