Steve Sisolak Governor

Director



DEPARTMENT OF HEALTH AND HUMAN SERVICES

DIVISION OF PUBLIC AND BEHAVIORAL HEALTH Helping people. It's who we are and what we do.



Lisa Sherych Administrator

Ihsan Azzam, Ph.D., M.D. Chief Medical Officer

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 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 highcomplexity 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 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: <u>https://www.leg.state.nv.us/App/Notice/A/</u>

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.