PROPOSED REGULATION OF THE

STATE BOARD OF HEALTH

LCB FILE NO. R184-24I

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

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 Division of Public and Behavioral Health of the Department of Health and Human Services.***

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;

(f) If the applicant is accredited by a nationally recognized accrediting agency or other body accepted by the State Board of Health:

(1) Proof of the accreditation;

(2) Any survey or inspection report prepared by the accrediting agency or body regarding the applicant; and

(3) 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; and

(g) 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 it 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 certificate issued to the organzation 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 plan for screening and testing donors;

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

(d) A plan 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. Establish a comprehensive quality improvement program to evaluate the provision of services by the nontransplant anatomical donation organization.

5. Appoint a committee to oversee the quality improvement program established pursuant to subsection 4.

Sec. 12. *A committee appointed pursuant to subsection 5 of section 11 of this regulation shall:*

1. Adopt a written plan for carrying out the comprehensive quality improvement program established pursuant to subsection 4 of section 11 of this regulation.

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

3. At least annually, review the plan adopted pursuant to subsection 1 and, if necessary, update the plan and submit the updated plan 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 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. *The director of a facility appointed pursuant to subsection 3 of section 11 of this regulation:*

1. Is responsible for the day-to-day operation and management of the facility.

2. Shall:

(a) 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

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

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 and address of each person who 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 pursuant to subsection 6 of section 12 of this regulation.

2. A nontransplant anatomical donation organization which sterilizes or disinfects its own supplies and equipment 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) Any standards for the control of infection established by the director of the facility pursuant to subsection 2 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 14 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.*