ADOPTED REGULATION OF THE

STATE BOARD OF HEALTH

LCB File No. R104-13

Effective March 28, 2014

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

AUTHORITY: §§1, 17, 19, 27, 28, 31 and 45, NRS 439.200, 652.123 and 652.130; §§2, 7 and 9-11, NRS 439.200, 652.123, 652.130, 652.225 and 652.260; §§3 and 18, NRS 439.200, 652.090 and 652.130; §§4 and 46, NRS 439.200, 652.123, 652.125, 652.127 and 652.130; §§5, 6 and 25, NRS 439.200, 652.123, 652.130 and 652.260; §§8, 15 and 26, NRS 439.200, 652.123, 652.130, 652.220, 652.225 and 652.260; §§12 and 16, NRS 439.200, 652.123, 652.130, 652.220 and 652.260; §13, NRS 439.200, 652.090, 652.123, 652.125, 652.130, 652.220 and 652.260; §§14, 29, 30, 32-34, 36-39 and 44, NRS 439.200, 652.123, 652.125 and 652.130; §20, NRS 439.200 and 652.130; §21, NRS 439.200, 652.090, 652.125 and 652.130; §22, NRS 439.200, 652.125 and 652.130; §§23, 24, 40 and 41, NRS 439.200 and 652.125; §35, NRS 439.200, 652.123 and 652.125; §42, NRS 439.200, 652.123, 652.125, 652.220, 652.225 and 652.260; §43, NRS 439.200, 652.123, 652.225 and 652.260.

A REGULATION relating to medical laboratories; requiring laboratories to adopt certain infection control guidelines; prescribing requirements for certain laboratory personnel; revising provisions relating to penalties for certain violations by laboratories; requiring certain applications for licensure or certification to operate or work in a laboratory to include certain information; transferring certain responsibilities from the Bureau of Licensure and Certification of the Division of Public and Behavioral Health of the Department of Health and Human Services and the State Board of Health to the Division of Public and Behavioral Health of the Department; amending certain requirements relating to the licensure and certification of laboratory personnel and the operation of laboratories; and providing other matters properly relating thereto.

Section 1. Chapter 652 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 15, inclusive, of this regulation.

Sec. 2. ***1. "Violation" means noncompliance with any provision of this chapter or chapter 652 of NRS.***

2. The term includes, without limitation:

(a) Any incident where an action, practice or situation occurs that appears to be inconsistent with any provision of this chapter or chapter 652 of NRS concerning a laboratory where there are no extenuating circumstances or where the laboratory has responded inappropriately to a complaint; and

(b) The failure of a laboratory or the personnel of a laboratory to:

(1) Prevent such an incident from occurring, if the incident could have been avoided;

(2) Identify such an incident;

(3) Take action to correct such an incident before the identification of the incident by the Division; or

(4) Implement a contingency plan if permanent action to correct such an incident has not been undertaken.

Sec. 3. *1. A laboratory must adopt nationally recognized laboratory safety guidelines that must include, without limitation, infection control guidelines to be followed by employees of the laboratory. Acceptable guidelines include, without limitation, the Guidelines for Environmental Infection Control in Health-Care Facilities published by the Centers for Disease Control and Prevention of the United States Department of Health and Human Services, the Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories published by the Centers for Disease Control and Prevention of the United States Department of Health and Human Services and Laboratory Safety Guidance published by the Occupational Safety and Health Administration of the United States Department of Labor. The guidelines adopted pursuant to this section must prescribe procedures for safe operation of the laboratory, including, without limitation:*

(a) Hand hygiene;

(b) The disposal of all waste that constitutes a biohazard, including, without limitation, needles, syringes, medical waste, microbial waste and specimens;

(c) The proper use of syringes, needles, vials and lancets; and

(d) The proper sterilization and disinfection of all reusable equipment, if such sterilization or disinfection is performed at the laboratory or by employees of the laboratory.

2. The director of the laboratory shall make a copy of the guidelines adopted by the laboratory available to all employees.

3. Each employee of a laboratory shall follow the manufacturer's guidelines for the use and maintenance of equipment, devices and supplies. The director of a laboratory shall make the manufacturer's guidelines available to each employee who uses or maintains the equipment, devices and supplies.

4. Each employee of a laboratory who has exposure to patients or patient specimens or participates in the disinfection or sterilization of equipment at the laboratory must receive training and must be evaluated by a supervisor on the employee's knowledge and skills concerning the infection control guidelines adopted pursuant to subsection 1 within 10 working days after commencing employment and at least once each year thereafter.

5. If a laboratory that has adopted infection control guidelines pursuant to subsection 1 adopts new or additional guidelines, the laboratory must notify each employee of the laboratory who has exposure to patients or patient specimens or participates in the disinfection or sterilization of equipment at the laboratory of the change and provide instruction to each such employee concerning the new guidelines within 10 working days after adopting the new guidelines.

6. As used in this section, "employee" includes, without limitation, any person providing services pursuant to a contract.

Sec. 4. *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 laboratory certified pursuant to the Clinical Laboratory Improvement Amendments, 42 U.S.C. § 263a, or a laboratory that is licensed by a federal or state governmental agency in any state or territory of the United States.

Sec. 5. *1. The severity scale set forth in this section must be used to assess the severity of a particular violation pertaining to the laboratory. The basis for the assessment must be the actual or potential harm to patients.*

2. Violations of severity level one concern requirements promulgated primarily for administrative purposes. No harm is likely to occur to a patient. No negative patient impact has occurred or is likely to occur.

3. Violations of severity level two indirectly threaten the health, safety, rights, security, welfare or well-being of a patient. A potential for harm, as yet unrealized, exists. If continued over time, a negative impact on one or more patients or a violation of one or more patients' rights would occur or would be likely to occur.

4. Violations of severity level three create a condition or incident in the operation or maintenance of a laboratory that directly or indirectly threatens the health, safety, rights, security, welfare or well-being of one or more patients. A negative impact on the health, safety, rights, security, welfare or well-being of one or more patients has occurred or can be predicted with substantial probability to occur.

5. Violations of severity level four create a condition or incident that has resulted in or can be predicted with substantial probability to result in death or serious harm to a patient. As used in this subsection, "serious harm" means serious mental harm, serious impairment of bodily functions, serious dysfunction of any bodily organ or part, life-threatening harm or death.

Sec. 6. *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 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.

Sec. 7. *For the purposes of any computation of time required pursuant to sections 8 to 12, inclusive, of this regulation:*

1. Any prescribed period of more than 5 days includes Saturdays, Sundays and holidays.

2. Any prescribed period of 5 days or less does not include Saturdays, Sundays or holidays.

3. If the date on which any action required to be performed falls on a Saturday, Sunday or holiday, the time is extended until the next day that is not a Saturday, Sunday or holiday.

4. The day of any act or event or on which notice is received is not included in the computation.

Sec. 8. *1. If necessary to protect the public health and safety, the Division may impose such disciplinary action as it deems necessary without notice to the laboratory or with verbal notice to the laboratory.*

2. The Division may suspend the license of a laboratory without notice or upon verbal notice if the Division finds a violation with a severity level of four where corrective action within 48 hours is necessary because the violation has caused, or if uncorrected is likely to cause, serious injury or harm or death to a patient.

3. Within 48 hours after the Division imposes disciplinary actions without written notice, the Division shall provide written notice in the manner set forth in NAC 439.345.

Sec. 9. *1. Except as otherwise provided in section 8 of this regulation, the Division shall, in addition to providing the statement of violations required pursuant to NAC 652.320, give notice in the manner set forth in NAC 439.345 before taking disciplinary action.*

2. If the Division imposes a monetary penalty pursuant to section 6 or 13 of this regulation, the notice provided to the laboratory pursuant to subsection 1 must state:

(a) The amount of each penalty;

(b) Whether the violation was a first, second, third or greater than third violation;

(c) The date on which payment is due;

(d) A statement that the Division will reduce the total amount due by 25 percent if the laboratory meets the requirements set forth in section 10 of this regulation; and

(e) The total amount due for all penalties and the amount that would be due if each penalty were reduced pursuant to section 10 of this regulation.

Sec. 10. *The Division will reduce the total amount due for all penalties as determined pursuant to section 9 of this regulation by 25 percent and no interest will be charged if the laboratory against which the penalties are 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.

Sec. 11. *1. Payments made to satisfy a monetary penalty imposed pursuant to section 6 or 13 of this regulation or NAC 652.320 are due within 15 days after the date on which the notice of the penalty is provided pursuant to section 9 of this regulation and must be paid irrespective of any administrative appeal.*

2. If the laboratory has appealed a decision imposing a monetary penalty pursuant to NAC 652.493, the penalty is due and must be paid after the final administrative decision is rendered and within 15 days after the laboratory has been notified of the amount of the monetary penalty and any interest that may be due.

3. The total monetary penalty assessed against any laboratory bears interest at the rate of 10 percent per annum. Except as otherwise provided in subsection 4, interest will be assessed on the unpaid balance of the penalty, beginning on the date on which the penalty is due.

4. The payment of any interest that accrues while the laboratory has a hearing pending on the initial determination of violations leading to the imposition of a monetary penalty will be stayed pending the appeal.

5. Any costs, including, without limitation, attorney's fees, incurred by the Division in the collection of any monetary penalty may be recovered from the laboratory.

Sec. 12. *1. If the laboratory fails to pay a monetary penalty on or before the date on which the penalty is due, the Division may suspend the license of the laboratory.*

2. If the Division determines to suspend the license of a laboratory pursuant to subsection 1, the Division must, in accordance with the requirements of NAC 439.345, provide notice of its intention to suspend the license of the laboratory.

3. If the laboratory fails to pay the monetary penalty, including any additional costs incurred in collection of the penalty, within 10 days after receipt of the notice described in subsection 2, the Division must suspend the license of the laboratory. The suspension must not be stayed during the pendency of any administrative appeal.

Sec. 13. *1. In addition to any applicable statutory or regulatory requirements, an application submitted pursuant to this chapter or chapter 652 of NRS must include a method by which the Division may communicate with the applicant other than by telephone or mail, which may include, without limitation, an electronic mail address or a telephone number that will accept electronic mail. The Division may exempt an applicant from the requirements of this subsection if the applicant attests that no additional methods of communication are feasible for the applicant and acknowledges that mail is the only means by which to communicate with the applicant.*

2. A person who files an application for any license or certification as a laboratory director or laboratory personnel or who is licensed or certified as a laboratory director or laboratory personnel pursuant to NAC 652.380 to 652.486, inclusive, and section 4 of this regulation shall notify the Division of any change to the information contained in the application within 30 days after the change. Such notice may be provided in writing, by electronic mail or by any other method authorized by the Division. The failure of an applicant to comply with the requirements of this subsection constitutes grounds for disciplinary action that may include, without limitation:

(a) Denial of the application;

(b) Suspension or revocation of the applicant's license or certificate;

(c) The imposition of a monetary penalty equal to the monetary penalty imposed for a violation of severity level two pursuant to section 6 of this regulation; and

(d) Any combination of the disciplinary actions described in paragraphs (a), (b) and (c).

Sec. 14. ***To qualify for a license as a director of a licensed laboratory in which the only tests performed are in the subspecialty of oral pathology, a person must be:***

1. Certified by the American Board of Oral and Maxillofacial Pathology, American Board of Pathology or the American Osteopathic Board of Pathology; and

2. A dentist licensed to practice dentistry in this State or a physician licensed to practice medicine in this State.

Sec. 15. ***Any notice that is required to be provided to a licensee, certificate holder or applicant for a license or certificate pursuant to this chapter or chapter 652 of NRS shall be deemed sufficient 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. 16. 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 652.148, inclusive, ***and section 2 of this regulation*** have the meanings ascribed to them in those sections.

Sec. 17. NAC 652.092 is hereby amended to read as follows:

652.092 "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. 18. NAC 652.170 is hereby amended to read as follows:

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]~~ ***an inspection*** of the facility ~~[and examine]~~ ***which may include an examination of*** 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 laboratory director shall include at least one of the following forms of proof of identity with the application:

(a) An electronic signature;

(b) A notarized statement;

(c) A copy of a form of government-issued identification, which may include, without limitation, a driver's license, passport, identification card issued by the Department of Motor Vehicles or other government-issued identification acceptable to the Division; or

(d) Other proof of identity acceptable to the Division.

5. As used in this section, "electronic signature" means a user name attached to or logically associated with a record and executed or adopted by an applicant with the intent to sign an electronic application or other document.

Sec. 19. NAC 652.175 is hereby amended to read as follows:

652.175 1. A laboratory operated by a licensed physician pursuant to NRS 652.235 must register with the ~~[Health]~~ Division as an exempt laboratory or a nonexempt laboratory.

2. A laboratory operated by a licensed physician pursuant to NRS 652.235 may register with the ~~[Health]~~ Division as an exempt laboratory if:

(a) The operating physician submits an application for registration as an exempt laboratory on a form provided by the ~~[Bureau;]~~ ***Division;***

(b) The operating physician pays the applicable fees set forth in NAC 652.488;

(c) Each test performed by personnel other than the physician has been classified as a waived test pursuant to 42 C.F.R. Part 493, Subpart A; and

(d) Either:

(1) The operating physician performs tests on his or her own patients and makes his or her own readings of the results of the tests; or

(2) Any manipulation of a person for the collection of a specimen is made by an employee of the laboratory who is qualified pursuant to NRS 652.210.

3. A laboratory operated by a licensed physician pursuant to NRS 652.235 may register with the ~~[Health]~~ Division as a nonexempt laboratory if:

(a) The operating physician submits an application for registration as a nonexempt laboratory on a form provided by the ~~[Bureau;]~~ ***Division;***

(b) The operating physician is licensed as a director and pays the applicable fees set forth in NAC 652.488;

(c) At least some tests performed by personnel other than the physician have not been classified as waived tests pursuant to 42 C.F.R. Part 493, Subpart A; and

(d) Either:

(1) The operating physician or an employee of the laboratory performs tests on the patients of the physician and the physician or the employee of the laboratory makes his or her own readings of the results of the tests; or

(2) Any manipulation of a person for the collection of a specimen is made by an employee of the laboratory who is qualified pursuant to NRS 652.210.

4. 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. 20. NAC 652.180 is hereby amended to read as follows:

652.180 1. Except as otherwise provided in subsection 2, the ~~[Bureau]~~ ***Division*** shall issue a certificate of registration to each laboratory which registers with the ~~[Health]~~ Division pursuant to NRS 652.235. A certificate of registration issued pursuant to this section is effective for 2 years after the date of issuance.

2. The ~~[Bureau]~~ ***Division*** may issue one certificate of registration for any number of laboratories which test specimens to protect the public health if each laboratory:

(a) Is supervised by the ~~[Health]~~ Division or a health district; and

(b) Performs at least 1 but not more than 15 tests which are classified pursuant to 42 C.F.R. Part 493, Subpart A, as moderate complexity tests or waived tests.

3. An application for renewal of a certificate must be on a form provided by the ~~[Bureau.]~~ ***Division.***

4. The failure to apply for renewal within 30 days after a certificate expires will result in termination of the laboratory's authority to operate in this State.

5. Upon acceptance of an application for renewal, the ~~[Bureau]~~ ***Division*** shall provide the laboratory with a new certificate of registration.

Sec. 21. NAC 652.200 is hereby amended to read as follows:

652.200 An application for a license as a director must be on a form provided by the ~~[Bureau,]~~ ***Division,*** giving complete information as indicated, including educational background, experience and the identity of the laboratory to be directed. The fee for licensure is not refundable.

Sec. 22. NAC 652.210 is hereby amended to read as follows:

652.210 A license as a director may be issued by the ~~[Bureau]~~ ***Division*** on behalf of the Board for those applicants who qualify for licensure under ~~[subsection 1 or 2 of]~~ NAC 652.380 ~~[.]~~ ***or section 14 of this regulation.*** If the ~~[Bureau]~~ ***Division*** cannot determine the qualifications of an applicant **,** ~~[or if the applicant is applying for licensure under subsection 3 of NAC 652.380,]~~ the ~~[Bureau]~~ ***Division*** shall submit the application to the Committee for its recommendation ~~[and to the Board for its]~~ ***before making a*** determination. The ~~[Bureau]~~ ***Division*** shall notify the applicant of the status of the application within 30 days after receipt of the application.

Sec. 23. NAC 652.230 is hereby amended to read as follows:

652.230 1. An application for renewal of a license as a director must be:

(a) Made on a form provided by the ~~[Bureau;]~~ ***Division;*** and

(b) Accompanied by the appropriate fee for renewal.

2. The failure to apply for renewal within 30 days after a license expires will result in termination of the licensee's authority to act as a director in this State.

Sec. 24. NAC 652.240 is hereby amended to read as follows:

652.240 A license as a director is not transferable. A duplicate of a license as a director may be obtained from the ~~[Bureau]~~ ***Division*** for each laboratory served.

Sec. 25. NAC 652.284 is hereby amended to read as follows:

652.284 A director shall ensure that:

1. The laboratory is enrolled in a program for proficiency testing regarding all the testing performed by the laboratory.

2. All procedures of the program are followed, including:

(a) The testing of samples as required; and

(b) The return of results within the required time.

3. Corrective action, which is approved by the ~~[Bureau,]~~ ***Division,*** is performed if any results are found to be unacceptable or unsatisfactory.

4. The maintenance of documentation to verify that all reports received regarding the program are reviewed by appropriate members of the staff for evaluation of the performance of the laboratory and identification of any problems requiring corrective action.

5. If the laboratory fails to perform satisfactorily in two out of any three testing events for a procedure, the laboratory ceases to perform that procedure until it demonstrates to the satisfaction of the ~~[Bureau]~~ ***Division*** that the ~~[deficiencies]~~ ***violations*** of the laboratory have been corrected in such a manner as to ensure that they will not recur.

Sec. 26. NAC 652.320 is hereby amended to read as follows:

652.320 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]~~ ***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 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 timely pursuant to subsection 3 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. 27. NAC 652.350 is hereby amended to read as follows:

652.350 1. A laboratory shall establish:

(a) Written policies and practices for personnel that encourage sound practice in a laboratory.

(b) A written program for the orientation of employees.

2. A laboratory shall maintain:

(a) Current records on each employee, which include documentation of each employee's training, experience and continuing education.

(b) A health record for each employee, including the results of any physical examinations and tests performed by a laboratory which are required by the employer.

3. For each licensed laboratory other than a specialty laboratory, at least one member of the technical staff must have the qualifications set forth in NAC 652.420 for a clinical laboratory technologist. At least one such technologist must be certified, in accordance with NAC 652.410, as a general supervisor unless the director or a physician associated with the laboratory is so designated.

4. For each specialty laboratory, at least one member of the technical staff must be a technologist qualified in the appropriate specialty, except that a specialty laboratory in a rural area may, with the approval of the ~~[Board,]~~ ***Division,*** instead employ a clinical laboratory technologist. At least one such technologist must be certified, in accordance with NAC 652.410, as a general supervisor unless the director or a physician associated with the laboratory is so designated.

5. As used in this section, "specialty laboratory" means a laboratory designated by the ~~[Board]~~ ***Division*** which specializes in histology, cytology, blood gases, nuclear medicine or another specialty.

Sec. 28. NAC 652.370 is hereby amended to read as follows:

652.370 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]~~ ***The*** director must be on the premises of the laboratory at least once ~~[every 30 consecutive days.]~~ ***each month.*** If the director is absent from the laboratory for ~~[30 consecutive days]~~ ***1 month*** 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. 29. NAC 652.380 is hereby amended to read as follows:

652.380 ~~[To]~~ ***Except as otherwise provided in section 14 of this regulation, 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 ***,*** ~~[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. 30. NAC 652.385 is hereby amended to read as follows:

652.385 To qualify for a license as a director of a licensed laboratory testing for pulmonary conditions, a person must:

1. Be a physician certified by the American Board of Internal Medicine in the subspecialty of pulmonary disease; or

2. In a geographical area which does not have a person who meets the qualifications set forth in subsection 1, be a physician licensed to practice in this State, whose experience is acceptable to the ~~[Board.]~~ ***Division.***

Sec. 31. NAC 652.450 is hereby amended to read as follows:

652.450 1. A laboratory assistant may perform ~~[only those procedures requiring the degree of skill commensurate with his or her education, training and technical abilities.]~~ ***any test that has been classified as a waived test pursuant to Subpart A of Part 493 of Title 42 of the Code of Federal Regulations and may collect and process specimens.*** Except as otherwise provided in NRS 652.217 and NAC 652.155, a laboratory assistant may not independently

perform *a* laboratory ~~[procedures,]~~ ***test which is classified as a test of moderate or high complexity pursuant to Subpart A of Part 493 of Title 42 of the Code of Federal Regulations,*** 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. 32. NAC 652.461 is hereby amended to read as follows:

652.461 1. Except as otherwise provided in subsection 2, any person desiring to have an inactive or a delinquent license or certificate reinstated shall submit evidence to the ~~[Bureau]~~ ***Division*** that he or she has completed 1 unit of continuing education within the 2 years immediately preceding the application for reinstatement of the license or certificate.

2. An inactive or delinquent license or certificate may be conditionally reinstated without the evidence required by subsection 1 if the applicant completes one unit of continuing education within a period established by the ~~[Bureau.]~~ ***Division.*** Any failure to complete the continuing education or satisfy any other condition established by the ~~[Bureau]~~ ***Division*** is a ground for revocation of the license or certificate.

Sec. 33. NAC 652.465 is hereby amended to read as follows:

652.465 1. Each person who is required to complete a program of continuing education shall retain proof of completion of the course of study or training for 4 years after the completion of the course or training.

2. Proof of completion of an approved course must be provided by a transcript, certificate of completion or other document furnished by the organization which offered the course.

3. Proof of completion of an unapproved course must be provided by:

(a) An explanation, by the employer of the holder of a license or certificate issued pursuant to this chapter, of a seminar or workshop developed and presented by the holder of that license or certificate;

(b) A record of attendance at a workshop offered at the place of employment of the holder of a license or certificate issued pursuant to this chapter, or presented by a manufacturer or vendor of medical technology;

(c) A copy of a book or article published by the holder of a license or certificate issued pursuant to this chapter; or

(d) A description of an exhibit prepared for a medical journal or meeting, including the number of hours spent in preparation of the exhibit.

4. A copy of the proof must be submitted to the ~~[Board]~~ ***Division*** upon request to verify the completion of the course or training by the holder of a license or certificate issued pursuant to this chapter.

Sec. 34. NAC 652.470 is hereby amended to read as follows:

652.470 1. Before working in a laboratory at any technical level:

(a) An application for certification must be made on a form provided by the ~~[Bureau]~~ ***Division*** giving information on the applicant's educational background;

(b) Substantiating documents such as college or other academic transcripts or copies of certificates of registration should accompany the application, but must be submitted within 6 months after the date of the application;

(c) The form must indicate the level and title for which certification is desired; and

(d) The fee prescribed in NAC 652.488 must accompany the application.

2. Temporary employment, for a period not exceeding 6 months, may be granted while the application is being processed, or when the applicant has been issued a provisional certificate.

3. The ~~[Bureau]~~ ***Division*** shall issue the appropriate certificate on behalf of the Board when it is determined that all requirements for certification are satisfied. Applications which are incomplete or require further review must be referred to the Committee for its recommendation.

4. A person may upgrade his or her certificate after completing the appropriate additional experience, training or academic requirements, or any combination thereof, by applying to the ~~[Bureau]~~ ***Division*** pursuant to subsection 1.

5. A person whose certification has lapsed for more than 5 years may reapply for certification by submitting an original application to the ~~[Bureau]~~ ***Division*** accompanied by the fee prescribed in NAC 652.488.

6. A person whose certification has lapsed for 5 years or less may reapply for certification by submitting an application for reinstatement to the ~~[Bureau]~~ ***Division*** accompanied by the fee prescribed in NAC 652.488.

7. A certificate will be placed in an inactive status upon the approval of the ~~[Health]~~ Division and payment of the fee prescribed in NAC 652.488.

Sec. 35. NAC 652.476 is hereby amended to read as follows:

652.476 1. A person certified pursuant to NAC 652.470 who wishes to renew the certification must submit to the ~~[Bureau]~~ ***Division*** a completed form for renewal. The ~~[Bureau]~~ ***Division*** shall, not less than 90 days before the expiration of the certificate, provide to the holder of the certificate the proper form for renewal.

2. The form for renewal must include a request for information regarding the current residence of the person holding the certificate.

3. The form for renewal must be accompanied by the fee for renewal.

4. A certificate issued pursuant to this section is effective for 2 years after the date of issuance. Failure to apply for renewal within 30 days after the certificate expires will result in the termination of the holder's authority to work in a laboratory at a technical level.

Sec. 36. 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 ~~[Bureau]~~ ***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 1 year of experience working 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 letter from the director of the laboratory in which the applicant obtained experience which verifies that the applicant has the experience required by subsection 1.

3. ~~[In addition to the requirements of subsection 1, an applicant for certification as a biotechnologist must obtain the written recommendation of his or her certification from the Committee before the applicant is eligible for that certification.~~

~~4.]~~ 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. 37. NAC 652.483 is hereby amended to read as follows:

652.483 The ~~[Bureau]~~ ***Division*** shall certify a technologist in a specialty for which a national examination is not given if he or she:

1. Has education and experience in the specialty which is acceptable to the ~~[Board;]~~ ***Division;***

2. Obtains a written recommendation of the proposed certification from ~~[:~~

~~(a) A]~~ ***a*** director licensed in this State who holds a doctoral degree; and

~~[(b) The Committee; and]~~

3. Has 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 has 1 year of experience 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.

Sec. 38. NAC 652.485 is hereby amended to read as follows:

652.485 1. To be certified in a specialty by the ~~[Bureau,]~~ ***Division,*** a technician must:

(a) Pass a national examination for certification in the specialty, if such an examination is given;

(b) Be a high school graduate or the equivalent; and

(c) Have:

(1) Completed at least 1 year of a formal program of training in the specialty, which is approved by the ~~[Board;]~~ ***Division;*** or

(2) At least 2 consecutive years of experience working in the specialty, during the 5 years immediately preceding application for certification, in a laboratory under the supervision of a director who possesses a doctoral degree.

2. An 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 a program of training required by subparagraph (1) of paragraph (c) of subsection 1; or

(b) A letter from the director of the laboratory in which the applicant obtained experience which verifies that the applicant has the experience required by subparagraph (2) of paragraph (c) of subsection 1.

3. ~~[In addition to the requirements of subsection 1, an applicant for certification as a biotechnician must obtain the written recommendation of his or her certification from the Committee before becoming eligible for that certification.~~

~~4.]~~ A certificate will designate the holder by:

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

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

Sec. 39. NAC 652.486 is hereby amended to read as follows:

652.486 The ~~[Bureau]~~ ***Division*** shall, upon request by a technologist or technician who is required to pass a national examination for certification and who has been accepted as a candidate for testing, issue him or her a provisional certificate. The provisional certificate expires 180 days after the date of issue and is not renewable. No technologist or technician may request

more than three provisional certificates pursuant to this section. The fee for a provisional certificate is the same as the fee set forth in NAC 652.488 for the certification of personnel.

Sec. 40. NAC 652.488 is hereby amended to read as follows:

652.488 The following ~~[nonrefundable]~~ fees will be charged:

1. Licensure of laboratory not described in subsection 2

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

2. 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

3. Licensure of director pursuant to paragraph (b) of subsection 3 of NAC 652.175, or NAC 652.380, 652.385 or 652.395 ***or section 14 of this regulation***

Initial.....$500

Biennial renewal.....300

Reinstatement 500

4. Registration of laboratory operated pursuant to NRS 652.235 which is nonexempt pursuant to NAC 652.155

Initial.....$1,500

Biennial renewal.....900

Reinstatement 1,500

5. Registration of laboratory operated pursuant to NRS 652.235 which is exempt pursuant to NAC 652.155

Initial.....$500

Biennial renewal.....300

6. 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

7. Placement of license or certificate in inactive status $50

8. Issuance of original duplicate license or certificate $50

9. Permit to operate laboratory at temporary location.....$300

10. Change of location of laboratory.....$300

11. Change of director of laboratory $300

12. Change of name of laboratory.....$300

13. Inspection for additional specialties and subspecialties in which tests will be performed at laboratory $300

Plus $50 for each additional specialty or subspecialty

14. Inspection of an outpatient center of a laboratory (per site)

Initial inspection $300

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

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

Sec. 41. NAC 652.491 is hereby amended to read as follows:

652.491 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 ***crime listed in NRS 449.174 that is punishable as 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;]~~

4. Is guilty of unprofessional conduct; or

5. Fails to meet the minimum standards prescribed by the Board.

Sec. 42. NAC 652.493 is hereby amended to read as follows:

652.493 ***1.*** If a person is aggrieved by a decision of the ~~[Health]~~ Division relating to the denial, suspension or revocation of a license or certificate based upon any of the grounds set forth in subsections 1 to 6, inclusive, of NRS 652.220 or NAC 652.461 or 652.491, ***or any disciplinary action imposed pursuant to section 6, 8, 12 or 13 of this regulation or NAC 652.320,*** the aggrieved person may appeal the decision pursuant to the procedures set forth in NAC 439.300 to 439.395, inclusive.

2. Except as otherwise provided in subsection 1 of section 11 of this regulation or in the case of an emergency or a summary suspension pursuant to section 8 of this regulation, the effective date of the disciplinary action is stayed upon receipt of an appeal until the hearing officer renders a decision regarding the appeal.

Sec. 43. NAC 652.496 is hereby amended to read as follows:

652.496 1. If a report is received pursuant to subsection 5 of NRS 228.420, the ~~[report must be placed on the agenda of the next regularly scheduled meeting of the Board or as soon thereafter as the schedule of the]~~ Board ~~[allows.]~~ ***will submit the report to the Division.***

2. The ~~[Board will]~~ ***Division shall*** consider the report and will determine whether ~~[the report should be referred to the Bureau for possible]~~ ***to take*** disciplinary action.

Sec. 44. NAC 652.510 is hereby amended to read as follows:

652.510 1. Any program of training intended to prepare a person for certification as a technician must be approved by the Board. Application for approval must be submitted in writing to the Board. The application must include:

(a) A description of the goals of the program;

(b) A description of the methods of instruction;

(c) A description of the contents of the courses;

(d) A description of the qualifications of the instructors;

(e) A description of the methods of evaluating the performance of the trainee; and

(f) The name of the director who is responsible for the program.

2. The director shall certify in writing to the ~~[Bureau]~~ ***Division*** each trainee who has successfully completed the program.

Sec. 45. NAC 652.037 and 652.290 are hereby repealed.

Sec. 46. A person who operates a laboratory that is licensed on or before March 28, 2014, shall adopt the infection control guidelines required pursuant to subsection 1 of section 3 of this regulation not later than April 11, 2014.

TEXT OF REPEALED SECTIONS

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.

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.

DIVISION OF PUBLIC AND BEHAVIORAL HEALTH

LCB File # R104-13

Information Statement per NRS 233B.066

1. A clear and concise explanation of the need for the adopted regulation.

There are several reasons for the need to adopt the proposed regulations. The major reasons are as follows:

- Nevada Revised Statutes (NRS) 652.090 requires the Board of Health to adopt regulations setting forth the acceptable forms of proof of identity that a laboratory director must include in an application; and
- NRS 652.127 requires the Board of Health to establish by regulation the requirements to qualify for certification as a laboratory assistant. The proposed regulations address both of these requirements.
- NRS 652.260 outlines new statutory penalties to be imposed on a laboratory for violations of NRS or NAC Chapter 652. The proposed regulations outline the procedures for imposing and collecting monetary penalties for violations of Nevada Administrative Code (NAC) or NRS Chapter 652. The imposition of monetary penalties is done in a progressive manner based on both the severity and frequency of the violation. In addition, it allows a laboratory, upon approval by the Division, to use a monetary penalty that would otherwise by paid to the Division to correct the violation and put measures in place to prevent the violation from reoccurring.
- Laboratory safety which includes infection control is important both to personnel and patient safety in laboratories. The proposed regulations help to ensure safety by requiring the adoption of nationally recognized standards.
- Current regulations require a laboratory director to be on-site at least every 10 or 30 consecutive days (depending on the testing). The Division had originally proposed lowering this to quarterly visits but laboratory directors contacted us and stated this was not frequent enough and may compromise patient safety. The monthly visits required in the proposed regulations provide more flexibility, which should be helpful to rural areas, than what is in current regulations and at the same time sets a frequency that the laboratory experts we spoke with felt would continue to protect patient safety.
- For laboratories that are able to conduct high complexity testing and serve the public such as Quest or hospital laboratories there are regulations in place to ensure the Laboratory Director is qualified to oversee such a laboratory. In rural areas, this would most likely be hospital laboratories. Currently all laboratory directors meet the requirements without the need for an exception and this omission would not impact them. Omitting this provision was discussed during the Medical Laboratory Advisory Committee because to the Division's knowledge it has never been used and because it was felt that at this level the laboratory director should meet the minimum requirements established in regulations.

2. A description of how public comment was solicited, a summary of the public response and an explanation how other interested persons may obtain a copy of the summary.

Public comment was solicited through the Notice of Public Hearing which could be obtained at Division of Public and Behavioral Health locations, State Library and Archives, county libraries, and the Division's website. In addition, the Notice of Public Hearing was mailed to medical laboratories and medical laboratory personnel as well as being sent out electronically through the Division's Medical Laboratory List Serv. A public workshop was also held in Carson City and Las Vegas via video conference. The proposed regulations were brought before the Medical Laboratory Advisory Committee for review and recommendations before they went to the public workshop. After the public workshop the proposed regulations were revised based on input received by stakeholders. The revised version was then taken back to the Medical Laboratory Advisory Committee again for review and recommendations. The following is a summary of the testimony provided during the State Board of Health Public Hearing on March 14, 2014:

One person testified on the proposed regulations at the public hearing. The individual testified in support of amending the proposed regulations to add the term laboratory safety to the proposed regulations as well as providing examples of OSHA and CDC laboratory safety guidelines.

A summary of the Hearing for Amendment of Nevada Administrative Code, Chapter 652 can be obtained by contacting the Bureau of Health Care Quality and Compliance, 727 Fairview Drive, Suite E, Carson City, NV 89701.

3. The number of persons who:

(a) Attended the hearing;

150 people were present at the hearing but it is unclear how many of those individuals came specifically to hear testimony on these proposed regulations.

(b) Testified at each hearing; and

As noted previously, one person provided testimony on the proposed regulations at the public hearing.

(c) Submitted to the agency written statements.

One person submitted a written statement recommending that language be added to include laboratory safety as well as adding two additional laboratory safety guidelines as examples of the types of guidelines that can be adopted by a laboratory. The Board of Health voted to amend the proposed regulations to adopt the recommended changes.

(d) For each person identified above, the following information if provided to the Division of Public and Behavioral Health: Name, telephone number, business address, business telephone number, electronic mail address and name of entity or organization represented. (Please see attached copies of sign-in sheet)

150 people were present at the hearing but it is unclear how many of those individuals came specifically to hear testimony on these proposed regulations. Leticia Metherell, Health Facilities Inspection Manager for the Bureau of Health Care Quality and Compliance presented the proposal to amend Nevada Administrative Code, Chapter 652. One individual provided testimony. The same individual also provided written testimony prior to the meeting; please see (c) above. A summary of the testimony can be found in number 2 above.

4. A description of how comment was solicited from affected businesses, a summary of their response, and an explanation how other interested persons may obtain a copy of the summary.

By June 28, 2013 a small business impact questionnaire and workshop notice which included information on how to obtain a copy of the proposed regulations was sent to medical laboratories and laboratory personnel. The workshop notice and draft regulations were also posted on the Division of Public and Behavioral Health's website, distributed through the Division of Public and Behavioral Health's List Serv and posted in accordance with open meeting law. Out of 12,298 small business impact questionnaires distributed, only 18 responses were received. The following is a summary of the 18 responses.

Summary of Response

Summary Of Comments Received (18 responses were received out of 12,298 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?**
No – 11 Yes – 6 No Response – 1	No – 17 Yes – 0 No Response - 1	No – 11 Yes – 6 No Response – 1	No – 16 Yes – 1 No Response – 1
Comments: Increase employee business taxes & A.C.A. Unknown costs. $183,000 Rh testing is essential for safe abortion – missing an Rh negative woman can cause serious handicaps in future pregnancies. Adhering to these regulations is estimated to cost $1000 to $5000 in staff time for additional meetings, education, documentation & continual policy & procedure review & updating in an office based surgical facility that already has CLIA, State Health & IMO overview. It is burdensome & unnecessary. Yes, if my assistant (medical assistant) also need to train as laboratory assistant. Dollar amount unknown.	**Comments**: The increased cost will make abortion impossible for low income women – increasing the cost of Medicaid to the state by millions! We only perform a single test – an exempted/waived; qualitative UCG with internal & external controls as a convenience & safety issue, prior to elective surgeries. We already in service OSHA, do hand washing surveillance: monitor & document temperatures; expiration dates, etc. This only adds more documentation without apparent increase in patient safety or quality of care. I already follow protocol & very strict control.	**Comments:** Possible closure of business in near future. Rh disease of the newborn will cost the state untold millions of dollars. 1) Burdensome documentation 2) Costs of documentation 3) Additional inspections interfering with patient flow 4) Possible monetary penalties for not understanding or documenting in prescribed manner. I currently utilize an in house lab in my office. Yes, if my only assistant need to train I will lose her while in training and have to cancel laboratory work.	**Comments**: Another certificate to frame which might give patients even more comfort/confidence in our office. CLIA does this certification & inspection quite well. Another layer of State regulation is unnecessary in offices that do waived testing & less than 200 tests/year.

Number of Respondents out 12,298	Adverse economic effect?	Beneficial effect?	Indirect adverse effects?	Indirect beneficial effects?
18	6	0	6	1

A summary of the Hearing for Amendment of Nevada Administrative Code, Chapter 652 can be obtained by contacting the Division of Public and Behavioral Health, 727 Fairview Drive, Suite E, Carson City, NV 89701.

5. If the regulation was adopted without changing any part of the proposed regulation, a summary of the reasons for adopting the regulation without change. The statement should also explain the reasons for making any changes to the regulation as proposed.

During the public workshop process several concerns were received including concerns that it would make abortions difficult for low income women, that there would be possible monetary penalties for not understanding or documenting in a prescribed manner and concerns that the on-site director visits were being reduced to quarterly visits. These concerns were all taken into consideration during the regulation development. In certain cases, individuals were contacted in order to get a better understanding of the concerns the regulation posed; for example, after speaking to the individual concerned about the increased costs for a safe abortion, he no longer had that concern. The monetary penalties are set up in a progressive manner in which no monetary penalty is applied when the violation is of an administrative purpose and no harm is likely to occur to a patient. The monetary penalties progressively increase based on the severity and frequency of violations. After concerns were expressed that on-site quarterly visits by a laboratory director were not enough, the proposed regulations were modified to make the required visits monthly. There was concern that just focusing on infection control and not on the broader issue of laboratory safety was not comprehensive enough to ensure the safety of both employees and patients. The change adding this component into the proposed regulations was made during the March 14, 2014 Board of Health meeting. In addition, concerns by customers have been expressed in the past regarding the length of time it takes to become a certified biotechnician or biotechnologist. The proposed regulations will reduce the amount of time it takes these individuals to become certified.

6. The estimated economic effect of the regulation on the business which it is to regulate and on the public. These must be stated separately, and in each case must include:

a. Both adverse and beneficial effects; and

A. Beneficial effects: Anticipated benefits to laboratory personnel and medical laboratories include the ability to move forward with electronic applications/renewals which should make it more efficient for applicants and should result in faster turnaround times, increasing the flexibility in criteria to become a laboratory assistant will ensure qualified individuals can become certified and reducing the on-site

requirement that a laboratory director be on the premises from 10 or 30 consecutive days to monthly will provided more flexibility for laboratory director's while ensuring patient safety.

B. Adverse effects: May have a negative economic impact on laboratories that have deficient practices that lead to an administrative sanction.

b. Both immediate and long term effects.

Immediate effects: Increased patient safety.

Long term effects: Increased patient safety.

7. The estimated cost to the agency for enforcement of the proposed regulation.

Currently it is expected that the provisions of these regulations would be incorporated into current inspection and licensing processes utilizing existing staff therefore no cost ($0) to the agency for enforcement is anticipated.

8. A description of any regulations of other state or government agencies which the proposed regulation overlaps or duplicates and a statement explaining why the duplication or overlapping is necessary. If the regulation overlaps or duplicates a federal regulation, name the regulatory federal agency.

There are no other state regulations that overlap or duplicate the proposed regulations.

Although federal regulations (Centers for Medicare and Medicaid Services) cover some aspects addressed in the proposed regulations (most of which are existing regulations which are being amended) federal regulations do not address issues specific to state licensure such as what is required for an application to obtain a state license. In addition, not all laboratories are federally certified by the Centers for Medicare and Medicaid Services therefore the federal regulations would not apply to state licensed only laboratories. This creates the need to also include the provisions in state regulations. In addition, the monetary penalty section allows for imposition of a penalty for the violation of state laws and regulations.

9. If the regulation includes provisions which are more stringent than a federal regulation which regulates the same activity, a summary of such provisions.

Current regulations require a laboratory director to be on-site at least every 10 or 30 consecutive days (depending on the testing). The proposed regulations relax this requirement to monthly visits but they still remain more stringent than federal regulations. When the Division originally proposed reducing the required on-site visits to quarterly we were contacted by Nevada experts in the field that felt reducing the required visit to less than once a month may compromise patient safety. Additionally, as mentioned in #8 the federal regulations do not apply to our laboratories that only have a state license and do not have certification from the Centers for Medicare and Medicaid Services.

10. If the regulation provides a new fee or increases an existing fee, the total annual amount the agency expects to collect and the manner in which the money will be used.

Due to the variability of how monetary penalties would be applied it is very difficult to estimate the amount of fines that would be collected. In addition, the proposed regulations allow a laboratory to use the penalty amount to correct the violation and to put measures into place to prevent the violation from reoccurring. In such instances the Division may not actually collect the monetary penalty. The following analysis was conducted in order to get a rough idea of what the amount collected in one year may look like: 103 (estimated number of monetary penalties issued in a year) X $233 (average of the amounts for a first, second and third violation at a severity level two which is the most common severity level issued) = $23,999 monetary penalties collected in one year. The monies would be used to improve quality in laboratories by allowing laboratories to use the monies to help prevent future violations and education of laboratory personnel.