

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

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NOTICE OF PUBLIC WORKSHOP

NOTICE IS HEREBY GIVEN that the Division of Public and Behavioral Health will hold a public workshop to consider amendments to Nevada Administrative Code (NAC) Chapter 652.

The workshop will be conducted via videoconference beginning at 9 a.m. on July 11, 2022, via the following online/phone methods:

- Click here to join the workshop online using Microsoft Teams
- 775-321-6111 (phone conference ID 302 933 072#)

These workshops will be conducted in accordance with NRS 241.020, Nevada's Open Meeting Law.

AGENDA

- 1. Introduction of workshop process
- 2. Public comment on proposed amendments to Nevada Administrative Code Chapter 652.
- 3. Public Comment

The proposed changes will revise Chapter 652 of the Nevada Administrative Code and are being proposed in accordance with NRS 652.080, 652.125, 652.220, 622.087 and 449.2455.

The proposed regulations provide provisions for the following:

1) 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.
- 2) 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.
- 3) 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 Chapter 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.
- 4) 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.
- 5) 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.
- 6) Section 8 allows for DPBH inspectors to inspect any premises to ensure compliance of NAC Chapter 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.
- 7) 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.

- 8) 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.
- 9) 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.
- 10) 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.
- 11) 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.
- 12) 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.
- 13) 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.

- 14) 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.
- 15) 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.
- 16) Section 19 addresses the numbering change in NAC 652.550 in response to the change that is being made in NAC 652.320.

Members of the public may make oral comments at this meeting. Persons wishing to submit written testimony or documentary evidence may submit the material to Bradley Waples, Acting Manager, Medical Laboratory Services at the following address:

Division of Public and Behavioral Health 4220 S. Maryland Pkwy., Ste. 100, Bldg. A Las Vegas, NV 89119 775-486-6520 (fax)

Members of the public who require special accommodations or assistance at the workshops are required to notify Bradley Waples in writing to the Division of Public and Behavioral Health, 4220 S. Maryland Pkwy., Ste. 100, Bldg. A, Las Vegas, NV 89119, or by calling 702-486-6515 *at least five* (5) working days prior to the date of the public workshop.

The same contact as above can be used to request further information on the proposed regulations or how to obtain copies of the supporting documents.

A copy of the notice and the proposed regulations are on file for inspection and/or may be copied at the following locations during normal business hours:

<u>List of offices where the proposed regulation will be on file for inspection:</u>

Division of Public and Behavioral Health 727 Fairview Drive, Suite E Carson City, NV 89701 Division of Public and Behavioral Health 4220 S. Maryland Parkway, Suite 100, Bldg. A Las Vegas, NV 89119

Nevada State Library and Archives 100 Stewart Street Carson City, NV 89701

A copy of the regulations and small business impact statement can be found on the Division of Public and Behavioral Health's web page:

https://dpbh.nv.gov/Reg/MedicalLabs/Notice_of_Public_Workshops_and_Proposed_Regulations/

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

A copy of this notice has been posted at the following locations:

- 1. Division of Public and Behavioral Health, 4150 Technology Way, First Floor Lobby, Carson City
- 2. Nevada State Library and Archives, 100 Stewart Street, Carson City
- 3. Legislative Building, 401 S. Carson Street, Carson City
- 4. Southern Nevada Health District, 280 S. Decatur Blvd., Las Vegas, NV 89107
- 5. Washoe County District Health Department, 9th Street and Wells Ave., Reno

Per NRS 233B.064(2), upon adoption of any regulations, 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.