DIVISION OF PUBLIC & BEHAVIORAL HEALTH
Bureau of Health Care Quality and Compliance
Medical Laboratory Licensing
LCB File No. R126-21

Informational Statement per NRS 233B.066

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

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.

2. **A description of how public comment was solicited, a summary of public response, and an explanation how other interested persons may obtain a copy of the summary**.

   The regulation development process, including required notices, current drafts of the regulations and Small Business Impact Statements (SBIS), are available for any interested parties at the Nevada Medical Laboratories regulation development web page.

   A public workshop was held on July 11, 2022, to allow for further input by the community and community leaders regarding the proposed regulations and how they will impact businesses of any size. A notice of the workshop was posted online and at two physical locations in northern and southern Nevada and was emailed to the same lists as the small-business impact questionnaire (SBIQ) as described in #4 below. The workshop was held virtually (online and phone-in options). Results from the workshop are described in #3 below.

3. **A statement indicating the number of persons who attended each hearing, 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 and/or provided written statements at each hearing regarding the proposed regulation, the following information, if provided to the agency conducting the hearing:**

   The public workshop, which was held on July 11, 2022, to allow for further input by the community and community leaders regarding the proposed regulations and how they will impact businesses of any size, had an attendance of 30 people. There were three people who introduced themselves during the public workshop, but only one person made a comment regarding the proposed regulation changes. The other two individuals only introduced themselves with no comment toward the proposed regulation changes.

   The one person that did make a comment during the workshop, was:

   - Name: Jennifer Archer
     - Telephone number: 702-463-2373
     - Business address: 620 Shadow Lane Las Vegas, NV 89106
     - Business telephone number: 702-463-2373
     - E-mail address: jennifer.archer@uhsinc.com
     - Name of entity or organization represented: Valley Health Systems

   Jennifer Archer made the comment that, as a representative of the Valley Health System laboratory services, she was in support of section 12 of the proposed regulation changes which addresses the ability for a General Supervisor of a laboratory located in a hospital, to act as the required General Supervisor of an associated stand-alone emergency department.

   No written response were received.

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.**

   The SBIQ was sent on Feb. 16, 2022, to 18,788 email addresses associated with medical laboratory licensees in Nevada and email addresses on an opt-in email list associated with medical laboratory

regulation in Nevada. No modifications to the proposed regulations were made as a result of the minimal input received.

Summary of SBIQ 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

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.**

   There were no statements made in SBIQ responses or by any of the attendees of the Public Workshop that were not in support of the proposed regulatory changes.

6. **Anticipated effects of Chapter 652 of the Nevada Administrative Code (LCB File No. R126-21) on the business which it is to regulate and on the public.**

   Anticipated effects on businesses which it is to regulate:

   A. Adverse effects: There are no adverse economic effects from the proposed regulation changes.

   B. Beneficial effects: The beneficial effect from the estimated economic effect of the proposed changes 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.

   C. Immediate: The immediate effects of the proposed changes are several. It will allow for the growth of patient specimen collection facilities in Nevada to be able to serve the rural areas, it will allow for the training of military personnel to better serve the needs of the military, it will better define qualifications of personnel so that it the laboratory personnel qualifications are less ambiguous, it will assist hospital laboratories to provide qualified laboratory personnel for their stand-alone emergency departments without sacrificing patient care needs and provide for trained Certified Nurse Assistants (CNA's) and students attending certified nursing programs, to be able to assist in hospitals to perform necessary glucose monitoring for their patients.

D. Long-term: The long-term effects will be the same as the immediate effects of the proposed regulation changes.

Anticipated effects on the public:

A. Adverse effects: There are no anticipated adverse financial effects on the public.

B. Beneficial effects: There are no anticipated direct beneficial financial effects on the public. There are, however, non-financial benefits for the public by expanding and providing a less restrictive pathway for patient specimen collection laboratories to accommodate the community needs especially for rural or underserved areas of Nevada. It will also authorize Certified Nurse Assistants 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. This will reduce the burden of performing necessary glucose testing by Registered Nurses and provide for better healthcare for patients while the Registered Nurses focus on other needed areas of patient care.

C. Immediate: There are no known immediate beneficial or adverse financial effects on the public.

D. Long-term: There are no known long-term beneficial or adverse financial effects on the public.

7. **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 patients' 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.

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.**

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

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 regulation changes do not include provisions that are more stringent than federal regulations that regulate the same activities.

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 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.

The money will be used will be to compensate staffing salaries, provide for continuing education of personnel and fund the needed infrastructure to support a growing medical laboratory program.

NOTE: **The Informational statement is essential. If this statement is not included with the final regulations or is incomplete or inaccurate, LCB will return the regulation to the agency. Unless a statement is supplied, the LCB will not submit the regulation to the Legislative Commission, and the regulation never becomes effective (NRS 233B.0665).**