# Required Language for Mammography Patient Lay Summaries

# Background

The <u>Code of Virginia § 32.1-229</u> has required letters be sent to patients identified to have dense breast tissue since July 1, 2013. Specific language included in § 32.1-229, and found below, must be included in letters to patients identified to have dense breast tissue.

On March 10, 2023, the U.S. Food and Drug Administration (FDA) amended the <u>Mammography</u> <u>Quality Standards Act (MQSA) regulations</u> to include breast density notification requirements. Facilities subject to the MQSA must comply with the new requirements by September 10, 2024, and include the specific language below in patient lay summaries for those identified as having dense or not dense breast tissue.

The following language must be included in patient correspondence according to federal and state laws and regulations. Both sets of language must be included, depending on whether or not the patient's breast tissue is dense or not dense.

### Federal Requirements

Mammography Quality Standards Act (MQSA); Effective September 10, 2024

#### Non-Dense breast tissue:

Breast tissue can be either dense or not dense. Dense tissue makes it harder to find breast cancer on a mammogram and also raises the risk of developing breast cancer. Your breast tissue is not dense. Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation.

#### Dense breast tissue:

Breast tissue can be either dense or not dense. Dense tissue makes it harder to find breast cancer on a mammogram and also raises the risk of developing breast cancer. Your breast tissue is dense. In some people with dense tissue, other imaging tests in addition to a mammography may help find cancers. Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation.

# Commonwealth of Virginia Requirements:

Code of Virginia § 32.1-229; Effective July 1, 2013

### Non-Dense breast tissue:

No Commonwealth of Virginia requirement.

### Dense breast tissue:

Your mammogram demonstrates that you have dense breast tissue. 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 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 mammography results has been sent to your referring physician's office, and you should contact your physician if you have any questions or concerns about this report.