HEALTH CARE PURCHASING AND COMPLIANCE DIVISION
BUREAU OF HEALTH CARE QUALITY AND COMPLIANCE
LCB File No. R184-24

Informational Statement per NRS 233B.066

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

The main purpose of the proposed regulation is to:

1) Move forward the regulations required by Senate Bill 387 passed in the 2019 legislative session to certify and regulate non-transplant anatomical donation organizations.

R184-24 addresses the following main topics:

- General certification application requirements.
- Initial certification application requirements.
- Renewal of certification requirements.
- Requirements for the governing body include policies and procedures for criteria for accepting anatomical material, screening and testing donors, monitoring the environment, monitoring equipment, and infection control.
- Requirements for the appointment of a facility director and medical director.
- Requirements for establishing a quality assurance performance improvement program.
- Requirements for maintaining a record of the donor and donations.
- Requirements for disposal of anatomical material.
- Requirements for sterilization and / or disinfection of reusable equipment / supplies.

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

Below is a summary of how public comment was solicited and a summary of the public's response.

Notice was sent to all interested parties. An email notice with a link to the small business impact questionnaire and proposed regulations was sent to those with an email address on file with DPBH/NVHA on July 9, 2024. The proposed regulations were also posted on the DPBH's website.

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 effects upon your business?

Summary of Responses

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

Public Workshop – July 9, 2024

Below is a summary of the testimony provided by individuals during the public workshop. Several people provided information regarding the reason for the requirement to provide written evidence of any corrective action underway or completed by the applicant in response to any

recommendations made by the accrediting agency or body, including, without limitation, any progress report prepared by the applicant. This was removed from the regulations as the legislature removed the accreditation in favor of developing regulations.

Defining the quality improvement program committee to include a small organization, may have a small committee comprised of members established by the governing body.

Changing the wording of the quality improvement plan to policy as a plan could be unofficial, but a policy would need to be written and adopted.

Instead of providing the name and address of each person who possessed the anatomical material before the date on which the organization took possession of the anatomical material to change it to the name of the company from which the organization received the body. The organization cannot attest to the accuracy of earlier records; the organization should be able to track the record history of donated bodies as the company is required to keep detailed records.

Providing a precise definition of equipment.

Any other person interested in obtaining a copy of the summary may e-mail, call, or mail a request to Dorothy Sims, RN, HFIM, at the Division of Purchasing and Compliance at:

Health Care Purchasing and Compliance Division
Bureau of Health Care Quality and Compliance
500 E. Warm Springs Rd, Suite 200
Las Vegas, NV 89119
Dorothy Sims, RN
Phone: 702-486-6515
Email: dsims@nvha.nv.gov

Public Hearing – December 5, 2025

The Board of Health approved the proposed regulations.

1. A statement indicating the number of persons who attended each hearing, testified at each hearing, and submitted written statements regarding the proposed regulation. This statement should include for each person identified pursuant to this section that testified and/or provided written statements at each hearing regarding the proposed regulation, the following information, if provided to the agency conducting the hearing:
   a) Name
   b) Telephone Number
   c) Business Address
   d) Business telephone number

e) Electronic mail address; and
f) Name of entity or organization represented

Public Workshop – July 9, 2024
Nine (9) individuals participated in the public workshop virtually. Two staff members participated in person, for a total of eleven (11) participants.

Three (3) individuals provided testimony during the public workshop.
1) Troy Farrell
2) Warren Hardy, Life Science Anatomical, warren@hardystrategies.com
3) Dan Musgrove, Strategies360, danm@strategies360.com

Public Hearing – December 5, 2025
The Nevada State Board of Health Carson City in person sign in sheet had six (6) individuals.
The Nevada State Board of Health Las Vegas in person sign in sheet had three (3) individuals.
The virtual attendance record noted 58 participants.
Total number of participants: 67

Note: As the Board of Health agenda included other agenda items in addition to the hearing on LCB File No. 184-24, it is possible that not all attendees were present for the hearing on LCB File No. R184-24.

4. A description of how comments were solicited (i.e., notices) from affected businesses, a summary of their response, and an explanation of how other interested persons may obtain a copy of the summary.

Pursuant to NRS 233B.0608 (2)(a), the Health Care Purchasing and Compliance Division (Division of Public and Behavioral Health (DPBH) at the time) requested input from small businesses that may be affected by the proposed regulations.

Notice was sent to all interested parties. An email notice with a link to the small business impact questionnaire and proposed regulations was sent to those with an email address on file with DPBH/NVHA on July 9, 2024. The proposed regulations were also posted on the DPBH's website.

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?
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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?**
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5. The regulation was adopted with no changes.

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 the adverse and beneficial effects; and
(b) Both immediate and long-term effects.

Anticipated effects on the business which NRS Chapter 451 regulates:

Adverse: Direct adverse effects include licensure fees. A potential for adverse financial impact for those business found not to be in compliance with the section of 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. A concern for the small businesses was regarding the proposed regulatory requirement for the organization to report on or before January 1 and July 1 of each year, the following information on the number and disposition of human bodies and parts procures by the nontransplant anatomical donation organizations for the immediately preceding 6 months.
Beneficial: The beneficial effects include businesses who operate a non-transplant anatomical donation organization would be certified and following regulatory requirements.
Immediate: The immediate effect would be the ability for nontransplant anatomical donation organizations to apply for certification.
Long-term: The long-term impacts would continue to be ongoing, renewal costs for continued certification.

Immediate: The financial impacts, both adverse and beneficial, would be immediate upon passage of the proposed regulations.

Long-term: The long-term impacts, both adverse and beneficial, would continue for the long-term until such time as the proposed regulations are amended in a manner that would change the impact.

Anticipated effects on the public:
Adverse: There are no adverse effects anticipated on the public.

Beneficial immediate and long-term: The beneficial effects may include standard requirements for the acquisition, distribution, and final disposition of anatomical materials.

Immediate: The beneficial impacts may not be realized immediately as the non-transplant anatomical donation organizations would need to apply and complete the survey process for initial certification.

Long-term: The beneficial impacts would include the standard requirements for the acquisition, distribution, and final disposition of anatomical materials.

7. The estimated cost to the agency for enforcement of the proposed regulation is $1,785 per organization. This includes the fee for the initial application and the certification survey.

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 regulating federal agency.

The proposed regulations do not overlap or duplicate any other Nevada state or federal 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.
The proposed regulations do not overlap, duplicate, or are more stringent than any other federal regulations which regulate the same activity.

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

The total annual amount the Division expects to collect is unknown because there is no way to determine how many facilities will need to be certified.

The money would be used to cover the Division's operating costs related to the work associated with the certification process which would include application processing and inspection costs.

Information on the proposed changes to Nevada Administrative Code Chapter 451: Non-Anatomical Transplant Donations (LCB File No. R184-24I, previously R036-22P) including Small-Business Impact, Public Workshop and Public Hearing can be located at https://www.dpbh.nv.gov/regulatory/hcqc/state-of-nevada-health-facility-regulation-public-workshops/.