SMALL BUSINESS IMPACT STATEMENT 2014

PROPOSED AMENDMENTS TO NAC 652 "Medical Laboratories"

The Division of Public and Behavioral Health (DPBH) has determined that the proposed amendments may impose an economic burden upon a small business if a business is not in compliance with laws and regulations governing medical laboratories but should not have a negative impact on 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 complies with the requirements of NRS 233B.0609.

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.

Background

Senate Bill 40 of the 2013 Legislative Session made changes to NRS Chapter 652 and required the adoption of regulations. In addition, existing regulations were amended that address infection control issues. Following is a summary of the proposed regulations:

- Currently it is required that an application for a laboratory be made under oath which is accomplished through the use of notarization. This presents a problem in moving forward with electronic transmission of applications and forms. SB 40 of the 2013 Legislative Session rectified this issue by removing the oath requirement in statutes and instead requiring that proof of identity by outlined in regulations. These proposed regulations allow the use of electronic signatures as one form of proof of identity that would be acceptable. Other forms of proof are also included to provide flexibility for instances in when an electronic signature may not be a viable option.
- Current regulations do not address the issue of laboratories following nationally recognized standards of practice as they relate to infection control, such as those of the Centers for Disease Control and Prevention (CDC). As we know from the Las Vegas hepatitis crisis following recognized standards for infection control are imperative to protecting the public's safety. These proposed regulations require laboratories to consider, select and implement nationally recognized infection control standards and ensure that staff are trained to the infection control guidelines.
- Currently there is no penalty if a laboratory fails to submit a plan of correction, and a plan of correction is essential to ensure that the noncompliant findings are corrected. This

regulation provides a penalty for the failure to submit a timely plan of correction which is consistent with regulations governing health facilities and will help ensure compliance with the submission of plans of corrections.

- Currently the requirements to qualify for certification as a laboratory assistant are outlined in statutes. These are outdated and prevent qualified individuals from becoming certified laboratory assistants in times of high unemployment. Senate Bill 40 of the 2013 Legislative Session removed the requirements from statutes and requires that they be outlined in regulations. These proposed regulations add increased options for an individual to become certified ensuring that qualified individuals may apply for certification.
- Senate Bill 40 of the 2013 Legislative Session removed barriers to be able to apply sanctions for violations of regulations as well as increased the amounts that can be fined according to the severity of the violation. Senate Bill 40 of the 2013 Legislative Session allows DPBH to impose an administrative penalty of not more than $10,000 per violation. Instead of starting at a $10,000 per violation penalty, the proposed regulations provide an incremental increase in how administrative sanctions are applied. The proposed regulations clearly outline how monetary penalties are to be assessed and outline the provisions for carrying out the issuance of these penalties.

In accordance with NRS 233B.0608 (2) (a), the Division of Public and Behavioral Health has requested input from all licensed laboratories and licensed/certified laboratory personnel. In addition, the proposed regulations were presented to the Medical Laboratory Advisory Committee on June 11, 2013 and were approved with minor revisions.

A Small Business Impact Questionnaire was sent to all licensed laboratories and licensed/certified laboratory personnel along with a public workshop notice outlining how a hard or electronic copy of the proposed regulations could be obtained by June 28, 2013. 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? 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.
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.
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 (18 responses were received out of 12,298 small business impact questionnaires distributed)			
Will a specific regulation have an adverse economic effect upon your business?	**Will the regulation (s) have any beneficial effect upon your business?**	**Do you anticipate any indirect adverse effects upon your business?**	**Do you anticipate any indirect beneficial effects upon your business?**
No – 11 Yes – 6 No Response – 1	No – 17 Yes – 0 No Response - 1	No – 11 Yes – 6 No Response – 1	No – 16 Yes – 1 No Response – 1
Comments: Increase employee business taxes & A.C.A. Unknown costs. $183,000 Rh testing is essential for safe abortion – missing an Rh negative woman can cause serious handicaps in future pregnancies. Adhering to these regulations is estimated to cost $1000 to $5000 in staff time for additional meetings, education, documentation & continual policy & procedure review & updating in an office based surgical facility that already has CLIA, State Health & IMO overview. It is burdensome & unnecessary. Yes, if my assistant (medical assistant) also need to train as laboratory assistant. Dollar amount unknown.	**Comments**: The increased cost will make abortion impossible for low income women – increasing the cost of Medicaid to the state by millions! We only perform a single test – an exempted/waived; qualitative UCG with internal & external controls as a convenience & safety issue, prior to elective surgeries. We already in service OSHA, do hand washing surveillance: monitor & document temperatures; expiration dates, etc. This only adds more documentation without apparent increase in patient safety or quality of care. I already follow protocol & very strict control.	**Comments:** Possible closure of business in near future. Rh disease of the newborn will cost the state untold millions of dollars. 1) Burdensome documentation 2) Costs of documentation 3) Additional inspections interfering with patient flow 4) Possible monetary penalties for not understanding or documenting in prescribed manner. I currently utilize an in house lab in my office. Yes, if my only assistant need to train I will lose her while in training and have to cancel laboratory work.	**Comments**: Another certificate to frame which might give patients even more comfort/confidence in our office. CLIA does this certification & inspection quite well. Another layer of State regulation is unnecessary in offices that do waived testing & less than 200 tests/year.

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

Any other persons interested in obtaining a copy of the summary may e-mail, call, or mail in a request to Leticia Metherell at the Division of Public and Behavioral Health at:

Division of Public and Behavioral Health
727 Fairview Drive, Suite E
Carson City, NV 89701
Leticia Metherell, Health Facilities Inspection Manager
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2) Describe the manner I which the analysis was conducted.

As noted previously, a small impact questionnaire was sent to all licensed laboratories and licensed/certified laboratory personnel. An analysis of the input provided by industry was conducted by the medical laboratories unit supervisor and manager. Out of 12,298 small impact questionnaires distributed only 18 were returned by industry therefore the analysis was based on a small sample size. A review of the comments revealed concerns about a significant increase in costs related to the proposed regulations and concerns about the training. During the input process several individuals that expressed concerns about the proposed regulations were contacted to review the proposed regulations with them. After these calls and with a better understanding of the proposed regulations the individuals expressed that the proposed regulations would not have the negative impact they had initially anticipated.

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.

If laboratories are in compliance with statutory and regulatory requirements there will be no impact; if laboratories are not in compliance with statutory and regulatory requirements there will be a financial impact. There will be a cost to laboratories associated with the monetary penalty portion of the regulations if a laboratory is not in compliance with the regulations or statutes. There would be no anticipated cost for a laboratory if the laboratory was in compliance with all regulations and statutes on every inspection conducted. In addition, the number and severity of violations may change from one inspection to the next which makes it difficult to predict the anticipated cost. The majority of violations would be at a severity level two. To have

a rough estimate a sample of 82 inspections were looked at over a one year period with an average of 2 violations per inspection. At a severity level of two, a monetary penalty of $100 may be imposed for each of those, resulting in an average of $200 per facility per inspection over a one year period. In subsequent inspections that amount may be raised to $200 per violation and may be raised to $400 per violation for a third or subsequent violations. If the facility continued to have the same violations it may cost about $800 per inspection. Less frequently there will be violations at a severity level of three or four which would result in higher monetary penalties which are outlined in the draft regulations.

In addition, laboratories would need to review the adopted regulations to update their policies and procedures and educate staff. Due to the nature of the regulations and the benefits to laboratories it is anticipated this would be at a minimal level as the majority of responses indicated that the proposed regulations would not have an adverse economic effect upon their business. Following safe infection control practices, including safe injection practices and ensuring staff are aware and trained in this area is critical to patient safety.

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

The Division of Public and Behavioral Health provided an opportunity for those impacted by the proposed regulations to provide input and comments regarding the proposed regulations, including the economic impact the proposed regulations may have on industry. Minor modifications were made to the proposed regulations as a result of input provided by the Medical Laboratory Advisory Committee. Workshops were held on July 17, 2013 allowing for further input by industry, laboratory personnel and the public regarding the proposed regulations and their impact. These comments were taken into consideration when conducting the impact the proposed regulations would have on industry.

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

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

6) Total amount DPBH expects to collect from any fees and the manner in which the money will be used.

Due to the variability of how monetary penalties would be applied it is very difficult to estimate the amount of fees that would be collected. In addition, the proposed regulations allow a laboratory to use the penalty amount to correct the violation and to put measures into place to

prevent the violation from reoccurring. In such instances the Division may not actually collect the monetary penalty. The following analysis was conducted in order to get a rough idea of what the amount collected in one year may look like: 103 (estimated number of monetary penalties issued in a year) X $233 (average of the amounts for a first, second and third violation at a severity level two which is the most common severity level issued) = $23,999 monetary penalties collected in one year. The monies would be used to improve quality in laboratories by allowing laboratories to use the monies to help prevent future violations, education of laboratory personnel and to cover the costs associated with carrying out the enforcement activities noted in number 4 of this document.

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

Although federal regulations cover some aspects addressed in the proposed regulations they do not address issues specific to state licensure such as what is required for an application to obtain a state license. In addition, not all laboratories are federally certified therefore the federal regulations would not apply to those laboratories therefore the need to also include the provisions in state regulations. In addition, the monetary penalty section allows for imposition of a penalty for the violation of state laws and regulations.

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

The reasons for the conclusions were based on several factors:

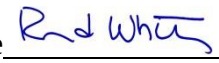
A) As noted in number 6, an analysis was conducted to determine the estimated financial impact the monetary sanctions would have on laboratories. As there are many factors that may impact this, this is a rough estimate. In reviewing the small impact questionnaire input and other input provided by stakeholders there were no significant concerns raised concerning the monetary penalty portion of the proposed regulations.

B) The small business impact questionnaire resulted in a small sample size as only 18 out of 12,298 laboratories/laboratory personnel provided input through the small business impact questionnaire. As the majority of laboratories/laboratory personnel did not respond to the small impact questionnaire it is difficult to make a comprehensive determination on the real impact to laboratories/personnel. For example, did laboratories/personnel not respond because they did not feel the proposed regulations would have a significant impact on them or was there another reason behind it?

C) After speaking to individuals who expressed concerns about the proposed regulations (including the one related to abortions) it was determined that those concerns were raised due to a lack of understanding of how the proposed regulations would truly impact the laboratory. Once the individual had a better understanding of the regulations the individual no longer felt it would have the negative impact the individual had originally thought it would.

All of the above factors were used to determine the conclusion by DPBH in how the proposed regulations would impact a small business.

I, Richard Whitley, Administrator of the Division of Public and Behavioral Health certify to the best of my knowledge or belief, the information contained in this statement was prepared properly and accurately.

Signature  Date: January 10, 2014