



## 101ST GENERAL ASSEMBLY

### State of Illinois

2019 and 2020

SB3419

Introduced 2/14/2020, by Sen. Patricia Van Pelt

#### SYNOPSIS AS INTRODUCED:

New Act  
30 ILCS 105/5.930 new

Creates the Non-Transplant Organ Donation Regulation Act. Requires non-transplant organ donation organizations that acquire or transfer human bodies or human body parts for education, research, or the advancement of medical, dental, or mortuary science to register with the office of the Secretary of State and be licensed by the Department of Public Health. Contains requirements for license application, accreditation, renewal, and fees. Provides that the Department may deny, suspend, or revoke a license; assess civil penalties; and perform inspections under the Act. Provides requirements for donor consent forms, identification of donated human bodies or human body parts, and other records. Contains requirements regarding the labeling, packaging, and final disposition of human bodies or human body parts under the Act. Provides disciplinary action for violation of the Act. Contains other provisions. Effective immediately.

LRB101 20120 CPF 69655 b

CORRECTIONAL  
BUDGET AND  
IMPACT NOTE ACT  
MAY APPLY

FISCAL NOTE ACT  
MAY APPLY

1 AN ACT concerning health.

2 **Be it enacted by the People of the State of Illinois,**  
3 **represented in the General Assembly:**

4 Section 1. Short title. This Act may be cited as the  
5 Non-Transplant Organ Donation Regulation Act.

6 Section 5. Definitions. As used in this Act:

7 "Accrediting body" means a nationally recognized agency,  
8 approved by the Department, that provides certification for a  
9 business organization operating a non-transplant organ  
10 donation organization.

11 "Department" means the Department of Public Health.

12 "Director" means the Director of Public Health.

13 "Distribution" means a process that includes selection and  
14 evaluation of intended use of non-transplant anatomical  
15 material or a non-transplant anatomical donation, a human body,  
16 or human body part for release to an education facility or a  
17 research facility according to State law.

18 "Donor" means a person who has knowingly consented in  
19 accordance with applicable law to the transfer of a person's  
20 deceased body or body part, not for use in transplantation, for  
21 education, research, or the advancement of medical, dental, or  
22 mortuary science.

23 "Donor consent form" means a legal record of a gift of

1 non-transplant anatomical material permitting and defining  
2 acquisition and use of non-transplant anatomical material for  
3 education and research, such as a document of authorization,  
4 gift, or gift and authorization.

5 "Entity" means a non-transplant organ donation  
6 organization that is accredited, licensed, or approved under  
7 federal law or the laws of this State to engage in the  
8 recovery, screening, testing, processing, distribution, or  
9 storage of human bodies or body parts.

10 "Exceptional release" means non-transplant anatomical  
11 material that is approved for usage before a donor  
12 acceptability assessment or by a researcher requesting  
13 non-transplant anatomical material that would not normally  
14 meet the established acceptability criteria.

15 "Environmental services" means activities such as  
16 housekeeping, laundry, facility maintenance, or equipment  
17 maintenance.

18 "Final disposition" means the final disposal of  
19 non-transplant anatomical material or a non-transplant  
20 anatomical donation through incineration, cremation,  
21 bio-cremation, burial, full depletion by virtue of a particular  
22 use, or by another legal means.

23 "Education" means the use of a human body or body parts for  
24 teaching or training individuals, including, but not limited  
25 to, medical, dental, or mortuary science students or  
26 professionals, with regard to the anatomy and characteristics

1 of the human body, disease detection, and such other uses as  
2 may be specified by the Department by rule.

3 "Human body" means a deceased human body or non-transplant  
4 anatomical donation.

5 "Human body part" or "body part" means an organ, tissue,  
6 eye, bone, blood vessel, or any other portion of a human body  
7 that is subject to an anatomical gift or other transfer made  
8 under State law. "Human body part" does not include:

9 (1) blood drawn for medical purposes; or

10 (2) a growing cell line.

11 "Institution" means a facility established by law for the  
12 purpose of education, research, or the advancement of medical,  
13 dental, or mortuary science.

14 "Licensee" means a person to whom the Department has issued  
15 a license to operate a non-transplant organ donation  
16 organization.

17 "Misuse" means to use non-transplant anatomical material  
18 and non-transplant anatomical donations for purposes other  
19 than education or research.

20 "Non-transplant anatomical donation" means a donation of a  
21 whole body, organ, or tissue authorized and used for education  
22 and research prior to release to distribution inventory.

23 "Non-transplant anatomical material" means a whole body or  
24 part of a body donated for use in education or research that  
25 has been prepared, packaged, labeled, and released to  
26 distribution inventory.

1 "Non-transplant organ donation organization" means an  
2 entity that is accredited, licensed, or approved under federal  
3 law or State law to engage in the recovery, screening, testing,  
4 processing, distribution, or storage of human bodies or body  
5 parts for purposes of education, research or the advancement of  
6 medical, dental, or mortuary science.

7 "Research" does not include an autopsy or examination  
8 conducted as part of a criminal investigation.

9 "Storage" means a designated area that contains equipment,  
10 instruments, and supplies necessary to maintain non-transplant  
11 anatomical donations or non-transplant anatomical material  
12 until distribution or final disposition.

13 "Transfer" means to move from a non-transplant organ  
14 donation organization to an institution.

15 Section 10. Registration. A non-transplant organ donation  
16 organization established by law to conduct business in the  
17 State of Illinois that acquires or transfers a human body or  
18 human body part for education, research, or the advancement of  
19 medical, dental, or mortuary science, and not for use in human  
20 transplantation, shall register with the office of the  
21 Secretary of State and be licensed by the Department at such  
22 time and in such manner as the Department may require.

23 Section 15. Contents of license application. An applicant  
24 for licensure or renewal of license under this Section shall

1 submit an application to the Department containing such  
2 information as the Department may require by rule on the  
3 activities to be carried out pursuant to registration. Unless  
4 otherwise set forth by administrative rule, the application  
5 shall include:

6 (1) the name of the applicant, including all trade  
7 names under which the applicant conducts business;

8 (2) the date on which the applicant first began or will  
9 begin commencing activities described in this Act;

10 (3) a list of all addresses at which the applicant  
11 conducts business;

12 (4) a description of the premises and equipment used by  
13 the applicant;

14 (5) a description of the types of service provided by  
15 the applicant;

16 (6) identification of all officers and administrators  
17 of the applicant;

18 (7) an attestation that the applicant will keep records  
19 in accordance with the requirements of this Act;

20 (8) an attestation that the applicant will label and  
21 package all human bodies or human body parts in accordance  
22 with the requirements of this Act; and

23 (9) an acknowledgment that the Department will be  
24 permitted to inspect the premises and records of the  
25 applicant as to the items and in the manner prescribed in  
26 this Act.

1           Section 20. Accreditation; licensure; renewal; fees;  
2 penalties; enforcement.

3           (a) An entity may not act as a non-transplant organ  
4 donation organization in this State unless the entity is  
5 accredited and licensed by the Department as a non-transplant  
6 organ donation organization. The entity shall apply in writing  
7 to the Department on a form specified by the Director, which  
8 shall include all information requested in the application, and  
9 shall pay the fees prescribed by the Department by rule.

10           (b) The Director shall grant a license to an entity if: (1)  
11 the organization is accredited by a nationally recognized  
12 accrediting agency that is approved by the Department and  
13 maintains full accreditation with the accrediting agency; and  
14 (2) the entity meets other requirements prescribed by the  
15 Department by rule.

16           (c) Each non-transplant organ donation organization  
17 applying for licensure or license renewal shall pay all  
18 applicable fees as prescribed by the Department by rule. All  
19 fees collected for the licensure and license renewal of  
20 non-transplant organ donation organizations shall be deposited  
21 in the Public Health Licensing Fund to be used by the  
22 Department for the administration and enforcement of this Act.

23           (d) The Director may sanction, impose civil penalties on,  
24 suspend the license of, or revoke the license of a  
25 non-transplant organ donation organization and may sanction or

1 impose civil penalties on any person who is an owner, officer,  
2 agent, or employee of a non-transplant organ donation  
3 organization if the person is in or continues to be in  
4 violation of this Act or rules adopted by the Department under  
5 this Act.

6 (e) Any person or entity operating as a non-transplant  
7 organ donation organization without proper accreditation or  
8 licensure in this State shall be subject to criminal  
9 prosecution and civil penalties as provided under Section 80  
10 and any applicable rules.

11 Section 25. Other fees.

12 (a) The Department shall establish a fee for licensure  
13 under Section 10 and renewal under Section 30.

14 (b) The Department shall determine the amount of licensing  
15 fees under this Act, taking into consideration, among other  
16 things, the projected implementation, enforcement, and  
17 inspection costs associated with this Act.

18 (c) Every fine accruing from a conviction under this Act  
19 shall be paid into the common school fund of the county in  
20 which the offense was committed.

21 Section 30. License renewal. The Department shall require  
22 that the license of an applicant be renewed by the applicant  
23 annually.



1 Section 35. Change of information.

2 (a) Not later than 30 days after any change of any  
3 information listed under Section 15, an applicant or licensee  
4 shall notify the Department of the change in writing as  
5 prescribed by the Department.

6 (b) A licensee shall notify the Department in writing at  
7 least 30 calendar days before the date of:

8 (1) termination of operation, including, but not  
9 limited to, the proposed termination date and the address  
10 and contact information for the location where the  
11 non-transplant organ donation organization records will be  
12 retained, if applicable;

13 (2) a proposed modification that alters the area for  
14 tissue recovery, if applicable;

15 (3) a change in the non-transplant organ donation  
16 organization's legal name;

17 (4) a change in the legal name of a licensee, including  
18 the licensee's new name; and

19 (5) a change in the address of the non-transplant organ  
20 donation organization, including the new address.

21 (c) A licensee shall notify the Department in writing no  
22 later than 30 calendar days after the date of:

23 (1) a change in the non-transplant organ donation  
24 organization's email address or mailing address, including  
25 the new email address or mailing address of the  
26 non-transplant organ donation organization;

1           (2) a change in the email address or telephone number  
2           of the licensee, including the new email address or  
3           telephone number;

4           (3) a change in an administrator or medical director,  
5           including his or her name and email address; and

6           (4) a change in the name or contact information of an  
7           officer affiliated with the licensee, including the name  
8           and contact information of the new officer.

9           (d) If the Department receives notification of termination  
10          of operation, the Department shall void the licensee's license  
11          to operate a non-transplant organ donation organization as of  
12          the termination date specified by the licensee.

13          (e) If the Department receives notification of a proposed  
14          modification that alters the area for tissue recovery, the  
15          Department:

16                 (1) may conduct an inspection of the premises; and

17                 (2) shall issue to the licensee an amended license that  
18                 incorporates the modification and retains the expiration  
19                 date of the existing license, if the non-transplant organ  
20                 donation organization is in compliance.

21          (f) If the Department receives a notification of a legal  
22          name change for a non-transplant organ donation organization,  
23          the Department shall issue to the licensee an amended license  
24          showing the licensee's changed legal name.

25          (g) If the Department receives notice of a change in the  
26          legal name of a licensee, the Department shall void the

1 licensee's license to operate and issue a new license to  
2 operate with the licensee's changed legal name.

3 (h) If the Department receives notice for a change in the  
4 address of a non-transplant organ donation organization, the  
5 Department shall require and review an amended application for  
6 a license.

7 (i) An individual or business organization planning to  
8 assume operation of an existing non-transplant organ donation  
9 organization shall obtain a new license before beginning  
10 operation.

11 Section 40. Denial; suspension; revocation; enforcement.

12 (a) The Department may:

13 (1) deny a license;

14 (2) suspend or revoke a license; or

15 (3) assess a civil penalty against a licensee.

16 (b) The Department may deny an application or suspend or  
17 revoke a license to operate a non-transplant organ donation  
18 organization if:

19 (1) an applicant or licensee does not meet the  
20 application requirements;

21 (2) a licensee does not comply with any statutory  
22 requirements or requirements of the Department;

23 (3) a licensee does not correct a deficiency identified  
24 during an inspection according to the plan of correction;

25 (4) an applicant or licensee provides false or

1 misleading information as part of an application or  
2 inspection; or

3 (5) the nature or number of violations revealed by any  
4 type of inspection or investigation of a non-transplant  
5 organ donation organization pose a direct risk to the life,  
6 health, or safety of individuals on the premises or the  
7 public at large.

8 (c) In determining which action is appropriate, the  
9 Department may consider:

10 (1) repeated violations of statutes or rules;

11 (2) a pattern of violations;

12 (3) the severity of violations; and

13 (4) the number of violations.

14 (d) The Department may suspend or revoke a non-transplant  
15 organ donation organization's license if the Department  
16 receives notice from the organization's accrediting body that  
17 the organization's accreditation has been suspended or  
18 revoked. An applicant or licensee may seek administrative  
19 review of the Department's determination.

20 Section 45. Inspections. The Department shall inspect a  
21 licensee's premises at least annually and any time after it  
22 receives a complaint or notice of a violation.

23 Section 50. Donor consent forms; non-transplant anatomical  
24 donation and non-transplant anatomical material

1 identification. A non-transplant organ donation organization  
2 must establish donor consent and ensure that:

3 (1) a donor consent form includes:

4 (A) the intended use of the non-transplant  
5 anatomical material;

6 (B) how the non-transplant anatomical material may  
7 not be used;

8 (C) a statement that the non-transplant anatomical  
9 material will be treated with dignity at all times; and

10 (D) a statement that the non-transplant anatomical  
11 material may require international export to an end  
12 user; and

13 (2) the donor consent form is maintained in the donor's  
14 record and retained for at least 10 years after the date of  
15 final disposition;

16 (3) an electronic identification system for donors is  
17 established and maintained that:

18 (A) assigns a unique identifier using a  
19 combination of letters, numbers, or symbols for a  
20 non-transplant anatomical donation and non-transplant  
21 anatomical material;

22 (B) tracks the complete history of all  
23 non-transplant anatomical material; and

24 (C) records the date and staff member involved in  
25 each significant step of the operation from the time of  
26 a non-transplant anatomical donation acquisition

1 through final disposition; and

2 (4) the information required to register the death of a  
3 non-transplant anatomical donation is submitted within 7  
4 calendar days after receiving the non-transplant  
5 anatomical donation.

6 Section 55. Donor records.

7 (a) A non-transplant organ donation organization shall  
8 maintain a legible, reproducible record for each donor from  
9 whom it releases non-transplant anatomical material for at  
10 least 10 years beyond the date of final disposition.

11 (b) To ensure traceability of a non-transplant anatomical  
12 donation and non-transplant anatomical material, a  
13 non-transplant organ donation organization shall:

14 (1) document each procedure performed on a  
15 non-transplant anatomical donation and non-transplant  
16 anatomical material related to processing and storing  
17 non-transplant anatomical donations and non-transplant  
18 anatomical material;

19 (2) for each document created under paragraph (1),  
20 include:

21 (A) the date, time, and location for each procedure  
22 completed; and

23 (B) the name of the technician who performed the  
24 procedure; and

25 (3) submit or have a contracted funeral home submit

1 information required to register the death of a  
2 non-transplant anatomical donation within 7 calendar days  
3 after receiving the non-transplant anatomical donation, if  
4 applicable.

5 (c) A donor record shall be:

6 (1) confidential;

7 (2) kept in a location with controlled access;

8 (3) stored in a manner to prevent unauthorized access;

9 and

10 (4) maintained in a manner to preserve the donor  
11 record's completeness and accuracy.

12 (d) A donor record shall include at least the following:

13 (1) donor information that includes:

14 (A) the donor's name;

15 (B) the donor's unique identifying number;

16 (C) the donor's date of birth and date of death;

17 and

18 (D) the name and contact information of the person  
19 responsible for a donor's anatomical gift, if  
20 applicable; and

21 (2) an informed consent record or documentation of  
22 authorization for an anatomical gift;

23 (3) a document of authorization, which is a legal  
24 record of the gift, to take place postmortem, permitting  
25 and defining the scope of the postmortem acquisition and  
26 use of non-transplant anatomical material for education

1 and research, signed or otherwise recorded by the  
2 authorizing person;

3 (4) a document of anatomical gift, which is the donor's  
4 legal record of the gift of non-transplant anatomical  
5 material permitting and defining the scope of the  
6 postmortem acquisition and use of non-transplant  
7 anatomical material for education and research;

8 (5) an authorization of gift, which must be signed or  
9 otherwise recorded by an individual authorized by law to  
10 make a gift during the donor's lifetime;

11 (6) the donor's death record;

12 (7) the human remains release form, if applicable;

13 (8) information for a death record, if applicable for  
14 transporting human remains into the State;

15 (9) a disposition transit permit, if applicable;

16 (10) a medical examiner's release of information, if  
17 applicable;

18 (11) all documents and permits that establish the chain  
19 of custody and identifies the individuals and  
20 organizations that had physical custody of the  
21 non-transplant anatomical material;

22 (12) medical records, including:

23 (A) a donor's physical assessment;

24 (B) a risk assessment questionnaire;

25 (C) pathology and laboratory testing and reports;

26 (D) physician summaries, if applicable;



1 (E) transfusion or infusion information, if  
2 applicable; and

3 (F) plasma dilution calculations if applicable;  
4 and

5 (13) information from the donor referral source;

6 (14) donor eligibility;

7 (15) a donor acceptability assessment;

8 (16) a physical assessment questionnaire;

9 (17) documentation related to distribution;

10 (18) serological results, if applicable;

11 (19) a cremation authorization document;

12 (20) documentation related to non-transplant  
13 anatomical material recovery, storage, and distribution  
14 activities;

15 (21) final disposition documentation, including all  
16 records demonstrating chain of custody; and

17 (22) documentation of the suspected misuse or harm to  
18 the donor, if any.

19 (e) A donor's record shall be accessible to:

20 (1) an agent legally authorized to have access, or an  
21 individual designated at the time a donor gives consent;

22 (2) an individual appointed by a court or authorized by  
23 State law;

24 (3) an individual of a non-transplant organ donation  
25 organization as identified by policies and procedures;

26 (4) an individual from an approved accrediting body, if

1 applicable; and

2 (5) an individual from the Department or other  
3 regulatory agency authorized by State or federal laws or  
4 rules adopted by the Department.

5 (f) Except for a donor record that must be maintained for a  
6 period of 10 years after final disposition, a non-transplant  
7 organ donation organization shall maintain documentation  
8 required under this Act for at least 3 years after the date of  
9 the documentation and shall provide copies of the documentation  
10 to the Department for review upon request.

11 Section 60. Recordkeeping.

12 (a) A licensee shall compile or maintain a record for each  
13 case in which the licensee acquires a human body, human body  
14 part, or non-transplant anatomical donation.

15 (b) A record shall contain the following information and  
16 any additional information required by the Department:

17 (1) documentation that the donor has knowingly  
18 consented to the transfer of the human body or human body  
19 part, not for use in transplantation, for education,  
20 research, or the advancement of medical, dental, or  
21 mortuary science in accordance with all applicable laws  
22 pertaining to the final disposition of human remains;

23 (2) documentation that the donor has been informed of  
24 the obligation of the licensee as to the proper disposal of  
25 the human body or human body part;

1           (3) the date and time of the donation or transfer from  
2 the donor;

3           (4) the name of the person, including any trade or  
4 business name, who transferred the human body or human body  
5 part to the licensee, if applicable;

6           (5) the full name and most recent address of the donor;

7           (6) a description of the human body or human body part  
8 being acquired or transferred;

9           (7) the medical history of the donor, including the  
10 autopsy report if any autopsy was conducted;

11           (8) the identity and address of each person who has  
12 been in possession of the human body or human body part  
13 prior to the registrant, including any funeral home,  
14 coroner, hospital, organ procurement organization, or  
15 tissue bank;

16           (9) documentation of the use and final disposition of  
17 each human body or human body part by the licensee;

18           (10) documentation of the name and address of each  
19 person to whom the licensee transfers the human body or  
20 human body part; and

21           (11) the implementation and maintenance of protocols  
22 and materials for procedures to properly screen end users.

23           (c) A licensee shall maintain the following records for 10  
24 years after the last date of tissue distribution:

25           (1) a copy or recorded consent of the donation  
26 authorization;

1           (2) a copy of the donor's death certificate and transit  
2 permit issued by the state where the death occurred;

3           (3) a copy of the donor's physical assessment and risk  
4 assessment questionnaire;

5           (4) a copy of the donor's serological results, if  
6 applicable; and

7           (5) a copy of all documentation relating to tissue  
8 recovery, storage, and distribution activities.

9           Section 65. Labeling and packaging.

10           (a) A licensee shall ensure that all human bodies and human  
11 body parts in the possession of, or transferred by, the  
12 licensee are labeled and packaged in accordance with this  
13 Section.

14           (b) Unless the Department specifies otherwise by rule, a  
15 label shall include the following:

16           (1) the proper name of the donor;

17           (2) a description of the contents of the package  
18 indicating whether it is a human body or human body parts,  
19 including a list of all human body parts;

20           (3) the name, address, and license and registration  
21 number of the person transferring the human body or human  
22 body part;

23           (4) the tissue types of the human body or human body  
24 part;

25           (5) the cause of death of the donor, if applicable and

1 known;

2 (6) serological test results, if any results exist;

3 (7) any known infectious disease agents of the human  
4 body or human body part;

5 (8) a statement about the use of personal protective  
6 equipment and universal precautions when handling a human  
7 body or human body part as required by law; and

8 (9) the statement "not for transplantation".

9 (c) Unless the Department specifies otherwise by rule, each  
10 human body or human body part under this Section shall be  
11 wrapped and packaged in a manner that:

12 (1) mitigates potential contamination and cross  
13 contamination;

14 (2) mitigates potential safety hazards;

15 (3) is sealed to prevent leakage; and

16 (4) ensures the integrity of the human body or human  
17 body part.

18 Section 75. Final disposition. A licensee shall ensure the  
19 proper final disposition of a human body, human body part, or  
20 non-transplant anatomical material, in accordance with  
21 applicable federal and State law, by:

22 (1) returning the human body, human body part,  
23 non-transplant anatomical material, or cremains to a  
24 relative or personal representative of the donor within a  
25 time frame designated by the non-transplant organ donation

1 organization at the time donation is established;

2 (2) carrying out the final disposition of the human  
3 body or human body part as set forth in Section 4 of the  
4 Cadaver Act; or

5 (3) if the licensee is releasing the human body or  
6 human body part to another institution, contracting with  
7 the institution to assume the obligations described in this  
8 Act.

9 Section 80. Violations.

10 (a) Any person, entity, officer, or administrator who  
11 violates a requirement of this Act shall be guilty of a Class 4  
12 felony.

13 (b) The Department may suspend or revoke the license of any  
14 licensee found to be in violation of this Act.

15 (c) It is a violation of this Act for any person or entity  
16 to alter or falsify any information in a label required under  
17 Section 65.

18 Section 85. General responsibilities.

19 (a) A licensee shall provide a copy of a renewed  
20 accreditation to the Department within 30 calendar days after  
21 the date of issuance.

22 (b) A licensee shall ensure that a non-transplant organ  
23 donation organization facility is in a building that provides a  
24 separate and designated area for tissue recovery.

1 (c) A licensee shall ensure policies and procedures are  
2 established, documented, and implemented that cover:

3 (1) labeling;

4 (2) packaging, including a packaging insert form that  
5 discloses the disease status of tissue to end users;

6 (3) transport;

7 (4) distribution; and

8 (5) final disposition.

9 Section 90. General plant standards; environmental  
10 services. A licensee shall ensure that a non-transplant organ  
11 donation organization:

12 (1) has preparation rooms that:

13 (A) are maintained in a clean and sanitary  
14 condition at all times;

15 (B) are only used for examining and preparing a  
16 non-transplant anatomical donation;

17 (C) contain equipment, instruments, and supplies  
18 necessary for examining and preparing a non-transplant  
19 anatomical donation and are disinfected or sterilized,  
20 as applicable, after each use to protect the health and  
21 safety of technicians and personnel members;

22 (D) have sanitary flooring, drainage, and  
23 ventilation;

24 (E) have proper and convenient receptacles for  
25 refuse, bandages, and all other waste materials; and

1 (F) are thoroughly cleansed and disinfected with a  
2 1% solution of chlorinated soda, or other suitable and  
3 effective disinfectant, immediately after examining  
4 and preparing each non-transplant anatomical material;  
5 and

6 (2) has equipment at the non-transplant organ donation  
7 organization that is:

8 (A) sufficient to support the service;

9 (B) maintained in working condition;

10 (C) maintained in a clean and sanitary condition;

11 (D) used according to the manufacturer's  
12 recommendations;

13 (E) if used during an examination or preparation of  
14 a non-transplant anatomical donation, cleaned and  
15 sanitized after every use; and

16 (F) if applicable, tested and calibrated according  
17 to the manufacturer's recommendations or, if there are  
18 no manufacturer's recommendations, according to  
19 policies and procedures approved by the Department.

20 Section 95. Transportation standards.

21 (a) If a non-transplant organ donation organization owns  
22 and maintains a vehicle for transporting non-transplant  
23 anatomical material, an administrator shall ensure that the  
24 vehicle is:

25 (1) not used for a purpose other than transporting



1 non-transplant anatomical donations and non-transplant  
2 anatomical material or conducting non-transplant organ  
3 donation organization business;

4 (2) only operated by a procurement organization  
5 technician or designated individual authorized to  
6 transport non-transplant anatomical donations or  
7 non-transplant anatomical material;

8 (3) maintained in clean and sanitary condition; and

9 (4) locked and secured at all time during transport of  
10 non-transplant anatomical donations or non-transplant  
11 anatomical material.

12 (b) If using a vehicle other than the vehicle described  
13 under subsection (a) for transporting a non-transplant  
14 anatomical donation or non-transplant anatomical material, an  
15 administrator shall ensure that the vehicle:

16 (1) is properly equipped for the transportation of  
17 non-transplant anatomical material;

18 (2) is compliant with all State and federal laws and  
19 rules pertaining to transporting humans remains; and

20 (3) if transport is by air, complies with applicable  
21 standards established by the International Air Transport  
22 Association and Transportation Security Administration.

23 (c) An administrator shall ensure that non-transplant  
24 anatomical donations and non-transplant anatomical material  
25 transported into the State have information of death  
26 documentation prior to transport.

1 Section 100. End user.

2 (a) A licensee shall establish, document, and implement  
3 policies and procedures to properly screen an end user that  
4 include:

5 (1) a written request for non-transplant anatomical  
6 material, including:

7 (A) the name, address, and affiliation of  
8 educators or research institutions accepting  
9 responsibility for the acceptance, use, and final  
10 disposition of the non-transplant anatomical material;

11 (B) a description of the intended use;

12 (C) the date and the approximate duration of  
13 non-transplant anatomical material use;

14 (D) a description of the venue in which the  
15 non-transplant anatomical material will be used and  
16 the security measures for the safe and ethical  
17 utilization of the venue;

18 (E) an assurance that precautions will be used when  
19 handling non-transplant anatomical material;

20 (F) the proposed final disposition of the  
21 non-transplant anatomical material;

22 (G) an agreement to comply with the licensee's  
23 policies, if applicable;

24 (H) an outline of proposed materials to be  
25 disseminated in connection with the use of

1 non-transplant anatomical material, if applicable; and  
2 (I) other supporting documentation that is  
3 relevant to the request; and  
4 (2) the criteria for approving requested  
5 non-transplant anatomical material for use, including:  
6 (A) the acceptability of the educator and  
7 researcher for non-transplant anatomical material  
8 utilization;  
9 (B) the appropriateness of the intended use;  
10 (C) the type of venue in which the non-transplant  
11 anatomical material will be used;  
12 (D) the proposed final disposition of the  
13 non-transplant anatomical material, unless returned to  
14 the non-transplant organ donation organization; and  
15 (E) proposed research materials.  
16 (b) A licensee shall establish, document, and implement a  
17 procedure that allows end users to request an exceptional  
18 release of non-transplant anatomical material.

19 Section 125. The State Finance Act is amended by adding  
20 Section 5.930 as follows:

21 (30 ILCS 105/5.930 new)

22 Sec. 5.930. The Public Health Licensing Fund.

23 Section 999. Effective date. This Act takes effect upon  
24 becoming law.