STATE OF NEVADA

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February 6, 2017

MEMORANDUM

To: Brian Saeman, Chair
State Board of Health

From: Cody Phinney, MPH, Secretary
State Board of Health

Re: Consideration and adoption of proposed regulation amendment(s) to Nevada Administrative Code (NAC) 652, "Medical Laboratories", LCB File No. R149-15.

PURPOSE OF AMENDMENT

The main purpose of the amendment is to protect public safety, bring the regulations into compliance with Assembly Bill (AB) 243 of the 2015 Legislative Session and to reduce the burden on individuals and businesses by:

1) 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.
2) Expanding the types of healthcare professionals that can serve as an exempt laboratory director.
3) 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.
4) Clarifying that a permit to operate a laboratory at a temporary location expires 90 days after the effective date of the permit.
5) Clarifying that exempt laboratories must adopt nationally recognized laboratory safety guidelines.
6) Expanding the certification that an applicant that holds a doctorate degree can use to qualify to be a licensed or registered laboratory director.
7) Outlining the fee to be assessed for a laboratory that only performs waived HIV tests.
8) 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.
9) Bringing proficiency testing standards in line with federal regulation requirements.

10) 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.
11) 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.

SUMMARY OF CHANGES TO NEVADA ADMINISTRATIVE CODE (NAC)

The Board of Health last revised regulations to NAC Chapter 652, "Medical Laboratories" in 2014.

The proposed regulations currently moving forward accomplish the following:

1) Protect public safety by clarifying that exempt laboratories must adopt nationally recognized laboratory safety guidelines, including infection control guidelines.
2) During the 2015 Legislative Session, the legislature passed a law with an intent to expand the accessibility of HIV waived testing by removing some of the regulatory requirements. NRS 652.130 requires that any regulations adopted by the Board must not require that the laboratory director of a laboratory in which the only test performed is an HIV waived test to be a licensed physician or to perform duties other than those prescribed in NRS 652.180. NRS 652.185 requires that a laboratory that performs HIV waived test conduct the test in accordance with the Centers for Disease Control and Prevention's (CDC) quality assurance guidelines, as well as comply with the reporting of communicable diseases. NRS 652.186 allows the individual performing the test from obtaining a laboratory personnel certification if the person submits proof of training approved by the Division. NRS 652.123 notes the Board may adopt regulations which are more stringent than federal regulations relating to any CLIA waived test, except an HIV test. The changes in the proposed regulations bring the medical laboratory regulations in compliance with these statutes by eliminating specific criteria to be a laboratory director, such as being a licensed physician, and instead only requiring that the individual carry out the duties of a laboratory director as outlined in NRS 652.180. 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.
3) Reduces the burden to industry by expanding the types of healthcare professionals that can serve as the laboratory director of an exempt laboratory, deems fire-fighting agencies and ambulance service providers permitted in accordance with NRS 450B.100 to have met laboratory licensing and personnel certification fee requirements, and other changes as noted in the purpose of amendment section.

POSSIBLE OUTCOME IF PROPOSED AMENDMENT IS NOT APPROVED

If the proposed amendments are not approved, current regulations would not be in compliance with Assembly Bill (AB) 243 of the 2015 Legislative Session as it relates to laboratories that only perform HIV waived tests. The laboratory licensing and laboratory personnel certification fees would not be deemed to be met for firefighting and ambulance service agencies increasing the regulatory burden for these agencies. Businesses that only perform glucose waived tests and exempt laboratories in which

more than one waived test is performed would be required to have a licensed physician serve as the laboratory director. In addition, the other proposed changes would not become effective.

APPLICABILITY OF PROPOSED AMENDMENT

These regulations will apply statewide to medical laboratories governed by NRS and NAC Chapter 652.

PUBLIC COMMENT RECEIVED

An outline of opportunities for public comment follows:

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.

Below is a summary of the responses to the questionnaire.

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	**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.	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	**Comments:** Will allow clinic to operate our CLIA waived lab with less cost. 1) Cost Savings 2) Time Savings

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 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.	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. 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.	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. 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 loose the benefit of having their test performed and adjusted, if necessary, at the same time	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 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

	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.	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-	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.

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 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 so they can do glucose testing with proper training through a certified medication program.

It was clarified that a HIRC, ADC, or group home that 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-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.

For the full text of the written comments provided above please refer to the letters included with your packet.

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 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 Skilled Nursing Facilities (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 part of it. She mentioned that it was brought to their attention that individuals 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 and 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.

For the full written comments please refer to the written responses included with your packet.

October 12, 2016 – A second meeting was held before the Medical Laboratory Advisory Council (MLAC) meeting. The objections outlined in your packet titled, Objection to #6 of the proposed regulation allowing a nurse to supervise a one test CLIA-waived medical lab, Industry Response to Small Business Impact Questionnaire two (9-24-16) and the proposed regulations document with the "See comments in Green" and hand written note, Nevada Assisted Living Association were submitted to MLAC prior to the meeting

for their review. 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 time frame 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.

Changes to Proposed Regulations

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 above, 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 time frame from which the director has to submit the plan of correction from 10 calendar days to 14 calendar days.

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.

STAFF RECOMMENDATION

Staff recommends the State Board of Health adopt the proposed regulation amendments to NAC 652, "Medical Laboratories", LCB File No.R149-15.

PRESENTER

Paul Shubert, Bureau Chief

Enclosures

NOTICE OF PUBLIC HEARING

Intent to Adopt Regulations
(LCB File No. R149-15)

NOTICE IS HEREBY GIVEN that the State Board of Health will hold a public hearing to consider amendments to Chapter 652 of Nevada Administrative Code (NAC), Medical Laboratories. This public hearing is to be held in conjunction with the State Board of Health meeting on March 10, 2017.

The State Board of Health will be conducted via videoconference beginning at 9:00 a.m. on Friday, March 10, 2017 at the following locations:

Division of Public and Behavioral Health 4150 Technology Way Room #303 Carson City, NV 89706	Southern Nevada Health District 280 S. Decatur Blvd Las Vegas, NV 89107	Division of Aging and Disability Services Early Intervention Services 1020 Ruby Vista Drive, Suite 102 Elko, NV

The proposed changes to NAC 652 include the following:

1) Brings the proposed regulations in compliance with Assembly Bill (AB) 243 of the 2015 Legislative Session which directs that any regulations adopted by the Board of Health must not require 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.
2) Expands the types of healthcare professionals that can serve as an exempt laboratory director.
3) Deems 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.
4) Clarifies that a permit to operate a laboratory at a temporary location expires 90 days after the effective date of the permit.
5) Clarifies that exempt laboratories must adopt nationally recognized laboratory safety guidelines.
6) Expands the certification that an applicant that holds a doctorate degree can use to qualify to be a licensed or registered laboratory director.
7) Outlines the fee to be assessed for a laboratory that only performs waived HIV tests.
8) Instead of requiring a $300 application fee plus $50 for each additional specialty or subspecialties in which tests will be performed, the proposed regulations allow a laboratory to add as many tests as it wants to on one application for a flat rate of $300.

9) Brings proficiency testing standards in line with federal regulation requirements.
10) Provides 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. If a technologist does not have the required experience to become certified as a technologist, a provisional certificate would be required in order to work.
11) Changes 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.

1. Anticipated effects on the business which NAC 652 regulates:
   A. *Adverse effects*: None.
   B. *Beneficial:* Potential cost savings for exempt laboratories who will have increased flexibility in the type of health care professional that can serve as the laboratory director, cost savings for agencies permitted as defined in NRS 450B.100 who are also licensed as a laboratory, and cost savings for laboratory personnel applicants that apply for a provisional certificate who would have to request more than one certificate. The proposed regulations would make it easier to open a laboratory that only performs HIV waived tests through lower licensing fees and by increasing the flexibility of who can serve as the laboratory director and perform the HIV waived tests.
   C. *Immediate:* The cost savings and flexibility noted above would be immediately available.
   D. *Long-term:* Continued cost savings.
2. Anticipated effects on the public:
   A. *Adverse*: None.
   B. *Beneficial:* It will also technologists educated in Nevada 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. It would also be a cost savings to applicants who have to pay for more than one provisional certificate.
   C. *Immediate*: The cost savings noted above would be immediately available.
   D. *Long-term:* May result in more newly educated technologists staying in Nevada to work.

3. The estimated cost to the Division of Public and Behavioral Health for enforcement of the proposed regulations is to be covered by current licensing and certification fees outlined in NAC 652.488, in addition to the proposed fee to license laboratories that only perform HIV waived testing in the proposed regulations.

The proposed regulations do not overlap or duplicate any other Nevada state regulations. Federal regulations do not have any requirements for the individual that serves as the laboratory director for an exempt laboratory. The proposed regulations expand the type of healthcare professionals that can serve as the laboratory director of an exempt laboratory, but remain more

stringent than federal regulations that do not require that the director be a healthcare professional.

Members of the public may make oral comments at this meeting. Persons wishing to submit written testimony or documentary evidence in excess of two typed, 8-1/2" x 11" pages must submit the material to the Board's Secretary, Cody Phinney, to be received no later than February 17, 2017 at the following address:

Secretary, State Board of Health
Division of Public and Behavioral Health
4150 Technology Way, Suite 300
Carson City, NV 89706

Written comments, testimony, or documentary evidence in excess of two typed pages will not be accepted at the time of the hearing. The purpose of this requirement is to allow Board members adequate time to review the documents.

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

Nevada Division of Public and Behavioral Health
727 Fairview Drive, Suite E
Carson City, NV 89701

Nevada State Library
100 Stewart Street
Carson City, NV 89701

Nevada Division of Public and Behavioral Health
4220 S. Maryland Parkway, Suite 810, Building D
Las Vegas, NV 89119

A copy of the regulations and small business impact statement can be found on-line by going to:
http://dpbh.nv.gov/Reg/MedicalLabs/Notice_of_Public_Workshops_and_Proposed_Regulations/

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

Copies may be obtained in person, by mail, or by calling the Division of Public and Behavioral Health at (775) 684-1030 in Carson City or (702) 486-6515 in Las Vegas.
Copies may also be obtained from any of the public libraries listed below:

Carson City Library
900 North Roop Street
Carson City, NV 89702

Churchill County Library
553 South Main Street
Fallon, NV 89406

Clark County District Library
1401 East Flamingo Road
Las Vegas, NV 89119

Douglas County Library
1625 Library Lane
Minden, NV 89423

Elko County Library
720 Court Street
Elko, NV 89801

Esmeralda County Library
Corner of Crook and 4th Street
Goldfield, NV 89013-0484

Eureka Branch Library
80 South Monroe Street
Eureka, NV 89316-0283

Henderson District Public Library
280 South Green Valley Parkway
Henderson, NV 89012

Humboldt County Library
85 East 5th Street
Winnemucca, NV 89445-3095

Lander County Library
625 South Broad Street
Battle Mountain, NV 89820-0141

Lincoln County Library
93 Maine Street
Pioche, NV 89043-0330

Lyon County Library
20 Nevin Way
Yerington, NV 89447-2399

Mineral County Library
110 1st Street
Hawthorne, NV 89415-1390

Pahrump Library District
701 East Street
Pahrump, NV 89041-0578

Pershing County Library
1125 Central Avenue
Lovelock, NV 89419-0781

Storey County Library
95 South R Street
Virginia City, NV 89440-0014

Tonopah Public Library
167 Central Street
Tonopah, NV 89049-0449

Washoe County Library
301 South Center Street
Reno, NV 89505-2151

White Pine County Library
950 Campton Street
Ely, NV 89301-1965

Per NRS 233B.064(2), upon adoption of any regulation, the agency, if requested to do so by an interested person, either prior to adoption or within 30 days thereafter, shall issue a concise statement of the principal reasons for and against its adoption, and incorporate therein its reason for overruling the consideration urged against its adoption.

REVISED PROPOSED REGULATION OF THE

STATE BOARD OF HEALTH

LCB File No. R149-15

December 13, 2016

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 the American Osteopathic Board of Internal Medicine 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 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 ~~[,]~~ ***by the:***

(a) American Board of Internal Medicine; or

(b) American Osteopathic Board of Internal Medicine; 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 Division.

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.

SMALL BUSINESS IMPACT STATEMENT 2016
PROPOSED AMENDMENTS TO NAC CHAPTER 652

The Division of Public and Behavioral Health (DPBH) has determined that the proposed amendments should not have a negative financial impact on a small business and in some circumstances may have a beneficial financial impact. The proposed regulations are not expected to negatively impact the formation, operation or expansion of a small business in Nevada.

A small business is defined in Nevada Revised Statutes NRS 233B as a "business conducted for profit which employs fewer than 150 full-time or part-time employees."

This small business impact statement is made pursuant to NRS 233B.0608 (3) and complies with the requirements of NRS 233B.0609. As required by NRS 233B.0608 (3), this statement identifies the methods used by the agency in determining the impact of the proposed regulations on a small business and provides the reasons for the conclusions of the agency followed by certification by the person responsible for the agency.

Background

The three main things the proposed regulations do include:

1) Bringing the proposed regulations in compliance with Assembly Bill (AB) 243 of the 2015 Legislative Session which directs that any regulations adopted by the Board of Health must not require 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.
2) Expanding the types of healthcare professionals that can serve as an exempt laboratory director. Many states in the United States do not have state licensure requirements and only follow federal guidelines. Federal guidelines have no requirements for who can serve as the laboratory director of a waived laboratory. In these cases the laboratory director can be an office worker with no healthcare experience. The Division recognizes that the laboratory director should have at a minimum, certification/licensure as a healthcare professional to ensure the appropriate quality control measures and infection control practices are adhered to in order to ensure accurate and safe results. The proposed regulations are more stringent than the federal regulations in this regard but at the same time relax current state regulation requirements to help reduce the financial burden on certain industry while maintaining patient safety.
3) Deems 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.

The regulations also:

1) Clarify that a permit to operate a laboratory at a temporary location expires 90 days after the effective date of the permit.

2) Clarify that exempt laboratories must adopt nationally recognized laboratory safety guidelines including infection control guidelines such as those put out by the Centers for Disease Control and Prevention (CDC) which can be obtained for free on the CDC's website.
3) Expands the certification that an applicant that holds a doctorate degree can use to qualify to be a licensed or registered laboratory director.
4) Outlines the fee to be assessed for a laboratory that only performs waived HIV tests.
5) Instead of requiring a $300 application fee plus $50 for each additional specialty or subspecialties in which tests will be performed, the proposed regulations allow a laboratory to add as many tests as it wants to on one application for a flat rate of $300.
6) Brings proficiency testing standards in line with federal regulation requirements.

1) A description of the manner in which comment was solicited from affected small businesses, a summary of their response and an explanation of the manner in which 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 all laboratories licensed in Nevada and licensed/certified laboratory personnel. The proposed regulations were also presented to the following advisory groups:

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 also sent to the Division of Public and Behavioral Health's Emergency Medical Services, Board of Nursing, Board of Pharmacy and Board of Medical Examiners for distribution to their licensees.

A Small Business Impact Questionnaire was sent to all licensed laboratories and licensed/certified 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. The questions on the questionnaire were:

1) How many employees are currently employed by your business?
2) Will a specific regulation have an adverse economic effect upon your business?
3) Will the regulation(s) have any beneficial effect upon your business?
4) Do you anticipate any indirect adverse effects upon your business?
5) Do you anticipate any indirect beneficial effects upon your business?

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.	**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.	**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	**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

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 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.	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. 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.	Increase cost of patient care. No added benefit that I can see. Increased financial responsibility. 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-	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 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 bene 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.

Any other persons interested in obtaining a copy of the summary may e-mail, call, or mail in a request to the:

Division of Public and Behavioral Health
727 Fairview Drive, Suite E
Carson City, NV 89701
Leticia Metherell: Phone: 775-684-1045; Email: lmetherell@health.nv.gov

2) Describe the manner in which the analysis was conducted.

An analysis of the input collected from stakeholders was conducted by the medical laboratories unit manager. Input was varied with some feeling there would be a cost savings, some feeling there would be no impact and some feeling it would result in a cost increase. To alleviate concerns it was explained to several individuals that the proposed regulations do not raise fees. That the proposed regulations expand the type of healthcare professionals that can serve as the director of an exempt laboratory and do not place greater restrictions on them. It was also noted that nationally recognized infection control guidelines such as those from the CDC could be obtained at no cost.

An analysis determined that the proposed regulations should not have a negative fiscal impact and may have a beneficial fiscal impact for some industries.

3) The estimated economic effect of the proposed regulation on the small business which it is to regulate including, without limitation both adverse and beneficial effects and both direct and indirect effects.

It is estimated that there would be no adverse economic effect on small businesses and may have a beneficial effect on some. This would vary based on each situation. For example, one small business estimated a cost savings of $500 per year while others noted there would be no changes. 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 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. Direct effects may include cost savings for some businesses. Indirect financial effects are unknown.

4) Provide a description of the methods that the agency considered to reduce the impact of the proposed regulation on small businesses and a statement regarding whether the agency actually used any of those methods.

The Division of Public and Behavioral Health has held several opportunities for stakeholders to provide input and comments regarding the proposed medical laboratory regulations, including the economic impact the proposed regulations may have on industry. Modifications to the proposed regulations have been made as a result of input received during the regulation development process including not allowing a laboratory assistant to serve as an exempt laboratory director. A public workshop was conducted on December 17, 2015 and a second public workshop will be scheduled allowing for further input by stakeholders and the public regarding the proposed regulations and how they will impact industry. Comments received during the public workshop will also be taken into consideration for possible further revisions to the regulations to reduce the economic impact on facilities.

5) 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. 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.

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

A new fee would be collected for medical laboratories that perform only waived HIV testing. The fee for an initial application would be $150 with a $150 renewal fee every two years. It is unknown how many applications will be submitted therefore the total amount DPBH expects to collect is unknown. If we anticipated 10 of these medical laboratories opening in the first year the collected amount would be $1,500. The money would be used to carry out the provisions to license and regulate these medical laboratories. There are no fee increases being proposed. Currently the Division may collect a $300 fee for the addition of specialties and subspecialties for tests performed plus $50 for each additional specialty or subspecialty. A modification was made to the existing fee so only one flat fee of $300 is assessed for as many tests as the laboratory wants to make on one application.

7) An explanation of why any duplicative or more stringent provisions than federal, state or local standards regulating the same activity are necessary.

Federal 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 the federal regulations that do not require that 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.

8) **Provide a summary of the reasons for the conclusions of the agency regarding the impact of a regulation on small businesses.**

After reviewing the proposed regulations, reviewing internal processes and evaluating the feedback provided by different stakeholders it was concluded that the proposed regulations would provide increased flexibility to small businesses without creating an adverse economic burden while providing a beneficial economic impact in certain cases. Recently, the Division has encountered infection control breaches in some exempt laboratories. Clarifying that these laboratories also must adopt nationally recognized safety standards including infection control standards will help ensure patient safety.

Explanation of Revisions and Effects of Changes on Small Business

Currently, applicants to become technologists pursuant to Nevada Revised Statutes (NRS) and Nevada Administrative Code (NAC) Chapter 652 who do not have the required 1 year of experience outlined in NAC 652.420 or 652.480, as applicable, that are educated in Nevada have to go out of state to obtain the necessary experience to become certified. The revisions allow an applicant to become a technologist the ability to gain this experience in Nevada instead of having to go out of state to obtain it. This would result in a cost savings to any individuals that move or travel out of state in order to obtain the necessary experience to become certified.

Currently, a provisional certificate is good for 180 days and can be renewed up to three times. The applicant has to pay a fee for each provisional certificate they apply for. The revisions would create only one provisional certificate with the amount of time equivalent to three 180 day provisional certificates for the cost of only one provisional certificate. This would result in a cost savings to all applicants that may require more than one provisional certificate because instead of paying the fee for a provisional certificate a second or third time the applicant would only pay the fee once.

These changes may therefore result in a cost savings to any small business that pays for these costs for their employees.

Certification by Person Responsible for the Agency

I, Cody Phinney, Administrator of the Division of Public and Behavioral Health certify to the best of my knowledge or belief, a concerted effort was made to determine the impact of the proposed regulation on small businesses and the information contained in this statement was prepared properly and is accurate.

Signature Cody N Phinney Date: 8/19/16

National Registry of Certified Chemists

125 Rose Ann Lane, West Grove, Pennsylvania, USA 19390
610-322-0657 / 800-858-6273 Fax / rphifer@nrcc6.org

American Chemical Society
American Institute of Chemists
American Board of Clinical Chemistry
American Industrial Hygiene Association
National Academy of Clinical Biochemistry
American Association for Clinical Chemistry

October 19, 2015

Nevada Division of Public & Behavioral Health
Medical Laboratory Services
727 Fairview Drive, Suite E
Carson City. NV 89701
Attn: Leticia Metherell

Dear Leticia –

I understand from one of our certified Clinical Chemists that this would be a good time to contact you regarding being added to the list of accepted boards for certification for Lab Director licensing in Nevada.

The National Registry of Certified Chemists was formed in 1967, and is an approved Certification Board for Laboratory Directors of High Complexity Testing by CLIA. We have an exemplary Board of Directors managing our certification exams and programs, and would appreciate being added to the approved list.

Please let me know if you need additional information, and thanks for your kind consideration.

Sincerely,

NATIONAL REGISTRY OF CERTIFIED CHEMISTS

Russell Phifer
Executive Director

MD LABS
PRESCRIPTION MONITORING AND PHARMACOGENETICS

Marc D. Julliard, PhD
General Laboratory Supervisor – MD Labs
10715 Double R Blvd, Suite 102
Reno, NV 89521.

Reno, Nov 1st 2015

To Whom It May Concern,

I am writing this letter in an effort to support the Proposed Regulation of The State Board of Health, section 4, article 2 – more particularly the addition of the National Registry of Certified Chemists (NRCC) to the list of approved Board certifications for High Complexity Laboratory Director (HCLD) licensing.

The NRCC is a well-established institution founded in the 1980's. Its Board members representing AACC, ABCC, AIHA, ACS and AIC are nominated for 3-year terms by their respective organizations. NRCC is an approved CLIA Board for laboratory directors of High Complexity Testing. As listed on the CMS website, board certification by the NRCC along with a PhD degree are sufficient requirements to qualify as a laboratory director of High Complexity Testing. Several US states already recognize the NRCC Board certification for HCLD licensing. It is my personal opinion that the addition of the NRCC to the accepted Board certifications for High Complexity Laboratory Director in the state of Nevada will greatly benefit the whole medical community.

Thanks a lot for your time and consideration,

Sincerely,

Marc D. Julliard

MD LABS • 10715 DOUBLE R BLVD SUITE 102 • RENO, NEVADA • 89521 • (775)-391-LAB1

AHONN & RCHCAN

Opposition statement to the proposed CLIA waived lab regulation.

On behalf of both trade associations that represent Residential Care Homes in Nevada – The Association of Homeowners of Northern Nevada (AHONN) in the north and The Residential Care Home Community Alliance of Nevada (RCHCAN) in the south we reiterating our previous objection to the proposed CLIA waived lab regulation, which was reflected in the small business impact statement submitted back in July 2015. (see attached)

We believe the proposed regulation allowing entities under RFFG's to apply for a CLIA waived laboratory adds more confusion and potentially leads to incomplete, less monitored care for disabled seniors who have diabetes and require assistance with finger sticks & insulin injections.

For hundreds of years nurses have been going into communities and patients homes teaching caregivers from all walks of life how to properly perform finger sticks and how to administering insulin injections.

The idea that caregivers who work in RFFG's are not allowed to be taught by professional RN's or be allowed to receive additional training on how to properly perform these tasks and convey the information to the proper health care professional does a great disservice and is discriminatory to the thousands of Diabetic Nevadans who are forced into institutions and on to Medicaid solely because they have diabetes and need assistance with these simple tasks that even young children can be taught.

This proposal misleads people away from more practical initiatives that would have direct, safe, clinical benefits such as letting nurses work within their scope of practice, and for caregivers to do observational tasks we listed previously.

Ways this proposed regulation hurt not help:

- Allowing certain health care professionals, like LPN'S, RN's, who are not trained or experienced in running or managing CLIA type laboratory will add unnecessary confusion and reduce quality and consistency of care to the facilities and to their residents. There is a significant difference between an office based doctor who has 1 million/3 million in liability insurance and supervises a CLIA waived lab in his own office where he orders lab tests on his own patients every day and an appointed "token" LPN, RN or PT or other health professional in a RFFG facility who likely does not have a vested interest in overseeing this type of lab and is only doing it for the sake of being able to perform a simple finger stick that is done by millions of people, young and old, at home every day.

- -If a facility does have a CLIA waived lab and performs a finger stick, it does very little for the resident or the physician ordering the test because the caregivers are still not allowed to administer insulin (even with a flex pen) if the doctor orders it, to treat an episode of high sugar. This forces the physician to have to unnecessarily send a diabetic resident to the hospital to get medication that could have been easily be administered at the facility. In addition, caregivers not being allowed to make common observations of weight, temp, digital BP's and report this information to the treating physician, clearly limits the doctor's ability get all pertinent information to make a decision on the best way to treat a low or high blood sugar. This lack of information will increase ER visits and hospitalizations and reduce quality & continuity of care.

- If passed, this regulation will add confusion and call into question the appropriate classification of a facility as a medical model of care instead of the social model it is built upon. Currently, RFFG's are classified as non-medical. RFFG's who might choose to utilize this waived laboratory will likely be faced with being misclassified as a medical facility when NRs 449 clearly states they are not a medical facility.

- This proposal will help very few, if any, diabetics who need assistance with performing blood glucose monitoring or administering their insulin because the amount of added fees, increases in liability insurance, responsibility and oversite needed to coordinate and supervise a CLIA waived lab, just for the sake of being able to perform finger sticks far outweighs the benefit. Therefore few people or facilities will utilize it even if it is allowed. Once again leaving the diabetics that are in desperate need of cost effective community based care options out in the cold.

PRACTICAL ALTERNATIVE SOLUTIONS:

Initiatives to work on collaboratively in the NRS that will improve quality of care & expand patient centered, community based care options for all Nevadans should be the goal. The following are initiatives that would dramatically improve quality and accessibility of care:

- Allow RN's who are owners are or who have a "financial interest" in a facility, to work within their scope of practice. Disallowing RN's who are personally involved or financially invested decreases continuity of care and does a disservice to residents.
- Allow caregivers to perform & record basic observational tasks like weights, temps, BP's/pulse with digital machines and report this information for the residents' health care professional.
- Allow medication techs to receive additional training on performing finger sticks & administration of the prefilled flex pens of varied medications including insulin (continue to disallow med techs from drawing any injectable medication into a syringe). That is only allowed by a nurse who is licensed to do so.

Industry requests to be involved in discussions and planning for regulatory changes, training initiatives & other relative issues

Again, as representatives of the RCH Industry, AHONN and RCHCAN request to be involved in discussions on regulatory changes, training initiatives, or other issues that relate to our industry The industry asks who the HCQC currently utilizes as consultants to gain information or insight on issues related to RCH's or RFFG's and what their experience and credentials are.

AHONN & RCHCAN have made repeated requests and continue to request to be involved in the revision of the state medication management program. We are aware of several active providers and administrators in the RFFG Industry who are not only long time certified medication trainers but also have vast professional experience as RN's & MD's that actively do the day to day work in their facilities who are interested in contributing unique points of view from years of actively working and teaching with in the industry which may not be represented by consultants that are currently used by the HCQC. Because we are not aware of who the HCQC uses as consultants or how they decide on what regulatory changes are being made we

have strong reservations about the potential changes that may be coming in relation to the medication program and/or other issues that have a direct effect on the industry. Our trade organizations provide a broad and vetted view of the overall positions of the industry which may differ from a nurse in the roles of regulator or private individual provider.

As 501c 6 trade organizations, we are continually looking for ways to improve quality of care industry wide. We support the HCQC getting additional funding to accommodate more staffing to help with monitoring and improved enforcement of RCH's who are not meeting or exceeding the minimum standards of care in the industry.

Shawn McGivney MD, RFA, President RCHCAN

Jose Castillo, President AHONN

Cc Mike Weldon, Chief of Staff for Governor Sandoval
CC Richard Whitley.

Here is the link to proposed regulation change and documents.
http://dpbh.nv.gov/Reg/MedicalLabs/Notice_of_Public_Workshops_and_Proposed_Regulations/

FAX COVER

From: Shawn McGivney MD, RFA, President RCHCAN

702 448 1222, cell 702 556 1639, fax 702 537 7001,

To: Leticia Metherell, HCQC Kyle Devine

Date: 7/22/15

727 Fairview drive, suite E

Carson City, NV 89701

775 – 684-1073 fax, ph 775 684-1045

lmetherell@health.nv.gov, kdevine@health.nv.gov,

4 pgs plus cover.

Dear sirs,

Please find my small business impact statement enclosed.

I typed some answers on a separate page when they were too crowded in the space provided.

While this is a well-intended effort by itself I believe it is misleading, unsafe, and will be very misleading to doctors, facilities, and seniors all of whom will undoubtedly think this is a full diabetes care / screening program complete with the option for a licensed RN to give insulin when needed when in fact it is a finger stick only program and has no mechanism of providing treatment for the finger sticks except for the doctor to send them to the ER.

I do believe there are safer alternatives the state and industry could adopt but this by itself is not it and seems to run the risk of misleading many in the medical and RFFG communities.

Shawn McGivney

Sent fax, email, and mail

This supplements my previous emails, calls, and discussions in many settings.

Small Business Impact Questionnaire

Medical Laboratory Proposed Regulations

Changes to Nevada Administrative Code (NAC) Chapter 652

The following questions pertain to how the changes in the Nevada Administrative Code presented in the enclosure will affect your business. If it is determined that the proposed regulation is likely to impose a direct and significant economic burden upon a small business; or directly restrict the formation, operation or expansion of a small business; then the agency will take any or all of the following actions:

1. Insofar as practicable, consult with owners and officers of affected small businesses,

2. Consider methods to reduce the impact of the proposed regulation, and

3. Prepare a small business impact statement and make copies of the statement available to the public at the workshop conducted and the public hearing held pursuant to NRS 233B.061.

The proposed regulations are included for your review and comments. Additional copies can be obtained by calling 775-684-1030.

Please answer each of the questions that apply and add any qualifying remarks that may help us to understand your position. **Mail, fax or email your completed form on or prior to July 22, 2015 to:**

Leticia Metherell, RN, CPM, Health Facilities Inspection Manager
Bureau of Health Care Quality and Compliance
727 Fairview Drive, Suite E
Carson City, NV 89701
775-684-1045
FAX 775-684-684-1073
lmetherell@health.nv.gov

Your Name Shawn McGivney

Organization Residential care home owner, administrator, doctor

Date 7/22/15

NRS 233B.0382 "Small Business defined." "Small business" means a business conducted for profit, which employs fewer than 150 full-time or part-time employees.

1. How many employees are currently employed by your business? 15 If more than 150, you will not need to answer the rest of the questions. Please MAIL or FAX questionnaire to the above address. If less than 150, please continue with the remaining questions.

2. Will a specific regulation have an adverse economic effect upon your business? If so, please indicate the estimated dollar amount(s) you believe the adopted regulations will cost you over one calendar year with a brief explanation as to how the dollar amount was calculated.

Yes X No_____ Explain: Please list each regulation and explain the impact.
see attached. 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 promis a diabetes screening program when in fact it is just a finger stick without giving insulin program. I cant help but believe a common person will not understand the subtle distinction as something the community senior and family should have known.

3. Will the regulation(s) have any beneficial effect upon your business? If so, please include any cost savings you believe the adopted regulations will save you over one calendar year with an estimated dollar amount if applicable.

Yes_____ No x

Explain:

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.

4. Do you anticipate any indirect adverse effects upon your business?

Yes x No_____

Explain:
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.

5. Do you anticipate any indirect beneficial effects upon your business?

Yes_____ No x

Explain:
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 finger stick 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 options for the state that are clear, transparent and safe for seniors. This is not it by itself.

Small business survey answers

7/22/15.

Follow up to previous emails and public comments in other settings.

1. 15 employees.

2. I anticipate this new ruling for a nurse to supervise a finger stick monitoring program will result in many civil law suits and raise assisted living, RFFG premiums for everyone.

It is clearly medical to check finger sticks and we are a non-medical model. When you check a finger stick and have no available treatment like giving insulin by injection the doctor will be forced to say send them to the ER as the only answer when / if a staff person calls to report high finger sticks.

Second, I am not confident that all nurse monitored, unlicensed, staff will call the doctor with all finger stick readings over a given level. While many doctors will want to be called for various levels that too will be very difficult to monitor and enforce. Doctors are use to finger stick **WITH** coverage as the plan and are likely to be very confused by finger sticks **WITHOUT THE ABILITY TO GIVE INSULIN COVERAGE BY INJECTION.** In a nursing home the nurse can address the issue herself but a nurse supervising a finger stick only program is not a nurse working as a nurse and giving insulin. Moreover, that nurse supervisor is not going to be the person doing the finger sticks she is delegating that to "staff". Without that essential part of giving insulin injections combined with the finger stick issue this program is ripe for misuse and under reporting to the doctor. Even if the non-licensed, largely untrained, staff who is supervised by the nurse director of the finger stick program their only recourse is to send the frail often times mildly confused and easily agitated senior to the ER which will create agitation, anxiety and a lot of unnecessary stress for patients.

This view re addresses concern I have made over the past several months in various discussion forums.

3. Answer on form.

4. 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.

5. In general there are no benefits from providing misleading information to seniors and unsuspecting assisted living / Residential care home providers 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 finger stick 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 options for the state that are clear, transparent and safe for seniors. This is not it by itself.

Shawn McGivney MD, RFA, president RCHCAN

FAISS FOLEY WARREN

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President, Public Affairs

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702-234-6500 Yolanda Accented

RFFG Trade Association Coalition
Comments on Post-Acute BDR Recommendations

Lorin Aaron.
Helen Foley

The RFFG's trade Association Coalition would like to applaud The Post-Acute Care Committee for working so diligently to dig in and better understand what each care setting offers relative to each other. While all settings provide "care", clearly the levels and amounts of 24hr protective supervision, care & monitoring vary widely. This is a fantastic first step at making safe, cost effective choices for custodial type care available to Nevada's seniors and disabled while holding providers accountable for the services they provide.

We appreciate your efforts to help establish consistent and transparent standards that seniors and the community can access and understand.

Upon reviewing your proposed regulation, we noted a few items that should be added and clarified to make this BDR as clear and concise as possible.

We would add in a line item under #3 on page 2 of your proposal requiring

- 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 hr 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.

Whether a person has a diagnosis of dementia, mental illness, poor mobility related to chronic illnesses, and or varied mood disorder like depression or mild memory loss most would agree they all need the safety of a sprinkled setting. Anyone with a diagnosis of chronic illness, mental illness or dementia who needs assistance with taking their medication in order to keep them stable and needs protective supervision and or assistance with care at any level, should be required to be in a sprinkled, highly monitored, more frequently inspected, care setting than people who are "transitional" and do not require that. Also to be considered in the functional analysis is a realistic expectation that they will get better or transition with treatment to independent status or if more likely with age they are more likely to need even more help despite standard therapies.

Having Clear definitions of the patient type allowed to reside in each setting can prevent miss classification or error in placements of disabled seniors or other patient type being improperly placed in a setting that does not offer the level of care to meet their functional needs. For example, disabled seniors who need 24 hr. care, protective supervision and medication assistance being inappropriately placed in SLA transitional living homes instead of Residential Facilities for Groups (RFFGS) with various endorsement which is safer & more appropriate.

Current regulations for SLA's under NRS 435 have fewer rules & regulations, protective supervision and monitoring in these SLA settings. This may be suitable for transitional residents who are more independent and have less care, protective supervision and monitoring needs. The recent incident of a fire in the less regulated, non-sprinkled SLA home which resulted in the death of a caregiver demonstrates how people who have mental illness and potential for risky behaviors may be better protected and served in a more regulated, monitored and sprinkled Residential Facility for Groups.

Also under # 3, on page 2 we would add a line item that states:

- Require 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.

It is important to have transparency with the community to let the community know who is living in their neighborhood. Currently many neighbors are not aware of what type of facility may be next door or down the block, as SLA's are not required to publicly list there address, facility type and phone number as RFFG's are.

Observational tasks, blood glucose testing and administering Insulin via injectable pen.

#5 on page 3, of the current proposed BDR address 3 separate issues – authorizing people employed by RFFG's, PCA Agencies providing personal care in the home, facility for the care of adults during the day and intermediary services organizations to:

- 1) check, record and report a list of observational tasks such as temperature, blood pressure, pulse, apical heart rate, respiration or oxygen saturation of a resident, or any combination of these.

We suggest the observational tasks of blood pressure, temperature, pulse and oxygen saturation only be allowed if a digital machine is used. The use of a digital machine for home use takes away the need for any assessment, and should greatly reduce variation in interpretation of the observational data gathered. A digital machine should give more reliable consistent data. We would add to the BDR that when reporting the observational data to the medical provider they must indicate the data obtained by a digital machine.

- 2) administer insulin furnished by a pharmacist to a resident for the treatment of insulin dependent diabetes as directed by a physician and using an auto injection device approved by the FDA for use in the home.
- 3) conduct a glucose test on a resident using a device for monitoring that is approved and described above and used only on that resident.

Concerns for allowing staff of PCA's & Adult Day Cares to check, record & report the tasks listed above

While we fully support the all above mentioned tasks being allowed to be performed in RFFG's we have reservations about allowing PCA's and employees of Adult Day Cares to check, record and report observational date like blood pressures, pulse & oxygen saturations, but have even greater concern for allowing employees of PCAs and Adult Day Cares to perform # 2 & #3 relating to insulin administration and blood glucose monitoring.

Observational task of Blood pressure, pulse, temperature and oxygen saturation.

In general, both PCA's and employees of Adult Day Cares (with the exception of a licensed nurse) have **far less,** required training and or obligation or access to report and communicate with a resident's medical provider than employees of RFFG's.

Residents who reside in a RFFG's have many more rules and regulations under NRS 449 guiding the care they receive. Including more protective supervision, annual state required training for caregiving and endorsement training, and oversite by a BELTCA certified Administrator who is responsible and liable for the resident and the care given by the employees. In addition, they have state approved Medication Techs who are required to completed the state medication training program annually.

Because the staff of RFFG are with the resident for long periods of time and assist them with their many or all of their ADL's on a 24hr basis, it allows them to have insight and knowledge to report other pertinent information to the doctor like changes in input & output, bowel patterns, appetite, variations in mood or energy. This added information can be useful to a medical provider to get a complete picture of the resident's status. It is already required under NRS 449, for RFFG's to report changes in clinical status to a resident's medical provider so it seems natural that adding the observational data items of BP, Pulse,

temperature and weight would provide a more complete and reliable data set to report to the doctor. If the doctor chooses to add or change a resident's medication based on the observational data, the Med tech of the RFFG's is able to contact the pharmacy, obtain the medication, update the Medication Administration Record and administer the medication according to the doctor's order. This is a great help to the doctor and the resident and helps to avoid sending the patient to the ER unnecessarily.

PCA employees have less training and on the job oversite by the agency than employees of RFFG's and while they may be scheduled to visit a patient at home on a regular basis, it is usually for a limited amount of time. Also, it is well known that the PCA's frequently change, causing inconsistency and confusion in the plan of care and data log. Because they are not in the home for long periods of time they most likely are unaware of a patient's patterns and routines. They don't keep track of what happens on a 24hr basis when they are not there.

To our knowledge PCA's have no obligation or training on reporting or communication changes in clinical status to the patient's medical provider, communication, if any, is usually to the family. In addition, PCA's are **NOT allowed** to assist with medications in any way, so if the observational data were reported to the doctor and the doctor asked to give an extra pill or medication the PCA would not be able to obtain or administer it. This increases our concerns on the accuracy, consistency and benefit of observational data like blood pressures, temperatures and the like being obtained, recorded and reported by this group.

Likewise, employees of Adult Dare Cares have minimal training, do not assist with personal care, do NOT manage mediations like employees of RFFG's who take doctors' orders, obtain, store, administer and document the medication received and administered in a consistent Medication Administration Record (MAR) record that stays in the RFFG and does not travel from place to place.

Participants of Adult Day Cares are at the facility for limited amounts of time, maybe 4 – 8 hrs a day. Employees of Adult day cares don't keep track of what happens on a 24hr basis when the participants are not on site and are not required to have consistent communication with or report changes in clinical status to the patient's medical provider.

Consistency and accuracy of data Log

There is also concern for the consistency of data log. A log that gets transported from place to place and/or recorded by several different employees increases our concerns on the accuracy and consistency of observational data like blood pressures, temperatures etc. being obtained, recorded and reported by employees of PCA agencies and Adult Day cares.

In RFFG's there is a consistent staff that reports to each other, over a 24hrs period. They are able to obtain and record observational data in a consist data log, by using the same home based machines to produce consistent results a by consistent staff in a RFFG.

PCA's and employees of Adult Day Cares should not be allowed to do finger sticks or use the flex pen.

With the exception of a licensed nurse, employees of Adult Day Cares or PCA agencies should **not be allowed** to perform blood glucose monitoring or administer insulin using an injectable pen for many of the same issues stated above; lack of consistency, lack of general training, lack of state approved Mediation Management training, no required communication with the doctor, moving the glucometer, data log and or insulin pen from place to place, and storing multiple peoples' meters, data logs and medications multiple times. This may promote an environment in Adult Day Cares of sharing a meter if one forgets it or leaves it at home and the clients individual meter is not available for the client to use. That is the main issue relating to finger stick testing and the CLIA waived medical lab, not sharing a meter.

Indeed, most PCA's workers or adult days' care employees likely don't know who their clients doctor is or how to get in touch with them. They rely on the family to do that. Currently, PCA's are **not allowed** to administer any medications and have no medication training and employees of Adult Day Care can only administer medication prepared in advance by the family, if at all. If either of these two were to perform a finger stick which was too high or too low and they were to report it to the doctor, they would still be unable to administer any medications if the doctor asked them to and the doctor would likely still be forced to send the client to the ER.

Example of relative value of Medicaid Adult Day care reimbursement from Medicaid.

Many may not be aware that the Medicaid reimbursement rate for Adult Day Care costs $57/ day for 6-10 hrs while on site, but often have the added cost of $20-30 each way for Medicaid reimbursed transportation increasing the cost to $100-$120 / day. Medicaid reimburses a participant who goes to Adult Day Care 5 days a week, 6-10hrs a day at $120/day or $2,400/mo. which is significantly higher than the maximum Medicaid reimbursement of $1,800 for someone receiving 24 hr. care 7 days a week and supervision in a RFFG's under a home and community based waiver. There is definitely something wrong with the payment system when one provider gets paid more for providing 6-8 hrs., 5 days a week of what equates to onsite babysitting than another provider type who provides 24 hr., personal ADL care, supervision, meals, medications, coordination of care with the doctor. etc.

We applaud this committee's effort to continue to learn and move toward a more relative value payment for all care choices in Nevada. We believe there is a need and place for all provider types, but believe RFFG's with all of its rules and regulations and high level training and monitoring, they are the most appropriate setting to allow observational tasks of blood pressure, pulse, temperature and oxygenation to be performed only with a digital machine and are the best equipped to assist with blood glucose testing using an individual home meter and administer insulin only via an injectable pen.

See comments in Green

Nevada Counties Living Interested

PROPOSED REGULATION OF THE STATE BOARD OF HEALTH

LCB File No. R149-15

These regulations are being proposed in accordance with NRS 652.125 and 652.090.

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

Chapter 652 of NAC is hereby amended by adding thereto the provisions set forth as sections 1 to 20, inclusive, of this regulation.

Section 1 ***"Temporary Location" defined. "Temporary Location" means a location established by a licensed laboratory that is located outside of the licensed laboratory and is established for no more than 90 days from the effective date of licensure.***

Section 2 ***"Exempt Laboratory" defined. Except as otherwise provided in NAC 652.175, "exempt laboratory" means a laboratory in which the only laboratory tests performed are:***

1. Classified as waived tests pursuant to 42 CFR Part 493, Subpart A; or

2. Categorized as provider-performed microscopy procedures pursuant to 42 CFR § 493.19.

Section 3 ***"Form" defined. "Form" means a paper form or electronic form including an online application as required by the Division.***

Section 4 ***1. Except as otherwise provided in this section and NRS 652.071, the provisions of this chapter do not apply to a laboratory in which the only test performed is for the detection of the human immunodeficiency virus that is classified as a waived test pursuant to the provisions of Part 496 of Title 42 of the Code of Federal Regulations.***

2. The provisions of this section do not relieve a laboratory in which the only test performed is for the detection of the human immunodeficiency virus that is classified as a waived test pursuant to the provisions of Part 496 of Title 42 of the Code of Federal Regulations from the requirement to submit an application in a format prescribed by the Division and pay the applicable fees as set forth in NAC 652.488.

3. The laboratory director of a laboratory pursuant to this section does not have to meet any qualifications except those as provided in NRS 652.180.

Section 5 NAC 652.155 is hereby amended to read as follows:

1. Except as otherwise provided in this section and NRS 652.230, 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

Shared testing lab that provides service to public, not individuals using their own personal meter.

Clia waived medical lab usually allowed as incident to existing care by existing providers

(b) Do not apply to an exempt laboratory which is registered 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. **controls of device & staff.**

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 pursuant to NAC 652.291; or

~~[(b)]~~ ***(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 categorized pursuant to 42 C.F.R. § 493.19.

5. Except as otherwise provided in subsection 3 of Section 4, to serve as the laboratory director of an exempt laboratory an individual must be a licensed physician, an advanced practice registered nurse licensed pursuant to Chapter 632 of NRS, a physician assistant licensed pursuant to chapter 630 or 633 of NRS, a general supervisor of a licensed laboratory licensed pursuant to Chapter 652 of NRS, or a clinical laboratory technologist licensed pursuant to Chapter 652 of NRS.

6. Except as otherwise provided in subsection 3 of Section 4, to serve as the laboratory director of an exempt laboratory that only performs one waived test classified as a waived test pursuant to the provisions of Part 493 of Title 42 of the Code of Federal Regulations an individual must be one of the individuals listed in subsection 5 of this section, a nurse licensed pursuant to Chapter 632 of NRS, a pharmacist licensed pursuant to Chapter 639 of NRS or any laboratory personnel licensed or certified pursuant to Chapter 652 of NRS except that a certified office laboratory assistant, blood gas assistant or laboratory assistant would not be able to serve as a laboratory director.

~~[5.]~~ 7. 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

NOTICE OF PUBLIC WORKSHOP

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

The workshop will be conducted via videoconference beginning at 2:00 PM on Thursday, December 17, 2015, at the following locations:

Division of Public and Behavioral Health Bureau of Health Care Quality and Compliance 727 Fairview Drive, Suite E Carson City, NV 89701	Division of Public and Behavioral Health Bureau of Health Care Quality and Compliance 4220 South Maryland Parkway, Suite 810, Building D Las Vegas, NV 89119

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

AGENDA

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

The proposed changes will revise Chapter 652 of the Nevada Administrative Code and are being proposed in accordance with NRS 652.125 and NRS 652.090.

The proposed regulations provide provisions for the following:

1) Brings the proposed regulations in compliance with Assembly Bill (AB) 243 of the 2015 Legislative Session which directs that any regulations adopted by the Board of Health must not require 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.
2) Expands the types of healthcare professionals that can serve as an exempt laboratory director.
3) Eliminates medical laboratory fees for permitted emergency medical services and firefighting agencies.
4) Allows the Division to enter into an agreement to allow SNHD to determine compliance with medical laboratory regulations and for the Division to use the determination of compliance to issue laboratory licenses and personnel certifications to these agencies without additional fees.
5) Defines temporary location.
6) Clarifies that exempt laboratories must adopt nationally recognized laboratory safety guidelines.
7) Expands the certification that an applicant that holds a doctorate degree can use to qualify to be a licensed or registered laboratory director.
8) Outlines the fee to be assessed for a laboratory that only performs waived HIV tests.

9) Instead of requiring a $300 application fee plus $50 for each additional specialty or subspecialties in which tests will be performed, the proposed regulations allow a laboratory to add as many tests as it wants to on one application for a flat rate of $300.
10) Brings proficiency testing standards in line with federal regulation requirements.

Members of the public may make oral comments at this meeting. Persons wishing to submit written testimony or documentary evidence may submit the material to Leticia Metherell, Health Facilities Inspection Manager at the following address:

Division of Public and Behavioral Health
727 Fairview Drive, Suite E
Carson City, NV 89701
775-684-1073 (FAX)

Members of the public who require special accommodations or assistance at the workshops are required to notify Leticia Metherell, Health Facilities Inspection Manager, in writing to the Division of Public and Behavioral Health, 727 Fairview Drive, Suite E, Carson City, Nevada, 89701, or by calling (775) 684-1030 at least five (5) working days prior to the date of the public workshop.

You may contact Leticia Metherell, Health Facilities Inspection Manager by calling 775-684-1045 for further information on the proposed regulations.

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

Division of Public and Behavioral Health
727 Fairview Drive, Suite E
Carson City, NV

Division of Public and Behavioral Health
4220 S. Maryland Parkway, Suite 810, Bldg D
Las Vegas, NV

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

A copy of the regulations and small business impact statement can be found on-line by going to: http://dpbh.nv.gov/Reg/MedicalLabs/Notice_of_Public_Workshops_and_Proposed_Regulations/
A copy of this notice has been posted at the following locations:

1. Division of Public and Behavioral Health, 4150 Technology Way, First Floor Lobby, Carson City
2. Nevada State Library and Archives, 100 Stewart Street, Carson City
3. Legislative Building, 401 S. Carson Street, Carson City
4. Grant Sawyer Building, 555 E. Washington Avenue, Las Vegas
5. Washoe County District Health Department, 9TH and Wells, Reno
6. Division of Public and Behavioral Health's web page: http://health.nv.gov/

Copies may be obtained in person, by mail, or by calling (775) 684-1030.

Copies may also be obtained from any of the public libraries listed below:

Carson City Library
900 North Roop Street
Carson City, NV 89702

Churchill County Library
553 South Main Street
Fallon, NV 89406

Clark County District Library
833 Las Vegas Boulevard North
Las Vegas, NV 89101

Douglas County Library
1625 Library Lane
Minden, NV 89423

Elko County Library
720 Court Street
Elko, NV 89801

Esmeralda County Library
Corner of Crook and 4th Street
Goldfield, NV 89013-0484

Eureka Branch Library
210 South Monroe Street
Eureka, NV 89316-0283

Henderson District Public Library
280 South Water Street
Henderson, NV 89105

Humboldt County Library
85 East 5th Street
Winnemucca, NV 89445-3095

Lander County Library
625 South Broad Street
Battle Mountain, NV 89820-0141

Lincoln County Library
93 Maine Street
Pioche, NV 89043-0330

Lyon County Library
20 Nevin Way
Yerington, NV 89447-2399

Mineral County Library
110 1st Street
Hawthorne, NV 89415-1390

Pahrump Library District
701 East Street
Pahrump, NV 89041-0578

Pershing County Library
1125 Central Avenue
Lovelock, NV 89419-0781

Storey County Library
95 South R Street
Virginia City, NV 89440-0014

Tonopah Public Library
167 Central Street
Tonopah, NV 89049-0449

Washoe County Library
301 South Center Street
Reno, NV 89505-2151

White Pine County Library
950 Campton Street
Ely, NV 89301-1965

Per NRS 233B.064(2), upon adoption of any regulations, the agency, if requested to do so by an interested person, either prior to adoption or within 30 days thereafter, shall issue a concise statement of the principal reasons for and against its adoption, and incorporate therein its reason for overruling the consideration urged against its adoption.

NOTICE OF PUBLIC WORKSHOP

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

The workshop will be conducted via videoconference beginning at 10:00 AM on Friday, September 30, 2016, at the following locations:

Division of Public and Behavioral Health Bureau of Health Care Quality and Compliance 727 Fairview Drive, Suite E Carson City, NV 89701	Division of Public and Behavioral Health Bureau of Health Care Quality and Compliance 4220 South Maryland Parkway, Suite 810, Building D Las Vegas, NV 89119

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

AGENDA

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

The proposed changes will revise Chapter 652 of the Nevada Administrative Code and are being proposed in accordance with NRS 652.125 and NRS 652.090.

The proposed regulations provide provisions for the following:

1) Brings the proposed regulations in compliance with Assembly Bill (AB) 243 of the 2015 Legislative Session which directs that any regulations adopted by the Board of Health must not require 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.
2) Expands the types of healthcare professionals that can serve as an exempt laboratory director.
3) Deems 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.
4) Clarifies that a permit to operate a laboratory at a temporary location expires 90 days after the effective date of the permit.
5) Clarifies that exempt laboratories must adopt nationally recognized laboratory safety guidelines.
6) Expands the certification that an applicant that holds a doctorate degree can use to qualify to be a licensed or registered laboratory director.
7) Outlines the fee to be assessed for a laboratory that only performs waived HIV tests.
8) Instead of requiring a $300 application fee plus $50 for each additional specialty or subspecialties in which tests will be performed, the proposed regulations allow a laboratory to add as many tests as it wants to on one application for a flat rate of $300.
9) Brings proficiency testing standards in line with federal regulation requirements.
10) Provides 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.

11) Changes 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.

Members of the public may make oral comments at this meeting. Persons wishing to submit written testimony or documentary evidence may submit the material to Leticia Metherell, Health Facilities Inspection Manager at the following address:

Division of Public and Behavioral Health
727 Fairview Drive, Suite E
Carson City, NV 89701
775-684-1073 (FAX)

Members of the public who require special accommodations or assistance at the workshops are required to notify Leticia Metherell, Health Facilities Inspection Manager, in writing to the Division of Public and Behavioral Health, 727 Fairview Drive, Suite E, Carson City, Nevada, 89701, or by calling (775) 684-1030 at least five (5) working days prior to the date of the public workshop.

You may contact Leticia Metherell, Health Facilities Inspection Manager by calling 775-684-1045 for further information on the proposed regulations.

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

Division of Public and Behavioral Health
727 Fairview Drive, Suite E
Carson City, NV

Division of Public and Behavioral Health
4220 S. Maryland Parkway, Suite 810, Bldg D
Las Vegas, NV

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

A copy of the regulations and small business impact statement can be found on-line by going to:
http://dpbh.nv.gov/Reg/MedicalLabs/Notice_of_Public_Workshops_and_Proposed_Regulations/

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

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

1. Division of Public and Behavioral Health, 4150 Technology Way, First Floor Lobby, Carson City
2. Nevada State Library and Archives, 100 Stewart Street, Carson City
3. Legislative Building, 401 S. Carson Street, Carson City
4. Grant Sawyer Building, 555 E. Washington Avenue, Las Vegas
5. Washoe County District Health Department, 9TH and Wells, Reno
6. Division of Public and Behavioral Health's web page: http://health.nv.gov/

Copies may be obtained in person, by mail, or by calling (775) 684-1030.

Copies may also be obtained from any of the public libraries listed below:

Carson City Library
900 North Roop Street
Carson City, NV 89702

Churchill County Library
553 South Main Street
Fallon, NV 89406

Clark County District Library
833 Las Vegas Boulevard North
Las Vegas, NV 89101

Douglas County Library
1625 Library Lane
Minden, NV 89423

Elko County Library
720 Court Street
Elko, NV 89801

Esmeralda County Library
Corner of Crook and 4th Street
Goldfield, NV 89013-0484

Eureka Branch Library
210 South Monroe Street
Eureka, NV 89316-0283

Henderson District Public Library
280 South Water Street
Henderson, NV 89105

Humboldt County Library
85 East 5th Street
Winnemucca, NV 89445-3095

Lander County Library
625 South Broad Street
Battle Mountain, NV 89820-0141

Lincoln County Library
93 Maine Street
Pioche, NV 89043-0330

Lyon County Library
20 Nevin Way
Yerington, NV 89447-2399

Mineral County Library
110 1st Street
Hawthorne, NV 89415-1390

Pahrump Library District
701 East Street
Pahrump, NV 89041-0578

Pershing County Library
1125 Central Avenue
Lovelock, NV 89419-0781

Storey County Library
95 South R Street
Virginia City, NV 89440-0014

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