NOTICE OF PUBLIC HEARING

Intent to Adopt Regulations
LCB File No. 126-21

NOTICE IS HEREBY GIVEN that the State Board of Health will hold a public hearing to consider amendments to Chapter 652 of Nevada Administrative Code (NAC), Medical Laboratories. This public hearing is to be held in conjunction with the State Board of Health meeting at 9 a.m. on September 2, 2022.

The State Board of Health will be conducted physical and virtually beginning at 9:00 am on Friday, September 2, 2022, using the following information:

- Rawson-Neal Psychiatric Hospital
  - Training Room B (193)
    1650 Community College Drive
    Las Vegas, NV 89146
- Nevada Division of Public and Behavioral Health
  - Hearing Room No. 303, 3rd Floor
    4150 Technology Way
    Carson City, NV 89706
- Online – click here to join using Microsoft Teams
- Phone – 775-321-6111 (ID Number: 655 825 021 #)

The proposed changes to NAC Ch. 652 include the following:

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 Division of Public and Behavioral Health (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. 21
- Section 19 addresses the numbering change in NAC 652.550 in response to the change that is being made in NAC 652.320.

1. Anticipated effects on the business which NAC Ch. 652 regulates:
   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 effects:* 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 effects:* The long-term effects will be the same as the immediate effects of the proposed regulation changes.

2. Anticipated effects on the public:
   A. *Adverse*: There are no anticipated adverse effects on the public from the proposed regulatory changes.
   B. *Beneficial:* The anticipated positive benefits to the public will be from the growth of the patient specimen collection laboratories to better serve the areas of Nevada in rural areas, it will allow for the training of military personnel in hospitals so that they will be better able to serve the needs of the military, 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.
   C. *Immediate*: As soon as the proposed regulations become effective, it would allow for all of the

benefits described in letter "B" above to be in place to positively affect the public.

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

3. 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 patient 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.

The proposed regulations do not overlap or duplicate any other Nevada state 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, Lisa Sherych, to be received no later than Aug. 12, 2022, 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 of Health 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
4150 Technology Way
Carson City, NV 89706

Nevada Division of Public and Behavioral Health
727 Fairview Dr., Suite E
Carson City, NV 89706

Nevada Division of Public and Behavioral Health
4220 S. Maryland Parkway, Suite 100, Building A
Las Vegas, NV 89119

A copy of the regulations and small business impact statement can be found online by going to the State of Nevada Medical Laboratories Notice of Public Workshops and Proposed Regulations web page at:
https://dpbh.nv.gov/Reg/MedicalLabs/Notice_of_Public_Workshops_and_Proposed_Regulations/

A copy of the public hearing notice can also be found at Nevada Legislature's web page: https://www.leg.state.nv.us/App/Notice/A/

A copy of the public hearing notice and proposed regulations were sent to:

Nevada State Library, Archives and Public Records
100 N Stewart St
Carson City, NV 89701

Copies may be obtained in person, by mail, or by calling the Division of Public and Behavioral Health at (775) 684-1030 in Carson City or (702) 486-6515 in Las Vegas.

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.

SECOND REVISED PROPOSED

REGULATION OF THE STATE

BOARD OF HEALTH

LCB File No. R126-21

June 27, 2022

EXPLANATION – Matter in ***italics*** is new; matter in brackets **[**~~omitted material~~**]** is material to be omitted.

AUTHORITY: §§ 1, 4, 6, 7, 9-11, 13-16 and 19, NRS 439.200, 652.123, 652.125 and 652.130; §§ 2, 3, 8 and 12, NRS 439.200, 652.123 and 652.130; § 5, NRS 439.200, 622.087, 652.123, 652.125 and 652.130; § 17, NRS 439.200, 652.123, 652.125, 652.127 and 652.130; § 18, NRS 439.150, 439.200 and 652.100.

A REGULATION relating to medical laboratories; exempting a licensed laboratory only for the collection of specimens that meets certain requirements from provisions governing laboratories; prescribing and revising the qualifications and duties of certain laboratory personnel; prescribing documentation necessary to verify the completion of certain training programs for the purpose of receiving equivalent credit toward the qualifications for the issuance of certain licenses and certificates; authorizing a medical officer of the Armed Forces of the United States to provide clinical laboratory services in a hospital under certain circumstances; revising requirements governing the supervision of certain licensed laboratories; prescribing certain fees relating to licensure as a licensed laboratory only for the collection of specimens; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law requires the operator of a medical laboratory to obtain a license from the Division of Public and Behavioral Health of the Department of Health and Human Services. (NRS 652.080) **Section 2** of this regulation defines the term "licensed laboratory only for the collection of specimens" to mean a licensed laboratory at which the only task performed is the collection of tissues, secretions or excretions of the human body for certain examinations by another licensed laboratory. **Section 6** of this regulation makes a conforming change to indicate the proper placement of **section 2** in the Nevada Administrative Code. **Sections 3 and 7** of this regulation provide that a licensed laboratory only for the collection of specimens that meets certain requirements related to the operation of the laboratory is otherwise exempt from most regulations governing medical laboratories. **Section 11** of this regulation prescribes the required qualifications of a director of a licensed laboratory only for the collection of specimens. **Section 18** of this regulation prescribes the fees for the issuance, renewal and reinstatement of the license of a licensed laboratory only for the collection of specimens.

Existing law requires the State Board of Health to adopt regulations for the certification and licensure of laboratory directors and laboratory personnel who perform technical duties other than the collection of blood. (NRS 652.125) Existing regulations prescribe the qualifications and duties of a general supervisor of a licensed laboratory. (NAC 652.400, 652.410) **Section 4** of this regulation prescribes the: (1) qualifications of a general supervisor in a specialty; and (2) duties of a general supervisor in a specialty, which consist of overseeing the technical and administrative functions of the laboratory relating to that specialty. **Sections 9-11 and 13-17** of this regulation revise the required qualifications of certain other laboratory personnel.

Existing law provides: (1) that persons who complete certain training programs for occupational, vocational, career, trade or technical education are eligible to receive equivalent credit towards related professional and occupational licenses and certifications; and (2) for the appeal of a denial of such equivalent credit. (NRS 622.087) For the personnel of a medical laboratory, **section 5** of this regulation prescribes the documents required to verify completion of such a program for the purpose of receiving equivalent credit toward a license or certificate. Existing law and regulations: (1) authorize the Division to deny the issuance of a license or certificate if the denial of equivalent credit for a training program results in the applicant failing to possess the required qualifications for the issuance of the license or certificate; and (2) establish a process for a person aggrieved by the denial of a license or certificate under those circumstances to appeal. (NRS 652.220; NAC 439.300-439.395, 652.491, 652.493)

Existing law authorizes a hospital to enter into an agreement with the Armed Forces of the United States to allow a medical officer who is not licensed or certified in this State but meets certain other requirements to provide care in the hospital as part of a training or educational program designed to further the employment of the medical officer. (NRS 449.2455) **Section 7** authorizes such a medical officer who is not licensed or certified in this State to provide clinical laboratory services in a hospital pursuant to such an agreement.

Existing regulations require the Division to inspect periodically the premises and operation of each medical laboratory. (NAC 652.320) **Section 8** of this regulation authorizes: (1) an authorized employee or contractor of the Division to enter and inspect any building or premises to secure compliance with statutes and regulations governing medical laboratories; and (2) the Division to request records from certain licensed health care facilities or a licensed laboratory that may have information pertinent to a complaint which is within the authority of the Division to investigate. **Section 19** of this regulation makes a conforming change to revise an internal reference to a provision amended by **section 8**.

Existing regulations require the general supervisor of a licensed laboratory to be on the premises during all hours in which routine tests are being performed. (NAC 652.400) **Section 12** of this regulation authorizes the general supervisor of a licensed laboratory in a hospital to also oversee a licensed laboratory in a freestanding emergency room operated by the hospital if: (1) the general supervisor, a certified clinical laboratory technologist or a certified medical technician are on the premises of the laboratory at all times; (2) the general supervisor is on the premises of the licensed laboratory in the freestanding emergency room at least monthly; and (3) certain other requirements are met.

Section 1. Chapter 652 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 5, inclusive, of this regulation.

Sec. 2. ***"Licensed laboratory only for the collection of specimens" means a licensed laboratory at which the only task performed is the collection of tissues, secretions or excretions of the human body for microbiological, serological, immunohematological, cytological, histological, chemical, hematological, biophysical or toxicological examinations by another licensed laboratory.***

Sec. 3. ***1. A licensed laboratory only for the collection of specimens that elects pursuant to subparagraph (3) of paragraph (b) of subsection 1 of NAC 652.155 not to comply with the provisions of this chapter, other than those listed in subsection 3, must:***

(a) Have physical premises and environmental conditions that:

(1) Are appropriate for the collection of specimens, including, without limitation, the maintenance of an appropriate temperature for the collection and maintenance of specimens for the purpose of the analyses for which the specimens are collected; and

(2) Provide a safe environment in which personnel of the laboratory are protected from biological, physical and chemical hazards;

(b) Be adequately ventilated; and

(c) Have one or more showers and eyewashes where necessary for safety.

2. A person who is employed by a licensed laboratory only for the collection of specimens described in subsection 1 may collect a specimen if:

(a) The employee is competent to collect specimens; and

(b) Each specimen is:

(1) Collected in accordance with the policies of the licensed laboratory to which the specimen will be sent for analysis; and

(2) Labeled with the name of the patient and a unique identifier for the patient.

3. A licensed laboratory only for the collection of specimens described in subsection 1 shall comply with the provisions of:

(a) NAC 652.291;

(b) Subparagraphs (1) and (2) of paragraph (b) of subsection 2 of NAC 652.310; and

(c) Subsections 1 and 2 of NAC 652.350.

4. The director, a designee of the director or a licensed physician at a licensed laboratory for the collection of specimens described in subsection 1 shall regularly verify compliance with the requirements of subsections 1, 2 and 3.

Sec. 4. *1. To qualify for a certificate as a general supervisor in a specialty, a person must be:*

(a) A person who:

(1) Is a technologist certified in a specialty pursuant to NAC 652.478; and

(2) Has at least 3 years of experience as a full-time employee working at least 30 hours per week in a licensed laboratory or a laboratory of a college, university or school in the specialty in which he or she is certified, with at least 2 of those years spent working as a technologist under the supervision of a director who holds a doctoral degree;

(b) A person who:

(1) Holds a doctoral degree from an accredited institution in a chemical, physical or biological science, clinical laboratory science or medical technology; and

(2) Has at least 1 year of clinical experience as a full-time employee working at least 30 hours per week as a technologist in a licensed laboratory or a laboratory of a college, university or school under the supervision of a person who:

(I) Holds a doctoral degree; or

(II) Possesses the qualifications necessary for certification as a general supervisor of a licensed laboratory prescribed by NAC 652.410; or

(c) A person who:

(1) Holds a master's degree from an accredited institution in a chemical, physical or biological science, clinical laboratory science or medical technology; and

(2) Has at least 2 years of clinical experience as a full-time employee working at least 30 hours per week as a technologist in a licensed laboratory or a laboratory of a college, university or school under the supervision of a person who:

(I) Holds a doctoral degree; or

(II) Possesses the qualifications necessary for certification as a general supervisor of a licensed laboratory prescribed by NAC 652.410.

2. A general supervisor in a specialty may be certified in any specialty in which a technologist may be certified pursuant to subsection 1 of NAC 652.478.

3. The general supervisor in a specialty shall oversee the technical and administrative functions of the laboratory relating to that specialty and may supervise other personnel, as assigned by the director. A general supervisor in a specialty shall not perform or supervise technical or administrative functions relating to another specialty.

Sec. 5. *A person who wishes to receive equivalent credit pursuant to subsection 1 of NRS 622.087, towards the satisfaction of requirements for the issuance of a license or certificate pursuant to this chapter or chapter 652 of NRS for a training program for occupational, vocational, career, trade or technical education approved by the State Board of Education must submit, as part of the application for the license or certificate:*

1. Transcripts or other documents substantiating the courses completed as part of the training program; and

2. A copy of the certificate issued for the completion of the training program.

Sec. 6. NAC 652.010 is hereby amended to read as follows:

652.010 As used in this chapter, unless the context otherwise requires, the words and terms defined in NAC 652.020 to 652.151, inclusive, ***and section 2 of this regulation*** have the meanings ascribed to them in those sections.

Sec. 7. NAC 652.155 is hereby amended to read as follows:

652.155 1. Except as otherwise provided in this section ***and section 3 of this regulation*** and NRS 652.071, the provisions of this chapter:

(a) Apply to:

(1) A laboratory which is licensed pursuant to NRS 652.080 and which provides services to the public; and

(2) A nonexempt laboratory which is registered pursuant to NAC 652.175; and

(b) Do not apply to:

(1) An exempt laboratory which:

(I) Is licensed pursuant to chapter 652 of NRS; and

(II) Pays the applicable fees required by NAC 652.488;

(2) An HIV testing laboratory which:

(I) Is licensed pursuant to chapter 652 of NRS; and

(II) Pays the applicable fees required by NAC 652.488; ~~[or]~~

(3) ***A licensed laboratory only for the collection of specimens which:***

(I) Is licensed pursuant to chapter 652 of NRS;

(II) Pays the applicable fees required by NAC 652.488;

(III) Has a director who possesses the qualifications prescribed by NAC 652.397; and

(IV) Complies with the requirements of section 3 of this regulation; or

(4) A laboratory which is registered as exempt pursuant to NAC 652.175.

2. Except as otherwise provided in subsection 3, a person who is employed by a laboratory that is licensed by or registered with the Division pursuant to chapter 652 of NRS may perform a test without complying with the provisions of this chapter if:

(a) The test has been classified as a waived test pursuant to 42 C.F.R. Part 493, Subpart A; and

(b) The director, a designee of the director or a licensed physician at the laboratory at which the test is performed:

(1) Verifies that the person is competent to perform the test;

(2) Ensures that the test is performed in accordance with instructions of the manufacturer of the test; and

(3) Validates and verifies the manner in which the test is performed by using controls which ensure that the results of the test will be accurate and reliable.

3. Except as otherwise provided in subsection 4, the provisions of subsection 2 do not relieve a person who performs a test from the requirement to:

(a) Comply with the policies and procedures that the director of the laboratory at which the test is performed has established pursuant to NAC 652.280;

(b) Comply with the laboratory safety guidelines adopted by the laboratory pursuant to NAC 652.291; or

(c) Obtain certification pursuant to NAC 652.470 and pay the applicable fees as set forth in NAC 652.488.

4. An advanced practice registered nurse as defined in NRS 632.012 or a physician assistant as defined in NRS 630.015 who is employed by a laboratory that is licensed by or registered with the Division pursuant to chapter 652 of NRS and who has not received certification pursuant to NAC 652.470 may perform a test without complying with the provisions of this chapter if the test:

(a) Has been classified as a waived test pursuant to 42 C.F.R. Part 493, Subpart A; or

(b) Is a provider-performed microscopy procedure categorized pursuant to 42 C.F.R. § 493.19.

5. Except as otherwise provided in this subsection, a person may perform a test for the detection of the human immunodeficiency virus that is classified as a waived test pursuant to 42 C.F.R. Part 493, Subpart A, without complying with the provisions of this chapter if he or she complies with NRS 652.186. This subsection does not apply to a person who holds a license or certification issued pursuant to this chapter or a license or certification described in NRS 652.210.

6. ***A medical officer employed by the Armed Forces of the United States to provide clinical laboratory services 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.***

7. As used in this section, "licensed physician" includes:

(a) A physician licensed as a doctor of medicine pursuant to chapter 630 of NRS;

(b) A physician licensed as a doctor of osteopathic medicine pursuant to chapter 633 of NRS;

(c) A chiropractic physician licensed pursuant to chapter 634 of NRS; and

(d) A podiatric physician licensed pursuant to chapter 635 of NRS.

Sec. 8. NAC 652.320 is hereby amended to read as follows:

652.320 1. Except as otherwise provided in this subsection, the Division shall inspect periodically the premises and operation of each laboratory, including, without limitation, the premises of an outpatient center of the laboratory, if any. A laboratory that is subject to inspection by an accrediting organization approved by the Centers for Medicare and Medicaid Services of the United States Department of Health and Human Services pursuant to 42 C.F.R. §§ 493.551 to 493.575, inclusive, is not required to be inspected periodically by the Division if the reports of the inspections are available to the Division.

2. ***An authorized employee or contractor of the Division may enter and inspect any building or premises to secure compliance with or prevent a violation of any provision of this chapter or chapter 652 of NRS.***

3. Upon receipt of a complaint against a laboratory or its personnel, except for a complaint concerning the cost of services, the Division may conduct an investigation into the premises, qualifications of personnel, methods of operation, policies, procedures and records of that laboratory or any other laboratory which may have information pertinent to the complaint.

~~[3.]~~ ***4. The Division may request records from any facility licensed pursuant to chapter 449 of NRS, including, without limitation, any facility which is required by the regulations adopted by the Board pursuant to NRS 449.0303 to be licensed, or any laboratory licensed pursuant to chapter 652 of NRS that may have information pertinent to a complaint which is within the authority of the Division to investigate.***

5. The Division shall report violations noted at the time of each inspection by providing the director, or the director's designee, with a statement of violations, which must include the severity level for the violation as determined by the Division, and a form for the director to submit a plan of correction. Any violation for which a severity level is not specified in the statement of violations is presumed to be a violation of severity level one. The director shall submit the plan of correction to the Division, containing thereon the plan of correction for each of the violations, within 14 days after receiving the form. The plan must indicate the date by which each violation will be corrected.

~~[4.]~~ ***6.*** Failure to submit the plan of correction timely pursuant to subsection ~~[3]~~ ***5*** to the Division constitutes a separate violation subject to monetary penalties with a severity level rated at the same level as the highest violation identified on the statement of violations.

Sec. 9. NAC 652.380 is hereby amended to read as follows:

652.380 Except as otherwise provided in NAC 652.383, to qualify for a license as a director of a licensed laboratory, a person must meet one of the following qualifications:

1. Be a physician who is licensed to practice medicine in this State and:

(a) Be certified in anatomical and clinical pathology, or in clinical pathology, by:

(1) The American Board of Pathology; or

(2) The American Osteopathic Board of Pathology;

(b) Possess qualifications which are equivalent to those required for certification by either of the institutions listed in paragraph (a);

(c) Within the 10 years immediately preceding application for a license, have successfully completed a 4-year program accredited by the National Accrediting Agency for Clinical Laboratory Sciences;

(d) Be certified, in accordance with NAC 652.410, as a general supervisor; or

(e) Have at least 4 years of experience as a technologist:

(1) In a licensed laboratory or a laboratory of a hospital, health department or university;

(2) As a full-time employee working at least 30 hours per week; and

(3) Under the supervision of a director who possesses a doctoral degree.

2. Hold an earned doctoral degree from an accredited institution, with a chemical, physical, biological or clinical laboratory science as the major, ***have at least 1 year of experience directing or supervising laboratory testing or performing laboratory testing at the level of a technologist in a laboratory which meets the requirements of NAC 652.170 to 652.600, inclusive,*** and:

(a) Be certified by:

(1) The American Board of Medical Microbiology;

(2) The American Board of Clinical Chemistry;

(3) The American Board of Bioanalysis;

(4) The American Board of Medical Laboratory Immunology;

(5) The American Board of Forensic Toxicology;

(6) The American Board of Medical Genetics and Genomics;

(7) The National Registry of Certified Chemists;

(8) The American Board of Histocompatibility and Immunogenetics; or

(9) Any other institution approved by the United States Department of Health and Human Services in accordance with 42 C.F.R. § 493.1443(b)(3); or

(b) Possess qualifications which are equivalent to those required for certification by any of the institutions listed in paragraph (a).

Sec. 10. NAC 652.395 is hereby amended to read as follows:

652.395 To qualify for a license as a director of a registered laboratory, a person must:

1. Be a physician licensed to practice in this State and have:

(a) At least 1 year of experience directing or supervising laboratory testing in a laboratory which meets the requirements of NAC 652.170 to 652.600, inclusive;

(b) Credit for at least 20 hours of continuing medical education in laboratory practice regarding the responsibilities of a director; or

(c) Laboratory training, obtained during medical residency, equivalent to the training required by paragraph (b); or

2. Hold an earned doctoral degree from an accredited institution, with a major in chemical, physical, biological or clinical laboratory science, and:

(a) Have at least 1 year of experience directing or supervising laboratory testing ***or performing laboratory testing at the level of a technologist*** in a laboratory which meets the requirements of NAC 652.170 to 652.600, inclusive;

(b) Be certified by:

(1) The American Board of Medical Microbiology;

(2) The American Board of Bioanalysis;

(3) The American Board of Medical Laboratory Immunology;

(4) The American Board of Clinical Chemistry;

(5) The American Board of Forensic Toxicology;

(6) The American Board of Medical Genetics and Genomics;

(7) The National Registry of Certified Chemists;

(8) The American Board of Histocompatibility and Immunogenetics; or

(9) Any other institution approved by the United States Department of Health and Human Services in accordance with 42 C.F.R. § 493.1443(b)(3); or

(c) Possess qualifications which are equivalent to those required for certification by any of the institutions listed in paragraph (b).

Sec. 11. NAC 652.397 is hereby amended to read as follows:

652.397 1. Except as otherwise provided in subsection 2 and NAC 652.395, to qualify to serve as a director of an exempt laboratory ~~[,]~~ ***or a licensed laboratory only for the collection of specimens,*** a person must be:

(a) A licensed physician;

(b) Qualified for a license as a director of a licensed laboratory pursuant to NAC 652.380;

(c) Qualified for a license as a director of a registered laboratory pursuant to NAC 652.395;

(d) An advanced practice registered nurse licensed pursuant to chapter 632 of NRS;

(e) A physician assistant licensed pursuant to chapter 630 or 633 of NRS;

(f) A general supervisor of a licensed laboratory certified in accordance with NAC 652.410; ~~[or]~~

(g) A clinical laboratory technologist certified in accordance with NAC 652.420 ~~[.]~~ ***; or***

(h) A dentist licensed pursuant to chapter 631 of NRS.

2. To qualify to serve as a director of an exempt laboratory in which the only tests performed are glucose tests that are classified as waived tests pursuant to 42 C.F.R. Part 493, Subpart A, a person must be:

(a) A person identified in subsection 1;

(b) A nurse licensed pursuant to chapter 632 of NRS;

(c) A pharmacist registered pursuant to chapter 639 of NRS; or

(d) A person licensed or certified pursuant to chapter 652 of NRS, other than a certified blood-gas assistant, certified laboratory assistant or certified office laboratory assistant.

3. As used in this section, "licensed physician" includes:

(a) A physician licensed as a doctor of medicine pursuant to chapter 630 of NRS;

(b) A physician licensed as a doctor of osteopathic medicine pursuant to chapter 633 of NRS;

(c) A chiropractic physician licensed pursuant to chapter 634 of NRS; and

(d) A podiatric physician licensed pursuant to chapter 635 of NRS.

Sec. 12. NAC 652.400 is hereby amended to read as follows:

652.400 1. The general supervisor of a licensed laboratory shall oversee the technical and administrative functions of the laboratory and may supervise other personnel, as assigned by the director.

2. ~~[The]~~ ***Except as otherwise provided in this section, the*** general supervisor shall be on the premises during all hours in which routine tests are being performed. The presence of the supervisor is not required during the performance of emergency testing procedures after scheduled work hours, but he or she shall review these procedures during his or her next period of duty.

3. A general supervisor of a licensed laboratory who works in a hospital that operates a freestanding emergency room may oversee the technical and administrative functions of a licensed laboratory in the freestanding emergency room if:

(a) The freestanding emergency room is covered by the license of the hospital issued by the Division pursuant to chapter 449 of NRS or, if applicable, the certification of the hospital to participate in Medicare, issued as provided in 42 C.F.R. Parts 482 to 498, inclusive;

(b) The general supervisor, a clinical laboratory technologist certified pursuant to NAC 652.420 or a medical technician certified pursuant to NAC 652.440 is on the premises of the licensed laboratory in the freestanding emergency room at all times;

(c) The general supervisor is on the premises of the licensed laboratory in the freestanding emergency room at least monthly to ensure that tests are performed in accordance with the instructions of the manufacturer of the tests and all applicable federal and state laws and regulations;

(d) Persons who collect human specimens or perform any test that is classified as a waived test pursuant to 42 C.F.R. Part 493, Subpart A, in the licensed laboratory in the freestanding emergency room are properly certified under the provisions of this chapter or exempt from such certification under the provisions of NRS 652.210;

(e) Persons who perform any test, other than a test that is classified as a waived test pursuant to 42 C.F.R. Part 493, Subpart A, in the licensed laboratory in the freestanding emergency room are properly certified under the provisions of this chapter; and

(f) The licensed laboratory in the freestanding emergency room is in compliance with all other federal and state laws and regulations.

4. A general supervisor who oversees the technical and administrative functions of a licensed laboratory in a freestanding emergency room pursuant to subsection 3 shall be deemed to be the general supervisor of that licensed laboratory for all purposes.

Sec. 13. NAC 652.410 is hereby amended to read as follows:

652.410 1. To qualify for a certificate as a general supervisor of a licensed laboratory, a person must, except as otherwise provided in this section, be:

(a) A qualified physician serving on behalf of the director; or

(b) A clinical laboratory technologist who has had at least 3 years of experience in a laboratory as a full-time employee working at least 30 hours per week, of which at least 2 years have been spent working ~~[:]~~ ***at the level of a technologist:***

(1) In a licensed laboratory or a laboratory of a hospital, university or health department; and

(2) Under the supervision of a director who possesses a doctoral degree.

2. A technologist certified by the Board in a specialty who has had at least 3 years of experience in a laboratory as a full-time employee working at least 30 hours per week, of which at least 2 years have been spent working ~~[:]~~ ***at the level of a technologist:***

(a) In a licensed laboratory or a laboratory of a hospital, university or health department; and

(b) Under the supervision of a director who possesses a doctoral degree,

➥ qualifies for a certificate as a general supervisor of a licensed laboratory if the tests performed in the laboratory are solely in his or her specialty.

3. A person who possesses a doctoral degree from an accredited institution with a major in chemical, physical or biological science ***, clinical laboratory science or medical technology*** and who has had at least 1 year of ***clinical*** experience ***at the level of a technologist*** in a licensed laboratory or a laboratory of a hospital, university or health department as a full-time employee working for at least 30 hours per week under the supervision of a director who possesses a doctoral degree qualifies for a certificate as a general supervisor of a licensed laboratory.

4. A person who possesses a master's degree from an accredited institution with a major in chemical, physical or biological science ***, clinical laboratory science or medical technology*** and who has had at least 2 years of ***clinical*** experience ***at the level of a technologist*** in a licensed laboratory or a laboratory of a hospital, university or health department as a full-time employee

working at least 30 hours per week under the supervision of a director who possesses a doctoral degree qualifies for a certificate as a general supervisor of a licensed laboratory.

Sec. 14. NAC 652.420 is hereby amended to read as follows:

652.420 1. A clinical laboratory technologist may:

(a) Perform tests which require the exercise of independent judgment, under minimum supervision or review by the director or general supervisor, in those specialties for which the technologist has had adequate education, training and experience and in which he or she has demonstrated a proficiency; and

(b) Supervise, if necessary, the work of the medical technicians and laboratory assistants.

2. To qualify for a certificate as a clinical laboratory technologist, a person must:

(a) Successfully complete a full course of study which meets all academic requirements for a bachelor's degree in medical technology from an accredited college or university, and pass a national examination for certification approved by the Board;

(b) Successfully complete a course of study for a bachelor's degree in one of the chemical, physical or biological sciences ***, clinical laboratory science or medical technology*** at an accredited college or university, have at least 1 year of additional full-time ***clinical*** experience or training ***at the level of a technologist*** in a licensed laboratory, or laboratory of a hospital, health department or university in the specialty or subspecialty in which the person performs tests, and pass a national examination for certification approved by the Board; or

(c) Pass the examination for clinical laboratory technologists given by the United States Department of Health and Human Services.

Sec. 15. NAC 652.454 is hereby amended to read as follows:

652.454 ***1.*** To qualify for a certificate as a point-of-care test analyst, a person must:

~~[1.]~~ ***(a)*** Be a:

~~[(a)]~~ ***(1)*** Registered nurse as defined in NRS 632.019;

~~[(b)]~~ ***(2)*** Advanced practice registered nurse as defined in NRS 632.012;

~~[(c)]~~ ***(3)*** Licensed practical nurse as defined in NRS 632.016;

~~[(d)]~~ ***(4)*** Practitioner of respiratory care as defined in NRS 630.023;

~~[(e)]~~ ***(5)*** Physician assistant as defined in NRS 630.015;

~~[(f)]~~ ***(6)*** Registered pharmacist as defined in NRS 639.015 who has participated in the development of written guidelines and protocols as described in ~~[subsection 8 of]~~ NRS 639.0124;

~~[or~~

~~(g)]~~

(7) Certified laboratory assistant who has successfully completed training approved by a director in performing point-of-care tests;

(8) Nursing assistant, as defined in NRS 632.0166; or

(9) Student enrolled in an accredited school of professional nursing or graduate of such a school pending the results of the first licensing examination scheduled by the State Board of Nursing following graduation; and

~~[2.]~~ ***(b)*** Provide verification from a director that the person has successfully completed training approved by a director in performing the preanalytic, analytic and postanalytic phases of point-of-care tests.

2. A nursing assistant who is certified as a point-of-care test analyst may only perform glucose testing classified as a waived test pursuant to 42 C.F.R. Part 493, Subpart A.

Sec. 16. NAC 652.480 is hereby amended to read as follows:

652.480 1. Except as otherwise provided in NAC 652.483, to be certified by the Division in a specialty, a technologist must pass a national examination for certification in the specialty and must have successfully completed a course of study for a bachelor's degree in one of the chemical, physical or biological sciences at an accredited college or university, and have at least 1 year of additional full-time ***clinical*** experience or training ***at the level of a technologist*** in a licensed laboratory, or a laboratory of a hospital, health department or university, in the chosen specialty under the supervision of a director who possesses a doctoral degree.

2. Each applicant for certification in a specialty must designate on the application the specialty in which he or she desires to be certified. The applicant must submit with the application:

(a) Verification of successful completion of the course of study required by subsection 1; and

(b) A signed and dated letter from the director of the laboratory in which the applicant obtained his or her experience, which verifies that the applicant has the experience required by subsection 1.

3. Each certificate will designate the holder by:

(a) The title of "Technologist" in a specialty; or

(b) An equivalent title and will show his or her area of specialty by a subtitle.

Sec. 17. NAC 652.4855 is hereby amended to read as follows:

652.4855 To qualify for certification as a laboratory assistant, an applicant must submit with the application proof that the applicant has a high school diploma or a general equivalency diploma and has:

1. Completed at least 6 months of training approved by the Division and demonstrated an ability to perform laboratory procedures in the laboratory where he or she has received such training;

2. Obtained a certification in phlebotomy from an organization approved by the Division, including, without limitation:

(a) The American Medical Technologists;

(b) The American Society for Clinical Pathology;

(c) The American Certification Agency for Healthcare Professionals;

(d) The National Center for Competency Testing;

(e) The National Healthcareer Association; and

(f) The National Phlebotomy Association; or

3. Worked at least 30 hours per week for at least 3 years during the immediately preceding 5 years in ~~[a]~~ ***:***

(a) A laboratory certified pursuant to the Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. § 263a ~~[, or a]~~ ***;***

(b) A laboratory that is licensed by a federal or state governmental agency in any state or territory of the United States ~~[.]~~ ***;***

(c) A clinical laboratory in another country accredited by:

(1) The Joint Commission International, or its successor organization, or

(2) The College of American Pathologists, or its successor organization;

(d) A clinical laboratory in another country accredited pursuant to ISO 15189 of the International Organization for Standardization by an appropriate organization that accredits medical laboratories in that country; or

(e) A clinical laboratory licensed or certified by an appropriate governmental entity in that country and approved by an International Advisory Board appointed by the Board of Certification of the American Society for Clinical Pathology, or its successor organization.

Sec. 18. NAC 652.488 is hereby amended to read as follows:

652.488 1. Except as otherwise provided in this section, the following fees will be charged:

(a) Licensure of laboratory not described in paragraph (b) ***,*** ~~[or]~~ (c) ***or (d)***

Initial:

Annual test volume less than 25,000 ..... $1,100

Annual test volume at least 25,000 but less than 100,000 3,000

Annual test volume 100,000 or more 4,000

Biennial renewal:

Annual test volume less than 25,000 800

Annual test volume at least 25,000 but less than 100,000 2,500

Annual test volume 100,000 or more 3,500

Reinstatement:

Annual test volume less than 25,000 1,100

Annual test volume at least 25,000 but less than 100,000 3,000

Annual test volume 100,000 or more 4,000

(b) Licensure of laboratory operated by health district, district board of health, county board of health or city or town board of health, or the State Public Health Laboratory

Initial:

Annual test volume less than 25,000 ..... $550

Annual test volume at least 25,000 but less than 100,000 800

Annual test volume 100,000 or more 1,150

Biennial renewal:

Annual test volume less than 25,000 400

Annual test volume at least 25,000 but less than 100,000 600

Annual test volume 100,000 or more 800

Reinstatement:

Annual test volume less than 25,000 550

Annual test volume at least 25,000 but less than 100,000 800

Annual test volume 100,000 or more 1,150

(c) ***Licensure of laboratory only for the collection of specimens***

Initial $500

Biennial renewal 300

Reinstatement 500

(d) Licensure of HIV testing laboratory

Initial $150

Biennial renewal 150

~~[(d)]~~ ***(e)*** Licensure of director pursuant to paragraph (b) of subsection 3 of NAC 652.175 or NAC 652.380 to 652.395, inclusive

Initial $500

Biennial renewal 300

Reinstatement 500

~~[(e)]~~ ***(f)*** Registration of laboratory operated pursuant to NRS 652.072 which is nonexempt pursuant to NAC 652.155

Initial $1,500

Biennial renewal 900

Reinstatement 1,500

~~[(f)]~~ ***(g)*** Registration of laboratory operated pursuant to NRS 652.072 which is exempt pursuant to NAC 652.155

Initial $500

Biennial renewal 300

~~[(g)]~~ ***(h)*** Certification of personnel

Initial:

General supervisor $225

Technologist 113

Technician 113

Pathologist's assistant 113

Point-of-care test analyst 75

Laboratory, blood-gas or office laboratory assistant 60

Biennial renewal:

General supervisor 150

Technologist 75

Technician 75

Pathologist's assistant 75

Point-of-care test analyst 60

Laboratory, blood-gas or office laboratory assistant.....45

Reinstatement:

General supervisor.....225

Technologist.....113

Technician.....113

Pathologist's assistant.....113

Point-of-care test analyst.....75

Laboratory, blood-gas or office laboratory assistant.....60

~~[(h)]~~ ***(i)*** Placement of license or certificate in inactive status.....$50

~~[(i)]~~ ***(j)*** Issuance of original duplicate license or certificate.....$50

~~[(j)]~~ ***(k)*** Permit to operate laboratory at temporary location.....$300

~~[(k)]~~ ***(l)*** Change of location of laboratory.....$300

~~[(l)]~~ ***(m)*** Change of director of laboratory.....$300

~~[(m)]~~ ***(n)*** Change of name of laboratory.....$300

~~[(n)]~~ ***(o)*** Inspection following receipt of an application to perform additional tests at a laboratory (per application).....$300

~~[(o)]~~ ***(p)*** Inspection of an outpatient center of a laboratory (per site)

Initial inspection.....$300

Inspection at time of biennial renewal.....150

2. If the Division conducts an inspection of a laboratory that is located outside of this State, the Division shall assess the expenses that the Division incurs as a result of the inspection to the laboratory. The laboratory shall reimburse the Division for the expenses assessed pursuant to this subsection.

3. The Division shall not charge or collect a fee set forth in paragraph ~~[(k),]~~ (l) **,** ~~[or]~~ (m) ***or (n)*** of subsection 1 to an HIV testing laboratory.

4. The holder of or an applicant for a license or certificate issued pursuant to chapter 652 of NRS, or an applicant for a permit to operate a laboratory at a temporary location issued pursuant to NAC 652.195, shall be deemed to have paid any fee otherwise required pursuant to subsection 1 if the holder or applicant:

(a) Is, or is employed by, a medical laboratory that is operated by a person, governmental entity or fire-fighting agency that holds a permit issued by a health authority pursuant to NRS 450B.200; and

(b) Has paid the fee for the permit established by a board pursuant to NRS 450B.200.

5. As used in this section:

(a) "Board" has the meaning ascribed to it in NRS 450B.060.

(b) "Health authority" has the meaning ascribed to it in NRS 450B.077.

(c) "Permit" has the meaning ascribed to it in NRS 450B.100.

Sec. 19. NAC 652.550 is hereby amended to read as follows:

652.550 1. In determining the amount of a monetary penalty, the Division:

(a) For a first violation with a severity level of four, shall impose a monetary penalty of $1,000 per violation.

(b) For a first violation with a severity level of three, shall impose a monetary penalty of $800 per violation.

(c) For a first violation with a severity level of two, may impose a monetary penalty of $100 per violation. The Division may suspend this penalty if the laboratory corrects the violations

within the time specified in the plan of correction submitted to the Division pursuant to NAC 652.320.

(d) For a second violation with a severity level of four discovered during any subsequent inspection, shall impose a monetary penalty of $5,000 per violation.

(e) For a second violation with a severity level of three discovered during any subsequent inspection, shall impose a monetary penalty of $1,600 per violation.

(f) For a second violation with a severity level of two discovered during any subsequent inspection, may impose a monetary penalty of $200 regardless of whether a penalty was imposed for the first violation.

(g) For a third or subsequent violation with a severity level of four discovered during any subsequent inspection, shall impose a monetary penalty of $10,000 per violation.

(h) For a third or subsequent violation with a severity level of three discovered during any subsequent inspection, shall impose a monetary penalty of $3,200 per violation.

(i) For a third or subsequent violation with a severity level of two discovered during any subsequent inspection, may impose a monetary penalty of $400 per violation regardless of whether a first or second monetary penalty was imposed.

2. The Division shall not impose a monetary penalty for a violation with a severity level of one.

3. If the same violation that was discovered during the initial inspection is found during a subsequent inspection conducted to evaluate compliance with a plan of correction submitted to the Division pursuant to subsection ~~[3]~~ ***5*** of NAC 652.320, there is a rebuttable presumption that the violation continued through the period between the inspection and the subsequent inspection. The Division may impose an additional monetary penalty for such a violation only if the

subsequent inspection is made and the violation is found to be present after the laboratory has been notified of the violation and given an opportunity to correct the violation.

4. A laboratory may, upon approval by the Division, use a monetary penalty that would otherwise be imposed by the Division to correct the violation and to put measures in place to prevent the violation from reoccurring. In such a case, the laboratory must provide proof to the Division that the money was used to correct the violation. If the amount of the monetary penalty is greater than the cost to correct the violation, the laboratory must pay to the Division the portion of the monetary penalty that was not used to correct the violation.

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
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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:

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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_____