



Information Bulletin 2023-02

October 12, 2023

To: Mammography Facility Registrants

From: David M. Howe, Program Director
Radiation Protection Services

Subject: Pending Mandatory Dense Breast Tissue Notification Language

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New Mandatory Dense Breast Notification

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Low Dense Breast Notification language

The lay summary must include the statement verbatim, *"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 language

The lay summary must include the statement verbatim, *"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 mammogram may help find cancers. Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation."*

Effective immediately, RPS is granting accredited mammography facilities the option to use existing OAR 333-106-0735 dense breast notification language **or** to utilize the above new FDA dense breast notifications because they also adhere to SB 420 statutory language elements. There is no need to request an exemption. **After September 10, 2024, all healthcare facilities offering mammography services will be required to use the above FDA dense breast notification language.**

The FDA breast density language is only one part of the new MQSA amendments. The MQSA amendments can be located at the link below:

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From: David M. Howe, Program Director
Radiation Protection Services

Subject: Pending Mandatory Dense Breast Tissue Notification Language

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The lay summary must include the statement verbatim, *"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*

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Dense Breast language

The lay summary must include the statement verbatim, *"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 mammogram may help find cancers. Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation."*

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The lay summary must include the statement verbatim, *"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 mammogram may help find cancers. Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation."*

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From: David M. Howe, Program Director
Radiation Protection Services

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From: David M. Howe, Program Director
Radiation Protection Services

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Subject: Pending Mandatory Dense Breast Tissue Notification Language

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The lay summary must include the statement verbatim, *"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*

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Dense Breast language

The lay summary must include the statement verbatim, *"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 mammogram may help find cancers. Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation."*

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From: David M. Howe, Program Director
Radiation Protection Services

Subject: Pending Mandatory Dense Breast Tissue Notification Language

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The lay summary must include the statement verbatim, *"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*

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Dense Breast language

The lay summary must include the statement verbatim, *"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 mammogram may help find cancers. Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation."*

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The lay summary must include the statement verbatim, *"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 mammogram may help find cancers. Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation."*

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From: David M. Howe, Program Director
Radiation Protection Services

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From: David M. Howe, Program Director
Radiation Protection Services

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Subject: Pending Mandatory Dense Breast Tissue Notification Language

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The lay summary must include the statement verbatim, *"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*

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Dense Breast language

The lay summary must include the statement verbatim, *"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 mammogram may help find cancers. Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation."*

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From: David M. Howe, Program Director
Radiation Protection Services

Subject: Pending Mandatory Dense Breast Tissue Notification Language

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The lay summary must include the statement verbatim, *"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*

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Dense Breast language

The lay summary must include the statement verbatim, *"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 mammogram may help find cancers. Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation."*

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The lay summary must include the statement verbatim, *"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 mammogram may help find cancers. Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation."*

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From: David M. Howe, Program Director
Radiation Protection Services

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From: David M. Howe, Program Director
Radiation Protection Services

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Subject: Pending Mandatory Dense Breast Tissue Notification Language

The State of Oregon, Oregon Health Authority, Radiation Protection Services (RPS) is issuing this information bulletin to all accredited mammography facilities regarding Mammography Quality Standards Act (MQSA) amendments to the Code of Federal Regulation 21.900 that will become effective September 10, 2024; while there are several amendments, one amendment includes dense breast tissue language that is in conflict with State of Oregon rules.

Background

During the 2013 legislative session, Oregon Senate Bill 420 established Oregon Revised Statute 431A.50 which mandates healthcare facilities offering mammography services to provide a notification in a form prescribed by the Oregon Health Authority to patients with dense breast tissue. Per Oregon Administrative Rule (OAR) 333-106-0735, specific language is required to provide the individual an explanation that dense breast tissue can make it harder to find cancer on a mammogram, including the possibility of the need for supplemental imaging based on the patient's risk factors. This information is provided within the lay person summary mammography report issued to the patient when dense breast tissue has been determined by a radiologist.

New Mandatory Dense Breast Notification

Effective September 10, 2024, RPS will incorporate, by OAR reference, a requirement for accredited mammography facilities to use new Food and Drug Administration (FDA) dense breast notification language from one of the two below italicized statements, depending upon the patients' status, including:

Low Dense Breast Notification language

The lay summary must include the statement verbatim, *"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 language

The lay summary must include the statement verbatim, *"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 mammogram may help find cancers. Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation."*

Effective immediately, RPS is granting accredited mammography facilities the option to use existing OAR 333-106-0735 dense breast notification language **or** to utilize the above new FDA dense breast notifications because they also adhere to SB 420 statutory language elements. There is no need to request an exemption. **After September 10, 2024, all healthcare facilities offering mammography services will be required to use the above FDA dense breast notification language.**

The FDA breast density language is only one part of the new MQSA amendments. The MQSA amendments can be located at the link below:

<https://www.federalregister.gov/documents/2023/03/10/2023-04550/mammography-quality-standards-act>

One can subscribe to the MQSA listserv to receive email updates as new information is posted on FDA's website: <https://www.fda.gov/radiation-emitting-products/mammography-quality-standards-act-and-program>

All questions concerning MQSA amendments should be directed to the FDA MQSA Hotline at 1-800-838-7715.

Any other questions should be directed to RPS Electronic Products Lead Worker, Brent Herring (brent.e.herring@oha.oregon.gov; 503-891-0098).



Information Bulletin 2023-02

October 12, 2023

To: Mammography Facility Registrants

From: David M. Howe, Program Director
Radiation Protection Services

Subject: Pending Mandatory Dense Breast Tissue Notification Language

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