

**PROPOSED REGULATION OF THE
STATE BOARD OF HEALTH**

LCB FILE NO. R067-201

**The following document is the initial draft regulation proposed
by the agency submitted on 06/05/2020**

Section 1. Each nontransplant anatomical donation organization that procures a human body or part in this State shall:

(a) Be certified by the Division;

DEFINITIONS:

“Non-Transplant Anatomical Donation Organization” (NADO) means a person 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.

“Anatomical gift” means a donation of all or part of a human body to take effect after the donor’s death for the purpose of transplantation, therapy, research or education as defined in NRS 451.513.

“Governing Body” means the person or group of persons, including a board of trustee, board of directors or other body, in whom the final authority and responsibility is vested for the conduct of a Non-Transplant Anatomical Donation Organization (NADO).

“Donor” means a natural person whose body or part is the subject of an anatomical gift was defined in NRS 451.525.

“High-level Disinfection” means a type of disinfection which destroys all microorganisms with the exception of high levels of bacterial spores. Such disinfection may be accomplished through the use of processes that include, without limitation, boiling items in water, steaming items in water and soaking items in chemical disinfectants.

“Low-level disinfection” means a type of disinfection which eliminates most bacteria, some viruses and some fungi, but which may not kill resistant microorganisms. Such disinfection may be accomplished through the use of processes that include, without limitation, soaking items in chemical disinfectants.

“Sterilization” means a process using medical equipment, including, without limitation, a dry heat sterilizer or an autoclave, to destroy all forms of microbial life.

“Survey” means an inspection of the premises or records of either an applicant for Licensure as a NADO or of a licensed NADO in order to determine the extent to which the entity is in compliance with NAC...

“Accredited” defined. “Accredited” means an accreditation by a nationally recognized accrediting agency or other body accepted by the Board.

“Board” has the meaning ascribed to it in NRS 449.0025

Section 1

Application for Certification

- 1. Persons meeting the definition of a non-transplant anatomical donation organization (NADO) may not act as a NADO or hold themselves out as a NADO unless certified as such by the Division.*
- 2. An applicant wishing to apply for a certificate to operate a NADO shall submit an application on the most current form prescribed by the Division and pay the application fee.*
- 3. An applicant that has obtained accreditation from an accrediting body shall provide proof of accreditation to the Division with its certification application and shall include:*

- (a) All of the approved accrediting body survey and inspection reports; and*
- (b) Written evidence of all corrective actions underway or completed in response to the approved accrediting body recommendations including progress reports.*
- 4. If any of the information delineated in a NADO's most recent application changes at a time other than the annual renewal date, it must submit a revised application to the Division within 30 calendar days of the change.*
- 5. Notwithstanding section (4) of this section, a NADO must submit a revised application to the Division 30 days prior to any of the following changes:*
 - (a) Change in ownership or management, acquisition by or of, or merger with another NADO;*
 - (b) Change in facilities because of expansion, relocation, renovations or structural changes that affect NADO operations; and*
 - (c) Change in the scope of operations of the NADO*
- 6. In order to allow the Division to review the changes reported in accordance with section (4) or (5) of this section, the Division shall request NADO documents, records or other materials for review or it may conduct an on-site inspection.*

CONTENTS OF APPLICATION FOR CERTIFICATION: *An application for certification must be submitted to the Division on a form furnished by the Division and must include:*

- (a) If applicable, a copy of the state business license of the organization 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 the applicant is exempt from any requirement to obtain a business license;*
- (b) The federal tax identification number of the organization;*
- (c) A copy of the bylaws, articles of incorporation, articles of association, articles of organization, partnership agreement, constitution and any other substantially equivalent documents of the applicant, and any amendments thereto;*
- (d) A list of the members of the governing body of the applicant;*
- (e) If the applicant is an association or a corporation:*
 - (1) The name, title and principal business address of each officer and member of its governing body;*
 - (2) The signature of the chief executive officer or an authorized representative; and*
 - (3) If the applicant is a corporation, the name and address of each person holding more than 10 percent of its stock;*
- (f) For each member of the governing body:*
 - (1) Three or more letters of professional reference*
- (g) A list of all satellite facilities which are operated by the non-transplant anatomical donation organization*
- (h) Such other information as may be required by the Division.*

REVIEW OF APPLICATION FOR CERTIFICATION; ACTIONS UPON DETERMINATION THE APPLICATION IS INCOMPLETE:

- 1. The Division shall review each application for certification to determine whether the application is complete.*
- 2. If the Division determines an application for certification is incomplete, the Division shall notify the applicant the application is incomplete and authorize the applicant to submit any required information or documentation to complete the application. The applicant must submit any additional information or documentation no later than 30 calendar days after receipt of the notice. The Division may deny the application if the applicant does not submit any required information or documentation in accordance with this subsection.*

3. The certification issued pursuant to this section is effective for 2 years after the date of issuance.

Denial, suspension or revocation of certification: Grounds. (NRS 451.XX)

1. A person who engages in the activity of a non-transplant anatomical donation organization without being certified by the Division pursuant to Chapter 451 of the NRS section 1 or who violates the standards and guidelines adopted by the State Board of Health pursuant to Chapter 451 of the NRS section 1 subsection 2 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 by both fine and the punishment provided in NRS 193.130.
2. The failure or refusal of a certification holder to return an adequate plan of correction to the Division within 14 days after the receipt by the certification holder of a statement of deficiencies.
3. The failure or refusal to cooperate fully with an investigation or inspection by the Division.

Renewal of certification.

1. An NADO certified pursuant to NAC XX who wishes to renew the certification must submit to the Division a completed form for renewal. The Division shall, not less than 90 days before the expiration of the certificate, provide to the holder of the certificate the proper form for renewal.
2. The form for renewal must be accompanied by the fee for renewal.
3. A certification issued pursuant to this section is effective for 2 years after the date of issuance. Failure to renew the certification by the date of expiration will result in the termination of the holder's authority to operate a nontransplant anatomical donation organization.

Return of Certificate

Each certification in the licensee's possession shall be returned to the Division immediately upon the suspension or revocation of the certification, failure to renew the certification by the date of expiration, loss of accreditation or if operation is discontinued by the voluntary action of the certificate holder.

Display of the certification; compliance with law; transfer of real property; change in director, ownership, location, or services.

1. Upon receipt of a certification, the certification holder shall display the certification at a conspicuous location within the facility.
2. During the term of the certification, the certification holder shall continuously maintain the facility in conformance with the provisions of NAC XX to NAC XX, inclusive, and Chapter 451 of NRS.
3. If there is a transfer of the real property on which the facility is located, but no change in the operator of the facility, the certification holder shall, within 10 days, notify the Division of the transfer in writing and provide the Division with a copy of any lease agreement relating to the transfer.
4. If there is a change in the director of the facility, the certification holder shall notify the Division of the change within 10 days. If the certification holder fails to notify the Division and submit an application for a new certification within 10 days after the change, the certification holder shall pay to the Division a fee in an amount equal to 150 percent of the fee required for a new application set forth in subsection 1 of NAC 451. XX.
5. A certification holder shall notify the Division immediately of any change in:
 - (a) The ownership of the facility;
 - (b) The location of the facility;
 - (c) The services provided at the facility; and
6. An initial application for the certification to operate a Non-Transplant Anatomical Donation organization (NADO) must pay to the Division a nonrefundable fee of \$1,785.
7. An applicant for the renewal of the certificate to operate an NADO must pay to the Division a nonrefundable fee of \$892.50.

Inspections: Duties and authority of the Division; submission of a plan for correction of violations

- 1. Upon receipt of a complaint against an NADO, except for a complaint concerning the cost of services, the Division may conduct an investigation into the premises, qualifications of personnel, methods of operation, policies, procedures and records of the NADO which may have information pertinent to the complaint.*
- 2. The Division shall report violations noted at the time of each inspection by providing the director, or the director's designee, with a statement of violations and a form for the director to submit a plan of correction. The director shall submit the plan of correction to the Division, containing thereon the plan of correction for each of the violations, within 14 days after receiving the form. The plan must indicate the date by which each violation will be corrected.*
- 3. Failure to submit the plan of correction timely pursuant to subsection 2 to the Division constitutes a separate violation subject to denial, suspension or revocation of the certification.*

Governing Body

Every facility which provides non-transplant anatomical donation organization must have a governing body which shall:

- 1. Appoint a director who shall be available for consultation with members of Governing Body for the operation of an NADO.*
- 2. Ensure that all services provided by the NADO are consistent with accepted standards of practice for non-transplant anatomical donation organization.*
- 3. The NADO shall dispose of any anatomical material not returned to a relative or responsible party of the donor in accordance with all laws pertaining to the disposition of human remains. This requirement does not apply to anatomical material the NADO has recovered or distributed for research or educational purposes.*

Donor Records and Notices

- 1. A non-transplant anatomical donation organization must maintain a legible, reproducible record of each donor from whom the organization obtains anatomical material. The record must include at least the following:
 - (a) Documentation showing the donor donated the anatomical material for the purpose of research or education. If the decision to donate is made after the donor's death, then documentation the donation was made by a person authorized to make an anatomical gift under the process set out in NRS 451.500 through NRS 451.598 and that this person donated the anatomical material for the purpose of research or education;*
 - (b) The name and address of each person that had possession of the anatomical material before the NADO took possession of the anatomical material;*
 - (c) Documentation of the disposition of the anatomical material by the organization, including the name and address of each person that receives the anatomical material from the NADO;*
 - (d) The records shall be retained for at least 10 years;*
 - (e) Reasonable precautions must be taken to protect the record from unauthorized access and destruction.*
 - (f) Authorized employees of the Division must be permitted to review the records upon request;*
 - (g) If a non-transplant anatomical donation organization changes ownership, all records must be maintained by the new owners and the new owners shall be responsible to protect and maintain these records; and*
 - (h) Before a non-transplant anatomical donation organization terminates its business, it must notify the Division of the location where the records will be stored, if the storage location changes, those responsible must notify the Division of each successive location.**

2. When a NADO accepts an offer from an individual to donate anatomical material it must provide the individual notice that clearly explains:

(a) How the NADO intends to dispose of the anatomical material and whether and how any anatomical material may be returned;

(b) Whether or not the NADO guarantees the coverage of costs related to transporting and disposing of the anatomical material and, if all costs will not be covered, what costs will be the responsibility of the individual making the donation; and

(c) What costs will be covered by the NADO and what costs will be the responsibility of the individual making the donation if the individual or relative or responsible party rescinds, or the NADO rejects the offer of anatomical material.

3. If a NADO returns any anatomical material to a relative or responsible party of the donor, the NADO must provide that person with a notice that discloses whether all or part of the donor's body is being returned.

4. The notice required by sections 2 and 3 of this section must be in writing.

Policies and Procedures

1. A non-transplant anatomical donation organization must establish and maintain policies and procedures for the operation of the facility that are consistent with accepted standards of practice for non-transplant anatomical donation organizations.

Infection Control

1. The Non-Transplant Anatomical Donation Organization (NADO) shall establish a donor screening and testing plan, acceptability criteria, application of appropriate environmental controls and personal protective equipment during preparation of Non-Transplant Anatomical Materials (NAM).

2. A non-transplant anatomical donation organization shall:

(a) Provide a sanitary environment to avoid sources and transmissions of infections and communicable disease; and

(b) Ensure cleaning of the environment and equipment is performed in a manner to minimize the spread of pathogenic organisms. Floors must be cleaned regularly.

(c) Develop and carry out an active program for the prevention, control and investigation of infections and communicable diseases.

3. A non-transplant anatomical donation organization shall provide a designated area for the preparation, sterilization and/or disinfection and storage of sufficient supplies and equipment.

4. A non-transplant anatomical donation organization which sterilizes and/or disinfects its supplies and equipment directly shall develop systems and standards that are consistent with:

(a) The standards for the control of infection established by the governing body of the non-transplant anatomical donation organization.

(b) The standards developed by the Occupational Safety and Health Administration for the preparation, sterilization and storage of such supplies and equipment;

(c) Based on acceptable standards of practice; and

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

Quality Assurance Program

1. The governing body of a non-transplant donation organization shall ensure the non-transplant donation organization has an effective, comprehensive quality improvement program to evaluate the provision of services.

2. The quality improvement program must:

(a) Be ongoing;

- (b) Include a written plan for carrying out the program; and*
- (c) Provide for the creation of a committee to oversee the program.*
- 3. All services, including services furnished by a contractor, must be evaluated by the committee.*
- 4. The committee shall initiate an assessment of a service when any statistical analysis detects an undesirable variation in performance.*
- 5. The committee shall take and document appropriate remedial action to address deficiencies found through the quality improvement program. The committee shall document the outcome of any remedial action taken.*
- 6. The quality improvement program shall include, at a minimum:*
 - (a) monitoring of the environment*
 - (b) infection control*
 - (c) periodic monitoring of equipment*

REPORTING THE NUMBER AND DISPOSITION OF HUMAN BODIES OR PARTS PROCURED BY THE NON-TRANSPLANT ANATOMICAL DONATION ORGANIZATION

- 1. Each non-transplant anatomical donation organization shall submit the number and disposition of the human bodies and parts procured by the non-transplant anatomical donation organization to the Division in a format approved by the Division on July 1 and January 1.*
- 2. The Division shall collect and analyze the information provided by the non-transplant anatomical donation organization on the number and disposition of human bodies and part and make such information available to the Governor and the Legislature upon request.*

ON-SITE SURVEY OF ORGANIZATION BY THE DIVISION.

- 1. An initial on-site survey of a nontransplant anatomical donation organization:*
 - (a) After the Division receives a completed application for certification to operate the nontransplant anatomical donation organization and the fee required; and an initial on-site inspection will be conducted prior to issuing a certificate to operate.*
- 2. Additional on-site surveys of the Non-Transplant Anatomical Donation organization will occur not less than once every 2 years after conducting the initial survey of the home pursuant to subsection 1.*