

**PROPOSED REGULATION OF THE
STATE BOARD OF HEALTH**

LCB File No. R100-13

SECTION 1

NAC 457.313 is hereby amended to read as following:

NAC 457.313 Preliminary interpretation and reports of mammograms; standards for mammography records and reports. (NRS 457.065) The operator of a facility shall ensure that:

1. Each mammogram has a preliminary interpretation not later than 7 working days after the mammogram is performed;

2. 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;

3. 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~~

4. For Dense Breast Reporting, each patient undergoing mammography will be provided with a report pursuant to 42 U.S.C. 263(f)(1)(G)(ii)(IV) which includes, without limitation a statement of the category of the patient's breast density which is determined based on the Breast Imaging Reporting and Database System or such other guidelines as may be require by the State Board of Health by regulation, and the notice prescribed by the State Board of Health.

(a) The owner, lessee or other person responsible for the radiation machine for mammography that was used is responsible for this notice.

(b) The notice must include:

(1) A statement regarding the benefits, risks and limitations of mammograms;

(2) A description of factors that may affect the accuracy of a mammogram, including, without limitation, the density of breast tissue or the presence of breast implants;

(3) A statement that encourages the patient to discuss with his or her provider of health care the patient's specific risk factors for developing breast cancer; and

(4) A statement that encourages the patient to discuss with his or her provider of health care whether the patient should adjust his or her schedule for mammograms or consider other appropriate screening options as a result the patient's breast density.

(c) The notice pursuant to section (2) may include, without limitation:

(1) A statement regarding the prevalence of dense breast tissue, the relationship between breast density and breast cancer and the manner in which breast density may change over time;

(2) A description of the factors that affect the risk of developing breast cancer; and

- (3) A statement that emphasizes other optional investigational tools such as ultrasound and MRI are only adjunct and are not primary for diagnosis.***
- (d) Nothing in this section shall be construed to:***
- (1) Create a duty of care or other legal obligation beyond the duty to provide the notice as set forth in this section;***
 - (2) Require a notice to be provided to a patient that is inconsistent with the notice required by the provisions of 42 U.S.C. 263b or any regulations promulgated pursuant thereto; and***
 - (3) Impinge on medical judgment or the patient physician relationship or imply or compel the ordering of additional testing and modalities; such testing should be done only after a risk assessment between the physician and patient. No such testing should be done that may provide false relief to the patient.***

[4.] 5. Mammography records and reports comply with the provisions of 21 C.F.R. § 900.12.

NOTICE OF PUBLIC WORKSHOP

NOTICE IS HEREBY GIVEN, the Nevada Division of Public and Behavioral Health will hold a public workshop to consider amendments to Nevada Administrative Code (NAC) Chapter 457.

The workshop will be conducted via videoconference beginning at 10:00AM on October 18, 2013, at the following locations:

Division of Public and Behavioral Health Building D Suite 810 4220 S. Maryland Parkway Las Vegas, Nevada 89119	Division of Public and Behavioral Health Suite E 727 Fairview Drive Carson City, Nevada 89701-5629
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These workshops will be conducted in accordance with NRS 241.020, Nevada’s Open Meeting Law.

AGENDA

1. Introduction of workshop process
2. Public comment on proposed amendments to Nevada Administrative Code Chapter 457

The proposed changes will revise Chapter 457 of the Nevada Administrative Code and is being proposed in accordance with Assembly Bill 147 of the 2013 Legislative Session, which modified NRS 457.

The proposed addition/change of regulations will provide provisions for:

- Patient information on dense breast mammograms.
- Identifies what information the radiologist must provide to the patient.

Members of the public may make oral comments at this meeting. Persons wishing to submit written testimony or documentary evidence may submit the material to Karen Beckley, Radiation Control Manager, at the following address:

Division of Public and Behavioral Health
Radiation Control Program
675 Fairview Drive, Suite 218
Carson City, NV 89701-5629
FAX (775) 687-7552

Members of the public who require special accommodations or assistance at the workshops are required to notify Karen Beckley, Radiation Control Program Manager, in writing at the Division of Public and Behavioral Health, 675 Fairview Drive, Suite 218, Carson City, NV 89701-5629 or by calling (775) 775-7550 no later than October 11, 2013.

A copy of the notice and the proposed regulations are on file for inspection and/or may be copied at the following locations during normal business hours:

Division of Public and Behavioral Health
675 Fairview Drive, Suite 218
Carson City, NV 89701-5629

Division of Public and Behavioral Health
4220 S. Maryland Parkway, Bldg. D, Ste. 810
Las Vegas, NV 89119

Nevada State Library and Archives
100 Stewart Street
Carson City, NV 89701

A copy of the regulations and workshop information can also be found on-line by going to:
http://www.health.nv.gov/HCQC_HealthFacilities_WShops.htm

A copy of this notice has been posted at the following locations:

1. Division of Public and Behavioral Health, 4150 Technology Way, First Floor Lobby, Carson City
2. Nevada State Library and Archives, 100 Stewart Street, Carson City
3. Legislative Building, 401 S. Carson Street, Carson City
4. Grant Sawyer Building, 555 E. Washington Avenue, Las Vegas
5. Washoe County District Health Department, 9TH and Wells, Reno
6. Nevada Division of Public and Behavioral Health web page: <http://health.nv.gov/>

Copies may be obtained in person, by mail, or by calling (775) 687-7550.

Copies may also be obtained from any of the public libraries listed below:

Carson City Library
900 North Roop Street
Carson City, NV 89702

Churchill County Library
553 South Main Street
Fallon, NV 89406

Clark County District Library
833 Las Vegas Boulevard North
Las Vegas, NV 89101

Douglas County Library
1625 Library Lane
Minden, NV 89423

Elko County Library
720 Court Street
Elko, NV 89801

Esmeralda County Library
Corner of Crook and 4th Street
Goldfield, NV 89013-0484

Eureka Branch Library
210 South Monroe Street
Eureka, NV 89316-0283

Henderson District Public Library
280 South Water Street
Henderson, NV 89105

Humboldt County Library
85 East 5th Street
Winnemucca, NV 89445-3095

Lander County Library
625 South Broad Street
Battle Mountain, NV 89820-0141

Lincoln County Library
93 Maine Street
Pioche, NV 89043-0330

Lyon County Library
20 Nevin Way
Yerington, NV 89447-2399

Mineral County Library
110 1st Street
Hawthorne, NV 89415-1390

Pahrump Library District
701 East Street
Pahrump, NV 89041-0578

Pershing County Library
1125 Central Avenue
Lovelock, NV 89419-0781

Storey County Library
95 South R Street
Virginia City, NV 89440-0014

Tonopah Public Library
167 Central Street
Tonopah, NV 89049-0449

Washoe County Library
301 South Center Street
Reno, NV 89505-2151

White Pine County Library
950 Campton Street
Ely, NV 89301-1965

Per NRS 233B.064(2), upon adoption of any regulations, the agency, if requested to do so by an interested person, either prior to adoption or within 30 days thereafter, shall issue a concise statement of the principal reasons for and against its adoption, and incorporate therein its reason for overruling the consideration urged against its adoption.

Small Business Impact Questionnaire

The following questions pertain to how the changes in the Nevada Administrative Code 457 presented in the enclosure will affect your business. If it is determined that the proposed regulation is likely to impose a direct and significant economic burden upon a small business; or directly restrict the formation, operation or expansion of a small business; then the agency will take any or all of the following actions:

1. insofar as practicable, consult with owners and officers of affected small businesses,
2. Consider methods to reduce the impact of the proposed regulation, and
3. Prepare a small business impact statement and make copies of the statement available to the public at the workshop conducted and the public hearing held pursuant to NRS 233B.061.

Please answer each of the questions that apply and add any qualifying remarks that may help us to understand your position. **Mail, fax or email your completed form on or prior to October 15, 2013** to:

Karen Beckley
Radiation Control Program Manager
675 Fairview Drive, Suite 218
Carson City, NV 89701
(775) 687-7550
FAX (775) 687-7552
kbeckley@health.nv.gov

Your Name _____

Organization _____

Date _____

NRS 233B.0382 “Small Business defined.” “Small business” means a business conducted for profit, which employs fewer than 150 full-time or part-time employees.

1. How many employees are currently employed by your business? _____

If more than 150, you will not need to answer the rest of the questions. Please MAIL or FAX questionnaire to the above address. If less than 150, please continue with the remaining questions.

2. Will a specific regulation have an adverse economic effect upon your business? If so, please indicate the estimated dollar amount(s) you believe the adopted regulations will cost you over one calendar year with a brief explanation as to how the dollar amount was calculated.

Yes _____ No _____ Explain: Please list each regulation and explain the impact.

3. Will the regulation(s) have any beneficial effect upon your business? If so, please include any cost savings you believe the adopted regulations will save you over one calendar year with an estimated dollar amount if applicable.

Yes _____ No _____

Explain:

4. Do you anticipate any indirect adverse effects upon your business?

Yes _____ No _____

Explain:

5. Do you anticipate any indirect beneficial effects upon your business?

Yes _____ No _____

Explain: