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 Phinney Date: 8/19/16