Chapter 220

(House Bill 190)

AN ACT concerning

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

FOR the purpose of altering the notice that certain mammography centers are required to include in a certain screening results letter<u>; to specify examples of additional breast</u> imaging tests that requiring the notice to state that together, a patient and the patient's physician can decide whether additional screening options might be right for the patient; and generally relating to notice of screening options for breast cancer.

BY repealing and reenacting, with amendments, Article – Health – General Section 20–115 Annotated Code of Maryland (2015 Replacement Volume and 2016 Supplement)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article – Health – General

20 - 115.

(a) (1) In this section the following words have the meanings indicated.

(2) (i) "Center" means any facility that produces, develops, or interprets:

- 1. Screening mammograms; or
- 2. Diagnostic mammograms.

(ii) "Center" includes a hospital, outpatient department, medical laboratory, clinic, radiology practice, office of a health care provider, or other testing facility conducting mammography testing.

(iii) "Center" does not include a facility of the federal Department of Veterans Affairs.

(3) "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.

(4) "Mammogram" means a radiographic image produced through mammography.

(5) "Mammography testing" means the imaging of the breast with ionizing radiation.

(b) On or after July 1, 1992, a person may not perform mammography testing unless:

(1) The individual performing mammography testing is qualified under Title 14 of the Health Occupations Article; and

(2) The center where the mammography testing is performed:

(i) Is accredited or has applied for accreditation under the American College of Radiology Screening Mammography Accreditation Program; and

(ii) Has obtained a certificate of approval from the federal Food and Drug Administration as specified in the federal Mammography Quality Standards Act of 1992.

(c) (1) (i) This section does not apply if the federal Mammography Quality Standards Act of 1992, or regulations adopted under the Act, requires a notice regarding breast density to be included in the screening results letter that is sent to a patient.

(ii) This section may not be construed to:

1. Require a notice regarding breast density to be sent to a patient that is inconsistent with the provisions of the federal Mammography Quality Standards Act of 1992, or regulations adopted under the Act; or

2. Create a standard of care, obligation, or duty that provides a basis for a cause of action.

(2) Subject to paragraph (3) of this subsection, a center where mammography testing is performed shall include in a screening results letter that is sent to a patient, as required by federal law, the following notice: "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] WHETHER ADDITIONAL BREAST IMAGING TESTS, INCLUDING DIGITAL MAMMOGRAPHY, BREAST ULTRASOUND, MAGNETIC RESONANCE IMAGING, OR BREAST TOMOSYNTHESIS, 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.".

(3) If the Department finds significant differences between the content of the notice that is required to be provided under paragraph (2) of this subsection and current medical evidence on breast density, the Department may adopt regulations that change the content of the notice.

(d) Notwithstanding any other provision of this title, the penalty for a violation of subsection (b) of this section may not exceed \$1,000.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2017.

Approved by the Governor, April 18, 2017.