

September 16, 2013

“Breast Density Awareness Bill”: New Maryland Legislation Effective October 1, 2013

- As of October 1, 2013 a new State law will go into effect mandating that mammography providers include a notice in the result letter sent to women undergoing screening mammography. The notice includes generic information about breast tissue density and prompts women to discuss this information with their health care provider.
- Currently, twelve States have passed a Breast Density Notification and/or Awareness Bill. Maryland was the seventh state to pass a bill. Since Governor O’Malley signed the HB 312 into law on May 16, 2013 five more states have enacted such legislations. The Maryland legislation is a Breast Density Awareness bill aimed to increase women’s awareness of breast density. It is not a Notification bill, as it does not mandate that mammography providers notify women of their own breast density. At the Federal level, the Breast Density and Reporting Act was introduced in the previous Congress in October 2011 but never enacted. Therefore, as of now, facilities of the federal Department of Veteran Affairs are exempt.
- For reference, the House Bill (HB 312) was signed into law as Chapter 457 of the Acts of 2013 in Maryland. The full text of the legislation is available online at the following link: <http://mgaleg.maryland.gov/2013RS/bills/hb/hb0312T.pdf>
- The Maryland Radiological Society is in full agreement with the position statement released by the American College of Radiology (ACR) in April 2012. Briefly, the ACR recognizes the impact of breast tissue density on mammographic screening and instructs radiologists to include breast composition in the medical report. While the ACR encourages education and awareness of the public, it is concerned about the consequences of including information regarding breast density in the lay summary to women due to the controversies regarding breast density assessment and significance as well as the lack of scientific evidence of benefit from additional supplemental screening tests. Additionally, reporting of fatty breasts may convey a sense of false security. The full position statement of the American College of Radiology can be found online in the ACR website at the following link: <http://www.acr.org/About-Us/Media-Center/Position-Statements/Position-Statements-Folder/Statement-on-Reporting-Breast-Density-in-Mammography-Reports-and-Patient-Summaries>
- A paper by Gierach et al published in the Journal of the National Cancer Scientific in August 2012 provides reassurance for women with dense breasts. The researchers studied the relationships between mammographic breast density and risk of death from breast cancer and all causes in 9232 women diagnosed with primary breast cancer. The study found that dense breast tissue is not associated with risk of breast cancer death or death from any cause in this large prospective study. The study can be found at the following link: <http://jnci.oxfordjournals.org/content/early/2012/08/21/jnci.djs327.full.pdf+html>

- Brief guidelines and references are offered below for mammography providers, referring health care providers, and the general public.
- Guidelines for Mammography providers. As of October 1, 2013, screening result letters need to include the notice stated in Chapter 457 and reported below. The screening result letter does not need to specify the patient's own breast density and may contain additional informative material or statements.
- The law requires that screening result letters sent to women must include the following notice *verbatim*:
 - *"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."*
- Guidelines for Referring Health Care Providers: The American College of Radiology encourages and instructs mammography providers to include information regarding breast density in every mammogram report released to the referring health care provider. Breast density varies depending on the composition of the breast and the proportion of fibroglandular tissue relative to fat. Breast composition is arbitrarily classified and subjectively assessed visually into four types according to the Breast Imaging-Reporting And Data System (BI-RADS): 1) almost entirely fat, 2) scattered fibroglandular densities, 3) heterogeneously, and 4) extremely dense breast tissue. The visual assessment is not reliably reproducible. Dense breast tissue may obscure an underlying breast cancer and may also represent a risk factor for breast cancer. However, as stated above, high mammographic breast density has not been shown to be associated with risk of death in patients with breast cancer in a large prospective study. Currently, there are no randomized trials data demonstrating that adding either MRI or ultrasound to mammography saves lives. Therefore, the decision to pursue additional screening should not be based on breast density alone but on the overall risk profile. The patient should be counseled regarding the potential for false positive findings and the need for additional interventional procedures. There should always be a conversation between the patient and her health care provider before ordering supplemental tests.

Informative material with answers to frequently asked questions about breast density and breast cancer risk is available online at the website www.breastdensity.info. The information in this website is based on current scientific knowledge and is provided by expert radiologists of the California Breast Density Information Group. This website can be utilized as a source of medical information but not as a reference for the law as California, as opposed to Maryland, has a notification provision which requires patients to be notified of their own breast density.

- Educational brochures for women are available at the ACR website at the following link: <http://www.acr.org/News-Publications/~media/180321AF51AF4EA38FEC091461F5B695.pdf>
- *Guidelines for the general public:*
Women receiving the notice in the result letter should consider the following important information:

1) What is breast density.

2) What are the implications of breast density in terms of the ability to detect breast cancer on a mammogram, the risk of breast cancer, and the risk of death from breast cancer.

3) The recommendations for breast cancer screening in women with dense breasts.

In general, breast density refers to the appearance of the breast tissue on mammography. A breast is composed of fat, glandular and connective tissue. A dense breast on mammography has less fat than glandular and connective tissue. The breast composition varies among individuals: it may be mostly fatty or very dense or contain a mixed amount of fat and glandular tissue. The vast majority of women have mixed breast composition, 10% of women have fatty breasts and 10% extremely dense breasts. Breast composition and breast tissue density may also vary with age and menstrual cycle.

A dense breast and breast cancer are both white on mammography. So, it may be more difficult to detect breast cancer in a dense breast. Additionally, some studies have shown that dense breast tissue increases risk for breast cancer. The good news is that women with dense breasts are not at increased risk of dying from breast cancer when compared to women with mostly fatty breasts.

Women with dense breasts should continue annual mammographic screening. Screening mammography is the only test that has been proven to decrease breast cancer mortality. Supplemental screening after mammography with breast MRI or ultrasound in women with dense breasts is not standard of care or supported by scientific evidence. A risk-based approach is advised. A woman should discuss the results of her mammogram with her health care provider and understand her risk of having breast cancer. If needed, a genetic counselor may be consulted. If a woman is at high risk for breast cancer, supplemental testing may be beneficial, in particular with breast MRI. It should be kept in mind that supplemental screening tests may generate unnecessary follow-up or biopsies and more “false alarms” compared to mammography.