

Department of Legislative Services
Maryland General Assembly
2017 Session

FISCAL AND POLICY NOTE
Third Reader - Revised

House Bill 190

(Delegate Queen, *et al.*)

Health and Government Operations

Finance

Mammography Centers - Dense Breast Tissue - Notification of Breast Cancer
Screening Options

This bill alters the contents of a notice required to be sent by mammography centers in a specified screening results letter to state that a patient with dense breast tissue can discuss with her physician *whether additional screening options* may be appropriate.

Fiscal Summary

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

Local Effect: The bill is not anticipated to materially affect local government operations or finances.

Small Business Effect: None.

Analysis

Current Law: A center where mammography testing is performed is required to include in a screening results letter that is sent to a patient, as required by federal law, a specified notice that states:

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 the notice and current medical evidence on breast density, DHMH may adopt regulations changing the content of the notice. The penalty for a violation of the notice requirement may not exceed \$1,000.

The notification requirement does not apply if the federal Mammography Quality Standards Act (MQSA) 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, statute 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.

Background: Breast cancer occurs in both women and men, although male breast cancer is rare. The National Breast Cancer Foundation advises 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 246,000 new cases of – and over 40,000 deaths from – breast cancer in the United States in 2017.

There is no federal law or regulation requiring that a screening results letter include information about a patient’s breast density or provide examples of additional breast imaging tests. According to densebreast-info.org, an information resource focused on providing breast density information to patients and health care professionals, the Breast Density and Mammography Reporting Act of 2015, introduced into both the U.S. House of Representatives and U.S. Senate, specified that mammography reports include information about breast density and “convey the effect of breast density in masking the presence of breast cancer on mammography.” The Act has not yet been introduced in the current congressional session which began in January 2017.

A national density notification standard could also be created through regulations adopted by the U.S. Food and Drug Administration (FDA). [Densebreast-info.org](http://densebreast-info.org) advises that, while FDA anticipates issuing a breast density reporting amendment to MQSA as a Notice of Proposed Rulemaking, the proposed language has not been made public.

Additional Information

Prior Introductions: None.

Cross File: None.

Information Source(s): Department of Health and Mental Hygiene; National Breast Cancer Foundation; National Cancer Institute; www.densebreast-info.org; Department of Legislative Services

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