Notice of Hearing for the Amendment of Regulations of the Board of Health

NOTICE OF INTENT TO ACT UPON A REGULATION
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 89701

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:

- Southern Nevada Health District (SNHD) 280 S. Decatur Boulevard, Las Vegas, Nevada 89107
- Nevada Division of Public and Behavioral Health - 4150 Technology Way, Suite #300, Carson City, NV 89706
- Nevada Health Authority – 4070 Silver Sage Dr. Carson City, NV 89701
- Nevada Health Authority – 727 Fairview Dr, Suite E, Carson City, NV 89701
- Nevada Health Authority – 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: State of Nevada Health Facility Regulation Public Workshops

A copy of the public hearing notice can also be found at Nevada Legislature's and Nevada Public Notice web page:

- https://www.leg.state.nv.us/App/Notice/A/
- Home - Nevada Public Notices Website - NV.gov

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

November 13, 2025

MEMORANDUM

To: Jon Pennell, DVM, Chair
State Board of Health

From: Todd Rich, Administrator
Nevada Health Authority
Division of Health Care Purchasing and Compliance

Re: Consideration and adoption of proposed regulation LCB File No. R184-24 Non-Transplant Anatomical Donation Organization.

PURPOSE OF REGULATIONS

The proposed regulations are required by Senate Bill 387 of the 80th Legislative Session (2019) needed to certify and regulate non-transplant anatomical donation organizations.

The proposed regulations will address the initial and renewal certification application requirements including documentation required and initial and renewal certification fees. The regulations will outline the requirements for the governing body to ensure policies and procedures for the criteria for accepting anatomical material, screening and testing donors, monitoring the environment, monitoring equipment, and infection control. Requirements for appointing a facility director and medical director. Requirements for establishing a quality assurance performance improvement program, maintaining a record of the donor and donations, disposal of anatomical material and for the sterilization and / or disinfection of reusable equipment / supplies.

POSSIBLE OUTCOME IF PROPOSED REGULATIONS IS NOT APPROVED

If the proposed regulations are not approved by the Board of Health, the certification of non-transplant anatomical donation organizations would not be available as outlined in Senate Bill 387 (2019).

APPLICABILITY OF PROPOSED AMENDMENT

The proposed regulations will apply statewide to any person or organization who engages in the recovery, screening, testing, processing, storage or distribution of human bodies or parts for a purpose other than

transplantation, including without limitation, education, research or the advancement of medical, dental or mortuary science.

PUBLIC COMMENT RECEIVED

Pursuant to NRS 233B.0608 (2)(a), the Division of Health Care Purchasing and Compliance has requested input from interested parties.

On 01/20/2023, information was sent to interested parties regarding how small businesses could provide input on the proposed regulations and to access the small business impact questionnaire and the proposed regulations through a link to the Division of Public and Behavioral Health's webpage (at the time of the small business impact questionnaire, the Bureau of Health Care Quality and Compliance was under the Division of Public and Behavioral Health).

The results of the small business impact study are summarized in the (attached) Small Business Impact Statement.

On June 5, 2024, a Notice of Public Workshop was sent to request input from interested parties. The Public Workshop was conducted under LCB File No. R036-22. A new LCB File No. was requested as the development of the regulations exceeded the two-year timeframe to adopt the regulations due to the public health emergency caused by the COVID-19 pandemic.

The Public Workshop was held on July 9, 2024, to receive recommendations regarding the proposed regulations.

All comments received during the public workshop were reviewed and considered.

STAFF RECOMMENDATIONS

Staff recommend the State Board of Health adopt the proposed regulations for LCB File No. R184-24 Non-Transplant Anatomical Donation Organization.

PRESENTER

Dorothy Sims, RN, Health Facilities Inspection Manager

Attachments:
LCB File No. R184-24P
Small Business Impact Statement
Public Workshop Notice
Public Hearing Notice

Joe Lombardo
Governor

Richard Whitley, MS
Director

DEPARTMENT OF HEALTH & HUMAN SERVICES
NEVADA DIVISION of PUBLIC and BEHAVIORAL HEALTH

Cody Phinney, MPH
Administrator

Ihsan Azzam, Ph.D., M.D.
Chief Medical Officer

NOTICE OF PUBLIC WORKSHOP

NOTICE IS HEREBY GIVEN that the Division of Public and Behavioral Health will hold a public workshop to consider amendments to Nevada Administrative Code (NAC) Chapter 451 (LCB File No. R036-22).

The workshop will be conducted via videoconference beginning at 9:00 am on July 9, 2024, and will be accessible via the following:

- Click here to join online via Microsoft Teams
- Call (775) 321-6111
    - Phone conference ID: 168 029 288#

These workshops will be conducted in accordance with NRS 241.020, Nevada's Open Meeting Law.

AGENDA

1. Introduction of workshop process
2. Public comment on proposed amendments to Nevada Administrative Code (NAC) Chapter 451
3. General public comment

The proposed changes will revise NAC Chapter 451 and are being proposed in accordance with Nevada Revised Statues (NRS) 451.587. The proposed regulations provide for the following:

The proposed regulations implement Senate Bill (SB) 387, enacted during the 2019 session of the Nevada Legislature. These regulations require each nontransplant anatomical donation organization that procures a human body or part to be certified by the Division of Public and Behavioral Health (DPBH). The proposed regulations would set standards and guidelines for the operation of a nontransplant anatomical donation organization; set the manner and frequency for the nontransplant anatomical donation organization to report the number and disposition of human bodies or parts procured by the organization; and set the fee for certification and the monitoring of all nontransplant anatomical donation organizations for compliance with state and federal regulations.

1. Who or what is affected by the proposed amendment: All organizations or business that procure a human body or parts through a nontransplant anatomical donation program.
2. Describe any fees the proposed amendment may affect: Does not affect any existing fees but will establish new fees for initial and continuing certification. The proposed regulations would set an initial certification fee of $1,785.00, a renewal of certification fee of $892.50, and a fee of $250.00 for any revisions to the application.
3. Describe any agreements or compliance issues with the proposed amendment: There are no agreements or compliance issues.
4. Describe any definitions or boundaries of the proposed amendment: None
5. Describe any clarifications that the proposed amendment would detail: No clarifications.

6. Certification: The proposed regulations would set forth the requirements a nontransplant anatomical donation organization must comply with to obtain and maintain certification.
7. Detail what the proposed amendment would highlight: Add to the NAC the regulations for a nontransplant anatomical donation organization to become certified per the NRS.

Members of the public may make oral comments at this meeting. Persons wishing to submit written testimony or documentary evidence may submit the material to the manager of the affected Regulatory Unit, Dorothy Sims, RN, Health Facilities Inspection Manager, at the following address:

Division of Public and Behavioral Health
4220 S. Maryland Parkway, Bldg. A, Suite 100
Las Vegas, NV 89119
Phone: 702-486-6515
Fax: 702-486-6520
Email: dsims@health.nv.gov

Members of the public who require special accommodations or assistance at the workshops are required to notify Dorothy Sims (contact information above) at least five (5) working days prior to the date of the public workshop.

Also contact Dorothy Sims for further information on the proposed regulations or how to obtain copies of the supporting documents.

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

Division of Public and Behavioral Health
727 Fairview Drive, Suite E
Carson City, NV

Division of Public and Behavioral Health
4220 S. Maryland Parkway, Suite 100, Bldg. A
Las Vegas, NV

Nevada State Library and Archives
100 Stewart Street
Carson City, NV

A copy of the regulations and small-business impact statement can be found on the Health Facility Regulation Development Processes web page:
https://dpbh.nv.gov/Reg/HealthFacilities/State_of_Nevada_Health_Facility_Regulation_Public_Workshops/

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

A copy of this public workshop notice has been posted at the Division of Public and Behavioral Health, 4150 Technology Way, First Floor Lobby, Carson City, NV.

Per NRS 233B.064(2), upon adoption of any regulations, the agency, if requested to do so by an interested person, either prior to adoption or within 30 days thereafter, shall issue a concise statement of the principal reasons for and against its adoption, and incorporate therein its reason for overruling the consideration urged against its adoption.

Joe Lombardo
Governor

Richard Whitley, MS
Director

DEPARTMENT OF
HEALTH AND HUMAN SERVICES

NEVADA DIVISION of PUBLIC
and BEHAVIORAL HEALTH

Cody Phinney, MPH
Administrator

Ihsan Azzam,
Ph.D., M.D.
Chief Medical Officer

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 Cody L Phinney Date: 2/26/2024

PROPOSED REGULATION OF THE

STATE BOARD OF HEALTH

LCB File No. R184-24

July 18, 2025

EXPLANATION – Matter in ***italics*** is new; matter in brackets **[**~~omitted material~~**]** is material to be omitted.

AUTHORITY: §§ 1-18, NRS 451.587, as amended by section 250 of Senate Bill No. 494, chapter 514, Statutes of Nevada 2025, at page 3728.

A REGULATION relating to anatomical gifts; prescribing requirements governing the certification and operation of a nontransplant anatomical donation organization; prescribing fees for the issuance or renewal of such a certification; prescribing the duties of certain persons and entities involved in the governance of a nontransplant anatomical donation organization; authorizing the Health Care Purchasing and Compliance Division of the Nevada Health Authority to conduct an investigation upon receipt of a complaint against a nontransplant anatomical donation organization; authorizing the suspension or revocation of the certification of a nontransplant anatomical donation organization under certain circumstances; requiring a nontransplant anatomical donation organization to biannually report certain information to the Division; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law provides for the making of anatomical gifts and for the procurement of human organs, tissues and eyes by certain organizations, including nontransplant anatomical donation organizations. (NRS 451.500-451.598) Existing law defines "nontransplant anatomical donation organization" to mean a person who engages in the recovery, screening, testing, processing, storage or distribution of human bodies or parts for a purpose other than transplantation. Existing law requires each nontransplant anatomical donation organization in this State to: (1) be certified by the Health Care Purchasing and Compliance Division of the Nevada Health Authority; (2) follow certain standards and guidelines established by the State Board of Health; and (3) report to the Division information relating to the human bodies and parts procured by the organization. (NRS 451.587, as amended by section 250 of Senate Bill No. 494, chapter 514, Statutes of Nevada 2025, at page 3728)

Sections 3 and 4 of this regulation define certain terms related to nontransplant anatomical donation organizations, and **section 2** of this regulation establishes the applicability of those terms. To obtain an initial certification, **section 5** of this regulation requires a nontransplant anatomical donation organization to submit an application and pay a fee to the Division. **Section 6** of this regulation prescribes the process and fee for renewing a certification as a nontransplant anatomical donation organization. **Section 7** of this regulation requires a

nontransplant anatomical donation organization to submit a revised application and pay a fee before making certain changes relating to the ownership, management or operation of the organization.

Section 8 of this regulation requires the Division to review and make a determination concerning each application for the issuance or renewal of a certification as a nontransplant anatomical donation organization. With certain exceptions, **section 8** requires the Division to conduct an inspection of any facility of an applicant before making such a determination. **Section 8** also specifies that an initial certification and a renewed certification are valid for 2 years after the date of issuance or renewal, as applicable.

Section 9 of this regulation requires a nontransplant anatomical donation organization to notify the Division not more than 30 days after any changes to the information provided to the Division on an application for an initial certification. **Section 9** also requires a nontransplant anatomical donation organization to notify the Division as soon as practicable after deciding to cease operations.

Section 10 of this regulation requires a nontransplant anatomical donation organization to: (1) display the certification issued to the organization at each facility operated by the organization; and (2) maintain each facility operated by the organization in conformance with existing laws and regulations. **Section 10** also requires a nontransplant anatomical donation organization that ceases operations to return to the Division each certification issued to the organization.

Section 11 of this regulation prescribes the duties of the governing body of a nontransplant anatomical donation organization, including requirements that such a governing body: (1) adopt policies and procedures; (2) appoint a director for each facility operated by the organization; (3) appoint a medical director for the organization; (4) establish a comprehensive quality improvement program to evaluate the provision of services by the organization; and (5) establish a committee or appoint a natural person to oversee the quality improvement program. **Section 12** of this regulation prescribes certain duties of such a committee or natural person. **Section 13** of this regulation prescribes certain duties of: (1) the director of each facility operated by a nontransplant anatomical donation organization; and (2) the medical director of a nontransplant anatomical donation organization.

Section 14 of this regulation requires each nontransplant anatomical donation organization to prepare and maintain a record of each donor from whom the organization obtains anatomical material in this State.

Section 15 of this regulation requires a nontransplant anatomical donation organization to provide certain written notice to each: (1) donor or person making a donation before accepting a donation; and (2) person to whom any anatomical material is returned. With certain exceptions, **section 15** also requires a nontransplant anatomical donation organization to dispose of any anatomical material that is not returned to a person making a donation in accordance with any applicable federal laws or regulations.

Section 16 of this regulation prescribes certain requirements regarding the operation of a nontransplant anatomical donation organization, including requirements intended to reduce the transmission of infection or communicable disease at each facility operated by the organization.

Section 17 of this regulation authorizes the Division to conduct an investigation of a nontransplant anatomical donation organization upon receipt of a complaint made against the organization. **Section 17** requires the Division to report any violation noted at the time of an inspection to the director of the facility at which the violation occurred and requires the director

to submit a plan of correction for each violation. **Section 17** also authorizes the Division to suspend or revoke the certification of a nontransplant anatomical donation organization for failure to cooperate with an investigation or for failure to submit a plan of correction.

Existing law requires the Division to collect and analyze information from each nontransplant anatomical donation organization in this State on the number and disposition of human bodies and parts procured by such organizations and make such information available to the Governor and the Legislature upon request. (NRS 451.587, as amended by section 250 of Senate Bill No. 494, chapter 514, Statutes of Nevada 2025, at page 3728) **Section 18** of this regulation requires each nontransplant anatomical donation organization to biannually report to the Division the number and disposition of human bodies and parts procured by the organization.

Section 1. Chapter 451 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 18, inclusive, of this regulation.

Sec. 2. ***As used in sections 2 to 18, inclusive, of this regulation, unless the context otherwise requires, the words and terms defined in sections 3 and 4 of this regulation have the meanings ascribed to them in those sections.***

Sec. 3. ***"Division" means the Health Care Purchasing and Compliance Division of the Nevada Health Authority.***

Sec. 4. ***"Governing body" means the governing body of a nontransplant anatomical donation organization.***

Sec. 5. ***1. To obtain an initial certification to procure a human body or part in this State as required pursuant to NRS 451.587, a nontransplant anatomical donation organization must submit an application to the Division on a form prescribed by the Division and pay a nonrefundable application fee of $1,785.***

2. An application submitted pursuant to subsection 1 must include:

(a) If applicable, a copy of the state business license of the applicant issued pursuant to chapter 76 of NRS and a copy of the current business license issued for the applicant's business by the county, city or town in which the applicant's business is located or written verification that the applicant is exempt from any requirement to obtain a business license;

(b) The federal tax identification number of the applicant;

(c) As applicable, a copy of the bylaws, articles of incorporation, articles of association, articles of organization, partnership agreement, operating agreement or constitution or any other substantially equivalent documents of the applicant, and any amendments thereto;

(d) The name, title and principal business address of each member of the governing body of the applicant and three or more letters of professional reference of each such member;

(e) A list of all facilities owned or operated by the applicant; and

(f) A statement regarding the scope of operations of the applicant and the services provided at each facility owned or operated by the applicant.

Sec. 6. *1. To renew a certification issued pursuant to section 8 of this regulation, a nontransplant anatomical donation organization must submit an application to the Division on a form prescribed by the Division and pay a nonrefundable renewal fee of $892.50.*

2. The Division shall provide the form required by subsection 1 to each nontransplant anatomical donation organization at least 90 days before the certification expires.

Sec. 7. *A nontransplant anatomical donation organization shall submit a revised application to the Division and pay a nonrefundable fee of $250:*

1. At least 30 days before:

(a) A change in the ownership or management of the organization, including, without limitation, acquisition of the organization by another nontransplant anatomical donation organization or merger with another nontransplant anatomical donation organization.

(b) A change in any facility used by the organization that may affect the operation of the organization, including, without limitation, a transfer of the real property on which a facility is located, an expansion of a facility, a relocation of a facility, the renovation of a facility or

structural changes in a facility. If the real property on which a facility is located is transferred, a nontransplant anatomical donation organization shall submit a copy of any lease agreement relating to the transfer with the revised application.

(c) A change in the scope of the operations of the organization or the services provided at a facility.

2. Within 10 days after the date on which the governing body appoints a new director to a facility operated by the organization.

Sec. 8. *1. The Division shall review each application submitted pursuant to section 5, 6 or 7 of this regulation for completeness and:*

(a) Accept the application if the Division finds that the application is complete; or

(b) Return the application to the applicant if the Division finds that the application is incomplete.

2. The Division shall include with an application returned to an applicant pursuant to subsection 1 written notification that the application is incomplete and a description of the additional information or documentation required to complete the application. An applicant must submit the required information or documentation not more than 30 days after the date on which the applicant receives the returned application.

3. Except as otherwise provided in subsection 4, upon receipt of a completed application and payment of any applicable application fees, the Division shall inspect any facility of the nontransplant anatomical donation organization and any records that the Division determines are necessary to evaluate compliance with any applicable federal laws or regulations. After completing the inspection, the Division shall:

(a) Issue or renew the certification, as applicable; or

(b) Deny the application, in writing, and include the reasons for the denial.

4. Upon receipt of a completed revised application submitted pursuant to section 7 of this regulation and payment of any applicable fee, the Division may inspect any facility of the nontransplant anatomical donation organization and any records that the Division determines are necessary to evaluate compliance with any applicable federal laws or regulations, if the Division determines such an inspection is in the best interest of the State. Upon receipt of the completed revised application and the completion of any inspection, the Division shall:

(a) Issue or renew the certification, as applicable; or

(b) Deny the application, in writing, and include the reasons for the denial.

5. An initial certification issued pursuant to this section is valid for 2 years after the date of issuance.

6. A certification renewed pursuant to this section is valid for 2 years after the date of renewal.

Sec. 9. *A nontransplant anatomical donation organization shall notify the Division in the form prescribed by the Division:*

1. Not more than 30 days after any information submitted on an application for an initial certification pursuant to section 5 of this regulation, an application for renewal submitted pursuant to section 6 of this regulation or a revised application submitted pursuant to section 7 of this regulation changes.

2. As soon as practicable after deciding to cease operations.

Sec. 10. *1. A nontransplant anatomical donation organization shall display the certification issued to the organization pursuant to section 8 of this regulation in a conspicuous manner at each facility operated by the organization.*

2. A nontransplant anatomical donation organization shall maintain each facility operated by the organization in conformance with NRS 451.587 and the provisions of sections 2 to 18, inclusive, of this regulation.

3. A nontransplant anatomical donation organization that ceases operations shall return to the Division each certification issued to the organization pursuant to section 8 of this regulation immediately upon ceasing operations, regardless of whether the nontransplant anatomical donation organization ceased operations voluntarily or was required to cease operations for any reason, including, without limitation, because:

(a) The organization failed to renew the certification by the date of expiration of the certification; or

(b) The Division suspended or revoked the certification pursuant to section 17 of this regulation.

Sec. 11. *A governing body shall:*

1. Adopt and maintain policies and procedures that are consistent with standards of practice for nontransplant anatomical donation organizations, including, without limitation:

(a) Criteria for accepting anatomical material;

(b) A policy for screening and testing donors;

(c) A policy for monitoring the environment in a facility operated by the organization;

(d) A policy for monitoring equipment in a facility operated by the organization;

(e) Standards for controlling infection in a facility operated by the organization and minimizing the transmission of communicable disease in such a facility; and

(f) Standards for the use of personal protective equipment while handling anatomical material.

2. Ensure that all services provided by the nontransplant anatomical donation organization comply with the policies and procedures adopted pursuant to subsection 1 and any applicable federal laws or regulations.

3. Appoint a director for each facility operated by the nontransplant anatomical donation organization.

4. Appoint a medical director of the nontransplant anatomical donation organization who must:

(a) Be licensed pursuant to chapter 630 or 633 of NRS; and

(b) Have training and experience in evaluating and determining the eligibility of a donor to donate anatomical material, including, without limitation, training and experience in infectious disease.

5. Establish a comprehensive quality improvement program to evaluate the provision of services by the nontransplant anatomical donation organization.

6. Establish a committee comprised of such members as prescribed by the governing body to oversee the quality improvement program established pursuant to subsection 5 or appoint a natural person to oversee the quality improvement program.

Sec. 12. *A committee established pursuant to subsection 6 of section 11 of this regulation or a natural person appointed pursuant to that subsection shall:*

1. Adopt written policies for carrying out the comprehensive quality improvement program established pursuant to subsection 5 of section 11 of this regulation.

2. Submit the written policies adopted pursuant to subsection 1 to the governing body for approval.

3. At least annually, review the written policies adopted pursuant to subsection 1 and, if necessary, update the policies and submit the updated policies to the governing body for approval.

4. Continually evaluate the provision of services by the nontransplant anatomical donation organization, including, without limitation, compliance with:

(a) The policies and procedures adopted by the governing body pursuant to subsection 1 of section 11 of this regulation; and

(b) The requirements prescribed by sections 14, 15 and 16 of this regulation.

5. Report to the governing body any area in which the committee or natural person, as applicable, determines, through an evaluation conducted pursuant to subsection 4, that the nontransplant anatomical donation organization is noncompliant.

6. Prescribe any remedial action necessary to address an area of noncompliance identified pursuant to subsection 5.

7. Document the outcome of any remedial action taken pursuant to subsection 6.

8. Make suggestions to the governing body to promote the efficient and effective operation of the nontransplant anatomical donation organization.

Sec. 13. *1. The director of a facility appointed pursuant to subsection 3 of section 11 of this regulation:*

(a) Is responsible for the day-to-day operation and management of the facility.

(b) Shall:

(1) Ensure that all services provided at the facility comply with the policies and procedures adopted by the governing body pursuant to subsection 1 of section 11 of this regulation; and

(2) Establish standards for the control of infection at the facility.

2. The medical director of the nontransplant anatomical donation organization appointed pursuant to subsection 4 of section 11 of this regulation must be available to consult with other staff of the nontransplant anatomical donation organization concerning the cause of death or medical history of a potential donor before the nontransplant anatomical donation organization accepts the donor.

Sec. 14. *1. Each nontransplant anatomical donation organization shall prepare and maintain a legible, reproducible record of each donor from whom the organization obtains anatomical material in this State. Such a record must include, without limitation:*

(a) Documentation that the donor donated the anatomical material for a purpose other than transplantation or, if the decision to donate the anatomical material is made by a person other than the donor after the death of the donor, documentation that the person making the donation is authorized to make the donation, that the donation is being made in accordance with NRS 451.500 to 451.598, inclusive, and that the donation is being made for a purpose other than transplantation;

(b) The name of any nongovernmental entity that possessed the anatomical material before the date on which the organization took possession of the anatomical material; and

(c) Documentation concerning the disposition of the anatomical material by the organization, including, without limitation, the name and address of each person that receives the anatomical material from the organization.

2. Each nontransplant anatomical donation organization shall:

(a) Notify the Division of the location at which a record prepared pursuant to subsection 1 is stored;

(b) Maintain for a period of not less than 10 years a record prepared pursuant to subsection 1;

(c) Take reasonable precautions to protect a record prepared pursuant to subsection 1 from unauthorized access or destruction; and

(d) Allow authorized employees of the Division to review a record prepared pursuant to subsection 1 upon request.

3. If a nontransplant anatomical donation organization changes ownership, the new owner must assume responsibility for complying with the requirements prescribed in subsection 2.

4. Before ceasing operations, a nontransplant anatomical donation organization that plans to cease operations in this State shall confirm the location at which any record prepared pursuant to subsection 1 will be stored.

5. An organization that has ceased to operate in this State shall notify the Division if the location at which records are stored changes at any time during the period prescribed in paragraph (b) of subsection 2.

Sec. 15. *1. Before accepting a donation, a nontransplant anatomical donation organization shall provide to each donor or person making a donation a written notice that explains:*

(a) The manner in which the organization intends to dispose of the anatomical material, including, without limitation, whether the organization plans to return any anatomical material and, if so, how such material will be returned;

(b) The manner in which any costs relating to transporting or disposing of the anatomical material will be allocated, including, without limitation:

(1) Whether the organization plans to pay such costs; and

(2) If such costs will not be paid by the organization, which costs will be the responsibility of the donor or person making the donation; and

(c) The manner in which any costs relating to rescission or rejection of a donation will be allocated.

2. A nontransplant anatomical donation organization that returns any anatomical material shall provide to each person to whom a return is made written notice of whether all or part of a donor's body has been returned.

3. Except as otherwise provided in this subsection, a nontransplant anatomical donation organization shall dispose of any anatomical material that is not returned in accordance with any applicable federal laws or regulations relating to the disposition of human remains. The provisions of this subsection do not apply to anatomical material that an organization has recovered or distributed for research or educational purposes.

Sec. 16. *1. Each nontransplant anatomical donation organization shall:*

(a) Comply with any policies and procedures adopted by its governing body pursuant to subsection 1 of section 11 of this regulation;

(b) Ensure that any facility operated by the organization is sanitary;

(c) Implement practices to reduce the transmission of infection or communicable disease at each facility operated by the organization;

(d) Develop and implement a program for the prevention, control and investigation of infection and communicable disease in each facility operated by the organization; and

(e) Perform any remedial action prescribed by a committee or natural person pursuant to subsection 6 of section 12 of this regulation.

2. A nontransplant anatomical donation organization which sterilizes or disinfects its own supplies, nondisposable surgical instruments and mechanical or electrical equipment used on donated bodies or body parts shall:

(a) Provide a designated area in each facility operated by the organization for the preparation, sterilization, disinfection and storage of sufficient sterile supplies and equipment; and

(b) Develop systems and standards for sterilization and disinfection that are based on acceptable standards of practice and consistent with:

(1) The policies and procedures adopted by its governing body pursuant to subsection 1 of section 11 of this regulation;

(2) The standards for the control of infection established by the director of the facility pursuant to subsection 1 of section 13 of this regulation;

(3) The standards developed by the Occupational Safety and Health Administration of the United States Department of Labor for the preparation, sterilization, disinfection and storage of such supplies and equipment; and

(4) When applicable, the manufacturer's guidelines for the use and maintenance of the equipment.

3. A nontransplant anatomical donation organization that does not sterilize or disinfect its own supplies and equipment shall provide a designated area in each facility operated by the organization for the preparation and storage of sterile supplies and equipment.

Sec. 17. *1. If it determines an investigation is in the best interest of the State, the Division may, upon receipt of a complaint against a nontransplant anatomical donation*

organization, except for a complaint concerning the cost of services, conduct an investigation into:

(a) The qualifications of personnel employed by the organization;

(b) The methods of operation of the organization;

(c) The recordkeeping practices of the organization;

(d) Any policies or procedures adopted by the organization; and

(e) Any other area determined necessary by the Division.

2. The Division shall report any violation noted at the time of an inspection by providing the director of the facility that is the subject of the complaint, or the director's designee, with a statement of each violation and a form on which the director must submit a plan of correction. The director must submit to the Division the plan of correction, which must contain the plan of correction for each violation, within 30 calendar days after receiving the form. The plan must indicate the date by which each violation will be corrected.

3. The Division may, as it determines in the best interest of the State, suspend or revoke the certification of a nontransplant anatomical donation organization for failure to cooperate with an investigation conducted pursuant to subsection 1 or for failure to submit the plan of correction pursuant to subsection 2.

Sec. 18. *Each nontransplant anatomical donation organization shall, on or before January 1 and July 1 of each year, report to the Division the information required by subsection 1 of NRS 451.587 for the immediately preceding 6 months.*