

PROPOSED REGULATION OF THE STATE BOARD OF HEALTH

LCB File No. R100-13

NOTICE OF PUBLIC HEARING

Intent to Adopt Regulations
(LCB File No. R100-13)

NOTICE IS HEREBY GIVEN that the State Board of Health will hold a public hearing to consider an amendment to Chapter 457 of Nevada Administrative Code (NAC), Cancer, Specifically to Mammography. This public hearing is to be held in conjunction with the State Board of Health meeting on December 13, 2013. The NAC 457 regulation change will be heard in the order placed on the State Board of Health agenda.

The State Board of Health will be conducted via videoconference beginning at 9:00 a.m. on Friday, December 13, 2013 at the following locations:

Division of Public and Behavioral Health	Division of Aging and Disability Services	Division of Aging and Disability Services
4150 Technology Way	Early Intervention Services	Early Intervention Services
Room #303	3811 W Charleston #112	1020 Ruby Vista Drive, Suite 102
Carson City, NV 89706	Las Vegas, NV 89102	Elko, NV 89803

The proposed changes to NAC 457 include the following:

- Adds a new section concerning the reporting of mammographic findings for patient with dense breast tissue.
- Provides for monetary penalty for non-compliance
- Directs the Certificate holders to report dense breast findings, ramifications and possible further diagnostic procedures. .

1. Anticipated effects on the business which NAC 457 regulates:

- A. *Adverse effects*: No adverse effects have been identified.
- B. *Beneficial*: Enhanced communication between providers and patients.
- C. *Immediate*: Positive communication between providers and specialists. More informed patients, involved in directing their care.
- D. *Long-term*: Better follow of patients who may be having pathology, but not be symptomatic.

2. Anticipated effects on the public:

- A. *Adverse*: None anticipated.
- B. *Beneficial*: Anticipated benefits to patients will be advising them of the limitations of their mammography exam and options possibly available.

C. *Immediate*: Increased patient involvement. More informed patients, involved in directing their care.

D. *Long-term*: Further investigation may reveal hidden pathologies otherwise not diagnosed; thence early discovery leads to improved survival rate.

3. The estimated cost to the Division of Public and Behavioral Health for enforcement of the regulations is none. This will be incorporated into part of the usual yearly inspection process of reviewing reports. The monetary penalty section of the proposed regulations is not expected to be an issue as staff already performs this function. Compliance within the industry is good and no issues are expected.

The proposed regulations do not overlap or duplicate any other Nevada state regulations or federal regulations.

Members of the public may make oral comments at this meeting. Persons wishing to submit written testimony or documentary evidence in excess of two typed, 8-1/2" x 11" pages must submit the material to the Board's Secretary, Richard Whitley, to be received no later than December 2, 2013 at the following address:

Secretary, State Board of Health
Division of Public and Behavioral Health
4150 Technology Way, Suite 300
Carson City, NV 89706

Written comments, testimony, or documentary evidence in excess of two typed pages will not be accepted at the time of the hearing. The purpose of this requirement is to allow Board members adequate time to review the documents.

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

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

Nevada State Library
100 Stewart Street
Carson City, NV 89701

Nevada Division of Public and Behavioral Health
2080 E. Flamingo Rd. Suite # 319
Las Vegas, NV 89119

Copies may be obtained in person, by mail, or by calling the Division of Public and Behavioral Health at (775) 687-7550 in Carson City or (702) 486-5280 in Las Vegas.

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

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
1401 East Flamingo Road
Las Vegas, NV 89119

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
80 South Monroe Street
Eureka, NV 89316-0283

Henderson District Public Library
280 South Green Valley Parkway
Henderson, NV 89012

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 regulation, 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 STATEMENT 2013
PROPOSED AMENDMENTS TO NAC 457**

The Division of Public and Behavioral Health (DPBH) has determined that the proposed amendments should not impose an economic burden upon a small business or have a negative impact on the formation, operation or expansion of a small business in Nevada.

A small business is defined in Nevada Revised Statutes NRS 233B as a “business conducted for profit which employs fewer than 150 full-time or part-time employees.”

This small business impact statement complies with the requirements of NRS 233B.0609.

1) A description of the manner in which comment was solicited from affected small businesses, a summary of their response and an explanation of the manner in which other interested persons may obtain a copy of the summary.

Background

During the 2013 Legislature, Assembly Bill 147 was passed in the interest of public health. AB 147 concerns the reporting requirements for mammographic examinations which demonstrate dense breast tissue. This bill was heard in the 2013 legislative session and public input was elicited and taken into consideration by the legislators. It passed and was signed into statute by Governor Sandoval.

AB 147 in similar form has been passed in many other states as noted in the bill. As you may be aware, the concern is that dense breast tissue 'may' mask pathology not visible on the mammographic examination. This regulation addresses the need for physician interpreters qualified under the NAC 457 and MQSA (Mammography Quality Standards Act) under 21 CFR part 900 to report the finding and relevance of dense breast issue to referring providers and to the patients in a letter that the patient can understand, suggesting possible use of other exploratory options that may be utilized as deemed necessary by the provider in consultation with the patient.

Pursuant to NRS 233B.0608 (2) (a), the Division of Public and Behavioral Health has requested input from mammography facilities.

A Small Business Impact Questionnaire was sent to mammography facilities along with a copy of the proposed regulation changes, on October 2, 2013. The questions on the questionnaire were:

- 1) How many employees are currently employed by your business?
- 2) Will a specific regulation have an adverse economic effect upon your business?
- 3) Will the regulation(s) have any beneficial effect upon your business?
- 4) Do you anticipate any indirect adverse effects upon your business?
- 5) Do you anticipate any indirect beneficial effects upon your business?

Summary of Response

Summary Of Comments Received (7 responses were received out of 98 small business impact questionnaires distributed)			
Will a specific regulation have an adverse economic effect upon your business?	Will the regulation (s) have any beneficial effect upon your business?	Do you anticipate any indirect adverse effects upon your business?	Do you anticipate any indirect beneficial effects upon your business?
1-Yes 2-No	3-No	1-Yes 1-No	3-No
		Thinking of closing facility as more regulations are imposed	

Number of Respondents out 98	Adverse economic effect?	Beneficial effect?	Indirect adverse effects?	Indirect beneficial effects?
7	1	0	1	0

Any other persons interested in obtaining a copy of the summary may e-mail, call, or mail in a request to Karen Beckley at the Division of Public and Behavioral Health at:

Division of Public and Behavioral Health
 627 Fairview Drive, Suite 218
 Carson City, NV 89701
 Karen Beckley, Radiation Control Program Manager
 Phone: 775-687-7550
 Email: kbeckley1@health.nv.gov

2) The manner in which analysis was conducted.

Karen Beckley, Manager, Radiation Control Program, in consultation with Adrian Howe, Supervisor, Radiation Control Program and Ed Sweeten, Supervisor, Radiation Control Program, conducted the analysis of the impact on business. The analysis considered the questionnaire answers and comments as well as past business practices of the regulated industry. Based upon this consideration the agency is following the directive of the legislature and is relying on their expertise in limiting the impact on small business.

3) A description of the methods that DPBH considered to reduce the impact of the proposed regulation on small businesses and statement regarding whether the agency actually used those methods.

The Division of Public and Behavioral Health has held several opportunities for the public and the regulated community to provide comments regarding the proposed NAC 457 regulations, including the economic impact the proposed regulations may have. No modifications to the proposed regulations have been made as a result of this input. Workshops will be held on October 18, 2013 allowing for further input by the public, regulated community or other interested parties regarding the proposed regulations and their any impact. These comments will be taken into consideration for possible further revisions to the regulations to reduce the economic impact on facilities.

4) The estimated cost to the agency for enforcement of the proposed regulation.

At this time, there is no estimated cost to the agency for enforcement of the proposed regulation as it can be incorporated into the inspection process.

5) Total amount DPBH expects to collect from any fees and the manner in which the money will be used.

There is no additional funding attached to this regulation.

6) An explanation of why any duplicative or more stringent provisions than federal, state or local standards regulating the same activity are necessary.

At this time there are no duplicative provisions. What necessitated these regulations to be adopted was to require facilities and mammographers to ensure that the public is notified of dense breast tissue issues and what course of action for additional diagnostic evaluations may or may not be of benefit to the patient.

7) The reasons for the conclusions of the agency regarding the impact of a regulation on small businesses.

AB 147 and the proposed regulations require that an additional notification regarding dense breast tissue issues be added to a letter already required by regulation to the patient. The agency received only one comment of a negative impact on small business with no evidence offered as to the nature of the perceived impact.

I, Richard Whitley, Administrator of the Division of Public and Behavioral Health, certify to the best of my knowledge or belief that the information contained in this statement was prepared properly and is accurate.

/s/
Richard Whitley, M.S., Administrator
Division of Public and Behavioral Health
Department of Health and Human Services