Joe Lombardo *Governor*

Richard Whitley, MS *Director*



DEPARTMENT OF HEALTH AND HUMAN SERVICES





Cody Phinney, MPH Administrator

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

NOTICE OF INTENT TO ACT UPON REGULATION

LCB FILE NO. R145-23 NEVADA ADMINISTRATIVE CODE CHAPTER 652, MEDICAL LABORATORIES

NOTICE IS HEREBY GIVEN that the State Board of Health will hold a public hearing to consider amendments to Chapter 652 of the Nevada Administrative Code (NAC). This public hearing is to be held in conjunction with the State Board of Health meeting on Sept. 6, 2024.

The State Board of Health will be conducted via videoconference beginning at 9 a.m., on Sept. 6, 2024, at the following locations:

- Click or type into a web browser the following link to join the meeting online: <u>https://teams.microsoft.com/l/meetup-</u> join/19%3ameeting_ZjcxNGQzYjQtMzM1OS00MTNiLTg1ZWYtMmExODkwZTBkMTQ0%40thread.v2/ <u>0?context=%7b%22Tid%22%3a%22e4a340e6-b89e-4e68-8eaa-</u> <u>1544d2703980%22%2c%22Oid%22%3a%22768e443d-3be6-48f0-9bb0-7e72f1276b8d%22%7d</u>
- Phone number: (775) 321-6111

 Conference ID: 382 183 728#
- Division of Public and Behavioral Health Hearing Room 303 4150 Technology Way Carson City, NV 89706
- Southern Nevada Health District Red Rock Trail Rooms A & B 208 S. Decatur Blvd. Las Vegas, NV 89107

The proposed changes to LCB File No. R145-23, as authorized by <u>2023's Assembly Bill (AB) 432</u>, proposed changes pursuant to Governor Lombardo's efforts to streamline burdensome regulations, and regulation changes to update and clarify, include the following:

- Bring the NAC into compliance with AB 432 of the 2023 Legislative Session; Chapter 230 Statutes of Nevada 2023 at page 1462; and changes to the Federal Register 42 CFR part 493 effective Dec. 28, 2024.
- Remove the requirement that an application for the issuance or renewal of a laboratory personnel certificate, and laboratory license, registration or permit be submitted on a form provided by the Division of Public and Behavioral Health (DPBH) and instead require such an application to be made in the form prescribed by DPBH.
- Replaces a requirement that DPBH provide that form to the holder of such certification not less than 90 days before the expiration of the certificate with a requirement that DPBH notify the

holder of the impending expiration of the certificate.

- Revise the qualifications for certification as a histotechnologist, a histologic technician and a technologist, respectively, in a manner that expands the persons eligible for such certification.
- Revises the length of such a period of temporary employment to not more than 6 months while the application is being processed, authorizes an additional period of temporary employment for not more than 30 days after an application has been reviewed and DPBH has requested additional information from the applicant, and revises the date by which substantiating documents for an application for certification as laboratory personnel must be submitted.
- Requires registered laboratory director of a laboratory to ensure that an office laboratory assistant performing certain testing is appropriately trained and educated and requires an office laboratory assistant performing certain testing to possess the qualifications required by certain federal regulations.
- Repeals NAC 652.600 which requires regulatory requirements for a program of training for certification as a technician in accordance with Governor Lombardo's effort to streamline burdensome regulations.
- Updates the names of certifying organizations.
- Clarifies when laboratories that are licensed by the state are to submit applications to update the changes to their laboratory.
- Adds a certifying organization that has been approved by the Centers for Medicare and Medicaid Services (CMS), to certify persons with an earned doctoral degree in a chemical, biologic or clinical laboratory science, to qualify for a Registered or Licensed laboratory director.
- In accordance with a change in the regulatory requirements of the Clinical Laboratory Improvement Amendments (CLIA) program that will occur on Dec. 28, 2024, the CLIA requirements for laboratory personnel, will remove the qualification of a person with a degree in a Physical Science. The regulation update to NAC Chapter 652 will also remove this qualification as of Jan. 1, 2025, but allow for persons that were qualified with this degree, continue to be qualified.
- Adds students that are in an accredited school for Licensed Practical Nursing (LPN) to be qualified for a Point-of-Care Analyst (POC) certification.

1. Anticipated effects on the business which LCB File No. R145-23 regulates:

- A. *Adverse effects*. There are no anticipated adverse economic effects on businesses in the State of Nevada.
- B. *Beneficial effects:* There are no anticipated beneficial or positive economic effects on businesses in the State of Nevada.
- C. *Immediate:* As soon as the proposed regulations become effective, there are no anticipated immediate economic effects on businesses in the State of Nevada.
- D. *Long-term:* There are no anticipated long-term economic benefits or adverse effects to businesses in the State of Nevada.

2. Anticipated effects on the public:

A. *Adverse*: There are no anticipated adverse effects for the public receiving medical laboratory services in health care facilities associated with the proposed regulation changes.

- B. *Beneficial:* There are no anticipated beneficial effects to the public receiving medical laboratory services in health care facilities associated with the proposed regulation changes.
- C. *Immediate*: There are no anticipated immediate effects to the public receiving medical laboratory services in health care facilities associated with the proposed regulation changes.
- D. *Long-term:* There are no anticipated immediate effects to the public receiving medical laboratory services in health care facilities associated with the proposed regulation changes.

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3. DPBH determined the impact on small businesses by distributing an email containing a link to the small-business impact questionnaire to 18,788 actively licensed medical laboratory facilities, and actively licensed and certified laboratory personnel, along with a copy of the proposed regulation changes to NAC Chapter 652. The results from the questionnaire were analyzed and tallied and then documented in a small business impact statement. DPBH also conducted a public workshop on July 12, 2024, and received additional information suggested to add an additional certifying agency for the qualification of laboratory personnel. This suggestion is incorporated into the proposed changes.

4. There should be no additional costs to the agency to enforce the proposed regulation changes.

5. The proposed regulations do not overlap or duplicate any other Nevada state or federal 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, Cody Phinney, to be received no later than Aug. 30, 2024, at the following address:

Secretary, State Board of Health Division of Public and Behavioral Health 4150 Technology Way, Suite 300 Carson City, NV 89706 <u>stateBOH@health.nv.gov</u>

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 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, Suite 300 Carson City, NV 89706
- Nevada Division of Public and Behavioral Health 4220 S. Maryland Parkway, Bldg. A, Ste. 100 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 online by going to the Health Facility Regulation Development Processes web page at <u>https://dpbh.nv.gov/Reg/HealthFacilities/State_of_Nevada_Health_Facility_Regulation_Public_Workshops/</u>

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

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Copies may be obtained in person, by mail, or by calling the Division of Public and Behavioral Health Division of Public and Behavioral Health Bureau of Health Care Quality and Compliance 4220 S. Maryland Parkway, Building A, Suite 100 Las Vegas, NV 89119 (702) 486-6515 <u>tcarney@health.nv.gov</u>

Copies may also be obtained from the Nevada State Library at the address listed below:

Nevada State Library & Archives 100 N. Stewart Street Carson City, NV 89701

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.