



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**
Division of Health Service Regulation

ROY COOPER • Governor
MANDY COHEN, MD, MPH • Secretary
MARK PAYNE • Director

FREQUENTLY ASKED QUESTIONS

What to expect during inspection

What does the new breast density law require?

Beginning Jan. 1, 2014 facilities providing mammography services in N.C. should identify each patient's individual breast density classification based on the Breast Imaging Reporting and Data System established by the American College of Radiology. If the facility determines that a patient has "heterogeneously" or "extremely" dense breasts, the results letter/notification provided to the patient must include the following statements:

"Your mammogram indicates that you may have dense breast tissue. Dense breast tissue is relatively common and is found in more than forty percent (40%) of women. The presence of dense tissue may make it more difficult to detect abnormalities in the breast and may be associated with an increased risk of breast cancer. We are providing this information to raise your awareness of this important factor and to encourage you to talk with your physician about this and other breast cancer risk factors. Together, you can decide which screening options are right for you. A report of your results was sent to your physician."

The law can be found on the Radiation Protection Website

Will this new requirement be evaluated during the annual mammography inspection?

Yes, the Radiation Protection Section will confirm that facilities are meeting this new requirement during the annual mammography inspection. This will be added to the state inspection checklist for 2014 as a state requirement. The Section will continue to provide guidance, when available, on this requirement through the listserv and during the inspection.

The facility may provide the inspector one of the following to show compliance:

1. Copies of letters sent to patients with heterogeneously dense or extremely dense breast tissue that contain the statement required by the new law.
2. Templates of the notification provided to patients with "heterogeneously" dense or "extremely" dense breast tissue that contain the statement required by the new law.
3. The facility's written policy to describe how the patient with "heterogeneously" or "extremely" dense breasts are identified to allow patient notification through the letters sent to the patient.

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AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

The new law suggests directing patients to informative material about breast density. How can facilities comply with this recommendation?

You may have printed materials, such as the ACR's Breast Density Brochure available for patients who would like more information on breast density and how it impacts mammography and breast cancer risks. You may also use similar materials that are available or produced by your facility. Also links to websites could be provided on printed materials or listed on the results letter provided to the patient.

I need clarification regarding the new Dense Breast Bill verbiage to be included in the letters sent to patients identified as having dense breasts. Is this verbiage required for all BIRADS categories or just BIRADS 1 and 2?

It is not the BIRADS overall assessment category but the breast density pattern that determines when to add the breast density statement to the letter sent to the patient. Instead of "BIRADS 1 and 2" it is "breast density patterns 3 and 4" that are affected by the new law. The Chronic Disease and Injury Section of the Division of Public Health (where the statute resides) has authorized Radiation Protection (with the resources) to audit facilities. MQSA inspectors will determine if facilities are including the required verbiage in the letter sent to the patient ONLY when the exam report identifies "extremely" or "heterogeneously" dense breast patterns. While on site, we will also encourage facilities to educate patients about breast density by directing them to more information. Here is a link to the Oct. 2, 2013 notice sent out on our listserve to facilities. It outlines what we will review while on site: DenseBreastBillNotice.pdf

I see sample letters sent to patients for all BIRADS categories on the ACR website. However, I only see 2 that include the dense breast verbiage. They are: 1. Sample Lay Letter for Negative or Benign Finding(s) (to be used with BI-RADS® 1-2) and 2. Sample Lay Letter for Negative or Benign Finding(s) and Patient has Physical Findings, Signs or Symptoms (to be used with BI-RADS® 1-2) Will the ACR examples be acceptable?

No. Notice that the ACR suggested verbiage is optional AND it doesn't match the verbiage in the N.C. statute. While the letters may be acceptable, the disclaimer is not.

Our Radiologists were questioning the following scenario: A patient comes in for an annual screening and has dense breasts but is required to come back for additional imaging or intervention. Do we include the dense breast verbiage in the letter requesting that the patient come back for follow up?

We will not require that breast densities appear in EACH report. But when the radiologist identifies "extremely" or "heterogeneously" dense breasts in any report regardless of the overall final assessment, then the verbiage as stated in the N.C. statute must appear in the letter sent to the patient.

Are we required to inform the patient of all breast density types, or are we only required to inform the patient if he/she has heterogeneously dense or extremely dense breast tissue?

You have to notify each patient with "heterogeneously" or "extremely" dense breast of their breast pattern type in the letter sent to the patient. You do not have to include the BIRADS code in the letter. Here is a link to the Oct. 2, 2013 notice sent out on our listserve to facilities. It outlines what we will be looking at while on site:

DenseBreastBillNotice.pdf

Must we include the patients BIRADS code in their result letter?

No. "BIRADS code" is a technical term for the ACR overall final assessment category. It is not necessary for the BIRADS code to appear in the letter sent to the patient.

When a patient returns to our office for spot compressions on a separate day, we are required to address that visit with a second notification letter. One of our radiologists is asking how they are supposed to determine the breast density for that patient based on spot compression images only. It will have already been addressed in the first report that recommended the patient return. If he is only viewing the follow up examination, which is limited in views, how can he properly assign a breast composition to the second notification?

RPS WILL NOT review reports for the assignment of each breast density level. We will evaluate to see that any report with a breast density designation of "extremely" or "heterogeneously" dense has the same verbiage as stated in the N.C. statute in the letter sent to the patient. Here is a link to the Oct. 2, 2013 notice sent out on our listserve to facilities. It outlines what we will be looking at while on site: [DenseBreastBillNotice.pdf](#)

What about our male patients?

MQSA requires that a report be sent to all patients (male or female). When a male patient has been identified as having "heterogeneously" or "extremely" dense breasts the verbiage as stated in the NC statute must appear in the letter that is sent to the patient. We will be checking that a breast density designation of "extremely" or "heterogeneously" dense is assigned when applicable whether the patient be male or female.

Does the radiologist have to dictate a breast density on all mammograms? It is my understanding that all positives will need a breast density identified as well. Please clarify.

We are evaluating the following 3 items only for each facility inspected:

- A breast density designation of "extremely" or "heterogeneously" dense is assigned.
- Any report with a breast density designation of "extremely" or "heterogeneously" dense has the same verbiage as stated in the N.C. statute in the letter sent to the patient.
- Breast density educational material is made available to patients.

Here is a link to the Oct. 2, 2013 notice sent out on our [listserve](#) to facilities. It outlines what we will be looking at while on site: [DenseBreastBillNotice.pdf](#)

Our radiologist told us that we were required to keep up with the breast density categories (1-4). Could you elaborate on the breast density categories? The radiologist told us that 1 and 2 were not to receive the letter and 3 and 4 were to receive the dense letter. Is that correct?

Yes. The upper 2 levels of "extremely" or "heterogeneously" dense ONLY will require the disclaimer in the letter sent to the patient. You are not expected to track all 4 breast density categories. However, compliance will be difficult without a method to track at least the upper 2 density levels of "extremely" and "heterogeneously" dense.

Why have we not received communication on the NC Dense Breast Bill?

Radiation Protection has worked with Division of Public Health Chronic Disease Section to draft communication for all facilities that was sent out on the RPS listserve on Oct. 2, 2013. This will be in the upcoming newsletter for Radiology Compliance Branch in the spring. Facilities must be subscribed to our listserve to receive newsletters and any important information regarding your inspections. Please go to these links to subscribe so you will be included on all future correspondence from our agency. It is highly recommended that you are subscribed to both links.

Mammography [Mammography News Subscription](#)

X-ray [X-ray News Subscription](#)

I have a radiologist that states breast composition by percentage in his reports. How will I know when to add the dense breast verbiage to the patient letter?

The [ACR BIRADS frequently asked questions](#) determines breast patterns by composition as follows:

1. The breast is almost entirely fat (<25% glandular)
2. There are scattered fibroglandular densities (approximately 25-50% glandular)
3. The breast tissue is heterogeneously dense, which could obscure detection of small masses (approximately 51-75% glandular)
4. The breast tissue is extremely dense. This may lower the sensitivity of mammography (>75% glandular)."