SMALL BUSINESS IMPACT STATEMENT 2022

Proposed Amendments to Nevada Administrative Code 652

The Division of Public and Behavioral Health (DPBH) has determined that the proposed amendments to Nevada Administrative Code (NAC) Ch. 652 contained in LCB File No. R126-21 should not have a negative impact upon a small business or restrict the formation, operation or expansion of a small business in Nevada. The only impact will be upon small businesses that choose to apply for a new license type created under the proposed regulations or choose to pay/reimburse employees for a certification created by the proposed regulations.

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 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

NAC 652.083 defines a Licensed Laboratory as laboratory that offers its services to the general medical profession. NAC 652.380 describes the qualifications for a Licensed Laboratory director to be either a pathologist certified in anatomic and clinical pathology or certified in clinical pathology or a person with an earned doctoral degree. NAC 652.488 describes the fees that are associated with a Licensed Laboratory for the initial application, for the renewal of the laboratory license and for the reinstatement of a laboratory license.

Because there is a need for laboratories to offer collection services only without performing any clinical laboratory testing by the laboratory and to provide this service to the general medical profession, the requirements for this type of collection laboratory which can be utilized by many authorized medical providers, was found to be too restrictive.

The proposed changes in regulation found in sections 1 through 3 and section 18 allow for a less restrictive laboratory director of a Licensed Laboratory for Collection Only that meets the requirement found in NAC 652.397(1) and a fee schedule for the initial, renewal and reinstatement of a laboratory license to be the same as an Exempt laboratory currently found in NAC 652.488(f). This regulatory change will provide a less restrictive pathway for patient specimen collection laboratories to provide the community needs especially for rural or underserved areas of Nevada while also providing the necessary oversight of a specimen collection business.

NAC 652.410 describes the qualifications for a General Supervisor of a Licensed Laboratory. It does not provide the qualifications for a General Supervisor of a Licensed Laboratory when the person is licensed with an area of specialty. Section 4 of the proposed changes creates a new personnel license for a General Supervisor of a Licensed Laboratory with an area of specialty. Before this change, a Clinical Laboratory Technologist with an area of specialty as described in NAC 652.478 would not have a pathway to apply for and obtain a General Supervisor of Licensed Laboratory personnel license. The proposed change can positively affect the requirement described in NAC 652.400(2), which requires a General Supervisor of a Licensed Laboratory to be on the premises of the laboratory during all hours of routine laboratory testing. A person with a specialty could provide that need in the area of personnel specialty licensure.

Section 5 of the proposed regulation changes what is required for a person who wishes to receive equivalent credit pursuant to Assembly Bill 330, towards the satisfaction of requirements for the issuance of licensure or certification pursuant to this chapter or NRS Ch. 652 for a training program for occupational, vocational, career, trade or technical education approved by the State Board of Education. The change states that the person applying for equivalent credit must provide transcripts or documents supporting the courses completed as part of the training program and a copy of the certificate issued as part of the completion of the training program.

Sections 6 and 7 of the proposed changes address the addition of a Licensed Laboratory for the Collection of Specimens and that this type of laboratory would also need to be in compliance with all of the regulations between NAC 652.010 and NAC 652.151 inclusive.

Section 7 also provides that a medical officer in the Armed Forces of the United States who is not licensed or certified pursuant to this chapter may provide clinical laboratory services in a hospital as part of a training or educational program pursuant to an agreement entered into in accordance with the provisions of NRS 449.2455. This will be beneficial for medical personnel in the Armed Forces to be able to receive training from Nevada health care facilities when it may be difficult for the Armed Forces medical personnel to provide educational certification when the personnel may have been educated overseas.

Section 8 allows for DPBH inspectors to inspect any premises to ensure compliance of NAC 652 regulations and statutes, which includes the request for documentation. This will be beneficial when inspectors are required to investigate facilities that may be collecting human specimens and/or performing laboratory testing when the facility may not be licensed as a laboratory by the State.

Section 9 addresses the need for a person with a doctoral degree in a chemical, physical or biological science who is applying for certification as a Licensed Laboratory Director to have at least one year of experience in directing or supervising a laboratory that is performing testing at the level of a technologist. There have been persons who have a doctoral degree in Chemical Hygiene who meet the educational requirement but have no experience in a laboratory that conducts human laboratory testing at a technologist level. This change will ensure that the laboratory director of a Licensed Laboratory will be more qualified to provide necessary oversight of a laboratory performing moderate and high complexity laboratory testing.

Section 10 addresses the need for a person with a doctoral degree in a chemical, physical or biological science who is applying for certification as a Registered Laboratory director to have at least one year of experience in directing or supervising a laboratory or performing laboratory testing at the level of a technologist. This change will ensure that the laboratory director of a Registered Laboratory will be more qualified to provide necessary oversight of a laboratory performing moderate- and possibly high-complexity laboratory testing.

Section 11 amends NAC 652.397 to add that the qualifications for this regulation will also include the requirements for a laboratory director of a Licensed Laboratory for Collection only. This will also include the

ability for licensed dentists to be qualified to be a director of an Exempt laboratory that performs waived laboratory testing.

Section 12 allows for a General Supervisor of a Licensed Laboratory from the main laboratory of a licensed health care facility to be the required General Supervisor of an associated stand-alone emergency department. Because of the difficulty of a health care facility with an associated stand-alone emergency department to be able to find qualified personnel for both facilities, this regulation change will relieve the health care facility from being overburdened in trying to hire personnel qualified to be General Supervisors of a Licensed laboratory for both facilities by having the General Supervisor of the main health care facility be able to oversee the daily laboratory operations of the stand-alone emergency department and require the General Supervisor to be on site of the stand-alone emergency department at least once a month.

Section 13 addresses NAC 652.410 to make more specific the level of laboratory experience required to be a Technologist and that the experience is of a clinical nature rather than an industrial or other area of laboratory testing. There are personnel who apply for and obtain a General Supervisor of a Licensed laboratory certification but their experience has been at a level that has not been performing moderate- and/or high-complexity types of tests. In addition, there have been some applicants that have not performed testing in a clinical laboratory. Their experience has been in industrial or other areas of laboratory testing that do not correlate well with the knowledge necessary to understand the requirements of performing clinical testing. This regulation change will help to alleviate any confusion as to what is required for the necessary experience for this personnel certification.

Section 14 addresses NAC 652.420 to make more specific the level of laboratory experience required to be a Technologist and that the experience is of a clinical nature rather than an industrial or other area of laboratory testing. There are personnel who seek to apply for and obtain a Clinical Laboratory Technologist laboratory certification but their experience has been at a level that has not been performing moderate- and/or high-complexity types of tests. In addition, there have been some applicants who have not performed testing in a clinical laboratory. Their experience has been in industrial or other areas of laboratory testing that do not correlate well with the knowledge necessary to understand the requirements of performing clinical testing. This regulation change will help to alleviate any confusion as to what is required for the necessary experience for this personnel certification.

Section 15 allows for Certified Nurse Assistants (CNAs) and students who are enrolled in an accredited school of professional nursing or a graduate pending the results of a licensing examination to be able to perform fingerstick glucose testing in a licensed health care facility. Each of the CNAs and nursing students wanting to perform this duty will be required to apply for and obtain a laboratory personnel license for a Point-of-Care analyst. The Nevada Board of Nursing does not allow for CNAs and nursing students to be able to perform fingerstick blood collection to perform Waived glucose testing. During the time that a CNA or nursing student would perform this function, they would be doing so under the direction of a licensed laboratory director. This will relieve Registered Nurses (RNs) from performing this necessary task and allow for this task to be performed by a CNA and a nursing student while the RN is able to focus on more complex patient needs.

Section 16 specifies that a clinical laboratory Technologist with a specialty will be required to have experience or training performing laboratory testing at the level of a Technologist and the experience will need to be in a clinical setting and not in an industrial or other type of laboratory setting.

Section 17 expands areas of experience or training to apply for and obtain a Laboratory Assistant personnel certification. There have been personnel who are seeking Laboratory Assistant certification and received their

training and/or certification from outside of the United States or by other entities within the United States. This regulation change will be beneficial to include other areas of certification.

Section 19 addresses the numbering change in NAC 652.550 in response to the change that is being made in NAC 652.320.

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), a link to access the small-business impact questionnaire and proposed regulations was emailed to laboratories licensed in Nevada and laboratory personnel licensed in Nevada as of February 16, 2022. In the email, recipients were given a link to DPBH's webpage containing links to the questionnaire and proposed regulations so recipients could provide informed feedback. 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 (4 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?**
1 - No	1 – No	1 – No	1 – No
Comments: None	Comments: None	Comments: None	Comments: None

Interested persons may obtain a copy of the regulations or the summary by calling, emailing or mailing:

Division of Public and Behavioral Health
Bureau of Health Care Quality and Compliance
Attention: Bradley Waples
4220 S Maryland Pkwy, Suite 100, Bldg A
Las Vegas, NV 89119
Phone: 775-430-0034
Email: bwaples@health.nv.gov

2) 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. Please see number 4 for the methods the agency considered to reduce the impact of the proposed regulations on small businesses. This information was then 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.

3) 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 Beneficial Effects: No known direct beneficial effects.

Indirect Beneficial Benefits: The new certification type created pursuant to sections 1 through 3 of the proposed regulations results in a reduction of the licensure fee for a Licensed Laboratory for the Collection of patient specimens, which will open a new business opportunity to those interested in providing specimen collection in rural or underserved areas of Nevada. The other sections will have no direct beneficial effect on small businesses.

Direct Adverse Effects: The associated fees that are indicated in section 15 for CNAs and nursing students affect small business that choose to pay for/reimburse employees for the certification costs.

Indirect Adverse Effect: There is no indirect adverse effects that are anticipated through the regulatory changes.

4) 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 distributed a small-business impact questionnaire to collect input and comments regarding the proposed updates and changes to NAC Ch. 652, including the economic impact the proposed regulations may have on their businesses. No modifications to the proposed regulations have been made as a result of the minimal input received. Workshops will be held to allow for further input by the community and community leaders regarding the proposed regulations and how they will impact businesses of any size. These comments will be taken into consideration for possible further revisions to the regulations to reduce the economic impact on facilities.

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

The estimated cost to the agency for the enforcement of the proposed regulations is the amount of the fees collected pursuant to Sec. 18. For example, if one initial laboratory application was received a $500 application fee would cover a two-year cycle of licensure for a Licensed Laboratory for the collection of patent specimens with a $300 biennial renewal fee to maintain these services, for a total cost of $800 to regulate and license one program over four years. After the four years, the $300 every two years will maintain the ongoing licensing costs to the state.

For personnel certification as a Point-of-Care analyst, the fee is $75, which covers a two-year cycle, and the biennial renewal fee for the personnel certification is $60. These fees will cover staff costs for processing of the certifications.

6) 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 Licensed Laboratory for the Collection of Patient Specimens is a *new* license type. During the COVID-19 pandemic, many rural areas of Nevada have been underserved because of a lack of providers to collect specimens for COVID testing. Medical Laboratory Licensing staff have received a number of inquiries from businesses interested in providing specimen collection services to such areas, however current regulations are very restrictive for this kind of business model and the proposed regulations attempt to be less restrictive while providing necessary oversight. Currently, at least four interested small businesses have called to inquire about providing this service.

The total annual amount DPBH expects to collect is unknown because it is based on the number of applications received. For example, if no applications are received, DPBH would collect nothing. The $500 fee paid for an initial license application (which is for two years) will be used to pay for the cost to the state to process (including inspection) the application for the laboratory. After the two years, the $300 biennial renewal fee will cover the cost to the state to maintain the license.

7) 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.

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

DPBH's conclusion on the impact of the proposed regulations 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 that apply for and operate a business under the Licensed Laboratory for Collection of Specimens Only, or that choose to pay for/reimburse employees for Point-of-Care Analyst certification costs.

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

Division of Public and Behavioral Health
4220 S. Maryland Pkwy., Ste. 100, Bldg. A
Las Vegas, NV 89119
Attn: Bradley Waples
Phone: 775-430-0034
Email: bwaples@health.nv.gov

Certification by Person Responsible for the Agency

I, Lisa Sherych, 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: ___06/17/2022_____