

**ADOPTED REGULATION OF THE  
STATE BOARD OF HEALTH**

**LCB File No. R100-13**

Effective January 1, 2014

EXPLANATION – Matter in *italics* is new; matter in brackets ~~omitted material~~ is material to be omitted.

AUTHORITY: §§1 and 2, NRS 457.065 and 457.1857.

A REGULATION relating to mammography; requiring a statement regarding breast density and certain other information to be included in a report provided to the patient; and providing other matters properly relating thereto.

**Section 1.** NAC 457.313 is hereby amended to read as follows:

457.313 *1.* The operator of a facility shall ensure that:

~~11~~ *(a)* Each mammogram has a preliminary interpretation not later than 7 working days after the mammogram is performed;

~~12~~ *(b)* For each mammogram that indicates cancerous or potentially cancerous tissue, the responsible provider of care of the patient is contacted at the time the preliminary interpretation is complete;

~~13~~ *(c)* For each mammogram that otherwise indicates the need for additional workup or evaluation which prevents the written report from being sent to the responsible provider of care of the patient within 7 working days, the responsible provider of care is contacted at the time the preliminary interpretation is complete; and

~~14~~ *(d)* Mammography records and reports comply with the provisions of 21 C.F.R. § 900.12.

2. *If a patient undergoes mammography, the owner, lessee or other person responsible for the radiation machine used to perform the mammography shall ensure that each written report provided pursuant to 42 U.S.C. § 263b(f)(1)(G)(ii)(IV) includes a statement of the category of the patient's breast density as required pursuant to NRS 457.1857 and a statement in substantially the following form:*

*Early detection of cancer is very important. Although mammography is one of the most accurate methods for early detection, not all cancers are found through mammography. Diagnosis by mammography may be limited by factors including, but not limited to, prior surgery, breast implants and breast density. Dense breast tissue is relatively common and is found in 40 percent of women. The presence of dense tissue makes it more difficult to detect cancer 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 discuss dense breast tissue and other breast cancer risk factors with your health care providers. Together, you can decide the appropriate schedule for your personal mammograms and whether any additional screenings should be considered because of your breast density or other breast cancer risk factors. Early detection of cancer is important and far outweighs any risk associated with a radiographic procedure. A report of your mammography results was sent to your physician.*

Sec. 2. This regulation becomes effective on January 1, 2014.

DIVISION OF PUBLIC AND BEHAVIORAL HEALTH

December 13, 2013

LCB File # R100-13

Information Statement per NRS 233B.066

1. A clear and concise explanation of the need for the adopted regulation.

The proposed addition to NAC Chapter 457 Cancer, specifically mammography, requires the interpreting physicians, qualified under NAC 457 and MQSA (Mammography Quality Standards Act) under 21 CFR part 900, to report the finding and relevance of dense breast tissue to the referring providers and to the patient in layman terms suggesting the possible use of other optional procedures if deemed necessary. The concern is that dense breast tissue may mask pathology not visible on a mammogram.

2. A description of how public comment was solicited, a summary of the public response and an explanation how other interested persons may obtain a copy of the summary.

Comment was solicited from the regulated community, in that each certificate holder under NAC 457 were mailed a copy of the proposed regulations, small business impact questionnaire and the notice of the public workshop.

The main county libraries were faxed the notice of the public workshop, proof of posting verification and the proposed regulations.

All interested parties on the phone list for AB 147 were e-mailed a copy of the proposed regulations, the small business impact questionnaire and the notice of the public workshop. The public workshop was held October 18, 2013 in Las Vegas and Carson City. The results of the Public Workshop held were as follows: twelve (12) people attended, three (3) people commented and one (1) letter was received.

The following comments were made:

- (1) Jennifer Whittington of Southwest Medical Associates would like to have the language that is to be on the reports to be spelled out in the regulation.

The regulation was revised with a blanket statement to be on the reports.

- (2) Lesley Pittman, representing Reno Diagnostic Centers suggested that the breast density be included in the body of the report not as a notification statement at the end. Requested additional website information to be furnished and deletion of the statement "adjusts his/her schedule for mammograms".

The statement can be on the report at the place of the facility's choosing. Website information can be utilized at the option of the facility. The language "adjusts his/her schedule for mammograms" has been dropped.

(3) Elisa Cafferata from Planned Parenthood forwarded her comments by email but attended the public workshop to read them into the record. She commented under 4(b) (4) to add “or other factors” to the end of the sentence. Under 4(c)(1), stated the sentence would be clearer if it matched the bill language. Under 4(c)(3) it should be considered to modify the statement that it is not necessary to distinguish between screening and diagnostic mammograms. It was also stated that she liked the idea of adding the additional information in that optional diagnostic tools are not the typical recommendation.

The regulation has been revised.

(4) James Ohrenschall, Nevada State Assemblyman, expressed concern regarding optional investigational tools such as ultrasound and MRI are only adjunct and are not primary for diagnosis under Subsection (3)(c) (4); second concern in Subsection (3)(d) (4) Impinge on medical judgment or the patient physician relationship or imply or compel the ordering of additional testing and modalities.

The regulation has been revised.

(5) Nancy Cappello, Executive Director & Founder, Are You Dense Advocacy, Inc. commented that much of the verbiage impinged on medical judgment or the patient physician relationship and also expressed concern with the definition of risk.

The regulation has been revised.

(6) Stacy Woodbury and David Hald, Nevada State Medical Association expressed concern that Paragraph 2 of Section 1 contained confusing terminology and language that was not supported by scientific or empirical data.

The regulation has been revised.

3. The number of persons who: 1) attended the hearing twenty-nine (29); 2) testified at each hearing three (3); and 3) submitted to the agency written statements five (5).

4. If provided, the name, telephone number, business address, business telephone number, electronic e-mail address and name of entity represented for individuals described above.

Name	Representing	Telephone	Location
Mary Ann Braun	Polst Coalition	982-7046	Carson
Cindy Ulch	NDPBH-EHS	775-623-6591	Carson
Karen Beckley	NDPBH-RCP	775-687-7540	Carson
Nicki Hoker	CCHHS	775-887-2190	Carson
Adrian Howe	NDPBH-RCP	775-687-7531	Carson
Erin Seward	NDPBH-EMS	684-4117	Carson
Steve Tafayg	NDPBH-EMS	233-3064	Carson
Jessica Ttlen	NDPBH-OPHIE	775-687-7559	Carson

Joe Pollock	DPBH_EHS	775-687-7537	Carson
Deborah Aguino	NDPBH-BCFCW-MCH	775-684-3479	Carson
Joanna Jacet	Ferrari Public Affairs	775-351-8978	Carson
Christi Meeks	DPBH CFCW	775-684-8914	Carson
Jo Malay	DPBH-RCHS	775-687-5162	Carson
	Reno Diagnostic		
Lesley Pittman	Centers	702-524-5054	Carson
Chad Westom	DPBH-HSPR	684-4155	Carson
Ryan Arnold	Kids Quest	702-261-5888	LV
Traci Peterson	Kids Quest	763-383-6193	LV
Lorrie Mendoz	Southwest Medical	702-877-5176	LV
Jennifer Whittingham	SMA	702-877-5176	LV
Victoria Taylor	CCL	702-877-8390	LV
Latish Brown	CCL	484-0514	LV
Stacy Woodbury	NV State Medical Assn	775-825-6788	LV
Ed Sweeten	LV RCP	702-486-5281	LV
Nutia Davis	LV RCP	702-486-5280	LV
Kyle Devine	DPBH	775-684-1062	LV
Donn McCafferty	DPBH	702-486-6515	LV
Kiph R. Shah	Board Member	702-606-0065	LV
Williams	Fernemore Craig	722-692-8039	LV
Lisa Torgerson	CCL	486-0575	LV

5. A description of how comment was solicited from affected businesses, a summary of their response, and an explanation how other interested persons may obtain a copy of the summary.

The Small Business Impact statement along with a copy of the proposed regulation changes was sent to all holders of certificates of authorization to operate a mammography machine under NAC 457. Postings were sent to all main libraries for posting of the workshops to be held in Las Vegas and in Carson City for October 18, 2013.

There were seven (7) responses received out of the ninety-eight (98) Small Business Impact Questionnaires distributed. Out of the seven (7) responses, only three (3) were businesses that were under 150 employees.

One (1) out of the three (3) respondents stated that the regulation would have an adverse economic effect upon their business.

All three respondents stated that there would not be any beneficial effect upon their business.

Two (2) out of the three (3) respondents stated that they do not anticipate any indirect adverse effects upon their business. One (1) respondent stated that it would have an indirect adverse effect upon their business and stated that he was “thinking of closing the facility as more regulations are imposed”. Upon researching the Small Business Impact Summary

Statement noted correction from one (1) to two (2) respondents stated that they do not anticipate any indirect adverse effects upon their business.

All three respondents stated that they did not anticipate any indirect beneficial effects upon the business.

A summary of the Hearing for Amendment of Nevada Administrative Code, Chapter 457 can be obtained by contacting the Division of Public and Behavioral Health, 675 Fairview Drive, Suite 218, Carson City, NV 89701.

6. If the regulation was adopted without changing any part of the proposed regulation, a summary of the reasons for adopting the regulation without change. The statement should also explain the reasons for making any changes to the regulation as proposed.

The proposed regulation has been revised to address public comment and it meets the NRS adoption.

7. The estimated economic effect of the regulation on the business which it is to regulate and on the public. These must be stated separately, and in each case must include:
  - > Both adverse and beneficial effects; and
  - >Both immediate and long-term effects

The beneficial effects would ensure that density reporting of breasts would be standardized across the State. The regulation requires the interpreting physician of the mammogram to report the density of breast tissue to the referring provider and to the patient in layman's terms. For patients, it would increase dialogue with their medical provider and enable them to partake in an active role with their own healthcare decisions and possible use of other optional procedures if deemed necessary.

The adverse economic impact could be increased call volume into the facility regarding patient concerns.

The immediate and long term effects could be increased screening of patients with dense breast tissue.

8. The estimated cost to the agency for enforcement of the proposed regulation:

The agency cost will be the additional time added to each inspection. Mammography facilities/machines change monthly, but on the average there are 70 inspections per year. They are divided among three active FDA certified inspectors in the Radiation Control Program.

Each inspection will have additional time of a minimum of 0.5 hours to review the reports of selected random patients meeting the criteria for the regulation. Based on that amount,

<u>Inspector</u>	<u>Grade/Step</u>	<u>Hourly</u> 0.5 hr. each	<u># of Inspections</u>	<u>Added Expense</u>
Inspector A	35/5	\$25.96	12 (=6)	\$155.76
Inspector B	37/5	\$28.35	40 (=20)	\$567.00
Inspector C	35/1	\$21.82	18 (=9)	\$196.38
<b>Total estimated cost if there are no issues found: \$919.14/year</b>				

No additional staff would be required for these inspections. There would be no additional expense incurred by the Division for administrative assistant staff.

No additional fees would be necessitated, charged or incurred to the facilities as this would be incorporated into the routine annual inspection.

9. A description of any regulations of other state or government agencies which the proposed regulation overlaps or duplicates and a statement explaining why the duplication or overlapping is necessary. If the regulation overlaps or duplicates a federal regulation, name the regulatory federal agency.

This regulation does not affect other State agencies, overlap, or duplicate authority. Currently, there is no federal involvement or regulation.

10. If the regulation includes provisions which are more stringent than a federal regulation which regulates the same activity, a summary of such provisions.

At this time, there are no federal regulations concerning the reporting of dense breast tissue.

11. If the regulation provides a new fee or increases an existing fee, the total annual amount the agency expects to collect and the manner in which the money will be used.

N/A