NOTICE OF INTENT TO ACT UPON A REGULATION

Notice of Hearing for the Amendment of Regulations of the Board of Health
LCB File No. R184-24
Non-Transplant Anatomical Donation Organization

NOTICE IS HEREBY GIVEN that the State Board of Health will hold a public hearing to consider the amendments to Nevada Administrative Code (NAC) Chapter 451 as a result of the passage of Senate Bill 387 of the 80th Legislative Session (2019). The public hearing is to be held in conjunction with the State Board of Health meeting on December 5, 2025, at 9:00 AM.

Physical Locations:
Southern Nevada Health District (SNHD)
Red Rock Trail Rooms A and B
280 S. Decatur Boulevard, Las Vegas, Nevada 89107

Nevada Division of Public and Behavioral Health (DPBH)
Hearing Room 303
4150 Technology Way, Carson City, NV 89706

Virtual Information Meeting Link:
https://teams.microsoft.com/l/meetup-join/19%3ameeting_ZDk3MjdmNDctZjk4Ny00YTE4LWIxMTUtYWZkN2Q3M2ZlZmVi%40thread.v2/0?context=%7b%22Tid%22%3a%22e4a340e6-b89e-4e68-8eaa-1544d2703980%22%2c%22Oid%22%3a%22768e443d-3be6-48f0-9bb0-7e72f1276b8d%22%7d

Join by Phone:
Call-in number: 775-321-6111
Meeting ID: 278 920 279 930

1. The purpose of R184-24 is to move forward the regulations required by Senate Bill 387 of the 80th Legislative Session (2019) needed to certify and regulate non-transplant anatomical donation organizations.

2. R184-24 addresses the following 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.

3. Anticipated effects on the business regulated by the proposed regulations:
A. Adverse effects: 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.

B. Beneficial effects: 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.

C. 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.

4. The Division of Health Care Purchasing and Compliance determined the impact on small business by conducting a public workshop on July 9, 2024.

Several people provided information regarding the reason 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 the 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 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 are required to keep detailed records.

Providing a precise definition of equipment.

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

6. The proposed regulations do not overlap or duplicate any other Nevada state or federal regulations.

Members of the public may make oral comments at this meeting. Persons wishing to submit written testimony or documentary evidence in excess of two types, 8-1/" x 11" pages must submit the material to the Board's Secretary, Dena Schmidt, to be received no later than November 19, 2025, at the following address:

Secretary, State Board of Health
Division of Public and Behavioral Health
4150 Technology Way, Suite 300
Carson City, NV 89706
stateBOH@health.nv.gov

Written comments, testimony, or documentary evidence in excess of two typed pages will not be accepted at the time of the hearing. The purpose of this requirement is to allow Board members adequate time to review the documents.

A copy of the notice and proposed regulations are on file for inspection and/or may be copied at the following locations during normal business hours:

•Nevada Division of Public and Behavioral Health - 4150 Technology Way, Suite #300, Carson City, NV 89706•Nevada Division of Public and Behavioral Health – 727 Fairview Dr, Suite E, Carson City, NV 89706
•Nevada Division of Public and Behavioral Health - 500 E Warm Springs Rd. Ste. 200, Las Vegas, NV 89119
•Nevada State Library and Archives - 100 Stewart Street, Carson City, NV, 89701

A copy of the regulations and small business impact statement can be found on-line by going to:
http://nvha.nv.gov/Consumers/HCPC_Public_Notices/

A copy of the public hearing notice can also be found at Nevada Legislature's web page:
https://www.leg.state.nv.us/App/Notice/A/

Copies may be obtained in person, by mail, or by calling the Division of Health Care Purchasing and Compliance at:
Division of Health Care Purchasing and Compliance
500 E. Warm Springs Road, Suite 200
Las Vegas, NV 89119
(702) 486-6515
dsims@health.nv.gov