

1.1 A bill for an act

1.2 relating to anatomical gifts; establishing requirements for nontransplant
1.3 anatomical recovery organizations and anatomical user organizations; amending
1.4 Minnesota Statutes 2008, sections 144.99, subdivision 1; 525A.11; proposing
1.5 coding for new law as Minnesota Statutes, chapter 525B.

1.6 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

1.7 Section 1. Minnesota Statutes 2008, section 144.99, subdivision 1, is amended to read:

1.8 Subdivision 1. **Remedies available.** The provisions of chapters 103I ~~and~~ 157₂
1.9 and 525B and sections 115.71 to 115.77; 144.12, subdivision 1, paragraphs (1), (2),
1.10 (5), (6), (10), (12), (13), (14), and (15); 144.1201 to 144.1204; 144.121; 144.1222;
1.11 144.35; 144.381 to 144.385; 144.411 to 144.417; 144.495; 144.71 to 144.74; 144.9501
1.12 to 144.9512; 144.992; 326.70 to 326.785; 327.10 to 327.131; and 327.14 to 327.28 and
1.13 all rules, orders, stipulation agreements, settlements, compliance agreements, licenses,
1.14 registrations, certificates, and permits adopted or issued by the department or under any
1.15 other law now in force or later enacted for the preservation of public health may, in
1.16 addition to provisions in other statutes, be enforced under this section.

1.17 Sec. 2. Minnesota Statutes 2008, section 525A.11, is amended to read:

1.18 **525A.11 PERSONS THAT MAY RECEIVE ANATOMICAL GIFT; PURPOSE**
1.19 **OF ANATOMICAL GIFT.**

1.20 (a) An anatomical gift may be made to the following persons named in the document
1.21 of gift:

1.22 (1) a hospital; accredited medical school, dental school, college, or university; organ
1.23 procurement organization; or ~~nonprofit organization in medical education or research;~~

2.1 for research or education, a nontransplant anatomical user organization or a registered
2.2 nontransplant anatomical recovery organization that meets the requirements of chapter
2.3 525B;

2.4 (2) subject to paragraph (b), an individual designated by the person making the
2.5 anatomical gift if the individual is the recipient of the part; and

2.6 (3) an eye bank or tissue bank.

2.7 (b) If an anatomical gift to an individual under paragraph (a), clause (2), cannot be
2.8 transplanted into the individual, the part passes in accordance with paragraph (g) in the
2.9 absence of an express, contrary indication by the person making the anatomical gift.

2.10 (c) If an anatomical gift of one or more specific parts or of all parts is made in a
2.11 document of gift that does not name a person described in paragraph (a) but identifies the
2.12 purpose for which an anatomical gift may be used, the following rules apply:

2.13 (1) if the part is an eye and the gift is for the purpose of transplantation or therapy,
2.14 the gift passes to the appropriate eye bank;

2.15 (2) if the part is tissue and the gift is for the purpose of transplantation or therapy, the
2.16 gift passes to the appropriate tissue bank;

2.17 (3) if the part is an organ and the gift is for the purpose of transplantation or therapy,
2.18 the gift passes to the appropriate organ procurement organization as custodian of the
2.19 organ; and

2.20 (4) if the part is an organ, an eye, or tissue and the gift is for the purpose of research
2.21 or education, the gift passes to the appropriate organ procurement organization or
2.22 nonprofit eye or tissue bank whose primary mission is transplantation and is overseen by
2.23 the Food and Drug Administration; or to a nontransplant anatomical user organization or a
2.24 registered nontransplant anatomical recovery organization that meets the requirements of
2.25 chapter 525B.

2.26 (d) For the purpose of paragraph (c), if there is more than one purpose of an
2.27 anatomical gift set forth in the document of gift but the purposes are not set forth in any
2.28 priority, the gift must be used for transplantation or therapy, if suitable. If the gift cannot
2.29 be used for transplantation or therapy, the gift may be used for research or education.

2.30 (e) If an anatomical gift of one or more specific parts is made in a document of gift
2.31 that does not name a person described in paragraph (a) and does not identify the purpose
2.32 of the gift, the gift may be used only for transplantation or therapy, and the gift passes in
2.33 accordance with paragraph (g).

2.34 (f) If a document of gift specifies only a general intent to make an anatomical gift
2.35 by words such as "donor," "organ donor," or "body donor," or by a symbol or statement

3.1 of similar import, the gift may be used only for transplantation or therapy, and the gift
3.2 passes in accordance with paragraph (g).

3.3 (g) For purposes of paragraphs (b), (e), and (f), the following rules apply:

3.4 (1) if the part is an eye, the gift passes to the appropriate eye bank;

3.5 (2) if the part is tissue, the gift passes to the appropriate tissue bank; and

3.6 (3) if the part is an organ, the gift passes to the appropriate organ procurement
3.7 organization as custodian of the organ.

3.8 (h) An anatomical gift of an organ for transplantation or therapy, other than
3.9 an anatomical gift under paragraph (a), clause (2), passes to the organ procurement
3.10 organization as custodian of the organ.

3.11 (i) If an anatomical gift does not pass pursuant to paragraphs (a) to (h) or the
3.12 decedent's body or part is not used for transplantation, therapy, research, or education,
3.13 custody of the body or part passes to the person under obligation to dispose of the body or
3.14 part.

3.15 (j) A person may not accept an anatomical gift if the person knows that the gift was
3.16 not effectively made under section 525A.05 or 525A.10 or if the person knows that the
3.17 decedent made a refusal under section 525A.07 that was not revoked. For purposes of
3.18 this paragraph, if a person knows that an anatomical gift was made on a document of gift,
3.19 the person is deemed to know of any amendment or revocation of the gift or any refusal
3.20 to make an anatomical gift on the same document of gift.

3.21 (k) Except as otherwise provided in paragraph (a), clause (2), nothing in this chapter
3.22 affects the allocation of organs for transplantation or therapy.

3.23 Sec. 3. **[525B.01] DEFINITIONS.**

3.24 **Subdivision 1. Scope.** The definitions in this section apply to this chapter.

3.25 **Subd. 2. Anatomical gift.** "Anatomical gift" has the meaning given in section
3.26 525A.02, subdivision 4.

3.27 **Subd. 3. Commissioner.** "Commissioner" means the commissioner of health.

3.28 **Subd. 4. Distribution.** "Distribution" means the removal of a human body or part
3.29 from a storage location to any other location for educational or research use.

3.30 **Subd. 5. Education.** "Education" means the use of a human body or part for the
3.31 purpose of teaching or training individuals, including, but not limited to, medical or
3.32 dental professionals and students, with regard to the anatomy and characteristics of the
3.33 human body.

3.34 **Subd. 6. Nontransplant anatomical recovery organization.** "Nontransplant
3.35 anatomical recovery organization" means a corporation or an entity that is a state, a

4.1 political subdivision of a state, or an agency or public educational organization of a state
4.2 or political subdivision that is engaged in the recovery or distribution of a human body
4.3 or part donation for education or research. This definition does not include an organ
4.4 procurement organization as defined in section 525A.02, subdivision 18, or a nonprofit
4.5 eye or tissue bank whose primary mission is transplantation and is overseen by the United
4.6 States Food and Drug Administration.

4.7 Subd. 7. **Nontransplant anatomical user organization.** "Nontransplant anatomical
4.8 user organization" means an organization that uses or facilitates the use of a human body
4.9 or part donation for education or research. This definition does not include an organ
4.10 procurement organization as defined in section 525A.02, subdivision 18, or a nonprofit
4.11 eye or tissue bank whose primary mission is transplantation and is overseen by the United
4.12 States Food and Drug Administration.

4.13 Subd. 8. **Organ procurement organization.** "Organ procurement organization"
4.14 has the meaning given in section 525A.02, subdivision 18.

4.15 Subd. 9. **Part.** "Part" means an organ, an eye, or tissue of a human being.

4.16 Subd. 10. **Recovery.** "Recovery" means obtaining the consent of an anatomical gift
4.17 and the obtaining, processing, storing, and distributing of a human body or part, including,
4.18 but not limited to, performing surgical or other technical procedures necessary for
4.19 recovering the body or part. Recovery does not include actions taken by a nontransplant
4.20 anatomical user organization or by a medical examiner or coroner as part of their
4.21 professional duties.

4.22 Subd. 11. **Research.** "Research" means the performance of scientific testing and
4.23 observation designed to result in the acquisition of generalizable knowledge. Research
4.24 does not include an autopsy or other investigation conducted for the purpose of obtaining
4.25 information related to the decedent, and does not include, at the discretion of the
4.26 commissioner, clinical studies, cellular-level research, brain autopsies for specific disease
4.27 research, and biomedical device explants.

4.28 Sec. 4. **[525B.02] REGISTRATION STANDARDS FOR NONTRANSPLANT**
4.29 **ANATOMICAL RECOVERY ORGANIZATIONS.**

4.30 Subdivision 1. **Prohibition.** Any nontransplant anatomical recovery organization
4.31 that engages in the recovery or distribution of a human body or part donation for education
4.32 or research where all or part of the recovery or distribution takes place in Minnesota
4.33 must be registered with the commissioner of health in accordance with this chapter. The
4.34 registration required under this chapter is in addition to any license or permit required by a
4.35 local board of health, other local health agency, or any state or federal agency.

5.1 Subd. 2. **Registration.** (a) To become registered, a nontransplant anatomical
5.2 recovery organization must submit to the commissioner an application for registration on
5.3 a form prescribed by the commissioner and any applicable fees required under subdivision
5.4 5. The application must contain, at a minimum:

5.5 (1) the name of the applicant;

5.6 (2) the type of organization to be registered;

5.7 (3) the location of the organization;

5.8 (4) the name of the organization's medical director and the state in which the director
5.9 is licensed; and

5.10 (5) any other information deemed applicable by the commissioner.

5.11 (b) The registration is valid for a one-year period and may be renewed subject to
5.12 compliance with the requirements of this section.

5.13 (c) The commissioner may enter and inspect the premises and records of
5.14 any nontransplant anatomical recovery organization as is deemed necessary by the
5.15 commissioner to enforce the provisions of this section.

5.16 Subd. 3. **Requirements for operating as a nontransplant anatomical recovery**
5.17 **organization.** A nontransplant anatomical recovery organization registered under this
5.18 section must comply with the following requirements:

5.19 (a) The organization's medical director must be a physician licensed in Minnesota or
5.20 the state in which the organization is incorporated. The medical director is responsible
5.21 for ensuring compliance with the provisions of this section and the maintenance of any
5.22 records required under this section.

5.23 (b) The organization shall create, compile, and maintain a complete record on each
5.24 donor from which it recovers a human body or part for educational or research purposes.
5.25 The record must include, at a minimum:

5.26 (1) documentation that the donor or other person authorized to make an anatomical
5.27 gift under chapter 525A designated the anatomical gift for educational or research
5.28 purposes, as required under chapter 525A;

5.29 (2) documentation of the identity and address of each person that has been in
5.30 possession of the human body or part prior to the organization, including, but not limited
5.31 to, a funeral home, coroner, medical examiner, hospital, or procurement organization;

5.32 (3) documentation of the use and disposition of each human body or part, including
5.33 the name and address of each person that receives a human body or part directly from the
5.34 organization;

5.35 (4) documentation that each anatomical gift has been screened for communicable
5.36 diseases reportable under Minnesota Rules, chapter 4605, or other applicable law; and

6.1 (5) documentation that the donor's death has been registered under section 144.221
6.2 or other applicable law if the death did not occur in Minnesota.

6.3 (c) The organization shall not solicit for donations as prohibited under section
6.4 149A.70, subdivision 5a, clause (1).

6.5 (d) The organization shall not provide reimbursement as prohibited under section
6.6 149A.70, subdivision 5.

6.7 (e) The organization shall clearly disclose the organization's incorporation status on
6.8 all marketing or informational materials distributed to the public.

6.9 (f) The organization shall clearly disclose the incorporation status on the informed
6.10 consent document signed by the donor or donor's next of kin.

6.11 (g) The organization may reimburse a donor's next of kin for any reasonable
6.12 expenses directly related to the donation, including the transportation, filing of mandatory
6.13 paperwork, serology testing, storage, handling, preservation, distribution, cremation, and
6.14 returning cremated remains to next of kin.

6.15 (h) The organization shall disclose the source of a donation in the event that the
6.16 nontransplant anatomical recovery organization did not directly receive the anatomical
6.17 gift from the donor or donor's next of kin. All sources of anatomical donations being
6.18 distributed in Minnesota must be registered as a nontransplant anatomical recovery
6.19 organization with the commissioner.

6.20 Subd. 4. **Transfers.** A nontransplant anatomical recovery organization shall not
6.21 transfer a whole human body or part to any other entity unless authorized in writing by
6.22 the nontransplant anatomical recovery organization from which the whole body or part
6.23 was obtained.

6.24 Subd. 5. **Registration fees.** (a) Each application for an initial registration or
6.25 registration renewal to operate a nontransplant anatomical recovery organization shall be
6.26 accompanied by a fee of \$.....

6.27 (b) All fees are nonrefundable and must be deposited in the state government special
6.28 revenue fund and appropriated to the commissioner of health to implement this section.

6.29 **Sec. 5. [525B.03] NONTRANSPLANT ANATOMICAL USER ORGANIZATION.**

6.30 Subdivision 1. **Standards.** (a) Any nontransplant anatomical user organization
6.31 that uses a human body or part donation for education or research when the education
6.32 or research takes place in Minnesota must comply with the requirements described in
6.33 subdivision 2. The requirements under this section are in addition to any license or permit
6.34 required by a local board of health, other local health agency, or any state or federal agency.

7.1 (b) The commissioner may enter and inspect the premises and records of any
7.2 nontransplant anatomical user organization as is deemed necessary by the commissioner
7.3 to enforce the provisions of this section.

7.4 Subd. 2. **Requirements for operating as a nontransplant anatomical user**
7.5 **organization.** (a) A nontransplant anatomical user organization must create, compile, and
7.6 maintain a complete record on each donor from which it uses a human body or part for
7.7 educational or research purposes. The record must include, at a minimum:

7.8 (1) the chain of custody for the anatomical gift from acquisition by the organization
7.9 through final disposition;

7.10 (2) documentation that the donor or other person authorized to make an anatomical
7.11 gift under this chapter designated the anatomical gift for educational or research purposes;

7.12 (3) compliance with section 149A.93 if the whole body is being transported and
7.13 compliance with all federal laws and regulations if parts of the body are being transported;

7.14 (4) that each human body or part used for anatomical education or research was
7.15 received from a nontransplant anatomical recovery organization registered under section
7.16 525B.02; and

7.17 (5) documented compliance with section 149A.95 upon the cremation of each
7.18 human body or part.

7.19 (b) Unless otherwise authorized by the commissioner of health, the use of an
7.20 anatomical gift by a nontransplant anatomical user organization must occur in a laboratory
7.21 setting that, at a minimum, meets the following requirements:

7.22 (1) walls and floors must be nonporous and doors, ceilings, and windows must be
7.23 constructed to prevent odors from entering any other part of the building;

7.24 (2) working sinks and adequate drainage throughout the laboratory space;

7.25 (3) nonporous tables for specimen dissection;

7.26 (4) adequate space for storage of chemicals and materials used in the preparation
7.27 of specimens;

7.28 (5) counters, tables, and cabinetry must be built of materials that can be easily
7.29 disinfected and cleaned;

7.30 (6) designated refrigerated or freezer storage for unpreserved specimens that is
7.31 lockable and equipped with an alarm that signals unacceptable temperature deviation;

7.32 (7) independent ventilation with an exhaust fan that provides at least 12 air changes
7.33 per hour;

7.34 (8) lockable doors with restricted private access. The laboratory setting must be
7.35 secure at all times and entry to the room must be limited to authorized persons;

8.1 (9) each door allowing ingress or egress must carry a hazard warning sign
8.2 incorporating the universal symbol for each applicable biohazard;

8.3 (10) decontamination and disposal procedures for regulated medical waste shall
8.4 be utilized. All hazardous and regulated waste materials shall be handled, stored, and
8.5 discarded as appropriate and in compliance with state law;

8.6 (11) eating, drinking, smoking, and the application of cosmetics or contact lenses
8.7 must not be permitted in work areas; and

8.8 (12) gloves, laboratory coats, gowns, or other protective clothing must be worn
8.9 while handling anatomic material. This protective clothing must not be worn outside the
8.10 work area and must be disposed of in an appropriate biohazardous waste receptacle.

8.11 Sec. 6. **[525B.04] ENFORCEMENT.**

8.12 The commissioner shall enforce this chapter in accordance with sections 144.989 to
8.13 144.993.