DIVISION OF PUBLIC AND BEHAVIORAL HEALTH

LCB File # R104-13

Information Statement per NRS 233B.066

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

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

- Nevada Revised Statutes (NRS) 652.090 requires the Board of Health to adopt regulations setting forth the acceptable forms of proof of identity that a laboratory director must include in an application; and
- NRS 652.127 requires the Board of Health to establish by regulation the requirements to qualify for certification as a laboratory assistant. The proposed regulations address both of these requirements.
- NRS 652.260 outlines new statutory penalties to be imposed on a laboratory for violations of NRS or NAC Chapter 652. The proposed regulations outline the procedures for imposing and collecting monetary penalties for violations of Nevada Administrative Code (NAC) or NRS Chapter 652. The imposition of monetary penalties is done in a progressive manner based on both the severity and frequency of the violation. In addition, it allows a laboratory, upon approval by the Division, to use a monetary penalty that would otherwise by paid to the Division to correct the violation and put measures in place to prevent the violation from reoccurring.
- Laboratory safety which includes infection control is important both to personnel and patient safety in laboratories. The proposed regulations help to ensure safety by requiring the adoption of nationally recognized standards.
- Current regulations require a laboratory director to be on-site at least every 10 or 30 consecutive days (depending on the testing). The Division had originally proposed lowering this to quarterly visits but laboratory directors contacted us and stated this was not frequent enough and may compromise patient safety. The monthly visits required in the proposed regulations provide more flexibility, which should be helpful to rural areas, than what is in current regulations and at the same time sets a frequency that the laboratory experts we spoke with felt would continue to protect patient safety.
- For laboratories that are able to conduct high complexity testing and serve the public such as Quest or hospital laboratories there are regulations in place to ensure the Laboratory Director is qualified to oversee such a laboratory. In rural areas, this would most likely be hospital laboratories. Currently all laboratory directors meet the requirements without the need for an exception and this omission would not impact them. Omitting this provision was discussed during the Medical Laboratory Advisory Committee because to

the Division's knowledge it has never been used and because it was felt that at this level the laboratory director should meet the minimum requirements established in regulations.

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

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

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

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

3. The number of persons who:

(a) Attended the hearing;

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

(b) Testified at each hearing; and

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

(c) Submitted to the agency written statements.

One person submitted a written statement recommending that language be added to include laboratory safety as well as adding two additional laboratory safety guidelines as examples of the

types of guidelines that can be adopted by a laboratory. The Board of Health voted to amend the proposed regulations to adopt the recommended changes.

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

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

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

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

Summary of Response

Summary Of Comments Received (18 responses were received out of 12,298 small business impact questionnaires distributed)			
Will a specific regulation have an adverse economic effect upon your business?	**Will the regulation (s) have any beneficial effect upon your business?**	**Do you anticipate any indirect adverse effects upon your business?**	**Do you anticipate any indirect beneficial effects upon your business?**
No – 11 Yes – 6 No Response – 1	No – 17 Yes – 0 No Response - 1	No – 11 Yes – 6 No Response – 1	No – 16 Yes – 1 No Response – 1

Comments: Increase employee business taxes & A.C.A. Unknown costs. $183,000 Rh testing is essential for safe abortion – missing an Rh negative woman can cause serious handicaps in future pregnancies. Adhering to these regulations is estimated to cost $1000 to $5000 in staff time for additional meetings, education, documentation & continual policy & procedure review & updating in an office based surgical facility that already has CLIA, State Health & IMO overview. It is burdensome & unnecessary. Yes, if my assistant (medical assistant) also need to train as laboratory assistant. Dollar amount unknown.	**Comments**: The increased cost will make abortion impossible for low income women – increasing the cost of Medicaid to the state by millions! We only perform a single test – an exempted/waived; qualitative UCG with internal & external controls as a convenience & safety issue, prior to elective surgeries. We already in service OSHA, do hand washing surveillance: monitor & document temperatures; expiration dates, etc. This only adds more documentation without apparent increase in patient safety or quality of care. I already follow protocol & very strict control.	**Comments:** Possible closure of business in near future. Rh disease of the newborn will cost the state untold millions of dollars. 1) Burdensome documentation 2) Costs of documentation 3) Additional inspections interfering with patient flow 4) Possible monetary penalties for not understanding or documenting in prescribed manner. I currently utilize an in house lab in my office. Yes, if my only assistant need to train I will lose her while in training and have to cancel laboratory work.	**Comments**: Another certificate to frame which might give patients even more comfort/confidence in our office. CLIA does this certification & inspection quite well. Another layer of State regulation is unnecessary in offices that do waived testing & less than 200 tests/year.

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

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

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

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

a. Both adverse and beneficial effects; and

A. Beneficial effects: Anticipated benefits to laboratory personnel and medical laboratories include the ability to move forward with electronic applications/renewals which should make it more efficient for applicants and should result in faster turnaround times, increasing the flexibility in criteria to become a laboratory assistant will ensure qualified individuals can become certified and reducing the on-site requirement that a laboratory director be on the premises from 10 or 30 consecutive days to monthly will provided more flexibility for laboratory director's while ensuring patient safety.

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

b. Both immediate and long term effects.

Immediate effects: Increased patient safety.

Long term effects: Increased patient safety.

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

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

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

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

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

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

Current regulations require a laboratory director to be on-site at least every 10 or 30 consecutive days (depending on the testing). The proposed regulations relax this requirement to monthly visits but they still remain more stringent than federal regulations. When the Division originally

proposed reducing the required on-site visits to quarterly we were contacted by Nevada experts in the field that felt reducing the required visit to less than once a month may compromise patient safety. Additionally, as mentioned in #8 the federal regulations do not apply to our laboratories that only have a state license and do not have certification from the Centers for Medicare and Medicaid Services.

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

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