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SMALL BUSINESS IMPACT STATEMENT

PROPOSED AMENDMENTS TO NEVADA ADMINISTRATIVE CODE CHAPTER 652

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

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

This small business impact statement is made pursuant to NRS 233B.0608 (3) and complies with the requirements of NRS 233B.0609. As required by NRS 233B.0608(3), this statement identifies the methods used by the agency in determining the impact of the proposed regulation on a small business in sections 1, 2, 3, and 4 below and provides the reasons for the conclusions of the agency in section 8 below followed by the certification by the person responsible for the agency.

Background

The following are the regulation changes that were solicited and a brief description of each:

Existing law: (1) requires the State Board of Health to adopt regulations carrying out provisions governing the requirements for an application for a license to operate a medical laboratory; and (2) authorizes the Board to adopt regulations for the certification and licensure of laboratory directors and certain laboratory personnel. (NRS 652.090. 652.130)

Existing law also exempts certain laboratories operated by licensed physicians from requirements governing medical laboratories if those exempt laboratories register with the Division of Public and Behavioral Health of the Department of Health and Human Services and comply with certain other requirements. (NRS 652.072)

Existing regulations require a licensed laboratory that wishes to collect specimens or perform tests, or both, at a location other than the location set forth in its license to obtain a permit from DPBH. (Nevada Administrative Code Ch. 652.195)

Sections 1-6, 13 and 17-19 of this regulation remove the requirement that an application for the issuance or renewal of such a certificate, license, registration, or permit be submitted on a form provided by DPBH and instead require such an application to be made in the form prescribed by DPBH.

Section 15 of this regulation similarly replaces references to a form for the renewal of certification as laboratory personnel with references to an application for the renewal of such certification. Section 15 accordingly replaces a requirement that DPBH provide that form to the holder of such certification not less than 90 days before the expiration of the certificate with a requirement that DPBH notify the holder of the impending expiration of the certificate. Existing law requires that regulations adopted by the Board that require the directors of laboratories that perform only certain tests to be licensed physicians must

include licensed optometrists among such physicians. (NRS 652.130, as amended by section 29 of Assembly Bill 432, chapter 230, Statutes of Nevada 2023, at page 1462)

Section 9 of this regulation provides that a licensed optometrist may serve as the director of a laboratory that performs only such tests or provider-performed microscopy procedures.

Sections 10, 11 and 16 of this regulation revise the qualifications for certification as a histotechnologist, a histologic technician, and a technologist, respectively, in a manner that expands the persons eligible for such certification. Section 12 of this regulation corrects a typographical error. Existing regulations generally require the technical personnel of a laboratory to be certified by DPBH. However, existing regulations authorize a laboratory to temporarily employ uncertified personnel for not more than 12 months while an application for certification is being processed. (NAC 652.470)

Section 13: (1) revises the length of such a period of temporary employment to not more than 6 months while the application is being processed; and (2) authorizes an additional period of temporary employment for not more than 30 days after an application has been reviewed and DPBH has requested additional information from the applicant. Section 13 also revises the date by which substantiating documents for an application for certification as laboratory personnel must be submitted.

Existing regulations generally require any technical personnel newly employed in a laboratory which only performs tests on patients of a particular physician and the partner and associates of his or her private practice to be certified as at least an office laboratory assistant. However, existing regulations authorize a person who does not hold such certification to serve as an office laboratory trainee for not more than 6 months. (NAC 652.472) Section 14 of this regulation removes such authorization, thereby requiring any person newly employed in such a laboratory to be certified as at least an office laboratory assistant. Section 14 also: (1) requires the laboratory director of such a laboratory to ensure that an office laboratory assistant performing certain testing is appropriately trained and educated; and (2) requires an office laboratory assistant performing certain testing to possess the qualifications required by certain federal regulations. Section 20 of this regulation repeals a requirement that a program of training intended to prepare a person for certification be approved by DPBH. Sections 7 and 8 of this regulation make conforming changes to remove references to the repealed section. Sections 7, 8, 10 and 11 update the names of certain organizations. Sections 18 and 19 of this regulation correct certain references to sections of the Nevada Administrative Code.

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.

Pursuant to NRS 233B.0608 (2)(a), DPBH has requested input from medical laboratories that meet the definition of a small business. A Small-Business Impact Questionnaire was sent to 18,788 medical laboratory facility and personnel emails, along with a copy of the proposed regulation changes, on April 9, 2024. 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 Responses

Two (2) responses were received out of 18,788 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?
2 – no	2 - yes	2 – no	1 – no 1 – yes
Comments – none	Comments: 1. Yes. It may reduce the costs associated with the additional training of my laboratory personnel. 2. Yes. Decreased labor costs.	Comments – none	Comments: 1. Yes. With expansion of qualified individuals able to work in the lab, it will bring awareness of this job industry.

1. Describe the manner in which the analysis was conducted.

An analysis of industry input collected was conducted by the acting Medical Laboratory Services manager. The analysis involved analyzing feedback obtained from the small-business impact questionnaire and review of statutes to determine how DPBH could implement the various proposed changes to NAC Ch. 652 while at the same time not being overly burdensome. See number 4 for the methods the agency considered to reduce the impact of the proposed regulations on small businesses. This information was used to complete this small-business impact statement, including the conclusion on the impact of the proposed regulation on a small business found in number 8.

2. The estimated economic effect of the proposed regulation on the small business which it is to regulate including, without limitation, both adverse and beneficial effects and both direct and indirect effects.

Direct Economic Beneficial Effects: No known direct economic beneficial effects.

Indirect Economic Beneficial Effects: No known indirect economic beneficial effects.

Direct Economic Adverse effects: No known direct adverse economic effects.

Indirect Economic Adverse Effects: No known indirect adverse economic effects.

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

DPBH has held several opportunities for medical laboratories to provide input and comments regarding the proposed regulations, including the economic impact that the proposed regulations may have on them. Modifications to the proposed regulations have been made as a result of this input. A workshop will be held on July 12, 2024, allowing for further input by the medical laboratory community and other interested individuals regarding the proposed regulations and how they will affect medical laboratories. 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.

There will be no additional costs to the agency for enforcement of the proposed regulation changes.

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

The total annual amount DPBH expects to collect is unknown because it is based on the number and type of applications received. For example, if no applications were received, DPBH would collect no additional fees. If one initial application was received for a new laboratory which would have an optometrist as the laboratory director, it would add \$500 for the initial application and \$300 for the biennial renewal of each of the state laboratory applications received.

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

There are no other state or federal regulations addressing the same activity.

7. Provide a summary of the reasons for the conclusions of the agency regarding the impact of a regulation on small businesses.

The reasons for DPBH's conclusion on the impact of the proposed regulations and regulation changes on small businesses is based on feedback received from the industry and its analysis as outlined in number two. The proposed regulations do establish fees to be collected, therefore there will be a financial impact on small business who apply for and operate medical laboratories.

Any persons interested in obtaining a copy of the summary may e-mail, call, or mail in a request to:

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Certification by Person Responsible for the Agency

I, Cody Phinney, Administrator of the Division of Public and Behavioral Health certify to the best of my knowledge or belief, a concerted effort was made to determine the impact of the proposed regulation on small businesses and the information contained in this statement was prepared properly and is accurate.

Signature: 

Date: May 28, 2024