

BILL 32

2006

HUMAN TISSUE AND ORGAN DONATION ACT

(Assented to , 2006)

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HER MAJESTY, by and with the advice and consent of the
Legislative Assembly of Alberta, enacts as follows:

Definitions

- 1 In this Act,
 - (a) “body” means a human body;
 - (b) “by-product” means tissue or an organ that is a waste product of a medical procedure;

- (c) “consent” means a consent given for a donation that meets the requirements of section 9;
- (d) “consenter” means a person who gives a consent;
- (e) “donation” means a donation of tissue, an organ or a body under section 4 or 5;
- (f) “donation agency” means an organization designated in the regulations that co-ordinates and supports donations for transplantation;
- (g) “donor” means a person whose tissue, organs or body is being considered for donation or in respect of whom a consent has been given;
- (h) “estranged” means living separate and apart for a year or more;
- (i) “immediate family” means the spouse or adult interdependent partner, parent, sibling and child of a person;
- (j) “independent assessment committee” means an independent assessment committee established in accordance with the regulations;
- (k) “Minister” means the Minister determined under section 16 of the *Government Organization Act* as the Minister responsible for this Act;
- (l) “organ” means a human organ whether whole or in sections, lobes or parts;
- (m) “tissue” means human tissue excluding organs;
- (n) “transplantation” means the operation of transferring tissue or an organ from a human donor to a human recipient.

Scope of Act

2 This Act does not apply to the following:

- (a) by-products that are used for a purpose other than transplantation;

- (b) blood or blood constituents;
- (c) zygotes, oocytes, embryos, sperm, semen and ova.

Transplantation, medical education, etc.

3(1) A person's tissue, organs or body may be donated for transplantation, medical education or scientific research only in accordance with this Act.

(2) No person shall offer, give or receive any reward or benefit for any tissue, organ or body for use in transplantation, medical education or scientific research.

(3) No person shall use any tissue, organ or body donated under this Act except for the purpose for which it was donated.

(4) Only a university with a medical, dental or related health program may use a body donated under this Act for medical education or scientific research.

(5) No person shall use, procure, transfer or process any tissue, organ or body for transplantation except in accordance with the regulations.

(6) No person shall perform a transplantation unless the person is registered in accordance with the regulations and the transplantation is performed in a surgical facility that is registered in accordance with the regulations.

Deceased donor

4(1) A person's tissue, organs or body may be donated for transplantation, medical education or scientific research from his or her deceased body if a consent is given

- (a) where that person is an adult, by the adult, or
- (b) by a person in accordance with subsection (2).

(2) When a person dies or his or her death is imminent, if the person is an adult who has not given a consent and, in the opinion of a medical practitioner, the person is incapable of doing so by reason of injury or disease, or if the person is a minor, a person in one of the following classes and in the following order of priority may give a consent:

- (a) the spouse or adult interdependent partner of the person if they are not estranged;
- (b) an adult child of the person;
- (c) a parent or guardian of the person;
- (d) an adult sibling of the person;
- (e) any other adult next of kin of the person.

(3) A person shall not seek or give a consent under subsection (2) if he or she has personal knowledge of the following:

- (a) a person in a higher priority class is readily available to provide a consent;
- (b) a person in the same class would refuse to give a consent;
- (c) the donor would have refused to give a consent.

Living donor

5(1) An adult's by-products, tissue or organs from the adult's living body may be donated for transplantation

- (a) if the adult gives a consent, or
- (b) where the adult lacks capacity to give a consent, if
 - (i) an agent designated in a personal directive under the *Personal Directives Act* gives a consent and the personal directive under which the agent is authorized to act states that such a consent may be given, or
 - (ii) a guardian appointed under the *Dependent Adults Act* gives a consent and the court order under which the guardian is authorized to act states that such a consent may be given.

(2) Subject to subsection (3), a minor's tissues or organs may be donated from the minor's living body for transplantation if the donation is approved by an independent assessment committee and a guardian gives a consent.

(3) A guardian shall not give a consent under subsection (2) if the guardian

- (a) has personal knowledge that another guardian would refuse to give a consent, or
- (b) lacks the authority to make medical decisions in respect of the minor.

(4) A minor's by-products may be donated from his or her living body for transplantation if a consent is given by the minor, if the minor is 16 years of age or over or lives independently of a guardian, or by a guardian.

(5) Before approving a donation under this section, the independent assessment committee must ensure that

- (a) the minor, to the extent possible considering his or her age, agrees to the donation without coercion or inducement and understands the nature and consequences of the donation,
- (b) if the minor is under 16 years of age, only regenerative tissue or organs are to be donated,
- (c) the donation poses minimal risk to the minor, and
- (d) all adult members of the immediate family of the recipient have been eliminated, for medical or other reasons, as donors.

(6) An independent assessment committee shall not approve a donation if all the members of the committee are not in agreement.

(7) The independent assessment committee shall provide to the minor and the guardian who gave a consent for the donation written notice, with reasons, of a decision to approve or disapprove a donation.

Determination of death

6(1) A physician shall not participate in the determination of a donor's death for the purposes of a donation under section 4 for transplantation if the physician

- (a) has had any association with the proposed recipient that might influence his or her judgment, or
- (b) will remove the tissue or organ or perform the transplantation.

(2) Subsection (1) does not apply to a physician who will remove a donor's eyes for corneal transplantation.

Mandatory consideration for donation

7(1) When a person dies, the medical practitioner who makes the determination of death must consider and document in the patient record the medical suitability of the deceased person's tissue or organs for transplantation.

(2) If a medical practitioner determines under subsection (1) that a person's tissue or organs may be suitable for transplantation, the medical practitioner must notify a donation agency, if any, in a manner satisfactory to the donation agency.

(3) A donation agency notified under subsection (2) must, unless it determines that the donor is medically unsuitable, seek a consent for a donation for transplantation under section 4(2) and document its efforts.

(4) Notwithstanding subsection (3), a donation agency shall not seek a consent for donation under section 4(2)

- (a) if the medical practitioner referred to in subsection (1) advises that he or she
 - (i) has personal knowledge that the deceased donor would have refused to give a consent, or
 - (ii) has already sought a consent under section 4,or
- (b) if a consent under section 4 has already been given.

Effect of donation

8(1) Subject to section 10, a consent given in accordance with this Act is binding and authorizes

- (a) any medical practitioner to make any examination necessary to assure medical acceptability of the donation, and
- (b) the use of the body or the removal and use of the specified tissue or organ for the specified purpose.

(2) If a person has custody or control of a consent given under section 4(1)(a) that has not been revoked pursuant to section 9(5), that person must provide that consent for the purposes of subsection (1).

(3) Notwithstanding subsection (1), a person shall not act on a consent if the person

- (a) has personal knowledge that the donor objected to the donation proceeding, or
- (b) has personal knowledge, where a consent was given under section 4(1)(b), that a person in the same class or a higher priority class as the consenter objected to the donation proceeding.

(4) If for any reason a donation cannot be used in the circumstances to which the consent relates, the consent is void and, if necessary, the donated tissue, organ or body must be dealt with and disposed of as if the donation had not been made.

Requirement of written consent

9(1) A consent required by this Act must be

- (a) in writing,
- (b) dated, and
- (c) signed
 - (i) by the consenter and a witness, or
 - (ii) if a consenter cannot sign for any reason, by 2 persons who witnessed the agreement to the donation by the consenter.

(2) A consent signed under subsection (1)(c)(ii) must

- (a) indicate that each witness received instructions from the consentor to document the consent,
- (b) identify the manner in which the consentor's agreement to the donation was obtained, and
- (c) if consent was given under section 4(1)(b), indicate that one witness was knowledgeable in the donation process and that the witness advised the consentor of the nature and consequences of the donation.

(3) A consent on the form provided on a certificate of registration issued under the *Health Insurance Premiums Act* is valid notwithstanding that it is not dated.

(4) The following persons shall not witness a consent:

- (a) the physician who will remove the tissue or organ or perform the transplantation;
- (b) the recipient of the transplant and his or her immediate family;
- (c) a person who is required to give a consent in respect of the same donation.

(5) If a consentor revokes a consent, that consentor must provide a revocation that meets the requirements of subsection (1) to any person the consentor knows has a copy of that consent as soon as practicable.

Fatality Inquiries Act

10(1) A medical examiner appointed under the *Fatality Inquiries Act* may, notwithstanding that death has not occurred, give any directions the medical examiner thinks proper respecting the removal of tissue or organs donated for transplantation under section 4 if the donor's death is imminent and the attending physician has reason to believe that section 10, 11, 12 or 13 of the *Fatality Inquiries Act* may apply when death occurs.

(2) A direction made under subsection (1) has the same force and effect as if it had been made after death.

(3) Except as provided in this section, nothing in this Act affects the operation of the *Fatality Inquiries Act*.

Liability

11 No action lies against any person in respect of anything done or omitted to be done in good faith pursuant to this Act.

Confidentiality of information

12(1) Subject to subsection (2), a person may collect, use or disclose the information necessary

- (a) to assess a donor's suitability to donate under section 4,
- (b) to use or obtain a donation under section 4 or 5, or
- (c) to assess medical suitability under section 7.

(2) Subject to subsection (3), no person shall disclose any information from which the identity of a person

- (a) who has given or refused to give a consent,
- (b) with respect to whom a consent has been given, or
- (c) into whose body any tissue or an organ has been, is being or may be transplanted,

could become known publicly.

(3) Subsection (2) does not apply if the disclosure

- (a) is permitted or required by an enactment or by an order of the court, or
- (b) has been agreed to in writing
 - (i) by the person whose identity could become publicly known or that person's guardian, or
 - (ii) where the identity of a person in respect of whom a consent was given under section 4(1)(b) could become publicly known, by the consentor.

Offences

13(1) Subject to subsections (2) and (3), a person who knowingly contravenes this Act is guilty of an offence and liable to a fine of not more than \$10 000.

(2) A person who contravenes section 12(2) is guilty of an offence and liable to a fine of not more than \$50 000.

(3) A person who contravenes section 3(2) is guilty of an offence and liable to a fine of not more than \$100 000 or to imprisonment for a term of not more than 6 months or to both.

Regulations

14 The Minister may make regulations

- (a) designating donation agencies for the purposes of this Act;
- (b) respecting the use, procurement, transfer or processing of tissue, organs or bodies for transplantation;
- (c) respecting registrations for the purposes of section 3(6);
- (d) respecting the establishment of independent assessment committees;
- (e) respecting any other matter that the Minister considers necessary to carry out the intent of this Act.

Consequential amendments

15(1) The *Fatality Inquiries Act* is amended in section 26

- (a) **by striking out “*Human Tissue Gift Act*,” and substituting “*Human Tissue and Organ Donation Act*”;**
- (b) **by adding “or organs” after “tissue” wherever it occurs.**

(2) The *Personal Directives Act* is amended in section 15(c)(i) by striking out “Part 1 of the *Human Tissue Gift Act*” and substituting “the *Human Tissue and Organ Donation Act*”.

Repeals

16 The *Human Tissue Donation Procedures Statutes Amendment Act*, RSA 2000 c15(Supp), and the *Human Tissue Gift Act*, RSA 2000 cH-15, are repealed.

Coming into force

17 This Act comes into force on Proclamation.

Explanatory Notes

15 Consequential amendments.

16 Repeals.

17 Coming into force.