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TECHNICAL BULLETIN

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TOPIC: Reporting Breast Density Information to Patients

CONTACT: John Follette, manager, Radiation Control Program

TO: Mammography Facilities and Radiation Producing Machine Registrants

This technical bulletin provides guidance to mammography facilities regarding compliance with lay summary reporting requirements in [Nevada Revised Statutes Chapter 457](#) (NRS 457) and [the new revisions to Title 21 of the Code of Federal Regulations Part 900](#) (21 CFR 900), which become effective Sept. 10, 2024.

[NRS 457.1857](#) requires mammography facilities to send reports (referred to as lay summary reports) of mammography exams to patients. The intent of the reports is to provide patients with information about their mammography results in terms that are easily understood. Since [Nevada Administrative Code Chapter 457](#) (NAC 457) adopts by reference 21 CFR 900, mammography facilities in Nevada must comply with both NRS 457 and 21 CFR 900.

The revisions to 21 CFR 900 will require mammography facilities to issue lay summary reports with breast density statements starting Sept. 10, 2024. The lay summary reports in NRS 457.1857(2) and 21 CFR 900.12(c)(2) have different wording but convey similar information. A strict application of both regulations would require mammography facilities to issue either two reports (one pursuant to NRS 457 and another pursuant to 21 CFR 900) or to combine both reports into one. Redundant reporting to convey this information is likely to confuse some patients, which will counteract the intent of the reports. After reviewing the requirements in NRS 457.1857(1), (2), and (3) and 21 CFR 900.12(c)(2) and taking into consideration the redundancy in reporting requirements, the State of Nevada Radiation Control Program (RCP) is taking the position that lay summary reports that comply with 21 CFR 900.12(c)(2) will be accepted as meeting the requirements in NRS 457.1857(2). This will make the lay summary reports less confusing for patients without reducing the effectiveness of the regulations. All lay summary reports will still need to include the wording in NRS 457.1857(1) and (3).

Starting Sept. 10, 2024, mammography facilities may comply with the lay summary reporting requirements in NRS 457 and 21 CFR 900 using one of the methods below:

- 1) Send two separate reports, one that contains the wording required by NRS 457.1857 (1), (2) and (3), and another that contains the wording in 21 CFR 900.12(c)(2); or
- 2) Send one report that contains all of the wording from both NRS 457.1857(1), (2) and (3) and 21 CFR 900.12(c)(2); or
- 3) Send one report that contains the wording in 21 CFR 900.12(c)(2) and NRS 457.1857(1) and (3) as shown below.

Lay summary reports with the following information will be accepted for compliance with both NRS 457 and 21 CFR 900:

- 1) The report shall include an overall assessment of breast density, classified in one of the following categories:
 - a) "The breasts are almost entirely fatty."
 - b) "There are scattered areas of fibroglandular density."
 - If the lay summary report uses 1a or 1b above, the lay summary must use 2a below.
 - c) "The breasts are heterogeneously dense, which may obscure small masses."
 - d) "The breasts are extremely dense, which lowers the sensitivity of mammography."
 - If the lay summary report uses 1c or 1d above, the lay summary must use 2b below.
- 2) Depending on whether the patient's breast density is dense or not dense and the statement chosen from above, the patient lay summary must include *one* of the following notification statements:
 - a) "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 health care provider about breast density, risks for breast cancer, and your individual situation.

Ten to twenty percent of all cancers can be categorized as hereditary and the clinical and financial value of identifying patients and families at risk is well documented. If you have a personal or family history of breast, ovarian, fallopian tube, peritoneal or other cancer, please consult your physician regarding genetic counseling and testing."

- b) "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.

Ten to twenty percent of all cancers can be categorized as hereditary and the clinical and financial value of identifying patients and families at risk is well documented. If you have a personal or family history of breast, ovarian, fallopian tube, peritoneal or other cancer, please consult your physician regarding genetic counseling and testing."

Questions

For updated guidance, review [the Division of Public and Behavioral Health Technical Bulletin](#) web page regularly. If you have questions or need additional information, contact the RCP by phone at (775) 687-7750 or by email at radiationcontrolprogram@health.nv.gov.



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