103RD GENERAL ASSEMBLY

State of Illinois

2023 and 2024

SB3604

Introduced 2/9/2024, by Sen. Mary Edly-Allen

SYNOPSIS AS INTRODUCED:

See Index

Creates the Consensual Non-Transplant Donation Regulation Act. Provides for licensing of non-transplant anatomical donation organizations by the Department of Public Health. Sets forth requirements for licensed non-transplant anatomical donation organizations, including application and renewal fees, penalties for failing to comply with the Act, and enforcement of the Act's provisions. Provides for deposit of licensing and renewal fees in the Public Health Licensing Fund, a special fund created in the State treasury. Provides that fines accruing from a conviction under the Act shall be paid into the common school fund of the county in which the offense was committed. Sets forth conditions under which a licensee must update a license or license application. Sets forth conditions under which the Department may deny, suspend or revoke, a license, or assess a civil penalty against a licensee. Provides for a universal donor consent form and sets forth requirements for the form. Sets forth requirements for donor records and record retention policies. Sets forth requirements for labeling and packaging the non-transplant anatomical donation. Provides for final disposition of a non-transplant anatomical donation. Sets forth general responsibilities and environmental standards for licensees. Provides for transportation standards while transporting non-transplant anatomical donations. Provides screening standards for end users by licensees. Makes conforming changes in the State Finance Act, Vital Records Act, Illinois Vehicle Code, and Illinois Anatomical Gift Act. Effective immediately.

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AN ACT concerning regulation.

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

Section 1. Short title. This Act may be cited as the
Consensual Non-Transplant 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 anatomical 10 donation organization.

"Arranger" means the individual who is talking with, 11 12 coordinating with, facilitating, or presenting the option of non-transplant anatomical donation to a potential donor, 13 14 donor's family, or responsible authorizing agent on behalf of non-transplant anatomical donation organization. 15 With а 16 regards to the Secretary of State's role in non-transplant anatomical donation under Section 6-117 of the Illinois 17 Vehicle Code, the Secretary of State shall not be considered 18 19 the arranger.

"Chain of custody documentation" means a record that establishes the continuous location and control of a dead body, body parts, or human remains, which includes: (i) the deceased's unique identifier; (ii) a list of each death care provider that came in contact with the dead body; (iii) a list of each service performed detailing the provider, location, and date; and (iv) the signature of the individual who executes final disposition.

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"Department" means the Department of Public Health.

"Director" means the Director of Public Health.

7 "Distribution" means a process that includes selection and 8 evaluation of intended use of non-transplant anatomical 9 material or a non-transplant anatomical donation, a human 10 body, or human body part for release to an education facility 11 or a research facility according to State law.

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

17 "Donor's family" means the next of kin to the donor with 18 the legal authority to consent to non-transplant anatomical 19 donation on behalf of the donor in accordance with Section 5-5 20 of the Illinois Anatomical Gift Act.

21 "End user" means the education or research institution 22 that receives the non-transplant anatomical donation from a 23 licensed non-transplant anatomical donation organization.

(1) A "primary end user" is the donor's, donor's
 family's, or the responsible authorizing agent's first in
 priority choice of an education or research institution to

receive the non-transplant anatomical material under this
 Act.

3 (2) A "secondary end user" is the donor's, donor's
4 family's, or the responsible authorizing agent's second in
5 priority choice of an education or research institution to
6 receive the non-transplant anatomical material under this
7 Act.

8 "Entity" means a non-transplant anatomical donation 9 organization that is accredited, licensed, or approved under 10 federal law or the laws of this State to engage in the 11 recovery, screening, testing, processing, distribution, or 12 storage of human bodies or body parts.

13 "Exceptional release" means non-transplant anatomical 14 material that is approved for usage before a donor 15 acceptability assessment or by a researcher requesting 16 non-transplant anatomical material that would not normally 17 meet the established acceptability criteria.

18 "Environmental services" means activities such as 19 housekeeping, laundry, facility maintenance, or equipment 20 maintenance.

21 "Final disposition" means the final disposal of 22 non-transplant anatomical material or a non-transplant 23 anatomical donation through incineration, cremation, 24 bio-cremation, burial, full depletion by virtue of a 25 particular use, or by another legal means.

26 "Education" means the use of a human body or body parts for

teaching or training individuals, including, but not limited to, medical, dental, or mortuary science students or professionals, with regard to the anatomy and characteristics of the human body, disease detection, and such other uses as may be specified by the Department by rule.

6 "Human body" means a deceased human body or non-transplant7 anatomical donation.

8 "Human body part" or "body part" means an organ, tissue, 9 eye, bone, blood vessel, or any other portion of a human body 10 that is subject to an anatomical gift or other transfer made 11 under State law. "Human body part" does not include blood 12 drawn for medical purposes or a growing cell line.

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

16 "Licensee" means a person to whom the Department has 17 issued a license to operate a non-transplant anatomical 18 donation organization.

19 "Misuse" means to use non-transplant anatomical material 20 and non-transplant anatomical donations for purposes other 21 than education or research.

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

25 "Non-transplant anatomical material" means a whole body or 26 part of a body donated for use in education or research that

1 has been prepared, packaged, labeled, and released to 2 distribution inventory.

3 "Non-transplant anatomical donation organization" means an 4 entity that is accredited, licensed, or approved under federal 5 law or State law to engage in the recovery, screening, 6 testing, processing, distribution, or storage of human bodies 7 or body parts for purposes of education, research or the 8 advancement of medical, dental, or mortuary science.

9 "Research" does not include an autopsy or examination 10 conducted as part of a criminal investigation.

11 "Responsible authorizing party" means an individual with 12 the legal authority to consent to non-transplant anatomical 13 donation on behalf of a donor in accordance with Section 5-5 of 14 the Illinois Anatomical Gift Act.

"Secondary specific use consent" means the opportunity for a donor's family or responsible authorizing agent to modify the specific use the donor, the donor's family, or responsible authorizing agent consented to in the universal donor consent form.

"Specific use" means the specified purpose, whether education or research related, consented to by the donor, the donor's family, or a responsible authorizing agent to a specified end user consented to by the donor, the donor's family, or a responsible authorizing agent within the universal donor consent form.

26 "Storage" means a designated area that contains equipment,

instruments, and supplies necessary to maintain non-transplant
 anatomical donations or non-transplant anatomical material
 until distribution or final disposition.

4 "Transfer" means to move from a non-transplant anatomical5 donation organization to an institution.

6 "Unique identifier" means providing the deceased with 7 individual identification, through tagging, numbering, QR 8 code, or other individualized means, that is affixed to the 9 dead body, the body bag, and any body part, organ, or tissue 10 separated from the deceased to be used in non-transplant 11 anatomical donation in order to prevent misidentification of 12 human remains.

"Universal donor consent form" means the legal record of a gift of non-transplant anatomical material permitting and defining acquisition and specific use of non-transplant anatomical material for education and research.

17 Section 10. License required. Except as provided by this 18 Act, no person shall open, manage, conduct, offer, maintain, 19 or advertise as а non-transplant anatomical donation organization without a valid license issued by the Department. 20 21 A non-transplant anatomical donation organization established 22 by law to conduct business in the State of Illinois that 23 acquires or transfers a human body or human body part for 24 education, research, or the advancement of medical, dental, or 25 mortuary science, and not for use in human transplantation,

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1 shall register and be licensed by the Department at such time 2 and in such manner as the Department may require. All 3 non-transplant anatomical donation organizations in existence 4 on the effective date of this Act shall obtain a valid license 5 to operate within 2 years after the adoption of rules by the 6 Department to implement this Act.

7 Section 15. Contents of license application. An applicant 8 for a license or license renewal under this Section shall 9 submit an application to the Department containing such 10 information as the Department may require by rule on the 11 activities to be carried out pursuant to licensure. Unless 12 otherwise set forth by administrative rule, the application 13 shall include:

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

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

18 (3) a list of all addresses at which the applicant 19 conducts business;

20 (4) a description of the premises and equipment used21 by the applicant;

(5) a description of the types of service provided bythe applicant;

24 (6) identification of all officers and administrators25 of the applicant;

1 (7) an attestation that the applicant will keep 2 records, including, but not limited to, the chain of 3 custody documentation, in accordance with the requirements 4 of this Act;

5 (8) an attestation that the applicant will use the 6 universal donor consent form in accordance with the 7 requirements of this Act;

8 (9) an attestation that the applicant will label and 9 package all human bodies or human body parts with a unique 10 identifier in accordance with the requirements of this 11 Act; and

12 (10) an acknowledgment that the Department will be 13 permitted to inspect the premises and records of the 14 applicant as to the items and in the manner prescribed in 15 this Act.

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

18 (a) An entity may not act as a non-transplant anatomical donation organization in this State unless the entity is 19 20 accredited and licensed by the Department as a non-transplant 21 anatomical donation organization. The entity shall apply in 22 writing to the Department on a form specified by the Director, include all information requested 23 which shall in the 24 application, and shall pay the fees prescribed by the 25 Department by rule.

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(b) The Director shall grant a license to an entity if:

2 (1) the organization is accredited by a nationally 3 recognized accrediting agency that is approved by the 4 Department and maintains full accreditation with the 5 accrediting agency; and

6 (2) the entity meets other requirements prescribed by 7 the Department by rule.

8 (c) Each non-transplant anatomical donation organization 9 applying for a license or license renewal shall pay all 10 applicable fees as prescribed by the Department by rule. All 11 fees collected for the license and license renewal of 12 non-transplant anatomical donation organizations shall be 13 deposited in the Public Health Licensing Fund, a special fund created in the State treasury, to be used by the Department for 14 the administration and enforcement of this Act. 15

16 (d) The Director may sanction, impose civil penalties on, 17 suspend the license of, or revoke the license of a non-transplant anatomical donation organization and may 18 sanction or impose civil penalties on any person who is an 19 20 owner, officer, agent, or employee of a non-transplant anatomical donation organization if the person is in or 21 22 continues to be in violation of this Act or rules adopted by 23 the Department under this Act.

(e) Any person or entity operating as a non-transplant
 anatomical donation organization without proper accreditation
 or licensure in this State shall be subject to criminal

1 prosecution and civil penalties as provided under Section 85
2 and any applicable rules.

3 Section 25. Other fees.

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

6 (b) The Department shall determine the amount of licensing 7 fees under this Act, taking into consideration, among other 8 things, the projected implementation, enforcement, and 9 inspection costs associated with this Act.

10 (c) Every fine accruing from a conviction under this Act 11 shall be paid into the common school fund of the county in 12 which the offense was committed.

Section 30. License renewal. The Department shall require that the license of an applicant be renewed by the applicant every 2 years.

16 Section 35. Change of information.

17 (a) Not later than 30 days after any change of any 18 information listed under Section 15, an applicant or licensee 19 shall notify the Department of the change in writing as 20 prescribed by the Department.

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

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(1) termination of operation, including, but not

limited to, the proposed termination date and the address and contact information for the location where the non-transplant anatomical donation organization records will be retained, if applicable;

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

7 (3) a change in the non-transplant anatomical donation
8 organization's legal name;

9 (4) a change in the legal name of a licensee, 10 including the licensee's new name; and

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

14 (c) A licensee shall notify the Department in writing no 15 later than 30 calendar days after the date of:

16 (1) a change in the non-transplant anatomical donation 17 organization's email address or mailing address, including 18 the new email address or mailing address of the 19 non-transplant anatomical donation organization;

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

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

(4) a change in the name or contact information of an
officer affiliated with the licensee, including the name

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and contact information of the new officer.

(d) If the Department receives notification of termination
of operation, the Department shall void the licensee's license
to operate a non-transplant anatomical donation organization
on the termination date specified by the licensee.

6 (e) If the Department receives notification of a proposed 7 modification that alters the area for tissue recovery, the 8 Department:

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

10 (2) shall issue to the licensee an amended license 11 that incorporates the modification and retains the 12 expiration date of the existing license, if the 13 non-transplant anatomical donation organization is in 14 compliance.

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

(g) If the Department receives notice of a change in the legal name of a licensee, the Department shall void the licensee's license to operate and issue a new license to operate with the licensee's changed legal name.

(h) If the Department receives notice for a change in the address of a non-transplant anatomical donation organization, the Department shall require and review an amended application for a license. - 13 - LRB103 37007 CES 69616 b

1 (i) An individual or business organization planning to 2 assume operation of an existing non-transplant anatomical 3 donation organization shall obtain a new license before 4 beginning operation.

- 5 Section 40. Denial; suspension; revocation; enforcement.
- 6 (a) The Department may:
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deny a license;

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(2) suspend or revoke a license; or

(3) assess a civil penalty against a licensee.

10 (b) The Department may deny an application or suspend or 11 revoke a license to operate a non-transplant anatomical 12 donation organization if:

13 (1) an applicant or licensee does not meet the 14 application requirements;

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

17 (3) a licensee does not correct a deficiency 18 identified during an inspection according to the plan of 19 correction;

20 (4) an applicant or licensee provides false or 21 misleading information as part of an application or 22 inspection; or

(5) the nature or number of violations revealed by any
 type of inspection or investigation of a non-transplant
 anatomical donation organization pose a direct risk to the

life, health, or safety of individuals on the premises or
 the public at large.

3 (c) In determining which action is appropriate, the 4 Department may consider:

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(1) repeated violations of statutes or rules;

6 (2) a pattern of violations;

(3) the severity of violations; and

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(4) the number of violations.

9 (d) The Department may suspend or revoke a non-transplant 10 anatomical donation organization's license if the Department 11 receives notice from the organization's accrediting body that 12 the organization's accreditation has been suspended or 13 revoked. An applicant or licensee may seek administrative 14 review of the Department's determination.

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

Section 50. Universal donor consent form; non-transplant anatomical donation. The Department shall create a universal donor consent form that allows a donor, the donor's family, or responsible authorizing agent to consent to non-transplant anatomical donation.

(1) The universal donor consent form shall include:(A) the name of the donor and name of the donor's

1 family member or responsible authorizing agent, if 2 applicable;

3 (B) the contact information for donor, donor's
4 family, or responsible authorizing agent;

5 (C) the definitions of "education" and "research" 6 as provided in Section 5 of this Act;

7 (D) the specific use consented to by the donor,
8 donor's family, or responsible authorizing agent of
9 the non-transplant anatomical material;

10 (E) uses of non-transplant anatomical material 11 that the donor, donor's family, or responsible 12 authorizing agent does not consent to;

(F) the end user or list of end users the donor,
donor's family, or authorizing agent consents to;

(G) a description of how, if the specific use consented to by the donor, donor's family, or responsible authorizing agent cannot be executed, the donor's family or responsible authorizing agent shall be contacted to execute secondary specific use consent in accordance with the procedure provided in Section 60 of this Act;

(H) the contact information for the individual
with the authority to execute secondary specific use
consent;

(I) an explanation of how remains would be
 returned, if applicable;

1 (J) the name, phone number, and license number for 2 the arranger;

(K) a statement that provides the donor, donor's family, or responsible authorizing agent with information regarding who to direct questions to;

6 (L) a statement that the non-transplant anatomical 7 material will be treated with dignity at all times; 8 and

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

12 (2) The universal donor consent form shall direct a 13 potential donor, the donor's family, or responsible 14 authorizing agent to websites that:

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(A) answer frequently asked questions;

(B) allow a potential donor, the donor's family,
or responsible authorizing agent to verify whether a
specific non-transplant anatomical donation
organization holds a valid license with the
Department; and

(C) provide a resource to contact if the donor,
the donor's family, or responsible authorizing agent
alleges a violation of this Act.

24 Section 55. Specific use.

25 (a) The Department shall establish rules, regarding the

1 donor's, donor's family's, or responsible authorizing agent's 2 consented specific use of the non-transplant anatomical 3 material, in accordance with the procedures provided for in 4 this Section.

5 (b) When the donor, donor's family, or responsible 6 authorizing agent consent to the gift of a non-transplant 7 anatomical donation, the donor, donor's family, or responsible 8 authorizing agent shall be provided the opportunity to consent 9 to the specific use of the non-transplant anatomical material.

10 (c) On the universal donor consent form, the donor, 11 donor's family, or responsible authorizing agent shall be 12 permitted to consent to the non-transplant anatomical donation 13 for the following purposes:

14 (1) education purposes, including, but not limited to,15 the training of new doctors;

16 (2) research purposes, including, but not limited to, 17 military advancements, vehicle safety, specific medical 18 research such as curing a specified ailment held by the 19 donor; or

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(3) a specific education or research purpose.

(d) On the universal donor consent form, the donor, donor's family, or responsible authorizing agent shall be permitted to specify that the donor, donor's family, or responsible authorizing agent does not consent to the non-transplant anatomical donation for the following purposes: (1) education purposes, including, but not limited to,

1 the training of new doctors; or

2 (2) research purposes, including, but not limited to, 3 military advancements, vehicle safety, or specific medical 4 research such as curing a specified ailment held by the 5 donor; or

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(3) a specific education or research purpose.

7 (e) On the universal donor consent form, the donor, 8 donor's family, or responsible authorizing agent shall be 9 permitted to specify a primary end user who the donor, donor's 10 family, or responsible authorizing agent consents may receive 11 the donor's non-transplant anatomical material. The donor, 12 donor's family, or responsible authorizing agent shall be permitted to specify a secondary end user who the donor, 13 14 donor's family, or responsible authorizing agent consents may 15 receive the donor's non-transplant anatomical material if the 16 primary end user is unable to accept the non-transplant 17 anatomical donation for any reason, including that the primary end user cannot satisfy the donor, donor's family, 18 or 19 responsible authorizing agent's consented purpose in 20 subsections (c) and (d) of this Section.

(f) If the specific use, including the consented purpose and end user, that the donor, donor's family, or responsible authorizing agent has consented to cannot be satisfied for any reason, the Department shall establish rules that require a licensee under this Act to contact the donor, donor's family, or responsible authorizing agent to execute secondary specific use consent in accordance with Section 60 of this Act. At this time, the licensee is required to notify the donor's family or responsible authorizing agent that if the consented secondary specific use cannot be satisfied, the donor's family or responsible authorizing agent is responsible for final disposition as the donation will not be accepted.

7 (g) If the licensee can honor the secondary specific use 8 consented to by the donor's family or responsible authorizing 9 agent, the licensee may transfer the non-transplant anatomical 10 material to the end user.

11 (h) If the licensee cannot satisfy the secondary specific 12 use consented to by the donor's family or responsible authorizing agent, the licensee may 13 not transfer the non-transplant anatomical material to an end user. 14 The 15 licensee shall preserve the decedent's body and no donation 16 shall be made.

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Section 60. Secondary specific use consent.

(a) The Department shall establish rules regarding the
donor's, donor's family's, or responsible authorizing agent's
secondary specific use consent of the non-transplant
anatomical material, in accordance with the procedures
provided for in this Section.

(b) If the specific use, including the consented purpose and end user, that the donor, donor's family, or responsible authorizing agent has consented to cannot be satisfied for any

1 reason, the donor's family or responsible authorizing agent 2 shall be given an opportunity from the licensee to provide 3 secondary specific use consent.

(c) A licensee shall notify the donor's family or 4 5 responsible authorizing agent that the specific use consented to in the universal donor consent form cannot be satisfied. 6 7 The licensee may provide the donor's family or responsible 8 authorizing agent with options for secondary specific use 9 consent based on the current demand for non-transplant 10 anatomical material for specific uses and specific end users. 11 The licensee may provide the donor's family or responsible 12 authorizing agent with the ability to provide secondary 13 specific use consent for any education or research purpose to any end user. The licensee shall notify the donor's family or 14 15 responsible authorizing agent that if the secondary specific 16 use consented to by the donor's family or responsible 17 authorizing agent cannot be satisfied, the licensee shall preserve the body and no donation shall be made. 18

(d) If the licensee can honor the secondary specific use consented to by the donor's family or responsible authorizing agent, the licensee may transfer the non-transplant anatomical material to the end user.

(e) If the licensee cannot satisfy the secondary specific use consented to by donor's family or responsible authorizing agent, the licensee may not transfer the non-transplant anatomical material to an end user. The licensee shall

1 preserve the decedent's body and no donation shall be made.

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Section 65. Donor records.

3 (a) A non-transplant anatomical donation organization 4 shall maintain a legible, reproducible record for each donor 5 from whom it releases non-transplant anatomical material for 6 at least 10 years after the date of final disposition.

7 (b) To ensure traceability of a non-transplant anatomical 8 donation and non-transplant anatomical material, a 9 non-transplant anatomical donation organization shall:

10 (1) document each procedure performed on a 11 non-transplant anatomical donation and non-transplant 12 anatomical material related to processing and storing 13 non-transplant anatomical donations and non-transplant 14 anatomical material;

15 (2) for each document created under paragraph (1), 16 include:

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(A) the donor's unique identifier;

(B) the date, time, and location for eachprocedure completed; and

20 (C) the name of the technician who performed the 21 procedure; and

(3) submit or have a contracted funeral home submit
 information required to register the death of a
 non-transplant anatomical donation within 7 calendar days
 after receiving the non-transplant anatomical donation, if

1	applicable.
2	(c) A donor record shall be:
3	(1) confidential;
4	(2) kept in a location with controlled access;
5	(3) stored in a manner to prevent unauthorized access;
6	and
7	(4) maintained in a manner to preserve the donor
8	record's completeness and accuracy.
9	(d) A donor record shall include at least the following:
10	(1) donor information that includes:
11	(A) the donor's name;
12	(B) the donor's unique identifier;
13	(C) the donor's date of birth and date of death;
14	and
15	(D) the name and contact information of the person
16	responsible for a donor's anatomical gift, if
17	applicable;
18	(2) an executed universal consent form that contains
19	the consented to specific use of the non-transplant
20	anatomical material;
21	(3) a secondary specific use consent, if applicable;
22	(4) a document of authorization, which is a legal
23	record of the gift, to take place postmortem, permitting
24	and defining the scope of the postmortem acquisition and
25	use of non-transplant anatomical material for education
26	and research, signed or otherwise recorded by the

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1 authorizing person; 2 (5) a document of anatomical gift, which is the 3 donor's legal record of the gift of non-transplant anatomical material permitting and defining the scope of 4 5 the postmortem acquisition and use of non-transplant anatomical material for education and research; 6 7 (6) an authorization of gift, which must be signed or 8 otherwise recorded by an individual authorized by law to 9 make a gift during the donor's lifetime; 10 (7) the donor's death record: (8) the human remains release form, if applicable; 11 12 (9) information for a death record, if applicable for 13 transporting human remains into the State; 14 (10) a disposition transit permit, if applicable; 15 (11) a medical examiner's release of information, if 16 applicable; 17 (12) chain of custody documentation; (13) medical records, including: 18 19 (A) a donor's physical assessment; 20 (B) a risk assessment questionnaire; 21 (C) pathology and laboratory testing and reports; 22 (D) physician summaries, if applicable; 23 (E) transfusion or infusion information, if 24 applicable; and 25 (F) plasma dilution calculations if applicable; 26 (14) information from the donor referral source;

1	(15) donor eligibility;
2	(16) a donor acceptability assessment;
3	(17) a physical assessment questionnaire;
4	(18) documentation related to distribution;
5	(19) serological results, if applicable;
6	(20) a cremation authorization document;
7	(21) documentation related to non-transplant
8	anatomical material recovery, storage, and distribution
9	activities;
10	(22) final disposition documentation, including all
11	records demonstrating chain of custody; and
12	(23) documentation of the suspected misuse or harm to
13	the donor, if any.
14	(e) A donor's record shall be accessible to:
15	(1) an agent legally authorized to have access, or an
16	individual designated at the time a donor gives consent;
17	(2) an individual appointed by a court or authorized
18	by State law;
19	(3) an individual of a non-transplant anatomical
20	donation organization as identified by policies and
21	procedures;
22	(4) an individual from an approved accrediting body,
23	if applicable; and
24	(5) an individual from the Department or other
25	regulatory agency authorized by State or federal laws or
26	rules adopted by the Department.

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(f) Except for a donor record that must be maintained for a 1 2 period of 10 years after final disposition, a non-transplant 3 anatomical donation organization shall maintain documentation required under this Act for at least 3 years after the date of 4 5 the documentation and shall provide copies of the 6 documentation to the Department for review upon request.

7 Section 70. Recordkeeping.

8 (a) A licensee shall compile or maintain a record for each 9 case in which the licensee acquires a human body, human body 10 part, or non-transplant anatomical donation.

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

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

19 (2) documentation that the donor has been informed of
20 the obligation of the licensee as to the proper disposal
21 of the human body or human body part;

(3) the date and time of the donation or transfer fromthe donor;

24 (4) the name of the person, including any trade or25 business name, who transferred the human body or human

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body part to the licensee, if applicable;

2 (5) the full name and most recent address of the 3 donor;

4 (6) a description of the human body or human body part
5 being acquired or transferred;

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

8 (8) the identity and address of each person who has 9 been in possession of the human body or human body part 10 prior to the registrant, including any funeral home, 11 coroner, hospital, organ procurement organization, or 12 tissue bank;

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

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

18 (11) the implementation and maintenance of protocols19 and materials for procedures to properly screen end users.

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

(1) a copy of recorded consent of the donationauthorization;

(2) a copy of the donor's death certificate and transit permit issued by the state where the death occurred; SB3604 - 27 - LRB103 37007 CES 69616 b

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

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

5 (5) a copy of all documentation relating to tissue 6 recovery, storage, and distribution activities.

7 Section 75. Labeling and packaging.

8 (a) A licensee shall ensure that all human bodies and 9 human body parts in the possession of, or transferred by, the 10 licensee are labeled and packaged in accordance with this 11 Section.

(b) Unless the Department specifies otherwise by rule, all anatomical material in a licensee's possession shall be affixed with a unique identifier. Each body part, organ, or tissue of the deceased that is separated from the body shall have its own additional identification that corresponds to the unique identifier of the deceased.

18 (c) A licensee shall ensure the unique identifier affixed 19 to the anatomical materials or the packaging of the anatomical 20 materials corresponds to the donor's file, which includes the 21 following information:

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(1) the proper name of the donor;

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

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(3) the name, address, and license and registration 1 2 number of the person transferring the human body or human 3 body part; (4) the tissue types of the human body or human body 4 5 part; 6 (5) the cause of death of the donor, if applicable and 7 known; 8 (6) serological test results, if any results exist; 9 (7) any known infectious disease agents of the human 10 body or human body part; 11 (8) a statement about the use of personal protective 12 equipment and universal precautions when handling a human 13 body or human body part as required by law; and (9) the statement "not for transplantation". 14 15 (d) Unless the Department specifies otherwise by rule, 16 each human body or human body part under this Section shall be 17 wrapped and packaged in a manner that: mitigates potential contamination 18 (1)and cross 19 contamination: 20 (2) mitigates potential safety hazards; 21 (3) is sealed to prevent leakage; and 22 (4) ensures the integrity of the human body or human 23 body part. 24 (e) The Department shall enforce the unique identifier 25 requirement on all licensees under its jurisdiction that are 26 required to fulfill this requirement.

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Section 80. Final disposition. A licensee shall ensure the proper final disposition of a human body, human body part, or non-transplant anatomical material, in accordance with applicable federal and State law, by:

5 (1) returning the human body, human body part, 6 non-transplant anatomical material, or cremains to the 7 donor's family or responsible authorizing agent of the 8 donor within a time frame designated by the non-transplant 9 anatomical donation organization at the time donation is 10 established;

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

14 (3) if the licensee is releasing the human body or 15 human body part to another institution, contracting with 16 the institution to assume the obligations described in 17 this Act.

18 Section 85. Violations.

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

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

24 (c) It is a violation of this Act for any person or entity

to alter or falsify any information on a label required under
 Section 75.

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Section 90. General responsibilities.

4 (a) A licensee shall provide a copy of a renewed
5 accreditation to the Department within 30 calendar days after
6 the date of issuance.

7 (b) A licensee shall ensure that a non-transplant 8 anatomical donation organization facility is in a building 9 that provides a separate and designated area for tissue 10 recovery.

11 (c) A licensee shall ensure policies and procedures are 12 established, documented, and implemented that cover:

13 (1) labeling;

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

- 16 (3) transport;
- 17 (4) distribution; and
- 18 (5) final disposition.

Section 95. General plant standards; environmental services. A licensee shall ensure that a non-transplant anatomical donation organization:

22 (1) has preparation rooms that:

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

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

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

8 (D) have sanitary flooring, drainage, and 9 ventilation;

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

12 (F) are thoroughly cleansed and disinfected with a 13 1% solution of chlorinated soda, or other suitable and 14 effective disinfectant, immediately after examining 15 and preparing each non-transplant anatomical material; 16 and

17 (2) has equipment at the non-transplant anatomical18 donation organization that is:

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(A) sufficient to support the service;

(B) maintained in working condition;

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

(D) used according to the manufacturer'srecommendations;

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

1 (F) if applicable, tested and calibrated according 2 to the manufacturer's recommendations or, if there are 3 no manufacturer's recommendations, according to 4 policies and procedures approved by the Department.

5 Section 100. Transportation standards.

6 (a) If a non-transplant anatomical donation organization 7 owns and maintains a vehicle for transporting non-transplant 8 anatomical material, an administrator shall ensure that the 9 vehicle is:

10 (1) not used for a purpose other than transporting 11 non-transplant anatomical donations and non-transplant 12 anatomical material or conducting non-transplant 13 anatomical donation organization business;

14 (2) only operated by a procurement organization 15 technician or designated individual authorized to 16 transport non-transplant anatomical donations or non-transplant anatomical material; 17

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(3) maintained in clean and sanitary condition; and

(4) locked and secured at all times during transport
 of non-transplant anatomical donations or non-transplant
 anatomical material.

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

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

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

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

8 (c) An administrator shall ensure that non-transplant 9 anatomical donations and non-transplant anatomical material 10 transported into the State have information of death 11 documentation prior to transport.

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Section 105. End user.

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

16 (1) a written request for non-transplant anatomical 17 material, including:

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

(B) a description of the intended use;

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

25 (D) a description of the venue in which the

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1 non-transplant anatomical material will be used and 2 the security measures for the safe and ethical 3 utilization of the venue;

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

6 (F) the proposed final disposition of the 7 non-transplant anatomical material;

8 (G) an agreement to comply with the licensee's9 policies, if applicable;

10(H) an outline of proposed materials to be11disseminated in connection with the use of12non-transplant anatomical material, if applicable; and

(I) other supporting documentation that isrelevant to the request; and

15 (2) the criteria for approving requested16 non-transplant anatomical material for use, including:

17 (A) the acceptability of the educator and
18 researcher for non-transplant anatomical material
19 utilization;

(B) the appropriateness of the intended use;

(C) the type of venue in which the non-transplant anatomical material will be used; a licensee shall determine that a hotel or other building held out to the public to be a place where lodging is offered for consideration to travelers and guests is not a suitable venue for the use of non-transplant SB3604 - 35 - LRB103 37007 CES 69616 b

1 anatomical material.

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2 (D) the proposed final disposition of the 3 non-transplant anatomical material, unless returned to 4 the non-transplant anatomical donation organization; 5 and

(E) proposed research materials.

7 (b) A licensee shall establish, document, and implement a
8 procedure that allows end users to request an exceptional
9 release of non-transplant anatomical material.

Section 900. The State Finance Act is amended by adding Section 5.1015 as follows:

12 (30 ILCS 105/5.1015 new)

13 <u>Sec. 5.1015. The Public Health Licensing Fund.</u>

Section 905. The Vital Records Act is amended by changing Sections 1 and 21.7 as follows:

16 (410 ILCS 535/1) (from Ch. 111 1/2, par. 73-1)

Sec. 1. As used in this Act, unless the context otherwise requires:

(1) "Vital records" means records of births, deaths, fetal
 deaths, marriages, dissolution of marriages, and data related
 thereto.

22 (2) "System of vital records" includes the registration,

collection, preservation, amendment, and certification of
 vital records, and activities related thereto.

3 (3) "Filing" means the presentation of a certificate,
4 report, or other record provided for in this Act, of a birth,
5 death, fetal death, adoption, marriage, or dissolution of
6 marriage, for registration by the Office of Vital Records.

7 (4) "Registration" means the acceptance by the Office of 8 Vital Records and the incorporation in its official records of 9 certificates, reports, or other records provided for in this 10 Act, of births, deaths, fetal deaths, adoptions, marriages, or 11 dissolution of marriages.

12 "Live birth" means the complete expulsion (5) or 13 extraction from its mother of a product of human conception, 14 irrespective of the duration of pregnancy, which after such 15 separation breathes or shows any other evidence of life such 16 as beating of the heart, pulsation of the umbilical cord, or 17 definite movement of voluntary muscles, whether or not the umbilical cord has been cut or the placenta is attached. 18

19 (6) "Fetal death" means death prior to the complete 20 expulsion or extraction from the uterus of a product of human conception, irrespective of the duration of pregnancy, and 21 22 which is not due to an abortion as defined in Section 1-10 of 23 the Reproductive Health Act. The death is indicated by the 24 fact that after such separation the fetus does not breathe or 25 show any other evidence of life such as beating of the heart, 26 pulsation of the umbilical cord, or definite movement of

1 voluntary muscles.

2 (7) "Dead body" means a lifeless human body or parts of
3 such body or bones thereof from the state of which it may
4 reasonably be concluded that death has occurred.

5 (8) "Final disposition" means the burial, cremation, or 6 other disposition of a dead human body or fetus or parts 7 thereof.

8 (9) "Physician" means a person licensed to practice 9 medicine in Illinois or any other state.

10 (10) "Institution" means any establishment, public or 11 private, which provides in-patient medical, surgical, or 12 diagnostic care or treatment, or nursing, custodial, or 13 domiciliary care to 2 or more unrelated individuals, or to 14 which persons are committed by law.

15 (11) "Department" means the Department of Public Health of16 the State of Illinois.

17 (12) "Director" means the Director of the Illinois18 Department of Public Health.

19 (13) "Licensed health care professional" means a person 20 licensed to practice as a physician, advanced practice 21 registered nurse, or physician assistant in Illinois or any 22 other state.

(14) "Licensed mental health professional" means a person who is licensed or registered to provide mental health services by the Department of Financial and Professional Regulation or a board of registration duly authorized to register or grant licenses to persons engaged in the practice of providing mental health services in Illinois or any other state.

4 (15) "Intersex condition" means a condition in which a 5 person is born with a reproductive or sexual anatomy or 6 chromosome pattern that does not fit typical definitions of 7 male or female.

8 (16) "Homeless person" means an individual who meets the 9 definition of "homeless" under Section 103 of the federal 10 McKinney-Vento Homeless Assistance Act (42 U.S.C. 11302) or an 11 individual residing in any of the living situations described 12 in 42 U.S.C. 11434a(2).

13 (17) "Advanced practice registered nurse" means: (i) an 14 advanced practice registered nurse with full practice 15 authority; or (ii) an advanced practice registered nurse with 16 a collaborative agreement with a physician who has delegated 17 the completion of death certificates.

18 (18) "Certifying health care professional" means a 19 physician, physician assistant, or advanced practice 20 registered nurse.

(19) "Physician assistant" means a physician assistant who practices in accordance with a written collaborative agreement that includes the completion of death certificates.

(20) "Unique identifier" means providing the deceased with
 individual identification, through tagging, numbering, QR
 code, or other individualized means, that is affixed to the

dead body, the body bag, and any body part, organ, or tissue separated from the deceased to be used in non-transplant anatomical donation in order to prevent misidentification of human remains as described in the Consensual Non-Transplant Donation Regulation Act. (Source: P.A. 101-13, eff. 6-12-19; 102-257, eff. 1-1-22;

7 102-844, eff. 1-1-23.)

8

(410 ILCS 535/21.7)

9 Sec. 21.7. Temporary removal of a dead body. No permit for 10 transportation signed by the local registrar is required prior 11 to transporting a dead human body out of the State of Illinois, 12 at the direction of a federally designated organ procurement organization, for the purpose of organ or tissue donation. The 13 14 dead human body being transported for the purpose of organ or 15 tissue donation shall be accompanied by a self-issued permit 16 in accordance with rules adopted by the Department of Public Health. The dead human body being transported shall have the 17 18 deceased's unique identifier affixed to the deceased, the body bag, and any body part, organ, or tissue separated from the 19 20 deceased to be used in non-transplant anatomical donation. 21 This self-issued permit shall be completed bv an 22 Illinois-licensed funeral director embalmer and or director and 23 Illinois-licensed funeral shall serve as 24 notification to the county medical examiner or coroner of the 25 jurisdiction or county in which the death occurred that the

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dead human body is being transported out of Illinois for a 1 2 period not to exceed 36 hours. This Section applies only to 3 instances in which the dead human body is to be returned to Illinois prior to disposition. This Section does not affect 4 5 any rights or responsibilities held by county medical examiners or coroners under the Local Governmental 6 and 7 Governmental Employees Tort Immunity Act. The Department of 8 Public Health shall adopt rules to implement this Section.

9 (Source: P.A. 99-262, eff. 1-1-16.)

Section 910. The Illinois Vehicle Code is amended by changing Section 6-117 as follows:

12 (625 ILCS 5/6-117) (from Ch. 95 1/2, par. 6-117)

13 Sec. 6-117. Records to be kept by the Secretary of State.

(a) The Secretary of State shall file every application
for a license or permit accepted under this Chapter, and shall
maintain suitable indexes thereof. The records of the
Secretary of State shall indicate the action taken with
respect to such applications.

(b) The Secretary of State shall maintain appropriate records of all licenses and permits refused, cancelled, disqualified, revoked, or suspended and of the revocation, suspension, and disqualification of driving privileges of persons not licensed under this Chapter, and such records shall note the reasons for such action.

The Secretary of State shall maintain appropriate 1 (C) 2 records of convictions reported under this Chapter. Records of 3 conviction may be maintained in a computer processible medium.

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(d) The Secretary of State may also maintain appropriate 5 records of any crash reports received.

6 (e) The Secretary of State shall also maintain appropriate 7 records of any disposition of supervision or records relative to a driver's referral to a driver remedial or rehabilitative 8 9 program, as required by the Secretary of State or the courts. 10 Such records shall only be available for use by the Secretary, 11 the driver licensing administrator of any other state, law 12 enforcement agencies, the courts, and the affected driver or, upon proper verification, such affected driver's attorney. 13

(f) The Secretary of State shall also maintain or contract 14 15 to maintain appropriate records of all photographs and 16 signatures obtained in the process of issuing any driver's 17 license, permit, or identification card. The record shall be confidential and shall not be disclosed except to those 18 entities listed under Section 6-110.1 of this Code. 19

(g) The Secretary of State may establish a First Person 20 21 Consent organ and tissue donor registry in compliance with 22 subsection (b-1) of Section 5-20 of the Illinois Anatomical 23 Gift Act, as follows:

(1) The Secretary shall offer, to each applicant for 24 25 or renewal of a driver's license issuance or 26 identification card who is 16 years of age or older, the

1 opportunity to have his or her name included in the First 2 Person Consent organ and tissue donor registry. The 3 Secretary must advise the applicant or licensee that he or she is under no compulsion to have his or her name included 4 5 in the registry. An individual who agrees to having his or 6 her name included in the First Person Consent organ and 7 tissue donor registry has given full legal consent to the 8 donation of any of his or her organs or tissue upon his or 9 her death. A brochure explaining this method of executing 10 an anatomical gift must be given to each applicant for 11 issuance or renewal of а driver's license or 12 identification card. The brochure must advise the 13 applicant or licensee (i) that he or she is under no 14 compulsion to have his or her name included in this 15 registry and (ii) that he or she may wish to consult with 16 family, friends, or clergy before doing so.

17 (2) The Secretary of State may establish additional 18 methods by which an individual may have his or her name 19 included in the First Person Consent organ and tissue 20 donor registry.

21 (2.5) Not later than 2 years after the effective date 22 of this amendatory Act of the 103rd General Assembly, the 23 Secretary of State shall provide each applicant under this 24 Section the universal donor consent form established by 25 the Department of Public Health in Section 50 of the 26 Consensual Non-Transplant Donation Regulation Act. - 43 - LRB103 37007 CES 69616 b

(3) When an individual has agreed to have his or her 1 2 name included in the First Person Consent organ and tissue 3 donor registry, the Secretary of State shall note that agreement in the First Person consent organ and tissue 4 5 donor registry. Representatives of federally designated 6 organ procurement agencies and tissue banks and the 7 offices of Illinois county coroners and medical examiners 8 may inquire of the Secretary of State whether a potential 9 organ donor's name is included in the First Person Consent 10 organ and tissue donor registry, and the Secretary of 11 State may provide that information to the representative.

(4) An individual may withdraw his or her consent to be listed in the First Person Consent organ and tissue donor registry maintained by the Secretary of State by notifying the Secretary of State in writing, or by any other means approved by the Secretary, of the individual's decision to have his or her name removed from the registry.

19 (5) The Secretary of State may undertake additional
20 efforts, including education and awareness activities, to
21 promote organ and tissue donation.

(6) In the absence of gross negligence or willful
misconduct, the Secretary of State and his or her
employees are immune from any civil or criminal liability
in connection with an individual's consent to be listed in
the organ and tissue donor registry.

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1 (Source: P.A. 102-982, eff. 7-1-23.)

2 Section 915. The Illinois Anatomical Gift Act is amended 3 by changing Sections 1-10, 5-5, 5-12, 5-20, 5-25, 5-27, and 4 5-47 and by adding Section 5-6 as follows:

5 (755 ILCS 50/1-10) (was 755 ILCS 50/2)

6 Sec. 1-10. Definitions. <u>In this Act:</u>

7 "Close friend" means any person 18 years of age or older 8 who has exhibited special care and concern for the decedent 9 and who presents an affidavit to the decedent's attending 10 physician, or the hospital administrator or his or her 11 designated representative, stating that he or she (i) was a 12 close friend of the decedent, (ii) is willing and able to authorize the donation, and (iii) maintained such regular 13 14 contact with the decedent as to be familiar with the 15 decedent's health and social history, and religious and moral beliefs. The affidavit must also state facts and circumstances 16 17 that demonstrate that familiarity.

18 "Death" means, for the purposes of the Act, when, 19 according to accepted medical standards, there is (i) an 20 irreversible cessation of circulatory and respiratory 21 functions; or (ii) an irreversible cessation of all functions 22 of the entire brain, including the brain stem.

23 "Decedent" means a deceased individual and includes a 24 stillborn infant or fetus.

"Disinterested witness" means a witness other than the spouse, child, parent, sibling, grandchild, grandparent, or guardian of the individual who makes, amends, revokes, or refuses to make an anatomical gift, or another adult who exhibited special care and concern for the individual. The term does not include a person to whom an anatomical gift could pass under Section 5-12.

8 "Document of gift" means a donor card or other record used 9 to make an anatomical gift. The term includes a donor 10 registry.

"Donee" means the individual designated by the donor as the intended recipient or an entity which receives the anatomical gift, including, but not limited to, a hospital; an accredited medical school, dental school, college, or university; an organ procurement organization; an eye bank; a tissue bank; for research or education, a non-transplant anatomic bank; or other appropriate person.

18 "Donor" means an individual whose body or part is the 19 subject of an anatomical gift.

20 "Hospital" means a hospital licensed, accredited or 21 approved under the laws of any state; and includes a hospital 22 operated by the United States government, a state, or a 23 subdivision thereof, although not required to be licensed 24 under state laws.

25 "Non-transplant anatomic bank" means any facility or 26 program operating or providing services in this State that is

accredited by the American Association of Tissue Banks and 1 2 that is involved in procuring, furnishing, or distributing 3 whole bodies or parts for the purpose of medical education. For purposes of this Section, a non-transplant anatomic bank 4 5 operating under the auspices of a hospital, accredited medical 6 school, dental school, college or university, or federally 7 designated organ procurement organization is not required to 8 be accredited by the American Association of Tissue Banks.

9 <u>"Non-transplant anatomical donation organization" means an</u> 10 <u>entity that is licensed under the Consensual Non-Transplant</u> 11 <u>Donation Regulation Act to engage in the recovery, screening,</u> 12 <u>testing, processing, distribution, or storage of human bodies</u> 13 <u>or body parts for purposes of education, research, or the</u> 14 <u>advancement of medical, dental, or mortuary science.</u>

15 "Organ" means a human kidney, liver, heart, luna, pancreas, small bowel, or other transplantable vascular body 16 17 determined by the Organ Procurement and part as Transplantation Network, as periodically selected by the U.S. 18 19 Department of Health and Human Services.

20 "Organ procurement organization" means the organ 21 procurement organization designated by the Secretary of the 22 U.S. Department of Health and Human Services for the service 23 area in which a hospital is located, or the organ procurement organization for which the Secretary of the U.S. Department of 24 25 Health and Human Services has granted the hospital a waiver pursuant to 42 U.S.C. 1320b-8(a). 26

"Part" means organs, tissues, eyes, bones, arteries,
 blood, other fluids and any other portions of a human body.

3 "Person" means an individual, corporation, government or 4 governmental subdivision or agency, business trust, estate, 5 trust, partnership or association or any other legal entity.

6 "Physician" or "surgeon" means a physician or surgeon 7 licensed or authorized to practice medicine in all of its 8 branches under the laws of any state.

9 "Procurement organization" means an organ procurement 10 organization or a tissue bank.

11 "Reasonably available for the giving of consent or 12 refusal" means being able to be contacted by a procurement 13 organization without undue effort and being willing and able 14 to act in a timely manner consistent with existing medical 15 criteria necessary for the making of an anatomical gift.

16 "Recipient" means an individual into whose body a donor's 17 part has been or is intended to be transplanted.

18 "State" includes any state, district, commonwealth, 19 territory, insular possession, and any other area subject to 20 the legislative authority of the United States of America.

21 "Technician" means an individual trained and certified to 22 remove tissue, by a recognized medical training institution in 23 the State of Illinois.

24 "Tissue" means eyes, bones, heart valves, veins, skin, and 25 any other portions of a human body excluding blood, blood 26 products or organs.

"Tissue bank" means any facility or program operating in 1 2 Illinois that is accredited by the American Association of 3 Tissue Banks, the Eye Bank Association of America, or the Association of Organ Procurement Organizations and is involved 4 5 in procuring, furnishing, donating, or distributing corneas, 6 bones, or other human tissue for the purpose of injecting, 7 transfusing, or transplanting any of them into the human body 8 or for the purpose of research or education. "Tissue bank" 9 does not include a licensed blood bank. For the purposes of 10 this Act, "tissue" does not include organs or blood or blood 11 products.

12 (Source: P.A. 98-172, eff. 1-1-14; 98-756, eff. 7-16-14.)

13 (755 ILCS 50/5-5) (was 755 ILCS 50/3)

14 Sec. 5-5. Persons who may execute an anatomical gift.

(a) An anatomical gift of a donor's body or part that is to be carried out upon the donor's death may be made during the life of the donor for the purpose of transplantation, therapy, research, or education by:

19 (1)the donor, if the donor is an adult, an emancipated minor, or 16 or 17 years of age and registered 20 21 in the First Person Consent organ and tissue donor 22 registry under subsection (g) of Section 6-117 of the 23 Illinois Vehicle Code if the First Person Consent was 24 executed prior to 2 years after the effective date of this 25 amendatory Act of the 103rd General Assembly;

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1	(1.5) the donor, if the donor is an adult, an
2	emancipated minor, or 16 or 17 years of age and registered
3	in the First Person Consent organ and tissue donor
4	registry under subsection (g) of Section 6-117 of the
5	Illinois Vehicle Code and executed the universal donor
6	consent form in accordance with Section 50 of the
7	Consensual Non-Transplant Donation Regulation Act, if the
8	First Person Consent was executed later than 2 years after
9	the effective date of this amendatory Act of the 103rd
10	General Assembly;

11 (2) an agent of the donor, unless the power of 12 attorney for health care or other record prohibits the 13 agent from making an anatomical gift;

14 (3) a parent of the donor, if the donor is an15 unemancipated minor; or

16

(4) the donor's guardian.

17 (b) If no gift has been executed under subsection (a), an anatomical gift of a decedent's body or part for the purpose of 18 19 transplantation, therapy, research, or education may be made 20 at the time of the decedent's death, or when death is imminent, by a member of the following classes of persons who is 21 22 reasonably available for the giving of authorization or 23 refusal, in the order of priority listed, when persons in available for 24 prior classes are not the giving of authorization or refusal and in the absence of actual notice 25 26 of contrary intentions by the decedent:

1	(1) an individual acting as the decedent's agent under
2	a power of attorney for health care;
3	(2) the guardian of the person of the decedent;
4	(3) the spouse or civil union partner of the decedent;
5	(4) an adult child of the decedent;
6	(5) a parent of the decedent;
7	(6) an adult sibling of the decedent;
8	(7) an adult grandchild of the decedent;
9	(8) a grandparent of the decedent;
10	(9) a close friend of the decedent;
11	(10) the guardian of the estate of the decedent; and
12	(11) any other person authorized or under legal
13	obligation to dispose of the body.

(b-5) If there is more than one member of a class listed in 14 item (2), (4), (5), (6), or (7) of subsection (b) of this 15 16 Section entitled to make an anatomical gift, an anatomical 17 gift may be made by a member of the class unless that member or a person to which the gift may pass under Section 5-12 knows of 18 an objection by another member of the class. If an objection is 19 20 known, the gift may be made only by a majority of the members 21 of the class who are reasonably available for the giving of 22 authorization or refusal.

(b-10) A person may not make an anatomical gift if, at the time of the decedent's death, a person in a higher priority class under subsection (b) of this Section is reasonably available for the giving of authorization or refusal. - 51 - LRB103 37007 CES 69616 b

(c) A gift of all or part of a body authorizes any blood or 1 2 tissue test or minimally invasive examination necessary to assure medical acceptability of the gift for the purposes 3 intended. The hospital shall, to the extent possible and in 4 5 accordance with any agreement with the organ procurement 6 organization, non-transplant anatomical donation organization, or tissue bank, take measures necessary to 7 8 maintain the medical suitability of the part until the 9 procurement organization has had the opportunity to advise the 10 applicable persons as set forth in this Act of the option to 11 make an anatomical gift or has ascertained that the individual 12 expressed a contrary intent and has so informed the hospital. 13 The results of tests and examinations under this subsection 14 shall be used or disclosed only for purposes of evaluating medical suitability for donation, to facilitate the donation 15 16 process, and as required or permitted by existing law.

17 (d) The rights of the donee created by the gift are 18 paramount to the rights of others except as provided by 19 Section 5-45(d).

(e) If no gift has been executed under this Act, then no part of the decedent's body may be used for any purpose specified in this Act.

23 (Source: P.A. 100-41, eff. 1-1-18.)

24 (755 ILCS 50/5-6 new)

25 <u>Sec. 5-6. Universal donor consent form. Two years after</u>

the effective date of this amendatory Act of the 103rd General Assembly, the execution of a gift under this Act shall be accompanied by the universal donor consent form provided for in Section 50 of the Consensual Non-Transplant Donation Regulation Act to consent to non-transplant anatomical donation.

7 (755 ILCS 50/5-12)

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8 Sec. 5-12. Persons who may receive an anatomical gift; 9 purpose of anatomical gift.

10 (a) An anatomical gift may be made to the following11 persons named in the document of gift:

12 (1) for research or education, a hospital; an 13 accredited medical school, dental school, college, or 14 university; an organ procurement organization; or other 15 appropriate person;

16 (2) subject to subsection (b) of this Section, an
17 individual designated by the person making the anatomical
18 gift if the individual is the recipient of the part;

(3) an eye bank or tissue bank; or

20 (4) for research or education, a non-transplant
 21 <u>anatomical donation organization licensed by the</u>
 22 <u>Department of Public Health</u> anatomic bank.

(b) If an anatomical gift to an individual under item (2)
of subsection (a) of this Section cannot be transplanted into
the individual, the part passes in accordance with subsection

(g) of this Section unless there is an express, contrary
 indication by the person making the anatomical gift or the
 <u>universal donor consent form provides the contrary indication</u>.

4 (c) If an anatomical gift of one or more specific parts or 5 of all parts is made in a document of gift that does not name a 6 person described in subsection (a) of this Section, but 7 identifies the purpose for which an anatomical gift may be 8 used, the following rules apply:

9 (1) If the part is an eye and the gift is for the 10 purpose of transplantation or therapy, the gift passes to 11 the appropriate eye bank.

12 (2) If the part is tissue and the gift is for the
13 purpose of transplantation or therapy, the gift passes to
14 the appropriate tissue bank.

15 (3) If the part is an organ and the gift is for the
purpose of transplantation or therapy, the gift passes to
the appropriate organ procurement organization as
custodian of the organ.

(4) If the part is an organ, an eye, or tissue and the
gift is for the purpose of research or education, the gift
passes to the appropriate <u>non-transplant anatomical</u>
donation organization procurement organization.

(d) For the purpose of subsection (c) of this Section, if there is more than one purpose of an anatomical gift set forth in the document of gift but the purposes are not set forth in any priority, and if the gift cannot be used for 1 transplantation or therapy, the gift may be used for research 2 or education, provided that the universal donor consent form 3 does not stipulate a purpose to the contrary.

4 (e) If an anatomical gift of one or more specific parts is 5 made in a document of gift that does not name a person 6 described in subsection (a) of this Section and does not 7 identify the purpose of the gift, the gift may be used only for 8 transplantation or therapy or research, and the gift passes in 9 accordance with subsection (g) of this Section.

10 (f) If a document of gift specifies only a general intent 11 to make an anatomical gift by words such as "donor", "organ 12 donor", or "body donor", or by a symbol or statement of similar 13 import, the gift may be used only for transplantation or 14 therapy or research, and the gift passes in accordance with 15 subsection (g) of this Section.

16 (g) For purposes of subsections (b), (e), and (f) of this 17 Section, the following rules apply:

18 (1) If the part is an eye, the gift passes to the19 appropriate eye bank.

20 (2) If the part is tissue, the gift passes to the21 appropriate tissue bank.

(3) If the part is an organ, the gift passes to the
 appropriate organ procurement organization organization
 <u>non-transplant anatomical donation organization</u> as
 custodian of the organ.

26 (h) An anatomical gift of an organ for transplantation or

1 therapy, other than an anatomical gift under item (2) of 2 subsection (a) of this Section, passes to the organ 3 procurement organization as custodian of the organ.

(i) If an anatomical gift does not pass under this Section 4 5 the decedent's body or part is not used for or 6 transplantation, therapy, research, or education, custody of 7 the body or part passes to the person under obligation to 8 dispose of the body or part.

9 (j) A person may not accept an anatomical gift if the 10 person knows that the gift was not effectively made under 11 Section 5-5 or subsection (e) or (e-5) of Section 5-20 or if 12 the person knows that the decedent made a refusal under 13 Section 5-43 that was not revoked.

(k) Except as otherwise provided in item (2) of subsection
(a) of this Section, nothing in this Act affects the
allocation of organs for transplantation or therapy.

17 (Source: P.A. 98-172, eff. 1-1-14.)

18 (755 ILCS 50/5-20) (was 755 ILCS 50/5)

19 Sec. 5-20. Manner of executing anatomical gifts.

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(a) A donor may make an anatomical gift:

(1) by authorizing a statement or symbol indicating
that the donor has made an anatomical gift to be imprinted
on the donor's driver's license or identification card;

(2) in a will;

(3) during a terminal illness or injury of the donor,

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by any form of communication addressed to at least 2 adults, at least one of whom is a disinterested witness; or

4 (4) as provided in subsection (b) and (b-1) of this 5 Section.

6 (b) A donor or other person authorized to make an 7 anatomical gift under subsection (a) of Section 5-5 may make a 8 gift by a donor card or other record signed by the donor or 9 other person making the gift or by authorizing that a 10 statement or symbol indicating that the donor has made an 11 anatomical gift be included on a donor registry. If the donor 12 or other person is physically unable to sign a record, the record may be signed by another individual at the direction of 13 14 the donor or other person and must:

(1) be witnessed by at least 2 adults, at least one of whom is a disinterested witness, who have signed at the request of the donor or the other person; and

18 (2) state that it has been signed and witnessed as19 provided in paragraph (1) of this subsection (b).

20 (b-1) A gift under Section 5-5 (a) may also be made by an 21 individual consenting to have his or her name included in the 22 First Person Consent organ and tissue donor registry 23 maintained by the Secretary of State under Section 6-117 of 24 the Illinois Vehicle Code. An individual's consent to have his 25 or her name included in the First Person Consent organ and 26 tissue donor registry constitutes full legal authority for the donation of any of his or her organs or tissue for purposes of transplantation, therapy, or research. Consenting to be included in the First Person Consent organ and tissue donor registry is effective without regard to the presence or signature of witnesses.

6 (b-5) Revocation, suspension, expiration, or cancellation 7 of a driver's license or identification card upon which an 8 anatomical gift is indicated does not invalidate the gift.

9 <u>(b-7) Not later than 2 years after the effective date of</u> 10 <u>this amendatory Act of the 103rd General Assembly, the</u> 11 <u>Secretary of State shall provide all donors with the universal</u> 12 <u>donor consent form in accordance with Section 6-117 of the</u> 13 Illinois Vehicle Code.

14 (b-10) An anatomical gift made by will takes effect upon 15 the donor's death whether or not the will is probated. 16 Invalidation of the will after the donor's death does not 17 invalidate the gift.

(c) The anatomical gift may be made to a specified donee or without specifying a donee. If the gift is made to a specified donee who is not available at the time and place of death, then if made for the purpose of transplantation, it shall be effectuated in accordance with Section 5-25.

(d) The donee or other person authorized to accept the gift pursuant to Section 5-12 may employ or authorize any qualified technician, surgeon, or physician to perform the recovery.

1 (e) A person authorized to make an anatomical gift under 2 subsection (b) of Section 5-5 may make an anatomical gift by a 3 document of gift signed by the person making the gift or by 4 that person's oral communication that is electronically 5 recorded or is contemporaneously reduced to a record and 6 signed by the individual receiving the oral communication.

7 (e-5) An anatomical gift by a person authorized under 8 subsection (b) of Section 5-5 may be amended or revoked orally 9 or in a record by a member of a prior class who is reasonably 10 available for the giving of authorization or refusal. If more 11 than one member of the prior class is reasonably available for 12 the giving of authorization or refusal, the gift made by a 13 person authorized under subsection (b) of Section 5-5 may be:

(1) amended only if a majority of the class members
reasonably available for the giving of authorization or
refusal agree to the amending of the gift; or

17 (2) revoked only if a majority of the class members 18 reasonably available for the giving of authorization or 19 refusal agree to the revoking of the gift or if they are 20 equally divided as to whether to revoke the gift.

(e-10) A revocation under subsection (e-5) is effective 21 22 only if, before an incision has been made to remove a part from 23 the donor's body or before invasive procedures have been 24 commenced to prepare the recipient, the procurement 25 organization, non-transplant anatomic bank, transplant 26 hospital, or physician or technician knows of the revocation.

(f) When there is a suitable candidate for organ donation 1 2 and a donation or consent to donate has not yet been given, 3 procedures to preserve the decedent's body for possible organ and tissue donation may be implemented under the authorization 4 5 of the applicable organ procurement organization, at its own expense, prior to making a donation request pursuant to 6 7 Section 5-25. If the organ procurement organization does not locate a person authorized to consent to donation or consent 8 9 to donation is denied, then procedures to preserve the 10 decedent's body shall be ceased and no donation shall be made. 11 The organ procurement organization shall respect the religious 12 tenets of the decedent, if known, such as a pause after death, before initiating preservation services. Nothing in this 13 Section shall be construed to authorize interference with the 14 15 coroner in carrying out an investigation or autopsy.

16 (Source: P.A. 100-41, eff. 1-1-18.)

17 (755 ILCS 50/5-25)

18

Sec. 5-25. Notification; authorization.

19 (a) Each hospital in this State shall enter into 20 agreements or affiliations with procurement organizations for 21 coordination of procurement and use of anatomical gifts. 22 Within 2 years after the effective date of this amendatory 23 Act, each hospital in the State shall enter into agreements or 24 affiliations with non-transplant anatomical donation 25 organizations licensed by the Department of Public Health for

1 <u>the purposes of coordinating non-transplant anatomical</u> 2 donations.

3 (b) Hospitals shall proceed in accordance with the 4 applicable requirements of 42 CFR 482.45 or any successor 5 provisions of federal statute or regulation, as may be amended 6 from time to time, with regard to collaboration with 7 procurement organizations to facilitate organ, tissue, and eye 8 donation.

9 In making a request for organ or tissue donation, the 10 hospital or the hospital's federally designated organ 11 procurement organization or tissue bank shall request any of 12 the persons, in the order of priority stated in items (1) 13 through (11) below, when persons in prior classes are not available and in the absence of (i) actual notice of contrary 14 15 intentions by the decedent, (ii) actual notice of opposition 16 by any member within the same priority class, and (iii) reason 17 to believe that an anatomical gift is contrary to the decedent's religious beliefs, to authorize the gift of all or 18 any part of the decedent's body for any purpose specified in 19 Section 5-12: 20

(1) an individual acting as the decedent's agent under
a power of attorney for health care;

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(2) the guardian of the person of the decedent;

24 (3) the spouse or civil union partner of the decedent;

25 (4) an adult child of the decedent;

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(5) a parent of the decedent;

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1		(6) an adult sibling of the decedent;
2		(7) an adult grandchild of the decedent;
3		(8) a grandparent of the decedent;
4		(9) a close friend of the decedent;
5		(10) the guardian of the estate of the decedent; and
6		(11) any other person authorized or under legal
7	obl	igation to dispose of the body.

- 8 (c) (Blank).
- 9 (d) (Blank).

- 10 (Source: P.A. 98-172, eff. 1-1-14.)
- 11 (755 ILCS 50/5-27) (was 755 ILCS 60/3.5)

12 Sec. 5-27. Notification of patient; family rights and options after circulatory death. 13

(a) In this Section, "donation after circulatory death" 14 means the donation of organs from a patient whose death is 15 16 declared based upon cardiopulmonary, and not neurological, 17 criteria, following the implementation of the decision to 18 withdraw life support.

19 (b) If (i) a potential organ donor, or an individual given 20 authority under subsection (b) of Section 5-25 to consent to 21 an organ donation, expresses an interest in organ donation, 22 (ii) there has not been a certification of brain death for the potential donor, and (iii) the potential donor is a patient at 23 24 a hospital that does not allow donation after circulatory 25 death, then the organ procurement organization shall inform

1 the patient or the individual given authority to consent to 2 organ donation that the hospital does not allow donation after 3 circulatory death.

4 (c) In addition to providing oral notification, the organ 5 procurement organization shall develop a written form that 6 indicates to the patient or the individual given authority to 7 consent to organ donation, at a minimum, the following 8 information:

9 (1) That the patient or the individual given authority 10 to consent to organ donation has received literature and 11 has been counseled by (representative's name) of the 12 (organ procurement organization name).

13 (2) That all organ donation options have been
14 explained to the patient or the individual given authority
15 to consent to organ donation, including the option of
16 donation after circulatory death.

17 (3) That the patient or the individual given authority 18 to consent to organ donation is aware that the hospital 19 where the potential donor is a patient does not allow 20 donation after circulatory death.

(4) That the patient or the individual given authority to consent to organ donation has been informed of the right to request a patient transfer to a facility allowing donation after circulatory death.

(5) That the patient or the individual given authority
to consent to organ donation has been informed of another

hospital that will allow donation after circulatory death and will accept a patient transfer for the purpose of donation after circulatory death; and that the cost of transferring the patient to that other hospital will be covered by the organ procurement organization, with no additional cost to the patient or the individual given authority to consent to organ donation.

8 The form required under this subsection must include a 9 place for the signatures of the patient or the individual 10 given authority to consent to organ donation and the 11 representative of the organ procurement organization and space 12 to provide the date that the form was signed.

13 (d) Within 2 years after the effective date of this 14 amendatory Act of the 103rd General Assembly, if the potential 15 donor's gift is for the purpose of research or education, the 16 patient or the individual given authority to consent to organ 17 donation shall be provided the universal donor consent form. 18 (Source: P.A. 98-172, eff. 1-1-14.)

19 (755 ILCS 50/5-47)

20 Sec. 5-47. Rights and duties of procurement organizations 21 and others.

(a) When a hospital refers an individual at or near death to a procurement organization, the organization shall make a reasonable search of the records of the Secretary of State and any donor registry that it knows exists for the geographical

1 area in which the individual resides to ascertain whether the 2 individual has made an anatomical gift.

3 (b) A procurement organization shall be allowed reasonable access to information in the records of the Secretary of State 4 5 to ascertain whether an individual at or near death is a donor. If the individual is a donor who is an unemancipated minor, the 6 7 procurement organization shall conduct a reasonable search for 8 a parent or quardian of the donor and shall provide the parent 9 or guardian with an opportunity to amend or revoke the 10 anatomical gift of the donor's body.

11 (c) Unless prohibited by law other than this Act, at any 12 time after a donor's death, the person to which a part passes 13 under Section 5-12 may conduct any reasonable examination 14 necessary to ensure the medical suitability of the body or 15 part for its intended purpose.

16 (d) Unless prohibited by law other than this Act, an 17 examination under subsection (c) may include an examination of 18 all medical and dental records of the donor or prospective 19 donor.

20 (e) Upon referral by a hospital under subsection (a) of 21 this Section, a procurement organization shall make а 22 reasonable search for any person listed in subsection (b) of 23 Section 5-5 having priority to make an anatomical gift on 24 behalf of a prospective donor. If a procurement organization 25 receives information that an anatomical gift to any other 26 person was made, amended, or revoked, it shall promptly advise

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1 the other person of all relevant information.

2 (f) Subject to subsection (i) of Section 5-12, the rights 3 of the person to which a part passes under Section 5-12 are superior to the rights of all others with respect to the part. 4 5 The person may accept or reject an anatomical gift in whole or in part. Subject to the terms of the document of gift and this 6 7 Act, a person who accepts an anatomical gift of an entire body may allow embalming, burial or cremation, and use of remains 8 9 in a funeral service. If the gift is of a part, the person to 10 which the part passes under Section 5-12, upon the death of the 11 donor and before embalming, burial, or cremation, shall cause 12 the part to be removed without unnecessary mutilation.

13 (g) Neither the physician who attends the decedent at 14 death nor the physician who determines the time of the 15 decedent's death may participate in the procedures for 16 removing or transplanting a part from the decedent.

(h) A physician or technician may remove a donated part from the body of a donor that the physician or technician is qualified to remove.

(i) Not later than July 1, 2020, the Secretary of State 20 shall create a database consisting of all individuals who have 21 22 consented to having their names included in the First Person 23 Consent organ and tissue donor registry maintained by the Secretary of State pursuant to Section 6-117 of the Illinois 24 25 Vehicle Code. This database shall include identifying 26 information for each individual, including, where available,

the individual's name, address, gender, date of 1 birth, 2 driver's license or identification card number, social security number only if the donor does not have a driver's 3 license or identification card number, and date of consent to 4 5 join the registry. The Secretary of State shall update the database not less often than every 7 days. Upon executing a 6 data access agreement with the Secretary of State, an organ 7 procurement organization, as defined in this Act, providing 8 9 services in the State of Illinois shall be granted online 10 access to the database for the purpose of determining whether 11 a potential organ and tissue donor is included in the First 12 Person Consent organ and tissue donor registry.

13 (j) Not later than 2 years after the effective date of this 14 amendatory Act of the 103rd General Assembly, the Department 15 of Public Health shall create a database consisting of all 16 universal donor consent forms.

17 The organ procurement organization shall indemnify and hold harmless the State of Illinois, its officials, and 18 19 employees for any judgments, assessments, damages, fines, 20 fees, and legal costs arising out of the acts, omissions, decisions, or other 21 conduct of the organ procurement 22 organization and its officials, employees, and agents in the 23 use of the database.

24 (Source: P.A. 100-41, eff. 1-1-18; 101-179, eff. 1-1-20.)

25 Section 999. Effective date. This Act takes effect upon 26 becoming law.

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