

June 12, 2019  
(updated June 14, 2019)

Food and Drug Administration  
Dockets Management (HFA-305)  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

**Re: Docket No. FDA-2013-N-0134 - Mammography Quality Standards Act; Amendments to Part 900 Regulations**

DenseBreast-info, Inc. (DB-I) commends the FDA for its work on identifying three categories of improvements to mammography regulations, including post-mammography reporting standards to assure that patients receive all necessary information about their mammogram, including an assessment of their breast density. DB-I is a medically-sourced, legally-vetted educational website on the topic of breast density. Included, among many other components on the website, is an analysis of state density inform laws; the DB-I map resource was referenced (citation 21), within the proposed rule. **As the leading source for density inform law analysis, we are responding to the public docket on *Mammography Quality Standards Act; Amendments to Part 900 Regulations*.**

Thirty-eight U.S. states, encompassing about 90% of American women, have enacted some level of density inform for women after their mammograms. DB-I supports a single national reporting standard that provides all American women with, at least, a base level of information about their breast density including the potential limitations of their mammogram results. DB-I comments below address both input on the FDA's proposed language content, as well as potential confusion points for states based on their existing density notification requirements. DB-I suggested language falls below the Flesch-Kincaid grade 10 readability level.

**Breast Density Notification:**

FDA developed two patient density paragraphs, one intended for patients with low breast density and one for patients with high breast density with input from FDA's Risk Communication Advisory Committee. The paragraphs contain an explanation of high breast tissue density, as well as specific topics for women to discuss with their healthcare providers.

**Low Density Paragraph Proposed in the Rule:**

If the mammography report identifies the patient's breast density as "The breasts are almost entirely fatty" or "There are scattered areas of fibroglandular density," the lay summary shall include: "Some patients have high breast tissue density (more glands than fat in the breasts), which makes it harder to find breast cancer on a mammogram. Your breast tissue density is low, not high. Follow the recommendations in this letter, and talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation."

**DB-I Suggested Changes to Low Density:**

"Breast tissue density can be low or high. This depends on how much fat and dense tissue is present in the breast. High density tissue makes it harder to find cancer on a mammogram. **Your breast tissue density is low\*** and your breasts are

not considered dense. Follow the advice in this letter, and talk to your healthcare provider about your risks for breast cancer and the recommended screening for your individual situation. It is important to continue routine screening mammograms. Risk factors can change and should be reviewed from time to time.”

**\*optional include: “... categorized as fatty (or scattered fibroglandular) tissue,”**

Reasons:

- The introductory info which begins with “Some patients” may cause alarm, we suggest a more informational lead-in.
- If mammography reporting software can accommodate, suggest bold font for “Your breast tissue density is low.”
- Technically, even dense breasts have more fat than dense tissue when quantified: “more glands than fat in the breasts” is factually inaccurate.
- Some states, like PA, currently require inclusion of the patient’s actual density category. We propose an elective option for those states that currently require category notification: **“Your breast tissue density is low, categorized as fatty (or scattered fibroglandular) tissue, and your breasts are not considered dense.”**
- The rule proposes the establishment of four categories of breast density for the mammography report. Since many facilities release the actual mammography report to patients through the medical record, it would further reduce confusion to change the wording of density category “scattered fibroglandular **density**” to “scattered fibroglandular **tissue**” in the mammography report/BI-RADS and lay letters. Feedback from states that currently report density categories to patients indicate that some women interpret “scattered fibroglandular density” to mean “dense breasts” which leads to confusion.
- Eliminate recommendation to discuss breast density with healthcare provider as this patient does not have dense breasts.

#### **High Density Paragraph Proposed in the Rule:**

If the mammography report identifies the breast density as “The breasts are heterogeneously dense, which may obscure small masses” or “The breasts are extremely dense, which lowers the sensitivity of mammography,” the lay summary shall include “Some patients have high breast tissue density (more glands than fat in the breasts), which makes it harder to find breast cancer on a mammogram. Your breast tissue density is high. Some patients with high breast density may need other imaging tests in addition to mammograms. Follow the recommendations in this letter, and talk to your healthcare provider about high breast density and how it relates to breast cancer risk, and your individual situation.”

#### **DB-I Suggested Changes to High Density Paragraph:**

“Breast tissue density can be low or high. This depends on how much fat and dense tissue is present in the breast. **Your breast tissue density is high\*** which makes it harder to find breast cancer on a mammogram. As a result, other imaging tests after your mammogram may be appropriate. Dense breasts are normal but do also raise the risk for getting breast cancer. Follow the advice in this letter and talk to your health care provider about high breast density, your other risk factors, and breast screening for your specific situation. It is important to continue routine screening mammograms. Breast density and other risk factors can change and should be reviewed from time to time.”

**\*optional include: “...categorized as heterogeneously (or extremely) dense,”**

Reasons:

- If mammography reporting software can accommodate, suggest bold for “Your breast tissue density is high...”
- Some states, like PA, currently require inclusion of the patient’s actual density category. We propose an elective option for those states that currently require category notification: **“Your breast tissue density is high, categorized as heterogeneously (or extremely) dense, which makes it harder to find breast cancer on a mammogram.”**

- Technically, even dense breasts have more fat than dense tissue when quantified: “more glands than fat in the breasts” is factually inaccurate.
- The proposed notification begins with “Some patients” while the notification is clearly for *this high-density* patient. This type of mixed messaging may create patient confusion.
- Notification includes “...may need other imaging tests in addition to mammograms.” but “other imaging” is not mentioned as a discussion topic for their healthcare provider talk.
  - Women may assume “other imaging” is not needed as it wasn’t previously discussed with a health provider. As worded, it is not clear that due to the density determination in *this* letter, “other imaging” is *now* a point for discussion as it relates to cancer detection.
  - “Need” is strong wording and any additional imaging carries risks of false positives and, in most situations, out-of-pocket costs, that must be balanced against potential benefits. Further, there should be use of national guidelines and appropriateness criteria to guide use of supplemental screening: “may be appropriate” covers that issue.
- As noted in the proposed rule, “...since the publication of the current MQSA regulations, peer reviewed scientific research has confirmed that dense breast tissue is one of the factors that increases the chances that a woman will develop breast cancer.” Information provided to patients about the inherent risk of dense tissue should be clear. The proposed language, “...talk to your healthcare provider about high breast density and how it relates to risk...” fails to communicate that breast density is, as confirmed by the cited peer reviewed scientific research, in and of itself, an independent risk factor for breast cancer.
- “Follow the recommendations (or, as DB-I suggests, “advice”) in this letter...” it would be most helpful if material could be provided/developed for health care providers (both breast imagers and referring providers), outlining the findings, data and resources mentioned within the rule to assist with appropriate recommendations. For instance, information on the benefits (cancer detection) vs. considerations (e.g. false positives) of supplemental screening would be beneficial.

**Stringency determination protocol:**

The inform language in the 38 existing state laws varies in depth, breadth, and terminology. As mentioned in the FDA’s April 2<sup>nd</sup> stake-holder call, clarification is needed on whether states would be *required* to use the new FDA reporting language. While under the MQSA, all facilities would be required to follow the new requirements, the Act also stipulates that nothing in the Act limits the authority of any state to “...impose more stringent requirements beyond those specified under MQSA and its implementing regulations.” It is not clear how states will determine “stringency” and lacking FDA input, this may create additional burden on states.

At the minimum, it would be helpful to make clear that patient notifications must explicitly state whether the patient herself has dense breasts. For instance, in the table below, while NY, CT and NJ all have “inform” laws, neither CT nor NJ currently require that notification to tell the woman if she has dense breasts.

Tri-State Comparison	Threshold for letter:	Notification text:
New York	Women with heterogeneously or extremely dense breasts	“Your mammogram shows that <b>your breast tissue is dense.</b> ”
Connecticut		“ <b>If</b> your mammogram demonstrates that you have dense breast tissue...”
New Jersey	ALL Women	“Your mammogram <b>may</b> show that you have dense tissue...”

Courtesy JoAnn Pushkin

To head off potential confusion and implementation hurdles at the state level when the rule becomes effective, will there be tools, references, or a list of “accepted” alternative language based on the most commonly used phrases in the existing laws that can be shared? Many state laws used the ACR suggested density-reporting language as template (see NY sample below). It would be helpful if guidance could be provided on which sentences would be “acceptable” vs. those that would not.

"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 on a mammogram and may also be associated with an increased risk of breast cancer. This information about the result of your mammogram is given to you to raise your awareness. Use this information to talk to your doctor about your own risks for breast cancer. At that time, ask your doctor if more screening tests might be useful, based on your risk. A report of your results was sent to your physician."

An alternative consideration would be to provide the key information points that must be included in existing state mandated patient letters, those being:

- Unambiguous notification as to whether or not the patient herself has dense breasts
- High breast density does hide some cancers on a mammogram
- High breast density does increase the risk of developing breast cancer
- To increase cancer detection, other imaging tests, in addition to the patient’s mammogram, may be appropriate to consider

DB-I supports the FDA in its goal to strengthen the communication of healthcare information in order to allow for more informed decision making by patients and their health providers. As such, we request careful consideration of this response and look forward to patient inform language that is relevant, informative, and unambiguous. If you have any questions, please contact JoAnn Pushkin, Executive Director at [jpushman@dense-info.org](mailto:jpushman@dense-info.org).

Sincerely,



JoAnn Pushkin  
Executive Director



Wendie A. Berg, MD, PhD, FACR  
Chief Scientific Advisor, DenseBreast-info, Inc.  
Professor of Radiology, University of Pittsburgh School of Medicine, Magee-Womens Hospital of UPMC