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SMALL BUSINESS IMPACT STATEMENT 2023

PROPOSED AMENDMENTS TO NAC Chapter 451

The Division of Public and Behavioral Health (DPBH) has determined that the proposed amendments should have a negative impact upon a small business or prevent 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 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 proposed regulations are being moved forward as required by Senate Bill 387 of the 80th (2019) Session.

Section 1 of the bill, requires each nontransplant anatomical donation organization that procures a human body or part in Nevada shall be certified by the Division, follow the standards and guidelines established by the State Board of Health, and report to the Division, in a manner and frequency prescribed by the State Board of Health, the number and disposition of human bodies or parts procured by the nontransplant anatomical donation organization. The State Board of Health shall adopt regulations that establish standards and guidelines for nontransplant anatomical donation organizations which must be substantially based upon federal laws and regulations relating to the procurement of human bodies and parts. Adopt regulations necessary to carry out the provision of this section, including regulations that establish a fee for an application for issuance or renewal of a certification as a nontransplant anatomical donation organization. The Division shall collect and analyze information from each nontransplant anatomical donation organization in Nevada on the number and disposition of human bodies and parts procured by the nontransplant anatomical donation organization and make such information available to the Governor and the Legislature upon request; and to monitor all nontransplant anatomical donation organizations in Nevada for compliance with federal and state laws and regulations. A person who engages in the activity of a nontransplant anatomical donation organization without being certified by the Division pursuant to this section or who violates the standards and guidelines adopted by the State Board of Health is guilty of a Category C felony and shall be punished as provided in NRS 193.130, or by a fine of not more than \$50,000, or both a fine and the punishment provided in NRS 193.130.

- 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 known parties expressing interest in the development of the regulations as required by Senate Bill 387. The Division of Public and Behavioral Health's website provided information on how the industry could provide their feedback on the proposed regulations and small business impact. The webpage included a copy of the draft regulations.

A Small Business Impact Questionnaire was sent to three interested parties along with a copy of the proposed regulation changes, on January 22, 2023, via email. 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 (2 responses were received out of 3 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?
Yes = 1 No = 0	Yes = 0 No = 1	Yes = 0 No = 1	Yes = 0 No = 1
Yes, we are a small family operated business. As written, it is anticipated we may need an additional employee to fulfill the reporting requirements.	No	No	No

Number of Respondents out 3	Adverse economic effect?	Beneficial effect?	Indirect adverse effects?	Indirect beneficial effects?
2	Yes	No	No	No

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

A health program manager reviewed the requirements of Senate Bill 387 of the 80th (2019) legislative session, the proposed regulations, and the small business impact questionnaire responses to determine the impact on small businesses. The proposed regulations carry out the requirement the Division adopt regulations for a nontransplant anatomical donation organization to become certified by the Division, follow the standards and guidelines adopted by the State Board of Health and for the nontransplant anatomical donation organization to report to the Division, in a manner and frequency prescribed by the State Board of Health, the number and disposition of human bodies or parts procured by the nontransplant anatomical donation organization.

The proposed regulations and the provisions of Section 1 were then analyzed along with the feedback received from the industry to complete the small business impact statement.

- 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.

Adverse effects – The overall adverse financial effects are anticipated to negatively impact most small businesses, with the potential for an adverse financial impact on small businesses that are found not to be in compliance with the section of the Senate Bill 387 which indicates a person who engages in the activity of operating a nontransplant anatomical donation organization without being certified by the Division or who violates the standards and guidelines adopted by the State Board of Health would be guilty of a category C felony and shall be punished as provided in NRS 193.130 or by a fine of not more than \$50,000 or both.

The main concern for the small business who responded to the questionnaire was regarding the reporting requirement. The proposed regulations would require the organization to report on or before January 1 and July 1 of each, the following information the number and disposition of human bodies and parts procured by the nontransplant anatomical donation organizations for the immediately preceding 6 months.

There were no indirect adverse effects identified.

There were no beneficial effects identified.

There were no indirect beneficial effects identified.

- 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 reviewed the responses from the small business impact questionnaire. The main concern for a negative financial impact was the need for the business to hire a person to handle the reporting of the number and disposition of human bodies or parts procured by the organization. The Division reviewed the information related to the financial impact and identified no solutions to mitigate the impact to the small business.

The Division of Public and Behavioral Health has held several opportunities for providers to provide input and comments regarding the proposed non-transplant anatomical donation organization regulations, including the economic impact the proposed regulations may have on providers with less than 100 employees. Modifications to the proposed regulations have been made as a result of this input. A workshop will be held on July 9, 2024 allowing for further input by providers regarding the proposed regulations and how they will impact their business. These comments will 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.

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.

The proposed regulations provide an initial certification fee of \$1,785 and a renewal fee for the certification of \$892.50 every two years.

The total annual amount DPBH expects to collect will be \$7140 for initial certifications and \$3570 for renewal certifications every two years, DPBH anticipates approximately four providers to become certified. The money will be used to process provider applications, conduct initial and renewal surveys and any complaint surveys.

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 current state provisions regulating non-transplant anatomical donation organization in Nevada.

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

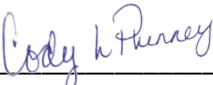
The concern of a small business needing to hire an additional employee to fulfill the reporting requirements has been taken under consideration. The reporting requirements to the Division on the number and disposition of human bodies and parts procured by the business so the Division could collect and analyze the information is written in the statute. The Division identified submitting the information twice a year would allow for better collection and analysis of the data to make the information available to the Governor or Legislature upon request.

Any other persons interested in obtaining a copy of the summary may e-mail, call, or mail in a request to Dorothy Sims, Health Facilities Inspection Manager - RN at the Division of Public and Behavioral Health at:

Division of Public and Behavioral Health
4150 Technology Way, Suite 300
Carson City, NV 89701
Dorothy Sims, Health Facilities Inspection Manager - RN
Phone: (702) 486-6515
Email: dsims@health.nv.gov

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  Date: 2/26/2024