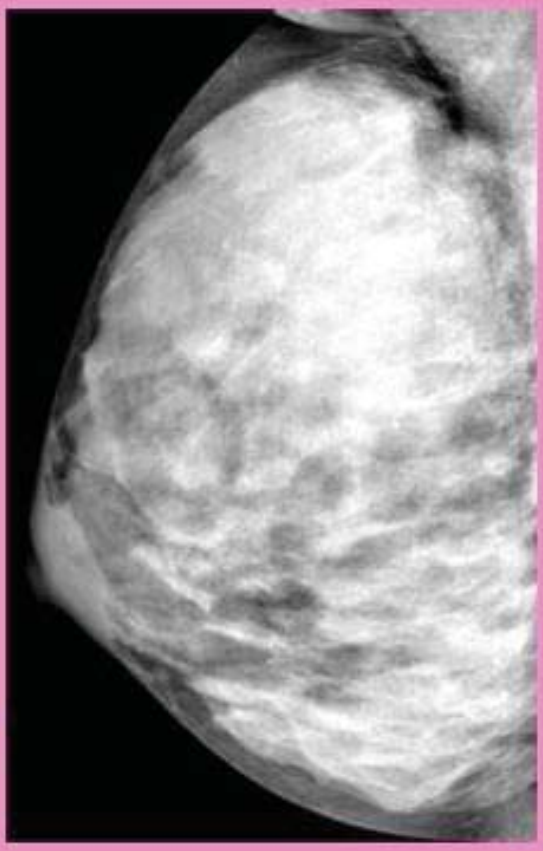
American Congress of Obstetricians and Gynecologists
New Jersey Section

Discussing Breast Density



A Toolkit for the New Jersey Obstetrician Gynecologist

American Congress of Obstetricians and Gynecologists
New Jersey Section

NEW JERSEY DENSE BREAST TOOLKIT

Dear ACOG-NJ Section Member,

As you may be aware, New Jersey has become the 14th state to pass legislation related to "**Dense Breasts**". Recent surveys have indicated that most Obstetrician-Gynecologists in New Jersey have limitations in their knowledge of both the clinical and legislative implications of this issue. In response, the Advisory Council of the New Jersey Section of the American College of Obstetricians and Gynecologists is pleased to provide you with this toolkit to assist you in managing your patients with dense breasts.

The passage of this legislation has resulted in a great deal of confusion among patients, radiologists and ordering physicians regarding obligations to inform patients about their breast tissue composition. Furthermore, in many cases, this confusion has led to clinical recommendations that are not congruent with official statements by the American College of Radiology (ACR), nor the American College of Obstetricians and Gynecologists (ACOG).

We hope that this guide will assist you as you talk with your patients about breast density and other risk factors for breast cancer. Please feel free to copy and distribute the FAQ sheets and Breast Density brochures to your patients. The data is still evolving, so we also invite you to utilize the NJ-ACOG website which will have updated toolkit materials available for download and distribution. We welcome your feedback.

Sincerely,

Sharon Mass, MD, FACOG
ACOG New Jersey Section Chair

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"Breast Density" refers to the relative amount of fatty and fibro-glandular tissue seen in the breast by mammogram. The category of breast density depends on the percentage of breast tissue made up of this denser tissue compared to the fatty tissue.

WHAT ARE THE CATEGORIES OF BREAST DENSITY AND HOW MANY WOMEN FALL INTO EACH GROUP?
Breast density is visually-determined by the radiologist who reads a mammogram. The American College of Radiology defines breast density in the following categories:

-***Almost entirely fatty*** - **10%** of women
-***Scattered areas of fibro-glandular density*** - **40%** of women
-***Heterogeneously dense*** - 4**0%** of women
-***Extremely dense*** -1**0%** of women

The 50% of women with "***Heterogeneously***" and "***Extremely***" dense breasts are those that are considered to have "***Dense breasts***".

WHAT IS THE SIGNIFICANCE OF BREAST DENSITY?
Having dense breasts may increase your risk of breast cancer in two ways. First, denser tissue may make it more difficult to detect breast cancer (masking). The sensitivity of mammogram (chance that disease will be detected) decreases with increasing density. Second, dense breasts are a risk factor for breast cancer.

WHAT IS MY RISK OF BREAST CANCER?
The risk that you will be diagnosed with breast cancer during the next ten years of your life depends on your current age:

-Age 30: 0.44% (1 in 227)
-Age 40: 1.47% (1 in 68)
-Age 50: 2.38% (1 in 42)
-Age 60: 3.56% (1 in 28)
-Age 70: 3.82% (1 in 26)

HOW DOES BREAST DENSITY CHANGE THE CANCER RISK?
Compared to women with ***average*** breast density, the risk for the 40% of women with "***Heterogeneously dense***" breasts is about 1.2 times greater and the risk for the 10% of women with "***Extremely dense***" breasts is about 2 times greater. A person's risk depends on this plus other risk factors such as gene mutations, family history, and personal history.

IF I WANT TO HAVE ADDITIONAL TESTS DONE, WHAT ARE THE "SCREENING OPTIONS" AND THEIR PROS AND CONS?
There are three additional tests that are available:

MAGNETIC RESONANCE IMAGING (MRI) – Screening breast MRI has been shown to increase the rate of cancer detection. However, it may also show more findings that are not cancer, which can result in added testing and unnecessary biopsies. MRI is recommended for screening in patients at very high risk (>20% lifetime risk of breast cancer). Some people recommend MRI for women with intermediate risk (15-20% lifetime risk of breast cancer) and dense breasts.

ULTRASOUND - In women with dense breasts but no other risk factors, some studies have shown that whole breast screening ultrasound can detect an additional 1.6 to 4 cancers for every 1000 women screened. However, ultrasound generates many more biopsies than mammogram (up to 300 for every 1000 women screened) and most of these additional biopsies ultimately end up not showing cancer.

TOMOSYNTHESIS – Screening breast tomosynthesis (sometimes referred to as "3-D mammography"), increases breast cancer detection and decreases the rate of false positives and biopsies, compared to traditional mammography, particularly in women with dense breasts. However, at this point, availability is limited. The radiation dose of tomosynthesis is slightly higher than mammography, but is still within FDA limits.

DO THE RADIOLOGISTS RECOMMEND ADDITIONAL SCREENING IN WOMEN WITH DENSE BREASTS?
There is currently no formal recommendation from the American College of Radiology regarding additional screening, beyond mammography, based solely on breast density.

DOES THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS HAVE A RECOMMENDATION FOR WOMEN WITH DENSE BREASTS?
As of April, 2014, The American College of Obstetricians and Gynecologists (ACOG) does not recommend routine use of alternative or adjunctive tests to screening mammography in women with dense breasts who are asymptomatic and have no additional risk factors.

WHAT IS THE COST OF SUPPLEMENTAL SCREENING TESTS?
The New Jersey legislature mandated insurance coverage for any supplemental breast cancer screening tests deemed medically necessary in patients with "***extremely"*** dense breasts or those who have other risk factors. Currently, there are no insurance billing codes for screening breast ultrasound or tomosynthesis. Screening breast MRI is usually covered for high-risk women, but not for women at average risk who simply have dense breasts. Women who desire supplemental screening may be asked to pay out-of-pocket.

WHERE CAN I FIND ADDITIONAL INFORMATION?
The American College of Radiology www.acr.org
The American College of Obstetricians and Gynecologists www.acog.org
The American Cancer Society www.cancer.org
Are You Dense Advocacy www.Areyoudenseadvocacy.org
The California Breast Density Information Group www.breastdensity.info

NEW JERSEY DENSE BREAST TOOLKIT
FAQ for Obstetrician-Gynecologists

HOW IS BREAST DENSITY DEFINED?
"Breast Density" refers to the relative amount of breast epithelial and connective tissue relative to fatty tissue seen in the breast by mammogram. Fatty tissue is relatively translucent, appearing dark on the mammogram while other tissues are radiologically dense, appearing as white areas. The category of breast density depends on the percentage of breast tissue made up of this denser tissue.

WHAT ARE THE CATEGORIES OF BREAST DENSITY AND HOW MANY WOMEN FALL INTO EACH GROUP?
Breast density is visually-determined by the radiologist who reads a mammogram. In the future, new technologies may offer a more objective and quantitative evaluation. The American College of Radiology defines breast density in the following categories:

- ***Almost entirely fatty*** - **10%** of women
- ***Scattered areas of fibro-glandular density*** - **40%** of women
- ***Heterogeneously dense*** - **40%** of women
- ***Extremely dense*** – **10%** of women

The 50% of women with "***Heterogeneously***" and "***Extremely***" dense breasts are those that are considered to have "***Dense breasts***".

WHAT IS THE SIGNIFICANCE OF BREAST DENSITY?
Mammographic density can impact screening mammography in two ways. First, denser tissue may make it more difficult to detect breast cancer (masking). The sensitivity of mammogram decreases with increasing density and may be diminished by 10-20% in women with dense breasts. Second, dense breasts are an independent risk factor for breast cancer.

HOW DOES BREAST DENSITY CHANGE THE CANCER RISK?
Much of the literature on risk of breast density on cancer risk is confused by the fact that the studies compare women with "***Almost entirely fatty***" breasts (lowest 10%) to those with "***Extremely***" dense breasts (highest 10%). These studies quote a 4-6x increased risk in the latter group compared to the former group. However, when risk is expressed relative to ***average*** breast density, the risk for the 40% of women with "***Heterogeneously dense***" breasts is about 1.2 times greater and the risk for the 10% of women with "***Extremely dense***" breasts is about 2 times greater.

WHAT ARE THE "SCREENING OPTIONS" FOR ADDITIONAL TESTING AND THEIR PROS AND CONS?

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DO THE RADIOLOGISTS RECOMMEND ADDITIONAL SCREENING IN WOMEN WITH DENSE BREASTS?

There is currently no formal recommendation from the American College of Radiology regarding additional screening beyond mammography based solely on breast density. While the ACR encourages education and awareness of the public, they do NOT currently have a recommendation for any additional action, due to controversies regarding breast density assessment as well as the lack of scientific evidence demonstrating benefit from additional supplemental screening tests.

DOES THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS HAVE A RECOMMENDATION FOR WOMEN WITH DENSE BREASTS?

As of April, 2014, The American College of Obstetricians and Gynecologists (ACOG) does not recommend routine use of alternative or adjunctive tests to screening mammography in women with dense breasts who are asymptomatic and have no additional risk factors.

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Breast Density

Breast cancer screening

The American Cancer Society, American College of Radiology, Society of Breast Imaging and American College of Obstetricians and Gynecologists, among others, recommend that all women have yearly mammograms beginning at age 40. Women at high risk may benefit from starting earlier.

Resources:

For more information on breast cancer screening, visit **MammographySavesLives.org** or **RadiologyInfo.org**.

MammographySavesLives™
... one of them may be yours

ACR® American College of Radiology
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SBI Society of Breast Imaging Since 1985

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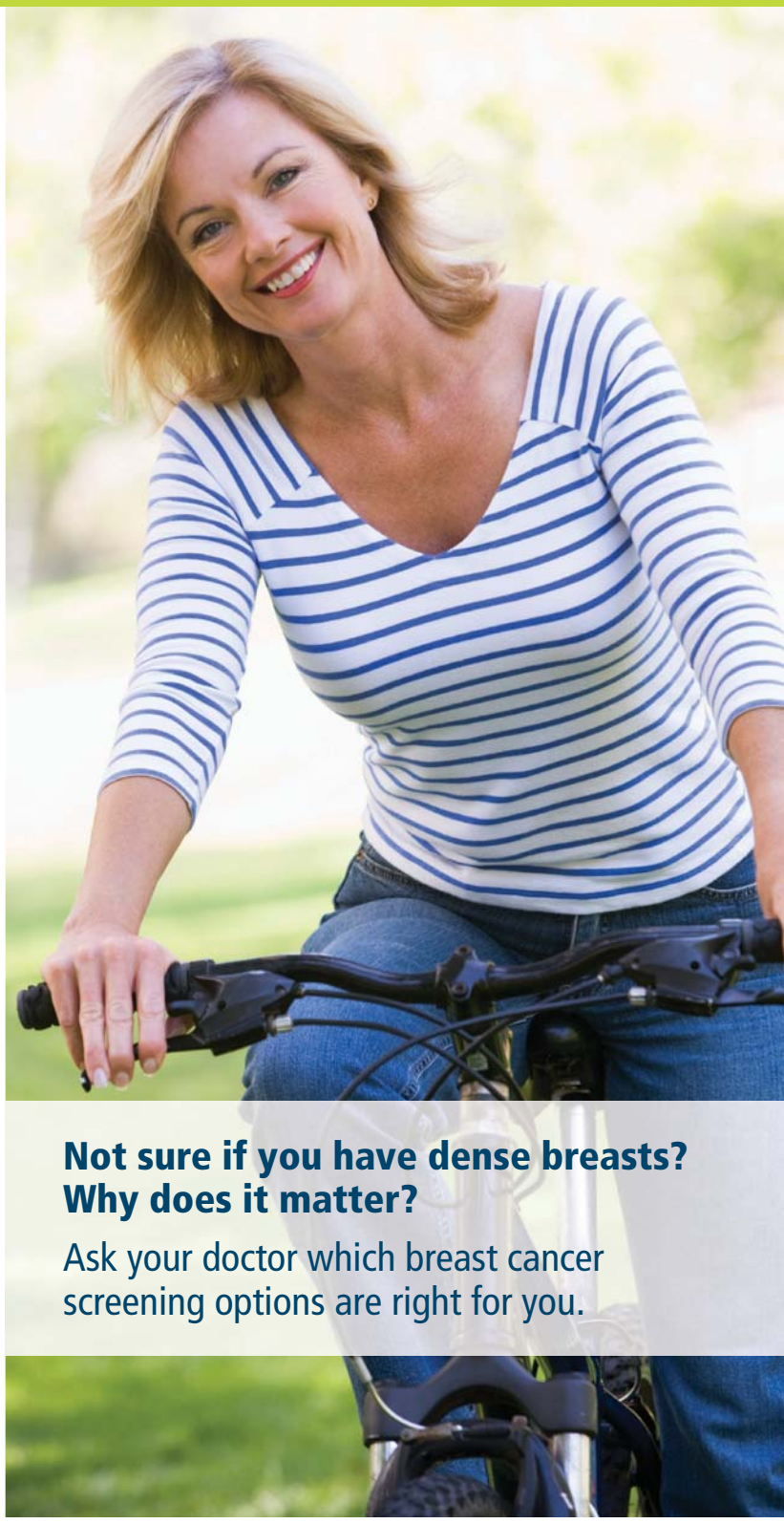


Not sure if you have dense breasts? Why does it matter?

Ask your doctor which breast cancer screening options are right for you.

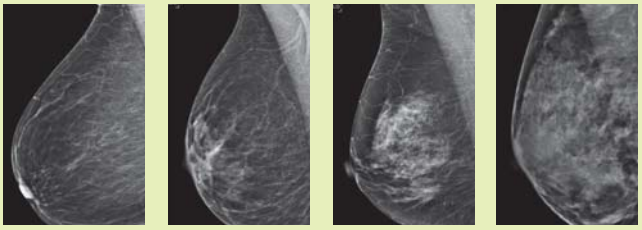
What is breast density?

Breasts are made up of a mixture of fibrous and glandular tissue and fatty tissue. Your breasts are considered dense if you have a lot of fibrous or glandular tissue but not much fat. Density may decrease with age, but there is little, if any, change in most women.

How do I know if I have dense breasts?

Breast density is determined by the radiologist who reads your mammogram. There are four categories of mammographic density. The radiologist assigns each mammogram to one of the categories. Your doctor should be able to tell you whether you have dense breasts based on where you fall on the density scale. (See scale below.)

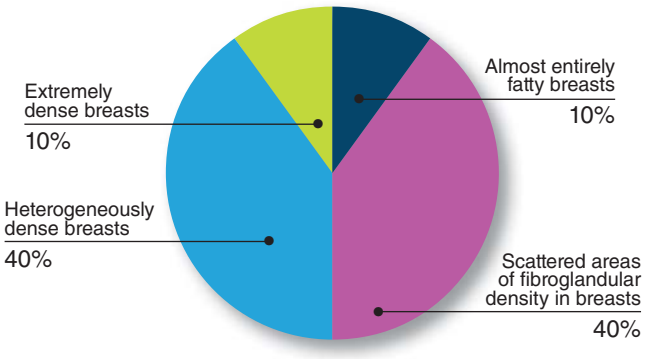
Radiologists classify breast density using a 4-level density scale:



Almost entirely fatty | **Scattered areas of fibroglandular density** | **Heterogeneously dense** | **Extremely dense**

Breast density in the U.S. (See pie chart)

- 10% of women have almost entirely fatty breasts
- 10% have extremely dense breasts
- 80% are classified into one of two middle categories



Why is breast density important?

Having dense breast tissue may increase your risk of getting breast cancer. Dense breasts also make it more difficult for doctors to spot cancer on mammograms. Dense tissue appears white on a mammogram. Lumps, both benign and cancerous, also appear white. So, mammograms can be less accurate in women with dense breasts.

If I have dense breasts, do I still need a mammogram?

Yes. A mammogram is the only medical imaging screening test proven to reduce breast cancer deaths. Many cancers are seen on mammograms even if you have dense breast tissue.

Are there any tests that are better than a mammogram for dense breasts?

In breasts that are dense, cancer can be hard to see on a mammogram. Studies have shown that **ultrasound** and **magnetic resonance imaging (MRI)** can help find breast cancers that can't be seen on a mammogram. However, both MRI and ultrasound, show more findings that are not cancer, which can result in added testing and unnecessary biopsies. Also, the cost of ultrasound and MRI may not be covered by insurance.

What should I do if I have dense breasts? What if I don't?

If you have dense breasts, please talk to your doctor. Together, you can decide which, if any, additional screening exams are right for you.

If your breasts are not dense, other factors may still place you at increased risk for breast cancer — including a family history of the disease, previous chest radiation treatment for cancer and previous breast biopsies that show you are high risk. Talk to your doctor and discuss your history.

Even if you are at low risk, and have entirely fatty breasts, you should still get an annual mammogram starting at age 40.

The American College of
Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

COMMITTEE OPINION

Number 593 • April 2014

Committee on Gynecologic Practice

This document reflects emerging clinical and scientific advances as of the date issued and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed.

Management of Women With Dense Breasts Diagnosed by Mammography

ABSTRACT: Women with dense breasts have a modestly increased risk of breast cancer and experience reduced sensitivity of mammography to detect breast cancer. However, evidence is lacking to advocate for additional testing until there are clinically validated data that indicate improved screening outcomes. Currently, screening mammography remains the most useful tool for breast cancer detection and has consistently demonstrated a reduction in breast cancer mortality. The American College of Obstetricians and Gynecologists does not recommend routine use of alternative or adjunctive tests to screening mammography in women with dense breasts who are asymptomatic and have no additional risk factors. The American College of Obstetricians and Gynecologists recommends that health care providers comply with state laws that may require disclosure to women of their breast density as recorded in a mammogram report.

Dense breast tissue is common in younger women. Dense breast tissue absorbs significantly more radiation during mammography compared with fatty breast tissue (1). This occurrence reduces the accuracy of mammography to detect breast cancer in women with dense breast tissue (2, 3). Currently, screening mammography remains the most useful tool for breast cancer detection and has consistently demonstrated a reduction in breast cancer mortality. Nonetheless, mammography does not detect all breast cancer.

Women with dense breasts (Breast Imaging Reporting and Data System [BI-RADS] 3 and 4) (see Table 1) have a modestly increased risk of breast cancer and experience reduced sensitivity of mammography to detect breast cancer (2). Although categories have been established, the assessment of breast density is subjective and based on the opinion of the radiologist. In women with heterogeneously dense or extremely dense breasts, digital mammography has been shown to be more effective compared with film mammography for breast cancer screening (2). Numerous states have passed legislation requiring health care providers to inform women of the modest increased risk of breast cancer and reduced sensitivity of mammography, and several states require practitioners to discuss supplemental tests to screening mammography for women with dense breasts. Current published evidence does not demonstrate meaningful outcome benefits (eg, reduction in breast cancer mortality) with supplemental tests (eg, ultrasonography and magnetic resonance imaging) to screening mammography or with alternative screening modalities (eg, breast tomosynthesis or thermography) in women with dense breasts who do not have additional risk factors. Evidence is lacking to advocate for additional testing until there are clinically validated data that indicate improved screening outcomes.

The American College of Obstetricians and Gynecologists (the College) does not recommend routine use of alternative or adjunctive tests to screening mammography in women with dense breasts who are asymptomatic and have no additional risk factors. The College strongly supports additional research to identify more effective screening methods that will both enhance meaningful improvements in cancer outcomes for women with dense breasts and minimize false-positive screening results. The College recommends that health care providers comply with state laws that may require disclosure to women of their breast density as recorded in a mammogram report.

Table 1. BI-RADS Breast Density Categories, Demographics, Sensitivity of Cancer Detection, and Breast Cancer Risk ⇦

BI-RADS category	Description	Percentage of population*	Sensitivity† (%)	Relative risk of breast cancer
1	Almost entirely fat	10	88	–
2	Scattered fibroglandular densities	43	82	–
3	Heterogeneously dense	39	69	1.2 (compared with average breast density)
4	Extremely dense	8	62	1.4 (compared with average breast density)

Abbreviation: BI-RADS, Breast Imaging Reporting and Data System.

*Pisano ED, Gatsonis C, Hendrick E, Yaffe M, Baum JK, Acharyya S, et al. Diagnostic performance of digital versus film mammography for breast-cancer screening. Digital Mammographic Imaging Screening Trial (DMIST) Investigators Group [published erratum appears in N Engl J Med 2006;355:1840]. N Engl J Med 2005;353:1773–83.

†Carney PA, Miglioretti DL, Yankaskas BC, Kerlikowske K, Rosenberg R, Rutter CM, et al. Individual and combined effects of age, breast density, and hormone replacement therapy use on the accuracy of screening mammography [published erratum appears in Ann Intern Med 2003;138:771]. Ann Intern Med 2003;138:168–75.

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NEW JERSEY DENSE BREAST TOOLKIT
Additional Resources for the OB-GYN

The American College of Radiology (ACR) www.acr.org
The ACR has numerous resources for information about breast imaging and breast density. Some resources include:

-The ACR BI-RADS Atlas Fifth Edition
-The 2012 ACR position statement on breast density laws
-The ACR patient information brochure (included in this packet)

The American College of Obstetricians and Gynecologists (ACOG) www.acog.org
ACOG has been actively involved in both the legislative and clinical issues surrounding breast density. Some resources about breast cancer screening options and modalities include:

-Committee Opinion No. 593, Management of Women With Dense Breasts Diagnosed by Mammography, April 2014 (included in this packet)
-Technology Assessment No. 9, Digital Breast Tomosynthesis, June 2013
-Practice Bulletin No. 122, Breast Cancer Screening, August 2011

The American Cancer Society (ACS) www.cancer.org
The ACS has numerous links to breast cancer facts and statistics as well as recommendations for screening guidelines. Specifically a breast density fact sheet that can be distributed to patients can be found at:
http://www.cancer.org/acs/groups/content/@editorial/documents/document/acspc-039989.pdf

The California Breast Density Information Group www.breastdensity.info
CBDIG is a working group of breast radiologists and breast cancer specialists in California that has provided a summary of the current literature with evidence-based recommendations. They also provide FAQ for patients and a flowchart of clinical situations involving breast density for providers.

Are you Dense Advocacy www.areyoudenseadvocacy.org
This is the national grassroots advocacy campaign that is responsible for promotion of various State and Federal regulatory efforts regarding breast density. Their website tracks the status of bills in various states.

SUMMARY OF KEY POINTS FOR CLINICIANS:

1. There are an increasing number of states, now including New Jersey, with "Breast Density Laws". Each of these laws is different with regard to the information that the patient receives, mandates for additional testing and coverage for this testing.

2. **50%** of women who have screening mammography may be told that they have "***Dense Breasts***" if they are classified as having "***Heterogeneously***" or "***Extremely***" dense breasts.

3. The relative risk of breast cancer for those with "***Extremely***" dense breasts is 2.0; for those with "***Heterogeneously***" dense breasts is 1.2.

4. Neither the American College of Radiology (ACR) nor the American College of Obstetricians and Gynecologists (ACOG) recommend routine use of alternative or adjunctive tests to screening mammography in women with dense breasts who are asymptomatic and have no additional risk factors.

5. Other breast screening options for high-risk patients include MRI, ultrasound and tomosynthesis (3-D mammography); each of these modalities has risks and benefits.

6. In the New Jersey law, baseline mammography, starting at age 40 and yearly thereafter is covered; additional testing including ultrasound, MRI and 3-D mammography is covered for those with "***Extremely***" dense breasts or those with other risk factors; all patients are informed that breast density can be a risk factor for breast cancer and are encouraged to include this information in their own risk assessment.

7. A working group will be formed and will be charged with educating women and clinicians in New Jersey.

NEW JERSEY DENSE BREAST TOOLKIT
Elements of the NJ Statute S792

Senate, No. 792/Assembly, No 2022
Signed into law January 21, 2014

Summary:

Requires insurers to cover breast evaluations and other additional medically-necessary testing under certain circumstances and requires certain mammogram reports to contain information on breast density.

Provisions:

Basic Screening

-One baseline mammogram examination for women who are 40 years of age;
-A mammogram examination every year for women age 40 years and over;
-In the case of a woman who is under 40 years of age and has a family history of breast cancer or other breast cancer risk factors, a mammogram examination at such age and intervals as deemed medically necessary by the woman's health care provider.

Additional Testing

-An ultrasound evaluation, a magnetic resonance imaging scan, a three-dimensional mammography, or other additional testing of an entire breast or breasts after a baseline mammogram examination if the mammogram demonstrates extremely dense breast tissue, if the mammogram is abnormal within any degree of breast density including “not dense”, “moderately dense”, “heterogeneously dense” or “extremely dense” breast tissue or if the patient has additional risk factors for breast cancer including but not limited to family history of breast cancer, prior personal history of breast cancer, positive genetic testing, extremely dense breast tissue based on the Breast Imaging and Reporting and Data System established by the American College of Radiology, or other indications as determined by the patient’s health care provider.

Utilization Review

-The coverage required under this paragraph may be subject to utilization review, including periodic review… of the medical necessity of the additional screening and diagnostic testing.

Patient Reporting (“lay letter”)

-A facility that provides a mammography report pursuant to the federal Mammography Quality Standards Act, 42 U.S.C. s.263b, shall include the following information, at a minimum, in the mammography report sent to the patient and the patient's health care provider:

“Your mammogram may show that you have dense breast tissue as determined by the Breast Imaging Reporting and Data System established by the American College of Radiology. Dense breast tissue is very common and is not abnormal. However, in some cases, dense breast tissue can make it harder to find cancer on a mammogram and may also be associated with a risk factor for breast cancer.. Discuss

this and other risks for breast cancer that pertain to your personal medical history with your health care provider. A report of your results was sent to your health care provider. You may also find more information about breast density at the website of the American College of Radiology, www.acr.org.".

No Implication of Standard of Care:
-Notwithstanding the provisions of any other law to the contrary, the provisions of section 10 of P.L. shall not impose a standard of care obligation upon a patient's health care provider. The information required to be provided by section 10 of P.L. is intended to increase awareness of breast cancer and help facilitate a conversation between a patient and a patient's health care provider regarding the patient's risks for breast cancer.

Formation of Work Group
-The Department of Health, in conjunction with the Medical Society of New Jersey, shall convene a work group to review and report on strategies to improve the dialogue between patients and health care professionals regarding risk factors for breast cancer and breast imaging options. The work group shall review breast imaging standards, the federal Mammography Quality Standards Act and breast imaging results protocols, and shall recommend strategies to improve the dialogue between patients and health care professionals regarding breast density and breast imaging options.

-The department shall invite to participate in the work group representatives of patient advocacy groups and health care professionals' organizations. The work group shall organize as soon as practical following the appointment of its members. The members of the work group shall serve without compensation, but shall be reimbursed for necessary expenses incurred in the performance of their duties and within the limits of funds available to the work group.

-The work group shall be entitled to call to its assistance and avail itself of the services of the employees of any State, county, or municipal department, board, bureau, commission, or agency as the work group may require and as may be available to the work group for its purposes.

-The work group shall report its findings and recommendations to the Governor, and to the Legislature along with any legislative bills that it desires to recommend for adoption by the Legislature, on an annual basis. The work group shall submit its first report no later than 12 months after the initial meeting of the work group.

Timing
-This act shall take effect on the first day of the fourth month following the date of enactment.

NEW JERSEY DENSE BREAST TOOLKIT
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