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Governor



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Director

**DEPARTMENT OF
HEALTH AND HUMAN SERVICES**
DIVISION OF PUBLIC AND BEHAVIORAL HEALTH
Helping people. It's who we are and what we do.



Lisa Sherych
Administrator

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SMALL BUSINESS IMPACT STATEMENT

**PROPOSED AMENDMENTS TO NEVADA ADMINISTRATIVE CODE (NAC) CHAPTER 442:
Newborn Screening, LCB File No. R088-20RP1**

The Division of Public and Behavioral Health (DPBH) has determined that the proposed amendment LCB File No. R088-20RP1 should not have an impact upon a small business or 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) Chapter 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 regulation on a small business in sections 1, 2, 3, and 4 below and provides the reasons for the conclusions of the agency in section 8 below followed by the certification by the person responsible for the agency.

Background

The value of the regulation is in detailing processes by which the State Public Health Laboratory (SPHL) can request information and payment related to laboratory and non-laboratory tests and examinations and specifies how the SPHL and primary care physicians will share relevant information and examination and testing results and ensure proper referral and care for infants suspected of or diagnosed with specific preventable or inherited conditions. The regulations also detail specific blood sample processes and standardized criteria by amending Nevada Administrative Code (NAC) 442.044. The benefit of the regulation is in creating a means by which the SPHL can detail a public process by which fees can be changed, includes examinations and non-laboratory tests related to newborn screening needed as part of diagnostic screening for all required conditions, establishes processes for parental or guardian information sharing, referral and care transition from SPHL and health care providers, and information sharing to the Department of Health and Human Services Chief Medical Officer and local health officers.

- 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 via posting on the Division website and mailed copies of the proposed regulation and the small business impact statement.

A Small Business Impact Questionnaire was sent to professional medical and hospital boards and associations and the Nevada Newborn Screening program along with a copy of the proposed regulation changes, on September 28, 2021. 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 (0 responses were received out of 11 small business impact questionnaires distributed by mail or by email in response to the information posted on the Division website here: https://dpbh.nv.gov/Programs/Maternal, Child and Adolescent Health (MCH)/)			
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 response	No response	No response	No response

Number of Respondents out of 11 mailings and posting to the Division website	Adverse economic effect?	Beneficial effect?	Indirect adverse effects?	Indirect beneficial effects?
0	0	0	0	0

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

No survey results were received for analysis.

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.

The possible adverse impact anticipated to small businesses is the pathway the regulation develops to create a public hearing process for fee increases and introduces a means to require payment either at the time of newborn screening kit purchase or at the time of testing. The regulation requires parent or guardian follow up in relation to positive test results or diagnosis for health care providers which might increase the length and possible cost of a visit. The benefit would be a public process for discussion of proposed newborn screening fee increases.

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 small businesses to provide input and comments regarding the proposed regulations, including the economic impact the proposed regulations may have on small businesses. The Small Business Impact Questionnaire was posted on the Division website and mailed to professional medical and hospital associations for distribution and to the Nevada Newborn Screening program. Workshops will be held on January 11, 2022, allowing for further input by interested parties regarding the proposed regulations and how they will impact small businesses. These comments will be taken into consideration for possible revisions to the regulations to reduce the economic impact on facilities.

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

There is no estimated cost to the agency for enforcement of the proposed regulation.

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.

DPBH is not expected to collect any fees as the fee increase relates to the SPHL.

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

There are no duplicative or more stringent provisions than federal, state or local standards regulating the same activity.

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

Pending any feedback from the public workshop on January 11, 2022, currently there are no responses to the small business impact questionnaire mailed and posted on the Division website on September 28, 2021. Any other persons interested in obtaining a copy of the summary may e-mail, call, or mail in a request to Vickie Ives at the Division of Public and Behavioral Health at:

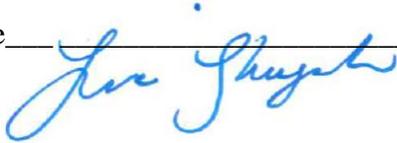
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Certification by Person Responsible for the Agency

I, Lisa Sherych, 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 _____



Date: 12/27/2021