ADOPTED REGULATION OF THE

STATE BOARD OF HEALTH

LCB File No. R149-15

Effective June 21, 2017

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

AUTHORITY: §§1-4, 6-9, 15-23 and 25, NRS 439.200, 652.123, 652.125 and 652.130; §§5 and 10, NRS 439.200, 652.090 and 652.130; §§11 and 12, NRS 439.200, 652.125 and 652.130; §§13 and 14, NRS 439.200, 652.123, 652.130 and 652.260; §24, NRS 439.150, 439.200, 652.100 and 652.125.

A REGULATION relating to medical laboratories; prescribing requirements for certain laboratory personnel; establishing provisions concerning the performance of certain tests for the detection of the human immunodeficiency virus; revising certain requirements relating to the licensure and certification of laboratory personnel and the operation of laboratories; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Under existing law, medical laboratories and their personnel are subject to both state and federal regulation. (42 U.S.C. § 263a; 42 C.F.R. Part 493; chapter 652 of NRS) The State Board of Health is responsible for adopting regulations governing medical laboratories and their personnel. (NRS 652.090, 652.123, 652.125, 652.127, 652.130, 652.135, 652.215, 652.225) The Division of Public and Behavioral Health of the Department of Health and Human Services is responsible for the enforcement of the applicable laws and regulations. (NRS 652.120)

Federal regulations classify laboratory tests into three categories: (1) simple tests with a low risk for an incorrect result, which are classified as waived tests; (2) tests of moderate complexity, which include certain tests categorized as provider-performed microscopy procedures; and (3) tests of high complexity. (42 C.F.R. § 493.5) **Section 2** of this regulation defines the term "exempt laboratory" as a laboratory in which, with certain exceptions, the only tests performed are: (1) waived tests; and (2) provider-performed microscopy procedures. **Section 6** of this regulation establishes the qualifications to serve as a director of an exempt laboratory.

Assembly Bill No. 243 of the 2015 Legislative Session made various changes concerning the performance of laboratory tests for the detection of the human immunodeficiency virus that are classified as waived tests under federal regulations. (Chapter 176, Statutes of Nevada 2015, at pages 847-49) **Sections 4 and 7-9** of this regulation make additional changes in connection with the performance of such tests. **Section 4** defines a laboratory in which the only test performed is

a test for the detection of the human immunodeficiency virus that is classified as a waived test pursuant to federal regulations as an "HIV testing laboratory." **Section 7** establishes the qualifications to serve as a director of an HIV testing laboratory. **Section 8** provides that, with certain exceptions, the provisions of chapter 652 of NAC do not apply to the director of an HIV testing laboratory. **Section 9** provides that, with the exception of the requirements for licensure and the payment of fees, the provisions of chapter 652 of NAC do not apply to an HIV testing laboratory. **Section 9** also provides that none of the provisions of chapter 652 of NAC apply to a person who performs tests for the detection of the human immunodeficiency virus that are classified as waived tests under federal regulations if the person meets certain statutory requirements to perform such tests that were established in A.B. 243.

Under existing regulations, a laboratory that wishes to perform tests at a temporary location must apply to the Division for a permit and pay a fee. (NAC 652.170) **Sections 5 and 10** of this regulation provide that: (1) only a licensed laboratory may obtain such a permit; and (2) such a permit expires 90 days after its effective date.

Section 11 of this regulation eliminates a provision of existing regulations which provides that the fee which accompanies an application for licensure as a laboratory director is not refundable.

Under existing law, the Medical Laboratory Advisory Committee advises the State Board of Health on matters of policy concerning medical laboratories, qualifications of laboratory directors and personnel and other matters. (NRS 652.160) **Section 12** of this regulation eliminates a provision of existing regulations, which requires the Division, if it cannot determine the qualifications of an applicant for a license as a director of a licensed laboratory, to submit the application to the Committee for its recommendation before making a determination. **Section 21** of this regulation eliminates a similar requirement that the Division refer to the Committee for its recommendation an application for certification to work in a laboratory at any technical level if the application is incomplete or requires further review.

Existing federal regulations require laboratories to participate in a program of proficiency testing. (42 C.F.R. § 493.801) Under existing regulations, the director of a laboratory that fails to perform a particular procedure satisfactorily in two out of any three proficiency testing events for the procedure must ensure that the laboratory ceases to perform the procedure until the laboratory corrects the violation. (NAC 652.284) **Section 13** of this regulation revises the pattern of test failures that triggers a director's duty to ensure that the laboratory ceases performing the procedure.

Section 14 of this regulation revises certain provisions of existing regulations concerning the provision by the Division of a statement of violations to a laboratory following an inspection and the submission to the Division of a plan of correction.

Existing law requires the Board to adopt regulations concerning the licensure of laboratory directors and authorizes the Board to establish the qualifications required for such licensure. (NRS 652.125, 652.130) Existing regulations identify certain professional credentialing institutions whose certifications the Board may accept in determining whether a person has the qualifications for a license as a director of certain licensed laboratories or a registered laboratory.

(NAC 652.380, 652.395) **Sections 15 and 17** of this regulation identify certain additional institutions whose certifications the Board may accept for those purposes. Under existing regulations, only a licensed physician certified in the subspecialty of pulmonary disease by the American Board of Internal Medicine is qualified for a license as a director of a licensed laboratory testing for pulmonary conditions. (NAC 652.385) **Section 16** of this regulation provides that certification by any other nationally recognized board of internal medicine acceptable to the Division is also sufficient for this purpose.

Existing regulations establish various alternative avenues to qualify for a certificate as a clinical laboratory technologist. One such avenue allows a person to qualify for such a certificate if the person: (1) has a bachelor's degree in one of the chemical, physical or biological sciences; (2) has passed an approved national examination for certification; and (3) has at least 1 year of additional full-time experience or training in the specialty or subspecialty in which the person performs tests. (NAC 652.420) **Section 18** of this regulation requires that the experience or training be obtained in a licensed laboratory or a laboratory of a hospital, health department or university. Under existing regulations, a technologist who wishes to be certified by the Division in a specialty must, in addition to other requirements, obtain 1 year of experience working in a licensed laboratory or a laboratory of a hospital, health department or university and must submit with his or her application a letter from the director of the laboratory in which the applicant obtained his or her experience which verifies that the applicant has the experience required. (NAC 652.480) **Section 22** of this regulation requires that the experience be full-time, but allows it to also consist of training. **Section 22** also requires that the letter from the laboratory director be signed and dated.

Section 19 of this regulation: (1) updates the name of the entity that certifies a program of histotechnology whose completion is an acceptable qualification for a certificate as a histologic technician; and (2) revises the qualifications for a certificate as a histologic technician to specify that an associate degree is a valid qualification only if the degree is in chemistry, biology or a physical science.

Section 20 of this regulation clarifies that the provisions of existing regulations concerning the requirement to complete a certain number of hours of continuing education as a condition to reinstate an inactive or delinquent license or certificate do not apply to a person certified as an office laboratory assistant or to such a certificate.

Under existing regulations, a person who has submitted an application for certification may be granted temporary employment for up to 6 months while the application is being processed. A person who has been issued a provisional certificate may also be granted temporary employment for up to 6 months. (NAC 652.470) **Section 21** of this regulation extends the period of temporary employment to up to 12 months for persons whose applications are being processed. **Section 21** also provides that temporary employment may be granted to a person who has been issued a provisional certificate until the expiration of the provisional certificate.

Under existing regulations, the Division will issue a provisional certification to a technologist or technician who is required to pass a national examination for certification if he or she has been accepted as a candidate for testing. A provisional certificate expires 180 days after issuance and

is not renewable. (NAC 652.486) **Section 23** of this regulation revises the circumstances under which a provisional certificate may be issued and provides that such a certificate expires 18 months after issuance.

Existing regulations set forth the various fees that the Division is authorized to charge and collect. (NAC 652.488) **Section 24** of this regulation: (1) establishes the fee for the licensure of an HIV testing laboratory; (2) clarifies that the inspection fee for a laboratory that files an application to perform additional specialty tests is assessed on the application as a whole regardless of the number of tests included in the application; and (3) exempts an HIV testing laboratory from otherwise applicable fees for changing the location, director or name of the laboratory. **Section 24** also provides that a person will be deemed to have paid any fee otherwise charged and collected by the Division in connection with a medical laboratory if the person is, or is employed by, a person, governmental entity or fire-fighting agency that holds and has paid the fee for a permit issued by a health authority to operate an ambulance or air ambulance service or to provide certain emergency medical services.

Under existing regulations, a program of training intended to prepare a person for certification as a technician must be approved by the Board. (NAC 652.600) **Section 25** of this regulation requires such programs to be approved instead by the Division.

Section 1. Chapter 652 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 8, inclusive, of this regulation.

Sec. 2. ***1. Except as otherwise provided in this section and NAC 652.175, "exempt laboratory" means a laboratory in which each test performed is:***

(a) Classified as a waived test pursuant to 42 C.F.R. Part 493, Subpart A; or

(b) Categorized as a provider-performed microscopy procedure pursuant to 42 C.F.R. § 493.19.

2. The term does not include an HIV testing laboratory.

Sec. 3. ***"Form" includes, without limitation, a printed form, an electronic form or an online or interactive process provided via the Internet.***

Sec. 4. ***"HIV testing laboratory" means a laboratory in which the only test performed is a test for the detection of the human immunodeficiency virus that is classified as a waived test pursuant to 42 C.F.R. Part 493, Subpart A.***

Sec. 5. *1. A licensed laboratory that wishes to collect specimens or perform tests, or both, at a location other than the location set forth in its license must obtain a permit to operate a laboratory at a temporary location.*

2. An application for a permit to operate a laboratory at a temporary location must be:

(a) Made on a form provided by the Division;

(b) Submitted to the Division in the manner set forth in NAC 652.170; and

(c) Accompanied by the fee set forth in NAC 652.488.

3. The Division shall notify an applicant of the disposition of an application within 30 days after receipt of a completed application.

4. A permit to operate a laboratory at a temporary location issued pursuant to this section expires 90 days after the effective date of the permit.

Sec. 6. *1. Except as otherwise provided in subsection 2 and NAC 652.395, to qualify to serve as a director of an exempt laboratory, a person must be:*

(a) A licensed physician;

(b) Qualified for a license as a director of a licensed laboratory pursuant to NAC 652.380;

(c) Qualified for a license as a director of a registered laboratory pursuant to NAC 652.395;

(d) An advanced practice registered nurse licensed pursuant to chapter 632 of NRS;

(e) A physician assistant licensed pursuant to chapter 630 or 633 of NRS;

(f) A general supervisor of a licensed laboratory certified in accordance with NAC 652.410; or

(g) A clinical laboratory technologist certified in accordance with NAC 652.420.

2. To qualify to serve as a director of an exempt laboratory in which the only tests performed are glucose tests that are classified as waived tests pursuant to 42 C.F.R. Part 493, Subpart A, a person must be:

(a) A person identified in subsection 1;

(b) A nurse licensed pursuant to chapter 632 of NRS;

(c) A pharmacist registered pursuant to chapter 639 of NRS; or

(d) A person licensed or certified pursuant to chapter 652 of NRS, other than a certified blood-gas assistant, certified laboratory assistant or certified office laboratory assistant.

3. 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. 7. *To qualify to serve as a director of an HIV testing laboratory, a person must:*

1. Possess the technical and managerial skills necessary to perform the duties of a laboratory director set forth in NRS 652.180; and

2. Satisfy the requirements set forth in NRS 652.186 to perform a test for the detection of the human immunodeficiency virus that is classified as a waived test pursuant to 42 C.F.R. Part 493, Subpart A.

Sec. 8. *Except as otherwise provided in section 7 of this regulation, the provisions of this chapter, including, without limitation, any requirement to perform duties other than those prescribed in NRS 652.180, do not apply to the director of an HIV testing laboratory.*

Sec. 9. NAC 652.155 is hereby amended to read as follows:

652.155 1. Except as otherwise provided in this section and NRS ~~[652.230,]~~ ***652.071,*** the provisions of this chapter:

(a) Apply to:

(1) A laboratory which is licensed pursuant to NRS 652.080 and which provides services to the public; and

(2) A nonexempt laboratory which is registered pursuant to NAC 652.175; and

(b) Do not apply to ~~[an exempt laboratory]~~ :

(1) ***An exempt laboratory which:***

(I) Is licensed pursuant to chapter 652 of NRS; and

(II) Pays the applicable fees required by NAC 652.488;

(2) An HIV testing laboratory which:

(I) Is licensed pursuant to chapter 652 of NRS; and

(II) Pays the applicable fees required by NAC 652.488; or

(3) A laboratory which is registered ***as exempt*** pursuant to NAC 652.175.

2. Except as otherwise provided in subsection 3, a person who is employed by a laboratory that is licensed by or registered with the Division pursuant to chapter 652 of NRS may perform a test without complying with the provisions of this chapter if:

(a) The test has been classified as a waived test pursuant to 42 C.F.R. Part 493, Subpart A; and

(b) The director, a designee of the director or a licensed physician at the laboratory at which the test is performed:

(1) Verifies that the person is competent to perform the test;

(2) Ensures that the test is performed in accordance with instructions of the manufacturer of the test; and

(3) Validates and verifies the manner in which the test is performed by using controls which ensure that the results of the test will be accurate and reliable.

3. Except as otherwise provided in subsection 4, the provisions of subsection 2 do not relieve a person who performs a test from the requirement to:

(a) Comply with the policies and procedures that the director of the laboratory at which the test is performed has established pursuant to NAC 652.280; ~~[or]~~

(b) ***Comply with the laboratory safety guidelines adopted by the laboratory pursuant to NAC 652.291; or***

(c) Obtain certification pursuant to NAC 652.470 and pay the applicable fees as set forth in NAC 652.488.

4. An advanced practice registered nurse as defined in NRS 632.012 or a physician assistant as defined in NRS 630.015 who is employed by a laboratory that is licensed by or registered with the Division pursuant to chapter 652 of NRS and who has not received certification pursuant to NAC 652.470 may perform a test without complying with the provisions of this chapter if the test:

(a) Has been classified as a waived test pursuant to 42 C.F.R. Part 493, Subpart A; or

(b) Is a provider-performed microscopy ***procedure*** categorized pursuant to 42 C.F.R. § 493.19.

5. ***Except as otherwise provided in this subsection, a person may perform a test for the detection of the human immunodeficiency virus that is classified as a waived test pursuant to 42 C.F.R. Part 493, Subpart A, without complying with the provisions of this chapter if he or***

she complies with NRS 652.186. This subsection does not apply to a person who holds a license or certification issued pursuant to this chapter or a license or certification described in NRS 652.210.

6. 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. 10. 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 Division. Upon receipt of a completed application, the Division shall conduct an inspection of the facility 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 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 Division an application on the form provided by the 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.]~~ ***4.*** 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. 11. 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 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. 12. NAC 652.210 is hereby amended to read as follows:

652.210 A license as a director may be issued by the Division on behalf of the Board for those applicants who qualify for licensure under NAC 652.380 ~~[or 652.383. If the Division cannot determine the qualifications of an applicant, the Division shall submit the application to the Committee for its recommendation before making a determination.]~~ ***to 652.395, inclusive.*** The Division shall notify the applicant of the status of the application within 30 days after receipt of ~~[the]~~ ***a completed*** application.

Sec. 13. 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 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 ***consecutive testing events or two*** out of ~~[any]~~ three testing events for a procedure, ***and thereafter fails to perform that procedure satisfactorily in one or more subsequent testing events,*** the laboratory ceases to perform that procedure until it demonstrates to the satisfaction of the Division that the violations of the laboratory have been corrected in such a manner as to ensure that they will not recur.

Sec. 14. NAC 652.320 is hereby amended to read as follows:

652.320 1. Except as otherwise provided in this subsection, the 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 Division if the reports of the inspections are available to the Division.

2. Upon receipt of a complaint against a laboratory or its personnel, except for a complaint concerning the cost of services, the 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 Division shall report violations noted at the time of each inspection by ~~[forwarding to]~~ ***providing*** the director ***, or the director's designee, with*** a statement of 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]~~ ***submit the plan of correction*** to the Division, containing thereon the plan of correction for each of the violations, within ~~[10 working]~~ ***14*** days after receiving the form. The plan must indicate the date by which each 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. 15. NAC 652.380 is hereby amended to read as follows:

652.380 Except as otherwise provided in NAC 652.383, 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, 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 ~~[,]~~ ***and Genomics;***

(7) The National Registry of Certified Chemists;

(8) The American Board of Histocompatibility and Immunogenetics; or

(9) Any other institution approved by the United States Department of Health and Human Services in accordance with 42 C.F.R § 493.1443(b)(3); or

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

Sec. 16. NAC 652.385 is hereby amended to read as follows:

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

~~[1.]~~ ***(a)*** Be a physician certified ~~[by the American Board of Internal Medicine]~~ in the subspecialty of pulmonary disease ~~[,]~~ ***by the:***

(1) American Board of Internal Medicine; or

(2) Any other nationally recognized board of internal medicine acceptable to the Division; or

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

2. As used in this section, "physician" means a physician licensed pursuant to chapter 630 or 633 of NRS.

Sec. 17. NAC 652.395 is hereby amended to read as follows:

652.395 To qualify for a license as a director of a registered laboratory, a person must:

1. Be a physician licensed to practice in this State and have:

(a) At least 1 year of experience directing or supervising laboratory testing in a laboratory which meets the requirements of NAC 652.170 to 652.600, inclusive;

(b) Credit for at least 20 hours of continuing medical education in laboratory practice regarding the responsibilities of a director; or

(c) Laboratory training, obtained during medical residency, equivalent to the training required by paragraph (b); or

2. Hold an earned doctoral degree from an accredited institution, with a major in chemical, physical, biological or clinical laboratory science, and:

(a) Have at least 1 year of experience directing or supervising laboratory testing in a laboratory which meets the requirements of NAC 652.170 to 652.600, inclusive;

(b) Be certified by:

(1) The American Board of Medical Microbiology;

(2) The American Board of Bioanalysis;

(3) The American Board of Medical Laboratory Immunology;

(4) The American Board of Clinical Chemistry;

(5) The American Board of Forensic Toxicology; ~~[or]~~

(6) The American Board of Medical Genetics ~~[,]~~ ***and Genomics;***

(7) The National Registry of Certified Chemists;

(8) The American Board of Histocompatibility and Immunogenetics; or

(9) Any other institution approved by the United States Department of Health and Human Services in accordance with 42 C.F.R § 493.1443(b)(3); or

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

Sec. 18. NAC 652.420 is hereby amended to read as follows:

652.420 1. A clinical laboratory technologist may:

(a) Perform tests which require the exercise of independent judgment, under minimum supervision or review by the director or general supervisor, in those specialties for which the technologist has had adequate education, training and experience and in which he or she has demonstrated a proficiency; and

(b) Supervise, if necessary, the work of the medical technicians and laboratory assistants.

2. To qualify for a certificate as a clinical laboratory technologist, a person must:

(a) Successfully complete a full course of study which meets all academic requirements for a bachelor's degree in medical technology from an accredited college or university, and pass a national examination for certification approved by the Board;

(b) Successfully complete a course of study for a bachelor's degree in one of the chemical, physical or biological sciences at an accredited college or university, have at least 1 year of additional full-time experience or training in ***a licensed laboratory, or laboratory of a hospital, health department or university in*** the specialty or subspecialty in which the person performs tests, and pass a national examination for certification approved by the Board; or

(c) Pass the examination for clinical laboratory technologists given by the United States Department of Health and Human Services.

Sec. 19. NAC 652.437 is hereby amended to read as follows:

652.437 1. To qualify for a certificate as a histologic technician, a person must:

(a) Successfully complete a program in histotechnology certified by the ~~[Committee]~~ ***Commission*** on ***Accreditation of*** Allied Health Education ~~[and Accreditation;]~~ ***Programs;***

(b) Have an associate degree ***in chemistry, biology or a physical science*** or successfully complete at least 60 semester hours or the equivalent of academic credit from an accredited college or university with at least 12 semester hours in science, of which 6 hours are in chemistry and 6 hours are in biology, and have 1 year of full-time experience in histotechnology in a histology laboratory under the supervision of a pathologist certified in anatomic pathology by the American Board of Pathology Incorporated or a pathologist eligible for certification in anatomic pathology; or

(c) Be a high school graduate or the equivalent and have 2 years of full-time experience in histotechnology, within the preceding 5 years, in a histology laboratory under the supervision of a pathologist certified in anatomic pathology by the American Board of Pathology Incorporated or a pathologist eligible for certification in anatomic pathology.

2. A histologic technician may only perform histologic procedures under the supervision of a histotechnologist or the director and may only perform cytologic procedures under the direction of a cytotechnologist, a histotechnologist or the director.

Sec. 20. NAC 652.461 is hereby amended to read as follows:

652.461 1. Except as otherwise provided in subsection 2 ~~[, any]~~ ***:***

(a) Any person desiring to have an inactive or a delinquent license or certificate reinstated shall submit evidence to the 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.]~~ ***(b)*** An inactive or delinquent license or certificate may be conditionally reinstated without the evidence required by ~~[subsection 1]~~ ***paragraph (a)*** if the applicant completes one unit of continuing education within a period established by the Division. Any failure to complete the continuing education or satisfy any other condition established by the Division is a ground for revocation of the license or certificate.

2. This section does not apply to a person certified as an office laboratory assistant or to such a certificate.

Sec. 21. 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 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 ***:***

(a) For a period not exceeding 12 months while the application is being processed ***;*** ~~[,]~~ or ~~[when]~~

(b) If the applicant has been issued a provisional certificate ~~[.]~~ ***, until the expiration of the provisional certificate.***

3. The 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 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 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 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 Division and payment of the fee prescribed in NAC 652.488.

Sec. 22. 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 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 ***at least*** 1 year of ***additional full-time*** experience ~~[working]~~ ***or training*** 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 ***signed and dated*** letter from the director of the laboratory in which the applicant obtained ***his or her*** experience ***,*** which verifies that the applicant has the experience required by subsection 1.

3. 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. 23. NAC 652.486 is hereby amended to read as follows:

652.486 ***1.*** The Division shall ~~[, upon request by]~~ ***issue a provisional certificate to*** a technologist or technician who is ***otherwise qualified for a certificate if he or she has not yet:***

(a) Passed a required ~~[to pass a]~~ national examination for certification ~~[and who]~~ ***, but*** has been accepted as a candidate for testing ~~[, issue him or her a provisional certificate. The]~~ ***; or***

(b) Accumulated the amount of experience or training required for certification.

2. A technologist or technician must apply for a provisional certificate on a form provided by the Division and pay the fee for initial certification of personnel set forth in NAC 652.488.

3. A provisional certificate ***issued pursuant to this section*** expires ~~[180 days]~~ ***18 months*** 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. 24. NAC 652.488 is hereby amended to read as follows:

652.488 ~~[The]~~

1. Except as otherwise provided in this section, the following fees will be charged:

~~[1.]~~ ***(a)*** Licensure of laboratory not described in ~~[subsection 2]~~ ***paragraph (b) or (c)***

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.]~~ ***(b)*** 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.]~~ ***(c) Licensure of HIV testing laboratory***

Initial.....$150

Biennial renewal.....150

(d) Licensure of director pursuant to paragraph (b) of subsection 3 of NAC 652.175 or NAC 652.380 to 652.395, inclusive

Initial $500

Biennial renewal 300

Reinstatement 500

~~[4.]~~ ***(e)*** Registration of laboratory operated pursuant to NRS ~~[652.235]~~ ***652.072*** which is nonexempt pursuant to NAC 652.155

Initial $1,500

Biennial renewal 900

Reinstatement 1,500

~~[5.]~~ ***(f)*** Registration of laboratory operated pursuant to NRS ~~[652.235]~~ ***652.072*** which is exempt pursuant to NAC 652.155

Initial $500

Biennial renewal 300

~~[6.]~~ ***(g)*** 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.]~~ ***(h)*** Placement of license or certificate in inactive status.....$50

~~[8.]~~ ***(i)*** Issuance of original duplicate license or certificate.....$50

~~[9.]~~ ***(j)*** Permit to operate laboratory at temporary location.....$300

~~[10.]~~ ***(k)*** Change of location of laboratory.....$300

~~[11.]~~ ***(l)*** Change of director of laboratory.....$300

~~[12.]~~ ***(m)*** Change of name of laboratory.....$300

~~[13.]~~ ***(n)*** Inspection ~~[for]~~ ***following receipt of an application to perform*** additional ~~[specialties and subspecialties in which]~~ tests ~~[will be performed]~~ at ***a*** laboratory ***(per application)*** $300

~~[Plus $50 for each additional~~

~~specialty or subspecialty~~

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

Initial inspection.....$300

Inspection at time of biennial renewal 150

~~15.~~ *2.* If the Division conducts an inspection of a laboratory that is located outside of this State, the Division shall assess the expenses that the Division incurs as a result of the inspection to the laboratory. The laboratory shall reimburse the Division for the expenses assessed pursuant to this subsection.

3. The Division shall not charge or collect a fee set forth in paragraph (k), (l) or (m) of subsection 1 to an HIV testing laboratory.

4. The holder of or an applicant for a license or certificate issued pursuant to chapter 652 of NRS, or an applicant for a permit to operate a laboratory at a temporary location issued pursuant to section 5 of this regulation, shall be deemed to have paid any fee otherwise required pursuant to subsection 1 if the holder or applicant:

(a) Is, or is employed by, a medical laboratory that is operated by a person, governmental entity or fire-fighting agency that holds a permit issued by a health authority pursuant to NRS 450B.200; and

(b) Has paid the fee for the permit established by a board pursuant to NRS 450B.200.

5. As used in this section:

(a) "Board" has the meaning ascribed to it in NRS 450B.060.

(b) "Health authority" has the meaning ascribed to it in NRS 450B.077.

(c) "Permit" has the meaning ascribed to it in NRS 450B.100.

Sec. 25. NAC 652.600 is hereby amended to read as follows:

652.600 1. Any program of training intended to prepare a person for certification as a technician must be approved by the ~~[Board.]~~ ***Division.*** Application for approval must be submitted ~~[in writing]~~ to the ~~[Board.]~~ ***Division in the manner prescribed by the Division.*** 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 Division each trainee who has successfully completed the program.

DIVISION OF PUBLIC & BEHAVIORAL HEALTH
BUREAU OF HEALTH CARE QUALITY AND COMPLIANCE
LCB File No. R149-15

Informational Statement per NRS 233B.066

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

The need for the adopted regulation is to protect public safety, bring the regulations into compliance with Nevada Revised Statutes (NRS) 652.130, NRS 652.186 and NRS 652.123 and to reduce the burden on individuals and businesses by:

- Not requiring the laboratory director in which only an HIV waived test is performed to be a licensed physician. It also does not require personnel performing the test to obtain certification as an assistant if the person submits proof of successful completion of training approved by the Division.
- Expanding the types of healthcare professionals that can serve as an exempt laboratory director.
- Deeming a laboratory licensed pursuant to Nevada Revised Statutes (NRS) and Nevada Administrative Code (NAC) of Chapter 652 which is also permitted, as defined in NRS 450B.100, and certified laboratory personnel who work in the laboratory, to have met the payment of required certification and licensure fees, as applicable.
- Clarifying that a permit to operate a laboratory at a temporary location expires 90 days after the effective date of the permit.
- Clarifying that exempt laboratories must adopt nationally recognized laboratory safety guidelines.
- Expanding the certification that an applicant that holds a doctorate degree can use to qualify to be a licensed or registered laboratory director.
- Outlining the fee to be assessed for a laboratory that only performs waived HIV tests.
- Allowing a laboratory to add as many tests as it wants to on one application for a flat rate of $300, instead of requiring a $300 application fee plus $50 for each additional specialty or subspecialties in which tests will be performed.
- Bringing proficiency testing standards in line with federal regulation requirements.
- Providing a method for a technologist to obtain the required one year of experience in Nevada instead of having to go out of state to obtain the experience, if they don't already have the experience.
- Changing the time a provisional certificate is good for from 180 days after the date of issue with the ability to request no more than three provisional certificates to one provisional certificate that cannot be renewed which would be good for 18 months.

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

Pursuant to NRS 233B.0608 (2) (a), the Division of Public and Behavioral Health has requested input from laboratories licensed in Nevada and licensed/certified laboratory personnel. Input was also received from the:

1) Adult Day Care Advisory Council;
2) Homes for Individual Residential Care Advisory Council;
3) Assisted Living Advisory Council; and the
4) Medical Laboratory Advisory Committee

The proposed regulations were sent to the Board of Nursing, Board of Pharmacy and Board of Medical Examiners.

A Small Business Impact Questionnaire was sent to medical laboratories and laboratory personnel along with a copy of the proposed regulation changes, in June of 2015. These were also posted on the Division's website and sent out through the Division's laboratory, medical and non-medical facilities listservs.

June 2, 2015 – The proposed regulations were presented to the Medical Laboratory Advisory Committee (MLAC). MLAC is composed of two pathologists, certified in clinical pathology by the American Board of Pathology, two medical technologists, a bioanalyst who is a laboratory director, a biochemist from the Nevada System of Higher Education and one licensed physician actively engaged in the practice of clinical medicine in this State. One of the roles of MLAC is to provide recommendations to the Board of Health relating to regulations. MLAC recommended restructuring the paragraphs related to who can serve as an exempt laboratory director. These were restructured so that each paragraph does not start off with, "In addition" and the word "or' was inserted to make it clear that any of the health care professionals listed in the paragraphs would be able to serve as the laboratory director.

December 17, 2015: A public workshop was held on the proposed regulations at the Division of Public and Behavioral Health located at 727 Fairview Drive, Suite E, Carson City and video conferenced to the Division's office located at 4220 South Maryland Parkway, Suite 810 in Las Vegas.

Two members of the public signed in at our Carson City office and both individuals signed in as supporting the proposed regulations.

Twenty-six individuals signed in at our Las Vegas location, twelve signed in as opposed to the proposed regulations, eleven signed in support, one signed in as undecided and two did not list a position.

Support for the proposed regulations expressed during the public workshop included:
One individual expressed support for expanding the types of healthcare professionals who can serve as an exempt laboratory director.

Concerns with the proposed regulations expressed during the public workshop included:
One individual expressed concern that she can give injections in HIRC (homes for individual residential care) homes but can't do glucose testing. She stated she can't accept certain residents

because they need help with glucose testing and she feels this is discriminatory. She would like an exemption for group homes, HIRCs, and ADCs (adult day care) so they can do glucose testing with proper training through a certified medication program.

It was clarified that a HIRC, ADC, or group home who wants to apply to provide tests can do so as long as they meet current requirements by applying to HCQC for an exempt laboratory license.

Another individual expressed concerns regarding a nurse who doesn't have any advanced training such as a nurse practitioner, MD, or PhD to supervise a CLIA (Clinical Laboratory Improvement Amendments)-waived lab. He feels that to assume that any nurse can manage and train staff and have the necessary diagnostic skills strains credulity. He does, however, feel that a nurse practitioner has the necessary skills. He asked why Nevada has tougher regulations than the federal government on finger sticks. He made three recommendations to improve clinical care: One, let nurses work within their scope of care. Two, let caregivers do observations. Currently they are not allowed to check a weight, read a thermometer or do a blood pressure cuff reading. Three, allow caregivers with some training to do finger sticks with the patient's own machine. If they're using a community machine like those used in a medical lab, then require a nurse practitioner or MD to administer the test. He feels it's common sense for finger sticks to be permitted in group homes and HIRCs with proper training, since people do their own finger sticks at home.

It was clarified that the regulations currently under consideration only cover medical laboratories and do not affect NAC 449 regulations covering the administration of medications. The medical laboratory regulations deal strictly with testing only.

Concerns were expressed regarding the cost of applying for an exempt laboratory license and requiring a medical professional to be its director. She said the $1,000 a year fee is not realistic for a HIRC.

It was clarified that the fee is not $1,000 a year. The initial fee is $500 for two years and $300 to renew every two years. It was explained that it is understood that it may be cost prohibitive to have a physician for just one glucose monitor in a facility, and that's a reason for expanding the individuals who can serve as laboratory directors, including an R.N., if there's only one test involved.

It was also explained that HCQC does an initial inspection for tests being performed and if a new test is added, a separate application must be submitted, allowing HCQC to ensure that everyone is properly trained. If a test is added to a one-test lab, then it is no longer a one-test lab.

It was commented that there have been deaths associated with the use of waived tests. One individual questioned whether someone can die from a finger stick glucose test.

One individual asked if she was required to have a monitor like the one used in hospitals for testing residents at her facilities. She wondered if she could use the standard home unit since it is less costly.

It was clarified that the definition of an "advanced practice registered nurse" is basically what the State Board of Nursing defines as an APRN.

Written comments provided to the Division of Public and Behavioral Health included:
Support of the proposed changes because "these changes will improve access to care and remove unnecessary barriers currently impeding access to care in Nevada."

Support of the proposed regulations relating to the addition of the National Registry of Certified Chemists (NRCC) to the list of approved Board certifications that would be allowed to qualify as the laboratory director of a registered or licensed laboratory.

Opposition to the proposed changes because it was felt the proposed regulations would add more confusion and potentially lead to incomplete, less monitored care for disabled seniors who have diabetes and require assistance with finger sticks and insulin injections.

Recommended changes to the proposed regulations expressed during the public workshop process included:

One individual recommended that HCQC allow facilities to use standard home units, not have to pay a licensing fee, and that nurses be allowed to do what they're licensed to do, whether they're in a residential facility, hospital, or home health agency.

Allowing RN's who are owners are or who have a financial interest in a facility, to work within their scope of practice.

Allowing caregivers to perform and record basic observational tasks like weights, temps, and blood pressures and pulses.

Allowing medication techs to receive additional training on performing finger sticks and administer prefilled flex pens of varied medications including insulin.

Recommendation that APRN's be allowed to oversee a CLIA waived laboratory but not allow a nurse to be able to do so.

September 30, 2016 – A second public workshop was held on the proposed regulations at the Division of Public and Behavioral Health located at 727 Fairview Drive, Suite E, Carson City and video conferenced to the Division's office located at 4220 South Maryland Parkway, Suite 810 in Las Vegas.

In the Carson City office, ten people signed in with five people signing in support of the proposed regulations, one signing in support with an addition, one signing as opposed and three individuals not indicating their position on the proposed regulations on the sign in sheet.

In the Las Vegas office, seventeen people signed in with one person signing in as opposed and the rest did not indicate their position on the proposed regulations on the sign in sheet.

Below is an overview of the testimony provided during the public workshop.
A recommendation was made that dentists be added to the list of those who can serve as the laboratory director of an exempt laboratory.

One individual testified in full support of APRN's acting as exempt laboratory directors and that it was within their scope of practice to do so.

One individual stated there was no prevention of a laboratory tree under the regulations and provided an example of what was meant by this. The example provided was an office with five nurses and each nurse served as the laboratory director of that office allowing each of them to do different tests in one office. Another concern expressed was related to quality issues and that people without laboratory experience don't have a good picture on how to evaluate tests. Allowing a lab to do a single test, with a focus on HIV screening, the largest population for syphilis, simple extension to then do a rapid syphilis test. She believes it is a danger to public health and healthcare in general. A concern that such laboratories would create an inspection burden. Our state inspectors are overburdened for them to go out to do one laboratory to assure appropriate evaluation and validation on tests may not be possible so putting in regulation that these waived tests can be done without any type of validation or proper control or education who are receiving the results. The safest of the CLIA waived test called the fingerstick glucose which the CDC says the risk is less than zero, or forgets exactly how it is said, but the risk is so low that doing the test incorrectly provides no risk, so because the CDC and CMS share that view we agree with them. This is very different from any CLIA waived test to their recommendation are narrow and focused and consistent with current standard of not sharing the meter.

It was expressed that exempt laboratories needed to comply with safety and efficiency standards.

One individual expressed concerns about allowing any nurse to do CLIA waived tests. He stated that noting one test is not specific enough, but even if it was fingerstick only with shared meters it should not be allowed. Adding fingersticks is over reaching due to liability insurance issues. He stated single patient use meters were okay. He also went on to say that patients using their own meters in adult day cares would be a problem because the meters would come and go with the patients. He stated it was okay for residential facilities for groups to do fingersticks with an individual's meter. He stated nurses working within their scope of practice is okay. He also stated that the CDC's position is that there is zero risk for fingerstick glucose testing.

One individual stated that the CLIA waived model used in SNF's should not be used in residential facilities. She opposes the regulations in the residential care facility setting.

She mentioned that the assisted living/residential facilities for groups industry worked closely with the Legislative Committee for Seniors, Veterans and Adults with special needs as well as the Legislative Commission subcommittee and that there was a post-acute care study that was looking as these issues and that Dr. Robin Titus and Dr. Joe Hardy were a part of it. She mentioned that it was brought to their attention that individual who lived there, if at home, friends, neighbors and daughters could check their glucose, blood pressure and heart rate and report it to the doctor but in residential facilities for groups it should not be allowed because they

are not a CLIA lab. Each individual facility has to have its CLIA lab. This is ridiculous. It makes no sense because you can do it at home but not in an environment with more people looking after you that have close contact with the physician on all of these things. Administration of flex pen and managing diabetes makes sense so the legislature is coming up with a recommendation for the State Board of Health to adopt regulations to allow the administration of the different types of observation tests as well as flex pens and other monitoring devices and glucose tolerance tests. We disagree with shared devices. Want to keep it with just personal devices.

An overview of written testimony included:

- Adding that all settings must have clear allowable patient types that include both diagnosis label and most importantly functional needs assessment. For example, if they need 24 hour protective supervision, help with medication and PRN medications and caregiving. In addition, define what patient types require the safety of a sprinkler and which patient types do not.
- Adding a requirement of public disclosure of locations for any shared living, congregate care, or any other site which provides any amount of protective supervision, assistance with medications, caregiving, to people who are not completely independent.
- Removing language which would allow certain health care professionals to serve as the laboratory director of an exempt laboratory that only performs one waived test because it is beyond current clinical practice standards.

October 12, 2016 – A second meeting was held before the Medical Laboratory Advisory Council (MLAC) meeting. MLAC's recommendation to the Board of Health was to move the proposed regulations forward with the following changes:

1) MLAC recommended that instead of allowing the individuals listed in Section 6, Subsection 2 to serve as the laboratory director of an exempt laboratory that performs one waived test that they only be allowed to serve in this capacity if only waived glucose testing is being performed.
2) MLAC recommended that the timeframe from which the director has to submit the plan of correction be changed from 10 calendar days to 14 calendar days.
3) MLAC recommended that if a technologist does not have the necessary experience to obtain certification as a technologist that he or she be required to have a provisional certificate in order to work.

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. Phone: 775-684-1030.

3. A statement indicating the number of persons who attended each hearing, testified at each hearing, and submitted written statements regarding the proposed regulation. This statement should include for each person identified pursuant to this section that testified and/or provided written statements at each hearing regarding the proposed regulation, the following information, if provided to the agency conducting the hearing:

   (a) Name
   (b) Telephone Number

(c) Business Address
(d) Business telephone number
(e) Electronic mail address; and
(f) Name of entity or organization represented

Fifty-two people were noted on the sign in sheet as having attended the March 2017 Board of Health. Of note, some of those individuals may have been at the hearing for other items being heard at the same hearing.

Five people testified in support of the proposed regulations:

Russ Phifer	National Registry of Certified Chemists (NRCC)	610-322-0657
Marc Julliard	MD Labs	530-574-7959
Robert Harding	Northern Nevada HOPES	775-750-8305
Cameron Duncan	Nevada Advanced Practice Nurses Association	775-843-8428

An APRN testified in Las Vegas (did not get name)

Two people testified in opposition:

Jeanne Bishop-Parise	Nevada Assisted Living Association	775-232-3379
Shawn McGivney	Doctors (according to BOH sign in sheet)	702-556-1639

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

A Small Business Impact Questionnaire was sent to medical laboratories and laboratory personnel along with a copy of the proposed regulation changes, in June of 2015. These were also posted on the Division's website and sent out through the Division's laboratory, medical and non-medical facilities listservs.

Summary of Response

Summary Of Comments Received (71* responses were received out of 12,865 plus*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 = 61 Yes = 5 No response/ unknown = 5	No = 62 Yes = 5 No response/ unknown = 4	No = 61 Yes = 5 No response/ unknown = 5	No = 64 Yes = 3 No response/ unknown = 4
Comments: Renewal Fee Increase liability insurance and push RFFG big and small into a medical insurance premium and out of the non-medical premiums they enjoy now. Lead to more negative images of the industry with misleading promises from the community. They promise a diabetes screening program when in fact it is just a finger stick without giving insulin program. I can't help but believe a common person will not understand the subtle distinction as something the community senior and family should have known. Does not affect us I will need to increase charges for the one test that we do – a nasal smear. Will have financial site impact. To get an estimated cost would have to go to corporate side. NAC 652.380 A physician to obtain a board cert not related to their primary specialty requires an enormous amount of time to study. Thousands of dollars for training courses and cost of the board exam. All these regulations will further push	**Comments:** I am a DNP and I own a family practice office. Allowing nurse practitioners to be laboratory directors will save me $500/year. I have to pay a physician to be my laboratory director. If NP's were able to be lab director our clinic would experience >12,000.00 cost savings. As a nonprofit saving fees is important. This potentially can lower costs associated with director fees. Remove the restriction for medical doctor. Will be in line with the 2013 changes for full practice authority for APRN. Elimination of secondary oversight and financial charge to be a lab that is more than over State EMS permit to operate. No. It only misleads seniors and families and doctors into thinking these facilities have a full time, fully functioning nurse, when in fact they do not. This is very misleading for the community.	Comments: While less on my business directly because we will not be using this program since I believe it is unsafe. As a medical doctor I see these risks as industry wide and hurting/agitating seniors, increasing ER visits unnecessarily, and leading to many civil suits. I believe that most big companies will not use this either and will recognize the risk to their liability insurance. I fear small providers and small more private big assisted living facilities trying to do good but who lack the medical and risk management knowledge to keep themselves and residents safe. N/A Increase cost of patient care. No added benefit that I can see. Increased financial responsibility.	**Comments:** Will allow clinic to operate our CLIA waived lab with less cost. 1) Cost Savings 2) Time Savings 3) Better oversight from EMS office of all providers not just a small annual percent. In general there are no benefits from providing misleading information to seniors apparently with the goal of discharging residents with complicated medical problems to non-medical facilities that can't manage and treat them. The issue is not doing a fingerstick but not having the full time RN's to give insulin. I do have ideas on how the state and industry can safely offer a complete diabetes screening program and will continue to share them as I and RCHCAN have in the last year. The industry remains open to sitting down and working with the state and HCQC and other agencies to find safe, cost effective, care

competent physicians out of medicine. I don't know yet until inspection. Unknown Makes my business have a ridiculous financial burden I may not need but for brief amounts of time, yet have to maintain annually.	Does not affect us It will just increase my overhead costs and increase the cost to my patient for test. We won't be able to afford to perform the waived test with newly imposed fees. We barely make a profit so the fees will create a negative profit margin. I won't know until inspection. Do not see anything beneficial all fees appear to be increasing. Only adds to what my low income, rural residents have to pay.	Financially because a current service will not be able to be provided which will cause a reduction in revenue. Also, patients who entrust their physicians at our office to monitor PTT/INR levels will lose the benefit of having their test performed and adjusted, if necessary, at the same time without a delay in care. I don't know as of yet Unknown. Restricts residents right to live where the want to! Financial burden, more intrusive, unnecessary way to limit my ability to make a living, care for those in need, punish my business because someone else screwed up! Anyone can learn to do a glucometer blood sugar check – I know that from home health nursing over the years. Lay people and children do it yet we who care for seniors need a lab license – too far state – too far! No-	options for the state that are clear, transparent and safe for seniors. This is not it by itself. It hurts the patients causing a delay in care. It hurts the physicians – taking away the ability to provide immediate care and hurts by removing a service that our patients want to be performed in their physician's office. I don't know until further inspection. **N/A** **Other Comments:** We perform only urine pregnancy tests on surgery patients. No other testing! Do not anticipate any adverse or beneficial effects. Our lab is an exempt lab, and there are no changes to fees that I can see.

Number of Respondents out of 12,865 plus	**Adverse economic effect?**	**Beneficial effect?**	**Indirect adverse effects?**	**Indirect beneficial effects?**
No	61	62	61	64
Yes	5	5	5	3
No Response/unknown	5	4	5	4

*questionnaires returned which indicated 150 or more employees were not included.
*questionnaires were also sent to the Board of Nursing, Board of Pharmacy and Board of Medical Examiners for distribution to their members.

A copy of the summary can be obtained by contacting the Bureau of Health Care Quality and Compliance, 727 Fairview Drive, Suite E, Carson City, NV 89701. Phone: 775-684-1030.

5. If, after consideration of public comment, 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.

The proposed regulations were modified after the public workshop processes and MLAC meetings. The main changes include:

1) All of MLAC's recommendations presented during the October 12, 2016 MLAC meeting, as outlined in number two, were incorporated into the proposed regulations.
2) Removing the requirement that if the Division cannot determine the qualifications of a license as a director that the Division is to submit the application to the Committee for its recommendation.
3) Adding CLIA approved Boards to the certification that an applicant that holds a doctorate degree can use to qualify to be a licensed or registered laboratory director.
4) Changing the provisional certificate time frame from a provisional certificate that expires 180 days after the date of issue with the ability to request no more than three provisional certificates to a provisional certificate valid for 18 months from the time of issuance without the ability to renew it. In addition, if a technologist does not have the necessary experience to obtain certification as a technologist, he or she shall be required to have a provisional certificate in order to work.
5) Allowing the individuals listed in Section 6, Subsection 2 to serve as the laboratory director of an exempt laboratory that only performs glucose waived test instead of any waived test.
6) Changing the timeframe from which the director has to submit the plan of correction from 10 calendar days to 14 calendar days.
7) The Board of Health adopted the regulations with one change, omitting the American Osteopathic Board of Internal Medicine from subsection (1) (b) of Section 16 to be replaced with the following language in Section 16, subsection 1: 1) Be a physician or osteopathic physician certified in the subspecialty of pulmonary disease by the American Board of Internal Medicine or any other nationally recognized board of internal medicine.

Medical laboratory regulations are specific to laboratory testing and do not cover medication administration, taking of blood pressures and other related items; therefore, none of these recommended changes were made. The Board of Dental Examiners was called to obtain permission to add dentists to the list of health care professionals that can serve as an exempt laboratory director but permission was never received to add them.

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
(b) Both immediate and long term effects.

Adverse effects: No adverse financial effects are anticipated. There was concern expressed that there would be an increase in liability insurance and it would push residential type facilities into a medical insurance premium and out of non-medical premiums. The proposed regulations do not require businesses to offer laboratory services if they do not want to. Currently these businesses are able to provide laboratory services if licensing requirements are met, so the proposed regulations do not add an additional service that can be provided by these businesses.

Beneficial effects: It is anticipated that there would be a beneficial financial effect for some individuals and businesses. For example, one small business estimated a cost savings of $500 per year while others noted there would be no changes. Beneficial effects include offering these small businesses flexibility in determining what is best for their business and does not dictate that they must use a health care provider other than a physician to serve as an exempt laboratory director. In addition, many States do not require a physician or even a healthcare professional to serve as an exempt laboratory director. Each business would be able to make the determination based on their liability insurance what is best for them.

Immediate effects: As soon as the regulations become effective individuals would be able to immediately implement the changes in the proposed regulations, such as applying for an exempt laboratory without the requirement that a physician serve as the laboratory director or having an existing exempt laboratory make a change in director. This may result in immediate cost savings to these businesses.

Long term effects: It is anticipated the cost savings for certain businesses would have a long term effect as they would be accumulative through the years. For example, the small business that estimated a cost savings of $500 per year.

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

At this time, it is estimated that there would be no additional cost to the agency to enforce the proposed regulations. It is anticipated that any increased workload caused by industry opening a medical laboratory to perform only waived HIV testing would be absorbed into exiting workload by existing staff. In addition, a licensing fee of $150 for HIV testing laboratories would help offset any additional licensing costs. Emergency Medical Services staff would incorporate the inspection of a medical laboratory located in permitted emergency medical services and firefighting agencies into their current inspection workload. It is estimated that the other provisions in the proposed regulations would not result in an additional cost to the agency.

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 regulating 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, 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.

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

The Centers for Medicare and Medicaid Services (CMS) federal CLIA regulations do not have any requirements for the individual that serves as the laboratory director for an exempt laboratory. Nevada's current regulations require that the laboratory director of an exempt laboratory be a licensed physician as defined in NAC 652. The proposed regulations expand who can serve as an exempt laboratory director to include certain, other healthcare professionals licensed or certified in Nevada. This requirement does remain more stringent than federal regulations that do not require a healthcare professional to serve in this capacity but due to input received during the regulation development process it was felt that having a healthcare professional serve in this capacity be a requirement to help ensure the safety and well-being of Nevada's public.

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

An initial licensing fee of $150 good for two years followed by a biennial renewal fee of $150 for the new laboratory type, HIV testing laboratory, is noted in the regulations. We anticipate having a total of seven HIV testing laboratories to start; although, we may have more in the future. We expect to collect $1,050 every two years from these 7 laboratories which comes out to $525 annually. We plan to use these funds to help offset the costs to license, inspect and regulate this new type of laboratory.