

# PROPOSED REGULATION OF THE STATE BOARD OF HEALTH

## LCB File No. R104-13

These regulations are being proposed in accordance with Senate Bill 40 of the 2013 Legislative Session and NRS 652.125 and 652.090.

EXPLANATION - Matter in *italics* is new; matter in brackets ~~{omitted material}~~ is material to be omitted.

**Chapter 652 of NAC is hereby amended by adding thereto the provisions set forth as sections 1 to 22, inclusive, of this regulation.**

**Section 1** NAC 652.071 is hereby amended to read as follows:

**NAC 652.071 “~~{Health}~~ Division” defined.** (NRS 439.200, 652.123, 652.125, 652.130)  
“~~{Health}~~ Division” has the meaning ascribed to it in NRS 652.035.

**Sec. 2** NAC 652.092 is hereby amended to read as follows:

**NAC 652.092 “Outpatient center of a laboratory” defined.** (NRS 439.200, 652.123, 652.125, 652.130) “Outpatient center of a laboratory” means a facility at a permanent location which is:

1. Operated by a licensed laboratory; and
2. Used to collect specimens ~~{and}~~ *or* perform any test which is classified as a waived test pursuant to Subpart A of Part 493 of Title 42 of the Code of Federal Regulations, *or both*.

**Sec. 3** NAC 652.170 is hereby amended to read as follows:

**NAC 652.170 Laboratory: Application for license or registration; action by ~~{Bureau}~~ *the Division* on application; performance of tests at temporary location.** (NRS 439.200, 652.090, 652.130)

652.170 1. An application for a license or registration for a laboratory must be made on a form provided by the ~~{Bureau}~~ *Division*. Upon receipt of a completed application, the ~~{Bureau}~~ *Division* shall conduct a survey of the facility and examine the policies and procedures of the laboratory to determine whether the laboratory is in substantial compliance with this chapter for the procedures for testing that the laboratory desires to provide.

2. The ~~{Bureau}~~ *Division* shall notify the applicant of the disposition of the application within 30 days after receipt of the application.

3. A laboratory seeking to perform tests at a temporary location must submit to the ~~{Bureau}~~ *Division* an application on the form provided by the ~~{Bureau}~~ *Division* and the fees required by NAC 652.488.

*4. The following proof of identity of the laboratory director must be included in the application:*

*(a) An electronic signature; or*

- (b) A notarized statement; or*
- (c) A copy of a government issued identification including but not limited to a driver's license, a passport, a Department of Motor Vehicles issued identification card or other government issued identification acceptable to the Division; or*
- (d) Other proof of identity acceptable to the Division.*

**Sec. 4 Add a new section titled, Infection Control**

- 1. A laboratory must include documentation that the laboratory has considered, selected, and implemented nationally recognized infection control guidelines such as those of the Centers for Disease Control and Prevention and the Occupational Safety and Health Administration including but not limited to the following areas:
  - (a) Hand hygiene;*
  - (b) The disposal of needles, syringes, medical waste and specimens;*
  - (c) The use of syringes, needles, vials and lancets; and*
  - (d) The sterilization and disinfection of reusable items.**
- 2. A copy of the nationally recognized infection control guidelines selected by the laboratory pursuant to subsection 1 must be available to all employees and contract employees.*
- 3. A laboratory must follow the manufacturer's guidelines for the use and maintenance of equipment, devices and supplies. The manufacturer's guidelines must be available to all employees and contract employees that use or maintain the equipment, devices and supplies.*
- 4. Each employee of a laboratory and each person under contract with a laboratory who works at the laboratory and has exposure to patients, patient specimens or the disinfection or sterilization of equipment at the laboratory shall receive training and must be evaluated by supervising staff on the employee's or contractor's knowledge and skills concerning the infection control guidelines selected pursuant to subsection 1 within the first 10 days of employment and at least every 12 months thereafter.*

**Sec. 5** NAC 652.320 is hereby amended to read as follows:

**NAC 652.320 Inspections: Duties and authority of ~~{Bureau}~~ the Division; submission of plan for correction of deficiencies.** (NRS 439.200, 652.123, 652.130)

1. Except as otherwise provided in this subsection, the ~~{Bureau}~~ **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 ~~{Bureau}~~ **Division** if the reports of the inspections are available to the ~~{Bureau}~~ **Division**.

2. Upon receipt of a complaint against a laboratory or its personnel, except for a complaint concerning the cost of services, the ~~{Bureau}~~ **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. The ~~{Bureau}~~ *Division* shall report ~~{deficiencies}~~ *violations* noted at the time of each inspection by forwarding to the director a statement of deficiencies and a form for the director to submit a plan of correction. The director shall return the form to the ~~{Bureau}~~ *Division*, containing thereon the plan of correction for each of the ~~{deficiencies}~~ *violations*, within 10 working days after receiving the form. The plan must indicate the date by which each ~~{deficiency}~~ *violation* will be corrected.

4. *Failure to submit the plan of correction to the Division within 10 working days constitutes a separate violation subject to monetary penalties with a severity rated at the same level as the highest violation identified on the statement of deficiencies.*

Sec. 6 NAC 652.370 is hereby amended to read as follows:

**NAC 652.370 Director: Availability and presence; prohibition against serving more than five laboratories; exception.** (NRS 439.200, 652.123)

1. A director shall be available to the personnel of a laboratory, in person or by telephone or other electronic means, for any necessary consultation.

2. ~~{If the laboratory provides:}~~

~~{(a) Only routine services regarding hematology, urinalysis, chemistry, blood gas and microbiology, }~~ The director must be on the premises of the laboratory at least once every ~~{30 consecutive days}~~ *quarter of each year*. If the director is absent from the laboratory ~~{for 30 consecutive days}~~ *once every quarter* or more, the director shall provide a licensed substitute to serve in his or her place, unless the laboratory is in a rural area and the ~~{Board}~~ *Division* determines that a substitute is not necessary.

~~{(b) Services regarding vaginal cytology, nonvaginal cytology, flow cytometry or histopathology, or toxicologic analysis involving high-pressure liquid chromatography or gas chromatography with mass spectroscopy, the director must be on the premises of the laboratory at least once every 10 consecutive days of testing. If the director is absent from the laboratory for 10 consecutive days or more of testing, the director shall provide for a licensed substitute to serve in his or her place.~~

~~{(c) Any services other than those set forth in paragraphs (a) and (b), the Bureau may establish the minimum frequency with which the director must be on the premises of the laboratory, which must be based upon the complexity of the testing performed by the laboratory and must not be less than once every 30 consecutive days.}~~

3. Except as otherwise provided in this subsection, a natural person shall not simultaneously serve as director of more than five laboratories. A natural person may simultaneously serve as director of more than five laboratories if the laboratories are registered under one certificate pursuant to subsection 2 of NAC 652.180.

Sec. 7 NAC 652.380 is hereby amended to read as follows:

**NAC 652.380 Director of licensed laboratory: Qualifications.** (NRS 439.200, 652.123, 652.125, 652.130) 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}~~ *or* clinical pathology, or ~~{in clinical pathology}~~ *both*, 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. To qualify for a license as a director of a licensed laboratory that only performs tests in the subspecialty of oral pathology, a person must meet the following qualifications:**

**(a) Be certified by the American Board of Oral and Maxillofacial Pathology, American Board of Pathology or the American Osteopathic Board of Pathology; and**

**(b) Be a dentist licensed to practice dentistry in this State or a physician who is licensed to practice medicine in this State.**

~~2~~ **3.** Hold an earned doctoral degree from an accredited institution, with a chemical, physical ~~or~~, biological **or clinical laboratory** science as the major, 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; or

(6) The American Board of Medical Genetics; or

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

~~3. In a geographical area which does not have a person who meets the qualifications set forth in subsection 1 or 2, be a physician, licensed to practice in the State of Nevada, whose experience is acceptable to the Board.~~

**Sec. 8** NAC 652.450 is hereby amended to read as follows:

**NAC 652.450 Laboratory assistant; blood-gas assistant.** (NRS 439.200, 652.123, 652.125, 652.130)

1. A laboratory assistant may perform ~~only those procedures requiring the degree of skill commensurate with his or her education, training and technical abilities~~ **tests that have been classified as a waived test pursuant to 42 C.F.R. Part 493, Subpart A and collect and process specimens.** Except as otherwise provided in NRS 652.217 and NAC 652.155, a laboratory assistant may not independently perform **moderate or complex** laboratory ~~procedures~~ **tests**, but may assist manually under direct supervision.

2. A blood-gas assistant may work only under the constant direct supervision of a blood-gas technologist or the director. To be certified as a blood-gas assistant, a person must be a high school graduate or the equivalent who is currently being trained in the determination of blood gases.

Sec. 9 NAC 652.491 is hereby amended to read as follows:

**NAC 652.491 Grounds for denial, suspension or revocation of certificate.** (NRS 439.200, 652.125) A certificate may be denied, suspended or revoked if an applicant, a person who holds a certificate or any technical employee of the laboratory:

1. Violates any provision of this chapter or chapter 652 of NRS;
2. Makes any misrepresentation in obtaining a certificate;
3. Has been convicted of a ~~felony relating to the position for which the applicant has applied or for which his or her certificate has been issued pursuant to chapter 652 of NRS~~ **crime that is punished as a felony listed in NRS 449.174;**
4. Is guilty of unprofessional conduct; or
5. Fails to meet the minimum standards prescribed by the Board.

**Sec. 10 Add a new section titled: Requirements to qualify for certification as a laboratory assistant.**

*To qualify for certification as a laboratory assistant, a person must be a high school graduate or have a general equivalency diploma and:*

*1. Must complete at least 6 months of training approved by the Division and demonstrate an ability to perform laboratory procedures in the laboratory where he or she receives the training; or*

*2. Must:*

*(a) Complete a course of instruction that qualifies him or her to take an examination for certification in phlebotomy that is administered by:*

*(1) The American Medical Technologists;*

*(2) The American Society of Clinical Pathologists;*

*(3) The American Certification Agency for Healthcare Professionals;*

*(4) The National Center for Competency Testing;*

*(5) National Healthcareer Association;*

*(6) National Phlebotomy Association; or*

*(7) An association deemed to have equivalent standards to those named in this section by the Division, and*

*(b) Pass an examination specified in paragraph (a); or*

*3. Must have a total of three years of full time phlebotomy experience in the past five years.*

**Sec. 11 Add a new section titled, Monetary Penalties**

*1. For the purposes of determining the severity of a violation the severity scale ascribed in NAC 449.99861 shall be used.*

*2. De minimis violation means a violation rated at a severity level of one.*

*3. In determining the amount of a monetary penalty, the Division shall:*

*(a) For a first violation with a severity level of four, a penalty of \$1,000 per violation must be imposed.*

*(b) For a first violation with a severity level of three a monetary penalty of \$800 per violation must be imposed.*

- (c) *For a first violation with a severity level of two an initial monetary penalty of \$100 per violation may be imposed. The payment of this monetary penalty may be suspended if the laboratory has corrected the deficiencies within the time specified in the plan of correction approved by the Division.*
  - (d) *For a second violation on any subsequent inspection with a severity level of four, a monetary penalty of \$5,000 per violation must be imposed.*
  - (e) *For a second violation on any subsequent inspection with a severity level of three, a monetary penalty of \$1,600 per violation must be imposed.*
  - (f) *For a second violation on any subsequent inspection with a severity level of two, a monetary penalty of \$200 per violation may be imposed regardless of whether a first monetary penalty was imposed or not.*
  - (g) *For a third or subsequent violations on any subsequent inspection with a severity level of four, a monetary penalty of \$10,000 per violation must be imposed.*
  - (h) *For a third or subsequent violations on any subsequent inspection with a severity level of three, a monetary penalty of \$3,200 per violation must be imposed.*
  - (i) *For a third or subsequent violations on any subsequent inspection with a severity level of two, a monetary penalty of \$400 per violation may be imposed regardless of whether a first or second monetary penalty was imposed.*
4. *A monetary penalty that is imposed may, upon approval by the Division be used by the laboratory 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 showing the monies were used to correct the violation. If the amount of the sanction is greater than the cost to correct the violation, the remainder shall be paid to the State Treasurer in accordance with the provisions of this Chapter.*

**Sec. 12 Add a new section titled, De minimis violations: monetary penalty: exception for de minimis deficiency; presumption of de minimis deficiency.**

- 1. *Any violation for which a severity is not specified is presumed to be a de minimis.*
- 2. *A laboratory is not subject to a monetary penalty for a de minimis violation.*

**Sec. 13 Add a new section titled, Imposition of sanctions in emergencies: Notice; authority; exception to notice requirement.**

- 1. *Except as otherwise provided in this section, the Division shall give notice pursuant to the provisions of NAC 439.300 to 439.395, inclusive, before taking disciplinary action against a laboratory.*
- 2. *If necessary to protect the public health and safety, the Division may impose such disciplinary action or monetary penalty as is necessary without notice to the laboratory or by oral notice to the laboratory.*

3. *If there is an immediate and serious threat to the health and safety of patients served by a laboratory, the provisions concerning notice contained in this section govern.*

4. *The Division may suspend the license of a laboratory without notice or upon oral notice if the Division finds that an emergency has caused a violation with a severity of four which places one or more patients in immediate jeopardy. For purposes of this subsection, “emergency” means any situation in which a laboratory is unable to operate in a safe manner.*

5. *In any case where disciplinary actions or monetary penalties are imposed without written notice, the Division shall provide written notice that complies with the requirements of NAC 439.345 within 48 hours after the imposition of the disciplinary actions or monetary penalties.*

**Sec. 14 Add a new title, Presumption when same violation found on subsequent inspection; imposition of violation for subsequent deficiency.**

*If the same violation is found during a subsequent inspection conducted to evaluate compliance with a plan of correction, there is a rebuttable presumption that the violation continued through the period between the inspection and the subsequent inspection. A monetary penalty may be imposed for a subsequent violation only if the subsequent inspection is made and the violation is again actually found to be present either after or during a laboratory’s opportunity to correct the violation.*

**Sec. 15 Add new section titled, Report of Violation by Division to Laboratory**

*A violation must be reported by the Division to the laboratory and, if applicable, to the Centers for Medicare and Medicaid Services. The notice to the laboratory must specify each violation found and the severity level for the violation as determined by the Division.*

**Sec. 16 Add a new section titled, Imposition of monetary penalty pending hearing or appeal; stay of payment of penalties pending appeal**

*If the Division imposes a monetary penalty pursuant to section 10, the Division shall impose the monetary penalty pending a hearing or appeal. The payment of the monetary penalty must not be stayed during the pendency of any administrative appeal.*

**Sec. 17 Add a new section titled, Reduction of penalty.**

*If a laboratory against which a monetary penalty is imposed:*

1. *Waives the right to a hearing;*
  2. *Corrects the violations that were the basis for the monetary penalty; and*
  3. *Pays the monetary penalty within 15 days after receipt of the notice of the penalty,*
- ☛ *the penalty must be reduced by 25 percent and no interest may be charged.*

**Sec. 18 Add a new section titled, Notice of Monetary Penalty**

*If the Division imposes a monetary penalty, the Division shall send a separate notice to the laboratory containing:*

- (a) The amount of the penalty;*
- (b) If it was a first, second, third or greater than third violation;*
- (c) The due date of the monetary penalty; and*
- (d) A statement that the Division will reduce the total amount due by 25 percent pursuant to Section 16 if the laboratory:
  - (1) Waives the right to a hearing; and*
  - (2) Pays the reduced amount within 15 days after receipt of notice of the penalty; and**
- (e) The total amount due and the amount reduced pursuant to paragraph (d).*

**Sec. 19 Add a new section titled, Time for payment of penalties.**

- 1. Monetary penalty assessment payments, imposed pursuant to section 10, are due within 15 days after the notice of the penalty and must be paid irrespective of any administrative appeal.*
- 2. If the laboratory has appealed a decision imposing a monetary penalty, the penalty is due and must be paid after the final administrative decision is rendered and 15 days after the laboratory has been notified of the amount of the monetary penalty and any interest that may be due.*

**Sec. 20 Add a new section, Application: Additional Requirements for Personnel Applications**

- 1. In addition to any applicable statutory or regulatory requirements, an application submitted pursuant to this Chapter or NRS Chapter 652 must include a method of electronic communication, including, without limitation, an electronic mail address, a telephone number that will accept electronic mail, or any other method by which the Division may communicate with the applicant other than by telephone or United States mail. The Division may exempt an applicant from the requirements of this paragraph if the applicant attests that the methods set forth in this paragraph are not feasible for him or her and acknowledges that the United States mail is the only means by which to communicate with the applicant.*
- 2. A laboratory personnel applicant pursuant to this Chapter or NRS Chapter 652 shall notify the Division of any change to the information contained in a personnel application within 30 days after the change. The notification may be made in writing, by electronic mail or by any other method authorized by the Division. The failure of a personnel applicant to comply with the requirements of this subsection constitutes grounds for the denial of the application, the suspension or revocation of the applicant's license or certificate or the imposition of a monetary penalty at a severity level of two or a combination of these.*

**Sec. 21 Add a new section, titled, Notices and Delivery**

*Any notice that is required by the provisions of this chapter or chapter 652 of NRS to be delivered to a licensee, certificate holder or an applicant shall be deemed to be validly given if the notice is sent to the last address or electronic mail address that was provided to the Division by the licensee, certificate holder or applicant.*

**Sec. 22 – *NAC 652.037 and 652.290 is hereby repealed.***

**TEXT OF REPEALED SECTION**

**NAC 652.290 Sterilization of equipment and materials; disposal.** (NRS 439.200, 652.130)

1. Blood-letting devices such as syringes, needles and lancets must be sterile and not reused unless they are properly packaged and sterilized before each use and marked “sterilized.”
2. All microbial materials and blood and its products must be properly decontaminated or placed in two bags and marked “biohazard” before they are discarded in a public disposal service.
3. All disposable needles and syringes must be properly decontaminated and discarded in a container which cannot be punctured.

**NAC 652.037 “Bureau” defined.** (NRS 439.200, 652.123, 652.125, 652.130) “Bureau” means the Bureau of Licensure and Certification of the Health Division.