Breast Density Notification Laws
Information For Primary Care Providers

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Module 1: Breast Density on Mammography

- Intended Learning Outcomes
  - Be familiar with the origin and current status of breast density legislation
  - Understand what breast density is, how it is assessed and how it is reported
  - Explain to patients how breast density affects interpretation of their mammogram
  - Apply understanding of risk conferred from breast density to a personalized assessment of a woman’s breast cancer risk
22 States have enacted legislation
7 States have introduced legislation
6 States are working on legislation
15 States have taken no action
* Insurance coverage law
Michigan Law

REGULAR SESSION OF 2014

Introduced by Senators Hildenbrand, Schuitmaker, Jansen, Anderson, Bieda, Booher, Brandenburg, Casperson, Emmons, Gregory, Hansen, Hood, Hunter, Jones, Kahn, Kowall, Marleau, Meekhof, Moolenaar, Nofs, Pappageorge, Pavlov, Proos, Richardville, Robertson, Rocca, Smith, Walker, Warren and Young

ENROLLED SENATE BILL No. 879

AN ACT to amend 1978 PA 368, entitled “An act to protect and promote the public health; to codify, revise, consolidate, classify, and add to the laws relating to public health; to provide for the prevention and control of diseases and disabilities; to provide for the classification, administration, regulation, financing, and maintenance of personal, environmental, and other health services and activities; to create or continue, and prescribe the powers and duties of, departments, boards, commissions, councils, committees, task forces, and other agencies; to prescribe the powers and duties of governmental entities and officials; to regulate occupations, facilities, and agencies affecting the public health; to regulate health maintenance organizations and certain third party administrators and insurers; to provide for the imposition of a regulatory fee; to provide for the levy of taxes against certain health facilities or agencies; to promote the efficient and economical delivery of health care services, to provide for the appropriate utilization of health care facilities and services, and to provide for the closure of hospitals or consolidation of hospitals or services; to provide for the collection and use of data and information; to provide for the transfer of property; to provide certain immunity from liability; to regulate and prohibit the sale and offering for sale of drug paraphernalia under certain circumstances; to provide for the implementation of federal law; to provide for penalties and remedies; to provide for sanctions for violations of this act and local ordinances; to provide for an appropriation and supplements; to repeal certain acts and parts of acts; to repeal certain parts of this act; and to repeal certain parts of this act on specific dates,” (MCL 333.1101 to 333.25211) by adding section 13524.
The People of the State of Michigan enact: 

Sec. 13524. (1) If a patient's mammogram demonstrates dense breast tissue, a person who provides mammography services in this state shall provide notification to the patient that includes, but is not limited to, the following information, in the summary of the written report of the results of a mammography examination that is sent directly to a patient pursuant to 42 USC 263b:

“Your mammogram shows that your breast tissue is dense. Dense breast tissue is very common and is not abnormal. However, dense breast tissue can make it harder to find cancer through a mammogram. Also, dense breast tissue may increase your risk for breast cancer. This information about the result of your mammogram is given to you to raise your awareness. Use this information to discuss with your health care provider whether other supplemental tests in addition to your mammogram may be appropriate for you, based on your individual risk. A report of your results was sent to your ordering physician. If you are self-referred, a report of your results was sent to you in addition to this summary.”.

(2) As used in this section, “dense breast tissue” means heterogeneously or extremely dense breast tissue as defined in nationally recognized guidelines or systems for breast imaging reporting of mammography screening including, but not limited to, the breast imaging reporting and data system established by the American college of radiology. If, after the effective date of this section, new terms are defined in revised guidelines or systems for breast imaging reporting of mammography screening, and the department determines that those new terms are more appropriate for the purposes of the information required to be provided under this section, the department, by order, may update the definition of dense breast tissue under this subsection to use those new terms. Upon issuance, the department shall forward an order issued under this subsection to the legislature.

Enacting section 1. This amendatory act takes effect June 1, 2015.

Carol Meyn Viventi
Secretary of the Senate

Terry E. Randall
Clerk of the House of Representatives
What is Breast Density?

- Mammography
- Differing X-ray absorption
  - Fibrous & glandular (FG) tissue
  - Fat
- Density
  - Relative amount
  - White (FG) vs black/gray (fat)
Assessing Breast Density

BI-RADS (Breast Imaging Reporting and Data System)

a. Almost entirely fatty
b. Scattered areas of fibroglandular density
c. Heterogeneously dense
d. Extremely dense


Assessing Breast Density

BIRADS: Qualitative
a) Almost entirely fatty
b) Scattered areas of fibroglandular density
c) Heterogeneously dense
d) Extremely dense

c & d = “DENSE BREASTS”


Density can change in same woman

- Decreases breast density
  - Increasing age over time
  - Increasing BMI ("dilutional")
  - Tamoxifen/others
- Increases breast density
  - Weight loss
  - Exogenous hormones
  - Lactation
### Distribution of Breast Density

<table>
<thead>
<tr>
<th>BIRADS breast density</th>
<th># of women (~600,000)</th>
<th>%</th>
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<tbody>
<tr>
<td>Predominantly fatty</td>
<td></td>
<td></td>
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<tr>
<td>Scattered densities</td>
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<tr>
<td>Heterogeneous</td>
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<tr>
<td>Extremely Dense</td>
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- **Fatty**: 57,961, 10%
- **Scattered**: 259,018, 44%
- **Heterogeneous**: 216,395, 37%
- **Extremely Dense**: 53,995, 9%
Clinical Relevance - Masking

Dense tissue hiding a cancer on a mammogram

Sensitivity:
Ex. Dense 63%
Fatty 87%

Clinical Relevance - Masking
Digital Imaging is more accurate
- Under age 50
- Dense breasts (>50% dense)
- Pre or peri-menopausal

>95% of units in US are digital

Diagnostic Performance of Digital versus Film Mammography for Breast-Cancer Screening
Pisano, E. et al for the Digital Mammographic Imaging Screening Trial (DMIST) Investigators Group

http://www.fda.gov.RadiationEmittingProducts
Clinical Relevance- Risk

Meta analysis of 11 studies with >14,000 cases

McCormack, VA Cancer Epidemiol Biomarkers Prev. 2006. 15(6);1159–1169.
Clinical Relevance - Risk*

* Compared to average density
  • Heterogeneously dense – 1.2x
  • Extremely dense – 2.1x