



Understanding Breast Density

A mammogram is a low-dose X-ray picture of the breast. For many women, a mammogram can help to detect breast cancer in its earliest, most treatable stages. By capturing detailed X-ray images of the breast, mammograms can find breast lumps often before they are big enough to feel or symptoms appear.

While breast cancer screening cannot prevent breast cancer, early detection of breast cancer can lead to earlier treatment and improved chances of survival. Regular screening has been shown to reduce the risk of dying from breast cancer. **One important factor that can impact the sensitivity of mammograms (the ability to detect breast cancer) is breast density.**

What is breast density?

Breast tissue is composed of fibrous tissue which holds the breast in place, glandular tissue which makes breast milk, and fatty tissue. Many different factors contribute to breast density including age, genetics, and the fatty, fibrous and glandular tissue that make up the breast.

Approximately half of women over the age of 40 in the U.S. have dense breast tissue based on a description of its appearance on a [mammogram](#).

Why does breast density matter?

It is important to know if you have dense breasts for two important reasons:

1. Dense breast tissue can make cancers more difficult to detect on a mammogram.
2. Dense breasts have been identified as a risk factor for developing breast cancer.

Knowing your breast density helps you and your health care provider make more informed decisions about your breast cancer screening results, overall risk for breast cancer, and whether you may benefit from additional imaging.

The FDA's role: requirements under the MQSA Final Rule

To ensure that all women have access to quality mammography for the detection of breast cancer in its earliest, most treatable stages, Congress enacted the [Mammography Quality Standards Act of 1992 \(MQSA\)](#). The MQSA establishes uniform baseline federal standards designed to ensure, among other things, that all patients nationwide have access to quality mammography services.

The MQSA and its implementing regulations require that mammography facilities are inspected, accredited, and certified, staff are properly trained, and that mammography reports are shared with health care providers and summarized for the patient.

In 2023, FDA issued a Final Rule updating the MQSA regulations for mammography facilities (effective September 2024). These changes require facilities to:

- **Inform patients about their breast density** - Facilities must provide each patient with a written summary containing information about their breast density. The regulations require the information to be provided within specific time frames but would allow for that information to be provided to the patient at the time of the exam or may be mailed or provided by electronic means.

The FDA's role: requirements under the MQSA Final Rule (cont.)

- **Provide uniform categories for breast density for health care providers** - For the report to the health care provider, the updates provide four categories that must be used to categorize breast density, and seven categories for the overall assessment of the mammography images.

The amended regulations also strengthen FDA oversight by providing FDA with additional tools to monitor and enforce compliance at mammography facilities.

The breast density notification requirements are some of the most significant changes under the MQSA Final Rule. This federal requirement helps ensure that breast cancer screening results are communicated consistently and clearly to both patients and their health care providers.

Here is what the amended mammography rules mean:

Mammography reports for health care providers:

- **Clear results in simple categories:** The report will classify the patient's mammogram results using one of seven categories, such as negative, benign, or suspicious.
- **Breast density:** The report will tell your health care provider which of these four breast density categories you fall into:
 - "The breasts are almost entirely fatty."
 - "There are scattered areas of fibroglandular density."

- "The breasts are heterogeneously dense, which may obscure small masses."
- "The breasts are extremely dense, which lowers the sensitivity of mammography."

Patient lay summaries

After your mammogram, you'll receive a letter that explains your results in plain language. This letter will now include important information about your breast density.

What should you do if you have dense breasts?

If the summary of your mammogram report says you have dense breasts, discuss your questions and concerns with your health care provider, including if you need to consider any next steps.

The bottom line

Mammograms remain a critical part of early detection of breast cancer. With the added information about breast density provided under the MQSA Final Rule, women have even more tools to manage their breast health.

Understanding breast density is an important step. Talk with your health care provider, ask questions, and work together to make informed breast health decisions.

This information was developed by the **FDA Office of Women's Health**. It is for educational purposes, not all inclusive and should not be used in place of talking with your health care provider.

To learn more, go to: www.fda.gov/womens

