

13 Sep 2024 | News

# Mammograms Should Inform Women About Breast Density, FDA Says

by [Brian Bossetta](#)

The US FDA now requires mammograms include information about breast density, a significant factor that raises breast cancer risk and can hide tumors.

The US Food and Drug Administration is now mandating that providers inform patients about their breast density on mammogram reports and any additional screenings they might need.

The FDA issued a [final rule](#) amending the Mammography Quality Standards Act (MQSA) to include the new requirement in March 2023. The new regulations took effect on 10 September.

Breast density, according to the American Cancer Society, is a measure of how much fibrous and glandular tissue is in the breast compared to fat tissue. It is not related to breast size or firmness. And because dense tissue appears as the same white color on mammograms as cancer, tumors are often missed putting women with dense breasts at higher risk.

But aside from masking tumors, density is also an intrinsic risk. A woman with dense breasts has the same level of risk for developing breast cancer as a woman who had a relative with the disease, according to the Mayo Clinic.

---

*“This is a great first step toward saving many lives.” – Rosa DeLauro*

---

As the Mayo Clinic points out, density is common and on its own does not necessarily indicate a problem. But it is essential that women know whether they have dense tissue due to the elevated risk it can pose. The Mayo Clinic describes four categories of density, ranging from “all fatty tissue to extremely dense tissue with very little fat.”

Marissa Fayer, CEO of DeepLook Medical as well as HERhealthEQ, told *Medtech Insight* the new requirement is “great news” for women. She added, however, that insurance plans need to cover whatever additional testing is needed for women with dense tissue.

“Screening alone with a mammogram isn't enough for women with dense breasts, and ultrasound and MRI screening is needed for best visualization in dense breasts, or AI solutions that can visualize in dense tissue,” Fayer said. “So, this dense breast notification is a great step, but it's not the last step required for equitable, accessible, and superior imaging for women with dense breasts.”

More than half of women in the US older than 40 have dense breasts, according to the FDA.

In May, the US Preventive Services Task Force (USPTF) issued new screening guidelines that lowered the starting age for breast cancer screenings from 50 to 40. (Also see "[New Guidance For Breast Cancer Screening Drops Age Of First Scan To 40](#)" - Medtech Insight, 1 May, 2024.)

The Mayo Clinic says women with dense breasts — even those receiving a “normal report” — should know how their breasts normally look and feel and notify their providers of any changes.

As Fayer noted, additional testing for women with density, such as MRIs, ultrasounds, contrast-enhanced mammograms, and molecular breast imaging, can improve the chances of finding tumors missed in routine screenings.

Congresswoman Rosa DeLauro, D-CT, who issued a statement on the FDA's new screening regulations, noted 99% of women who receive an early breast cancer diagnosis survive.

“Early detection is key,” DeLauro said. “Women will be notified of whether they have dense breasts and the additional screenings that may be required to detect breast cancer. This is a great first step toward saving many lives.”

But like Fayer, DeLauro said more needed to be done, including passing the “[Find It Early Act](#),” which DeLauro introduced in the House with her colleague Brian Fitzpatrick, R-PA. The legislation provides health coverage with no cost-sharing “for additional breast screenings for certain individuals at greater risk for breast cancer.”