

DIVISION OF PUBLIC & BEHAVIORAL HEALTH
Office of Public Health Informatics and Epidemiology
Nevada Central Cancer Registry
LCB File No. R057-16RP2

Informational Statement per NRS 233B.066

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

The main purpose of the amendment is to improve compliance with cancer reporting requirements to ensure the uniform application of standardized data definitions and codes. The proposed amendments will: 1) Re-align Nevada's regulations with updated national guidelines and recommendations, 2) improve compliance with cancer reporting requirements to avoid under-reporting, 3) ensure complete, timely, and quality production of cancer incidence data, and 4) improve data use for cancer control and prevention activities. The proposed regulations to NAC 457 include the following:

- Amend the requirement of reporting incidence of neoplasms other than cancer to the system for reporting such information established and maintained by the Chief Medical Officer.
- Expand the applicability of the reporting requirements that were previously applicable to physicians who provided treatment for cancer to, with limited exceptions, any provider of health care who diagnoses or provides treatment for cancer or other neoplasms.
- Adopt by reference the most current version of certain volumes of the Standards for Cancer Registries, the International Classification of Diseases for Oncology and the Facility Oncology Registry Data Standards (FORDS), and any subsequent revision of those publications that have been approved by the Chief Medical Officer for use in this State.
- Amend existing regulations to instead reference the neoplasms listed in one of the publications adopted by reference as the types of neoplasms which are required, with certain limited exceptions, to be reported pursuant to existing law.
- Existing regulations require health care facilities to abstract information concerning malignant neoplasms and provide that information to the Chief Medical Officer or his or her designee. (NAC 457.050) This regulation expands: (1) the scope of the information abstracted to include information on cases of cancer and other neoplasms; and (2) the applicability of the requirement to certain providers of health care and other facilities that provide screening, diagnostic or therapeutic services to patient with respect to cancer and other neoplasms.
- Establish an administrative penalty not more than \$5,000 to impose against any person who violates certain provisions which govern the abstracting of records of a health care facility relating to cancer and other neoplasms the Board requires to be reported.

- Establish the amount of and the procedures for notice and appeal about the imposition of such an administrative penalty.
 - A provider of health care who has directly referred or previously admitted a patient to a hospital, medical laboratory or other facility that provides screening, diagnostic or therapeutic services may report limited information to the Chief Medical Officer to obtain information from the hospital, medical laboratory or other facility that provides screening, diagnostic or therapeutic services to patients with respect to cancer or other neoplasms to which the patient was referred or admitted to.
 - Increase from \$32 to \$250 the fee that the Chief Medical Officer must collect from a health care facility if the Division abstracts information and expand the applicability of that fee to providers of health care and other facilities that provide screening, diagnostic or therapeutic services to patients with respect to cancer and other neoplasms.
 - Remove the \$8 fee imposed on a health care facility that abstracts information from its own records at the request of the Division.
 - Increase from \$35 to \$200 the fee that the Chief Medical Officer must collect from a medical researcher who obtains data from the registry.
2. A description of how public comment was solicited, a summary of public response, and an explanation how other interested person may obtain a copy of the summary;

The Division of Public and Behavioral Health requested input from licensed physicians and healthcare facilities and laboratories in Nevada. Input was also received from the:

- 1) Nevada Cancer Coalition-Cancer Registry Advisory Board;
- 2) Nevada Hospital Association;
- 3) Nevada Rural Hospital Association; and the
- 4) Nevada State Medical Association

Pursuant to NRS 233B.0608 a Small Business Impact Questionnaire were sent to licensed health care facilities, facilities that provide screening, diagnostic or therapeutic services, medical laboratories, and individual physicians affected by the proposed regulations, in June of 2016. These were also posted on the Division's website and sent out through the Nevada Cancer Coalition listservs.

June 9, 2016 a small business impact questionnaire and draft regulations was sent to licensed health care facilities, facilities that provide screening, diagnostic or therapeutic services, medical laboratories, and individual physicians affected by the proposed regulations. Out of 1,648 notifications, 23 responses were received back, and 22 responses had less than 150 employees. Of those, 11 reported that the change would have an adverse economic effect on their business and 7 reported an indirect adverse effect. Most of responses received from the questionnaire that

indicated an adverse economic effect upon their business were health care facilities that provide home health, adult care, nursing home, or hospice services. The Division understands that the meaning of a health care facility that is required to report as outlined under NRS 457.020 section 3 includes health care facilities that would not typically diagnose or treat cancer. The form prescribed to abstract these cases contains limited information to reduce the burden of these facilities.

July 7, 2016 workshop notices and draft regulations were sent to licensed health care facilities, facilities that provide screening, diagnostic or therapeutic services, medical laboratories, and individual physicians affected by the proposed regulations. The workshop notices and draft regulations were posted on the Division of Public and Behavioral Health's (DPBH) website and distributed through the Nevada Cancer Coalition and Nevada Hospital Association listserv. Notice was provided in accordance with the open meeting law.

July 22, 2016: A public workshop on LCB File No. R057-16 was held at the Division of Public and Behavioral Health locations in Carson City 4150 Technology Way, Suite 303 and in Las Vegas 1650 Community College Drive via videoconference. Notice was provided in accordance with the open meeting law. Mail notice was provided to all registry providers.

During workshop process public comments were received. A non-affiliated imaging company believed they should be exempt from reporting because the company does not diagnose cancers but simply interpret what is seen in the image and then forward the report to the requesting physician or facility. One hospital responded to this request that this puts additional burden on them when the case becomes one of their patients and they are then forced to track down the information. A representative of multiple groups felt that the regulations needed to be phased in over time especially in light of the dollar amount of the fine. There appeared to be some confusion on just how much the fine would be. They also expressed a want to work with their software vendors to help technically with the collection and delivery of the data. Small practices expressed how burdensome cancer reporting would be because they do not have the extra staff or technical expertise they felt this would require reporting cases as well as detract from helping patients. They went as far as to infer that this could potentially drive small practices out of business. They felt the State should provide dollars and or technical support to help them implement any changes. The term "burden" was echoed by other commenters especially considering what federal reporting requirements have been implemented in recent years. Several suggestions were made to clarify language in the proposed regulation draft. Finally, there was concern about sharing personal information about their patients, especially social security numbers as well as raised issue as to whether we had the authority to fine physicians.

September 9, 2016: During the Board of Health meeting the proposed regulation changes did not pass.

Public comment included concerns about the burden and financial impact of cancer reporting and it was suggested to make additional changes to the regulation draft and hold another workshop. Written comments received identified that providers needed clarification on the reporting requirement and fines. The registry responded to all written comments.

December 2016 through December 2017: Work group meetings were held with representative of medical associations and medical facilities, as well as providers of healthcare to make additional changes to the proposed regulations.

January 4, 2018 workshop notices and draft regulations were sent to licensed health care facilities, facilities that provide screening, diagnostic or therapeutic services, medical laboratories, and individual physicians affected by the proposed regulations. The workshop notices and draft regulations were posted on the Division of Public and Behavioral Health's (DPBH) website and distributed through the Nevada Cancer Coalition and Nevada Hospital Association list serv. Notice was provided in accordance with the open meeting law.

January 19, 2018: A public workshop on LCB File No. R057-16RP2 was held at the Division of Public and Behavioral Health locations in Carson City 4150 Technology Way, Suite 303 and in Las Vegas 6161 West Charleston Blvd. via videoconference. Notice was provided in accordance with the open meeting law. Mail notice was provided to all registry providers.

During the workshop process public comments were received. A small language change was requested, and the modification was included in the draft send to LCB. Public comments included appreciation of holding work group meetings and additional changes to the proposed regulations. No opposition to the proposed regulation changes was made.

A summary of the Hearing for Amendment of Nevada Administrative Code, Chapter 457 can be obtained by contacting the Nevada Central Cancer Registry, 4126 Technology Way, Suite 200, Carson City, NV 89701. Phone: 775-684-3221.

3. A statement indicating the number of persons who attended each meeting or workshop, testified at each hearing, and submitted written statements regarding the proposed regulation. This statement should include for each person identified pursuant to this section that testified at each hearing and/or submitted written statements regarding the proposed regulation, the following information, if provided to the agency conducting the hearing or workshop:
 - (a) Name
 - (b) Telephone Number
 - (c) Business Address

- (d) Business telephone number
- (e) Electronic mail address; and
- (f) Name of entity or organization represented

July 22, 2016 Public Workshop: Thirteen members of the public signed in at the workshop locations.

Two people testified in support of the proposed regulations:

Holly Kulhawick	Renown Regional Medical Center	775-982-4100
Ginger Fidel	Summerlin Hospital	702-233-7000

Seven people testified in opposition of the proposed regulations:

Ronald Milbank	Reno Diagnostic Center	775-323-5083
Joanna Jacob	Ferrari Public Affairs	775-351-8978
Catherine O'Mara	Nevada State Medical Association	775-825-6788
Becky Bailey	Nevada Rural Hospital Partners	775-827-4770
Diane Sheridan MD	Dermatologist	775-782-0700
Margaret Hendrickson	Couture Dermatology and Plastic Surgery	702-919-6144
John Ellerton MD	Medical Oncologist	702-724-8787

September 9, 2016 Board of Health: Twenty-eight people were noted on the sign in sheet as having attended the September 2016 Board of Health. Of note, some of those individuals may have been at the hearing for other items being heard at the same hearing.

One person testified in support of the proposed regulations:

Cari Harrington	Nevada Cancer Coalition	775-737-9720
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Seven people testified in opposition of the proposed regulations:

Lesley Pittman	Reno Diagnostic Center	775-323-5084
Joanna Jacob	Comprehensive Cancer Centers	775-351-8978
Catherine O'Mara	Nevada State Medical Association	775-825-6788
Blayne Osborn	Nevada Rural Hospital Partners	775-827-4770
Diane Sheridan MD	Dermatologist	775-782-0700
John Ellerton MD	Medical Oncologist	702-724-8787
Sally Johnson	Nathan Adelson Hospice	702-860-6658

Seven people wrote in opposition of the proposed regulations:

Jane Johnson RN	Skin Cancer and Dermatology Institute	775-336-3669
Ronald Milbank	Reno Diagnostic Center	775-323-5083
Reuel Aspacio MD	Summerlin Dermatology	702-243-4501
Douglas Fife MD	Las Vegas Dermatological Society	702-858-4298
Mark Turner MD	Gynecologic Oncology	702-438-4694
Catherine O'Mara	Nevada State Medical Association	775-825-6788

January 19, 2018 Public Workshop: Fourteen members of the public signed in at the workshop locations.

Three people testified in support of the proposed regulations:

Catherine O'Mara	Nevada State Medical Association	775-825-6788
Sam McMullin	Comprehensive Cancer Center	775-848-0332
Leslie Pitman	Reno Diagnostic Centers	775-323-5084

No one testified in opposition of the proposed regulations.

March 9, 2018 Board of Health: Sixteen people were noted on the sign in sheet as having attended the March 2018 Board of Health. Of note, some of those individuals may have been at the hearing for other items being heard at the same hearing.

Three people testified in support of the proposed regulations:

Joseph Iser MD	Clark Co Health District	702-759-1201
Cari Harrington	Nevada Cancer Coalition	775-737-9720
Catherine O'Mara	Nevada State Medical Association	775-825-6788

Letters supporting the proposed regulations were received from the Nevada Cancer Coalition and Heath Foundation.

One person testified in opposition:

John Ellerton MD	Nevada State Medical Association	702-724-8787
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4. A description of how comment was solicited (i.e., notices) from affected businesses, a summary of their response, and an explanation how other interested persons may obtain a copy of the summary.

A small business impact questionnaire and draft regulations were sent to licensed health care facilities, facilities that provide screening, diagnostic or therapeutic services, medical laboratories, and individual physicians affected by the proposed regulations. Out of 1,648 notifications, 23 responses were received back, and 22 responses had less than 150 employees. Of those, 11 reported that the change would have an adverse economic effect on their business and 7 reported an indirect adverse effect. Most of responses received from the questionnaire that indicated an adverse economic effect upon their business were health care facilities that provide home health, adult care, nursing home, or hospice services. The Division understands that the meaning of a health care facility that is required to report as outlined under NRS 457.020 section 3 includes health care facilities that would not typically diagnose or treat cancer. The form prescribed to report cancer information for these facilities contains limited information to reduce the burden of reporting.

Summary of Response

Summary Of Comments Received (23 responses were received out of 1,648 small business impact questionnaires distributed to valid addresses, 22 had less than 150 employees)			
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?
Yes=11	Yes=0	Yes=7	Yes=0
No=7 No Response=4	No=16 No Response=6	No=9 No Response=6	No=16 No Response=6

Number of Respondents out of 1,648 mailings	Adverse economic effect?	Beneficial effect?	Indirect adverse effects?	Indirect beneficial effects?
23	11	0	7	0

A copy of the summary can be obtained by contacting the Nevada Central Cancer Registry, 4126 Technology Way, Suite 200, Carson City, NV 89701. Phone: 775-684-3221.

5. If, after consideration of public comment, 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 Board of Health had no proposed changes to R057-RP2 thus the proposed regulations were adopted by the Board of Health without any changes.

6. 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:
 - (a) Both adverse and beneficial effects; and
 - (b) Both immediate and long-term effects.

Adverse effects: Health care facilities are subject to an administrative penalty for non-reporting to the registry system as per NRS 457.250. Before this penalty may be imposed, the Division may amend or extend the deadline for corrective action to avoid the penalty. There was concern expressed that cancer reporting will place a financial burden on reporting entities. The registry has several different electronic reporting options available depending on the size and caseload of the provider office or healthcare facility. The registry will work with any reporting entity and electronic medical record vendor to find the best and most cost-efficient way to report cancer information. The proposed regulations do not require businesses to hire a certified tumor registrar to abstract cancer information if they don't want to. Simple one-page paper reporting forms and instructions for the various reporting entities are available for medical staff to complete if electronic reporting is not feasible.

Beneficial effects: The beneficial effects of these changes include overall improvement in protecting the public of a notifiable condition by improved reporting and treatment policies, case identification and reduce the potential exposure to diseases for business, agencies, and the community. These proposed regulations will re-align Nevada's regulations with updated national guidelines and recommendations. Cancer has been under-reported in Nevada for many years, national standards have not been met and a true picture of the cancer burden in Nevada cannot be presented. These changes will ensure complete, timely, and quality production of cancer incidence data to assess and monitor the cancer burden in Nevada and increase patient and public safety. For reporting entities who registered their intent for the Meaningful Use cancer reporting objective, the registry can provide technical support, so the reporting entity can receive Center for Medicare and Medicaid Services incentives. Patients often need information on their cancer case, but their medical provider no longer has the medical record available. Since the registry is a repository of cancer information over time this provides an important resource to the public to obtain a summary of their cancer record.

Immediate effects: As soon as the proposed regulations become effective reporting entities would be able to immediately implement the changes in the proposed regulations. The Division plans to roll out a phased approach to implement the regulations to reduce the burden on reporting entities.

Long term effects: The proposed regulations will provide Nevada with missing cancer data to present a true picture of the cancer burden and cancer trends in our population. As a result, this enables public health professionals, researchers, the medical community, and policy makers to understand and address the cancer burden more effectively and provides a data-driven foundation to improve cancer control and prevention activities in Nevada. Complete cancer data will include Nevada in national statistics and research activities and can provide new federal funding opportunities.

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

The estimated cost to the Division of Public and Behavioral Health for enforcement of the proposed regulations is estimated to be \$0. Currently it is expected that the provisions of these regulations would be incorporated into current processes utilizing existing staff therefore no cost (\$0) to the agency for enforcement is anticipated.

8. 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 regulating federal agency.

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

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

The proposed regulations are not more stringent than federal regulations.

10. If the regulation establishes a new fee or increases an existing fee, a statement indicating the total annual amount the agency expects to collect and the way the money will be used.

The proposed regulation change will:

- Remove the \$8 fee imposed on a health care facility that abstracts information from its own records at the request of the Division.
- Establish an administrative penalty not more than \$5,000 to impose against any person who violates certain provisions which govern the abstracting of records of a health care facility

relating to cancer and other neoplasms the Board requires to be reported. The Division does not anticipate collecting any penalties.

- Increase from \$32 to \$250 the fee that the Chief Medical Officer must collect from a health care facility from whose records regarding cases of neoplasms the Division abstracts information and expand the applicability of that fee to providers of health care and other facilities that provide screening, diagnostic or therapeutic services to patients with respect to cancer and other neoplasms. If a provider chooses to have Division program staff abstract cancer information, the fee would go to hiring contract staff and travel/lodging expenses.

The annual revenue is too hard to predict since no facilities have requested that the Division abstract cancer information in the last five-year period.

- Increase from \$35 to \$200 the fee that the Chief Medical Officer must collect from a medical researcher who obtains data from the registry. The increased fee would supplement program funds received from Center of Disease Control-National Program of Cancer Registries.

An exact amount is difficult to determine due to the lack of requests received over the previous five -year period.