Mammography: What You Need to Know

The FDA is proposing updates to mammography regulations to reflect advances in technology and processes. How could these changes affect you?

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Mammograms continue to be the best primary tool for breast cancer screening. The U.S. Food and Drug Administration (FDA), along with some FDA-approved state agencies, certify facilities to perform mammography; and the FDA clears and approves new mammography devices for sale in the U.S.

Congress enacted the Mammography Quality Standards Act (MQSA) in 1992 to ensure all women have access to quality mammography for the detection of breast cancer in its early, most treatable stages. Always look for the MQSA certificate at the mammography facility, which is required to be displayed, and indicates that the facility met the national baseline standards for mammography.

To continue to protect women's health, the FDA is proposing updates to the mammography regulations to reflect advances in mammography technology and processes since the current regulations were published.

How Does a Mammogram Work?

A mammogram is a series of low-dose X-ray pictures of the breasts. Getting a regular mammogram is the best way to find breast cancer early, because it can show growths in the breast or other signs of breast cancer when they are too small for you or your health care provider to feel them.

Thermograms and nipple aspirate tests are not substitutes for mammograms. Regular screenings are important, and the risk of breast cancers varies from person to person, so it's a good idea to ask your health care provider when and how often you should schedule a mammogram.

To get a mammogram, you will need to take off your shirt and bra. While standing in front of the machine, a technologist will position your breast on a small platform. A clear plastic plate will press down on your breast while the mammogram is acquired. This compression of the breast helps spread out the breast tissue so it doesn't overlap, allowing for a clearer look at the breast tissue.

If you're worried about how the procedure feels, you should know that most women do not find it painful. Some women may find the pressure on the breast uncomfortable, but it lasts for only a few seconds.

FDA regulations already require that facilities provide patients a summary, in easy-to-understand language, of their mammography results within 30 days after the mammogram, and that they make reasonable attempts to communicate the results as soon as possible if indications of potential cancer are found.

Under the proposed rule, facilities would also have to provide you with information about whether your breast density is low or high. Dense breasts have a higher proportion of fibroglandular tissue compared to fatty tissue. This is important, because dense breast tissue can make cancers more difficult to find on a mammogram, and is also now known to be an independent risk factor for developing breast cancer.

In addition, facilities would be required to advise you to talk to your health care provider about breast density, risks for breast cancer, and your individual situation. The idea is to provide information you can discuss with your provider in order to make better informed decisions, including if you need to take any next steps.

If you do not receive your mammography summary, call the provider who sent you for the mammogram to get your results, and contact the facility where you had the mammogram performed to get the letter resent to you.

As a rule, you should also call your health care provider if you notice any change in either of your breasts. A lump, thickening or nipple leakage, or changes in how the nipple or skin looks can signal a potential problem.

Why Is Facility Certification Important?

Under the MQSA, mammography facilities must be certified by FDA, or an FDA-approved state certifying agency, in order to provide mammography services. Certification is important because it indicates that a facility has met the MQSA requirements for practicing quality mammography. A high-quality mammogram can help detect breast cancer in its earliest, most treatable stages.

Each mammography facility is inspected every year. During the inspection, an FDA- trained inspector checks the facility's equipment, staff training qualifications, and quality control records. Each facility also undergoes an in-depth accreditation process every three years in order to be eligible for an MQSA certificate.

The certificate, which is required to be prominently displayed, shows that the facility has met the MQSA quality standards and may legally perform mammography. When you arrive for your mammogram, look for the certificate and if you don't see it ask where the certificate is in the facility.

What Is the Difference Between 3D and 2D Mammograms?

New breast imaging equipment must receive FDA approval or clearance before being sold in the U.S. In recent years, FDA has approved advanced mammography devices that create cross-sectional (3D) images of the breast from X-rays taken from multiple angles. These devices provide informative images of the breast tissue, and are particularly helpful in evaluating dense breast tissue.

Before granting approval, FDA determined there was a reasonable assurance that the new 3D devices were safe and effective for their intended use. This determination was based on a review of clinical studies involving multiple radiologists and hundreds of cases. FDA also sought input on the safety and effectiveness of the devices from a panel of non-FDA clinical and technical experts.

Ask your doctor if 3D mammography or additional imaging methods, such as ultrasound or Magnetic Resonance Imaging (MRI), are good options for you.

Where Is the Closest Certified Facility?

There are about 8,700 certified facilities across the country. To find a certified mammography facility in your area, you can search the list on the FDA's website by your zip code. The list is updated weekly.

How Will the Proposed Changes Help You?

Proposed amendments would:

- Better inform you and your health care provider about your mammography results by providing specific information on breast density, an important risk factor for breast cancer;
- Strengthen FDA's ability to suspend or revoke the certificates of facilities that are noncompliant with the regulations; and
- Require facilities to provide mammography personnel access to their own records of MQSA-qualifying training and experience upon their reasonable request, so they may continue to provide mammography services.

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