

BILL NO. 133

Government Bill

2nd Session, 63rd General Assembly Nova Scotia 68 Elizabeth II, 2019

An Act Respecting Human Organ and Tissue Donation

CHAPTER 6 ACTS OF 2019

AS ASSENTED TO BY THE LIEUTENANT GOVERNOR APRIL 12, 2019

The Honourable Stephen McNeil President of the Executive Council

Halifax, Nova Scotia
Printed by Authority of the Speaker of the House of Assembly



An Act Respecting Human Organ and Tissue Donation

Be it enacted by the Governor and Assembly as follows:

1 This Act may be cited as the *Human Organ and Tissue Donation Act*.

2 In this Act,

- (a) "best interests" includes consideration of the physical, psychological, emotional and social well-being of the living potential donor;
- (b) "capacity" means the ability to understand the information that is relevant to a decision to be made and the ability to appreciate the reasonably foreseeable consequences of a decision or lack of a decision;
- (c) "Chief Medical Examiner" means the Chief Medical Examiner appointed pursuant to the *Fatality Investigations Act*;
- (d) "continuing-care home" means any facility licensed under the *Homes for Special Care Act*, any facility for which a resident may be approved for admission by the Department of Health and Wellness or the Department of Community Services and any facility prescribed by the regulations;
 - (e) "court" means the Supreme Court of Nova Scotia;
 - (f) "critical functions" means
 - (i) respiration,
 - (ii) circulation, and
 - (iii) consciousness:
- (g) "death" means the irreversible cessation of the functioning of the organism as a whole as determined by the irreversible loss of the brain's ability to control and co-ordinate the organism's critical functions;
- (h) "donation after death" means a donation of any human organ, tissue or body after death in accordance with this Act;
- (i) "donor" means an individual who has consented, is deemed to have consented or in respect of whom a consent has been given to donate the individual's organs, tissue or body for transplantation, scientific research or education;
- (j) "guardian" means a person appointed as the guardian of the person of a child under the *Guardianship Act* or a person who is a guardian under the *Children and Family Services Act*;
- (k) "health authority" means the provincial health authority or the IWK Health Centre;
- (l) "health-card number" means a unique identification number assigned by the Department of Health and Wellness to individuals insured under the *Health Services and Insurance Act* and reflected on the Nova Scotia health card;

- (m) "irreversible" means not physically possible to reverse without violating consent law;
- (n) "living donation" means a donation of organs or tissues in accordance with this Act while the donor is living;
 - (o) "Minister" means the Minister of Health and Wellness;
 - (p) "organ" means an organ, whether whole or in sections, lobes or parts;
- (q) "organ-donation program" means an organ donation program operated by the provincial health authority or another prescribed entity;
 - (r) "physician" means a duly qualified medical practitioner;
- (s) "pre-death transplantation optimizing interventions" means interventions that are performed on a person before the person's death for the purpose of optimizing the chances of a successful transplantation;
 - (t) "Registry" means the Registry established or designated under Section 7;
 - (u) "spouse" of an individual means
 - (i) another individual who is cohabiting with that individual in a conjugal relationship as a married spouse,
 - (ii) a registered domestic partner of the individual, or
 - (iii) an individual who is cohabiting with the individual in a conjugal relationship for a period of at least one year as common-law partners;
- (v) "substitute decision-maker" means a substitute decision-maker as determined under Section 6;
 - (w) "tissue" means a functional group of human cells, excluding organs;
- (x) "tissue bank" means a regional tissue bank operated by the provincial health authority or another prescribed entity;
- (y) "transplantation" means the operation of transferring organs or tissues from a donor, whether living or dead, to a living human recipient;
 - (z) "transplantation activities" means
 - (i) the storage or transportation of the body of a deceased person for use in transplantation,
 - (ii) the removal from the body of a deceased person, for use for the purpose of transplantation, of organs and tissues of which the body consists or that it contains,
 - (iii) the storage or transportation for the purpose of transplantation of organs and tissues that have come from a human body, or
 - (iv) the use for the purpose of transplantation of organs and tissues that have come from a human body.
- 3 (1) This Act does not apply to
 - (a) blood or blood constituents; or
 - (b) zygotes, oocytes, embryos, sperm, semen or ova.

- (2) This Act applies only to a donation made on or after the date this Act comes into force.
- 4 A donation after death or a living donation may be done only in accordance with this Act.
 - 5 Only individuals with the capacity to do so may consent or refuse consent.
- 6 (1) A substitute decision-maker is, with respect to an individual, a person determined in the following order of priority:
 - (a) a person authorized to give consent under the *Medical Consent Act* or the *Personal Directives Act*, unless the authorization excludes decisions about organ or tissue donation and, where there is more than one delegate authorized pursuant to the *Personal Directives Act*, the delegate authorized to make health-care decisions;
 - (b) a guardian or representative under the *Adult Capacity and Decision-making Act* with the appropriate authority to deal with organ donation decisions;
 - (c) a spouse;
 - (d) a child who has reached the age of majority;
 - (e) a parent;
 - (f) a person standing in *loco parentis*;
 - (g) a sibling;
 - (h) a grandparent;
 - (i) a grandchild;
 - (i) an aunt or uncle;
 - (k) a niece or nephew;
 - (1) another relative; or
 - (m) the person lawfully in possession of the individual's body.
- (2) For the purpose of subsection (1), "person lawfully in possession of the body" does not include
 - (a) the Chief Medical Examiner or medical examiner in possession of the body for the purpose of the *Fatality Investigations Act*;
 - (b) where the person died in hospital, the administrative head of the hospital;
 - (c) where the person died in a continuing-care home, the administrative head of the continuing-care home;
 - (d) the Public Trustee in possession of the body for the purpose of its burial under the *Public Trustee Act*;
 - (e) an embalmer or funeral director in possession of the body for the purpose of its burial, cremation or other disposition; or

- (f) the superintendent of a crematorium in possession of the body for the purpose of its cremation.
- (3) For greater certainty, where two or more persons who are not described in the same clause of subsection (1) claim the authority to give or refuse consent under that subsection, the one under the clause occurring first in that subsection prevails.
- (4) A person referred to in subsection (1) may not act as a substitute decision-maker unless the person
 - (a) excepting a spouse, has been in personal contact with the person over the preceding 12-month period or has been granted a court order to shorten or waive the 12-month period;
 - (b) is willing to assume the responsibility for making the decision;
 - (c) knows of no person of a higher order of priority who is able and willing to make the decision; and
- (d) makes a statement in writing certifying the relationship to the person and the facts and beliefs set out in clauses (a) to (c).

DONATION AFTER DEATH

- 7 The Minister shall establish or designate a Registry to record consents and refusals respecting donation after death for transplantation made under this Act.
- **8** (1) An individual may consent to or refuse donation after death for transplantation by providing information respecting the consent or refusal to the Registry in the manner specified by the Minister.
- (2) A consent to donation after death under subsection (1) may be restricted to the donation of specified organs and tissues.
- 9 (1) Subject to Section 15, a consent under Section 8 is full authority for transplantation activities to the extent of the consent.
- (2) Subject to Section 15, where an individual has refused donation after death for transplantation under Section 8, the individual's organs and tissues may not be used for transplantation activities.
- 10 A physician or the Chief Medical Examiner shall, before undertaking transplantation activities, check the Registry to determine whether a decision made under Section 8 is on record in the Registry.
- 11 (1) Subject to Sections 12 to 15, where an individual has not made a consent or refusal under Section 8, the individual is deemed to consent to the individual's organs and tissues being used for transplantation activities.
- (2) A deemed consent under subsection (1) is full authority for transplantation activities.

- 12 (1) An individual is not deemed to consent under Section 11 if the individual has died and for a significant period before dying lacked the capacity to make a decision respecting donation after death.
- (2) For the purpose of subsection (1), a significant period means a sufficiently long period as would lead a reasonable person to conclude that it would be inappropriate for consent to be deemed to have been given.
- (3) Nothing in this Section affects the ability of a substitute decision-maker to give consent on behalf of the individual.
- 13 (1) An individual is not deemed to consent under Section 11 if the individual has died and the individual was not ordinarily resident in the Province for a period of at least 12 months immediately before dying.
- (2) Nothing in this Section affects the ability of a substitute decision-maker to give consent on behalf of the individual.
- 14 (1) An individual is not deemed to consent under Section 11 if the individual was under the age of majority at the time of death.
- (2) Nothing in this Section affects the ability of a substitute decision-maker to give consent on behalf of the individual.
- 15 (1) Where a substitute decision-maker provides information that would lead a reasonable person to conclude that an individual would have made a different decision respecting donation after death than the decision recorded in the Registry or deemed under Section 11, the substitute decision-maker may consent or refuse on behalf of the individual in accordance with that information.
- (2) A consent under subsection (1) is full authority for transplantation activities to the extent of the consent.
- 16 The medical tests to demonstrate that death has occurred are those established by the medical profession from time to time.
- 17 (1) For the purpose of organ donation after death for transplantation, death must be determined by at least two physicians who have skill and knowledge in conducting the specific medical tests established by the medical profession for determining death.
- (2) A physician who has had an association with a proposed organ recipient that might influence the physician's judgement may not take part in the determination of the death of an organ donor.
- (3) No physician who took any part in the determination of death of the organ donor may participate in the organ transplant procedures.

18 Where

- (a) in the opinion of a physician the death of an individual is imminent by reason of injury or disease;
- (b) the physician has reason to believe that Sections 9 to 12 of the *Fatality Investigations Act* may apply when death does occur; and
- (c) a consent under this Act has been obtained for donation after death, the Chief Medical Examiner may allow the removal of organs or tissue after the death of the person notwithstanding that death has not yet occurred.
- 19 (1) Where an individual dies, or in the opinion of a physician death is imminent, in a hospital or in circumstances set out in Sections 9 to 12 of the *Fatality Investigations Act*, the hospital or the Chief Medical Examiner shall, as soon as possible, provide to the organ-donation program and the tissue bank
 - (a) the age of the individual;
 - (b) the cause, or expected cause, of the death of the individual;
 - (c) the time of death of the individual, if death has occurred; and
 - (d) any available past and current personal information, including medical and social history, that is relevant to organ or tissue transplantation.
- (2) The organ-donation program and the tissue bank, shall make a determination as to whether the organs and tissue of the individual may be medically suitable for use in another person by assessing the information provided under subsection (1).
- (3) Where the organ-donation program or the tissue bank determines that the organs or tissue of the individual may be medically suitable for use in another person, the hospital or the Chief Medical Examiner shall, as soon as possible, provide the individual's name and health-card number to the organ-donation program and the tissue bank for the purpose of determining whether the individual has provided a consent or refusal in the Registry and whether deemed consent applies.
- (4) Notwithstanding subsection (1), the hospital or the Chief Medical Examiner shall not provide the information referred to in subsection (1) to the tissue bank and the organdonation program if the individual clearly meets criteria established by the tissue bank and the organ-donation program that set out circumstances in which an individual's organs or tissues would not be medically suitable for use in another person.
- (5) Where the hospital or Chief Medical Examiner does not provide the information referred to in subsection (1), the reasons for the decision must be placed in the record of the person.
- (6) Where the organ-donation program or the tissue bank determines that a medical or other condition exists that may make the organs or tissue of the individual medically unsuitable for use in another person, the reason for the determination must be placed in the record of the individual.

- 20 (1) The chief executive officers of a health authority and the Chief Medical Examiner shall submit a report annually to the Minister.
 - (2) The report referred to in subsection (1) must include
 - (a) the number of deceased persons who were medically suitable to be a donor, based upon criteria established by the tissue bank and the organ-donation program, but were not referred to the tissue bank and the organ-donation program;
 - (b) any actions undertaken or proposed to address issues related to missed referrals and their effectiveness; and
 - (c) any information prescribed by the regulations.
- 21 (1) A person may consent to donation after death for scientific research or education purposes by express personal consent or by consent given by a substitute decision-maker.
- (2) For greater certainty, a deemed consent under Section 11 does not include consent to donation after death for scientific research or educational purposes.
- 22 (1) Consent to donate organs does not imply consent to pre-death transplantation optimizing interventions.
- (2) An individual with the capacity to give voluntary and informed consent may consent to the use of pre-death transplantation optimizing interventions on the individual's body
 - (a) in writing signed by the individual; or
 - (b) orally in the presence of at least two witnesses with documentation of the consent signed by the witnesses at the time the consent or refusal was made.
- (3) Where an individual has not provided consent, the individual lacks capacity to consent and in the opinion of a physician the individual's death is imminent, a substitute decision-maker shall
 - (a) follow any instructions in a personal directive made pursuant to the *Personal Directives Act*, unless
 - (i) there are expressions of a contrary wish made subsequently by the individual while the individual had the capacity to do so,
 - (ii) technological changes or medical advances make the instruction inappropriate in a way that is contrary to the intentions of the individual, or
 - (iii) circumstances exist that would have caused the individual to set out different instructions had the circumstances been known based on what is known of the values and beliefs of the individual and from any other written or oral instructions; or
 - (b) in the absence of instructions, act according to what the substitute decision-maker believes the wishes of the individual would be based on what the substitute decision-maker knows of the values and beliefs of the individual and from any other written or oral instructions.

- (4) The consent of a substitute decision-maker must be given
 - (a) in writing, signed by the substitute decision-maker;
- (b) orally, in person or otherwise, by the substitute decision-maker in the presence of at least two witnesses with documentation of the consent signed by the witnesses at the time the consent or refusal was made; or
- (c) by telegraphic, recorded telephonic or other recorded message of the substitute decision-maker.
- (5) Consent to pre-death transplantation optimizing interventions given under this Act is full authority for a physician or hospital to perform such interventions
 - (a) when it is made; or
 - (b) where it is contained in a personal directive made pursuant to the *Personal Directives Act* or other lawful advance directive, when the personal directive or advance directive is activated.

LIVING DONATION

- 23 (1) Any individual with the capacity to do so may, in writing signed by the individual, consent to donate specific organs or tissues from the individual's living body.
 - (2) The consent must be
 - (a) voluntary and informed; and
 - (b) given by a person with the legal authority to give, refuse or withdraw consent.
- 24 (1) Where an individual lacks the capacity to give a valid consent and the individual has a valid personal directive setting out clear instructions or expressions of wishes that the individual would want to consent to a living donation, a person authorized to give consent pursuant to clause 6(1)(b) or Section 14 of the *Personal Directives Act* who gives voluntary and informed consent may, in writing signed by that person, consent to the living donation of organs for transplantation on behalf of the individual.
- (2) When a person authorized pursuant to subsection (1) is making a decision about a living donation by an individual, the person shall follow any instructions of the individual in a personal directive made pursuant to the *Personal Directives Act* unless
 - (a) there are expressions of a contrary wish made subsequently by the individual while the individual had the capacity;
 - (b) technological changes or medical advances make the instruction inappropriate in a way that is contrary to the intentions of the individual; or
 - (c) circumstances exist that would have caused the individual to set out different instructions had the circumstances been known based on what is known of the values and beliefs of the individual and from any other written or oral instructions.

- 25 (1) Where an individual lacks the capacity to give a valid consent, and the criteria set out in Section 24 are not met, the individual's organs may not be donated from the individual's living body for transplantation without court authorization.
- (2) When the court is deciding whether to authorize a donation for transplantation pursuant to subsection (1), the court shall consider
 - (a) whether the proposed recipient has a close personal relationship with the individual;
 - (b) a written report by a physician stating that the donation by the individual who lacks capacity is the best option for a successful transplant for the recipient;
 - (c) a written report by the ethics program associated with the hospital where the transplant will be performed that has reviewed the case;
 - (d) a written psychosocial report about the donor by an independent psychologist or psychiatrist who has experience working with
 - (i) adults without capacity if the donor is an adult, or
 - (ii) minors without capacity if the donor is a minor;
 - (e) a written statement by the substitute decision-maker who has the authority to make health-care decisions in respect of the individual consenting to the donation;
 - (f) whether the donation
 - (i) where the individual is an adult, is consistent with the known prior wishes of the individual while the individual had the capacity or, where such wishes are not known, is in the best interests of the individual, or
 - (ii) where the individual is a minor, is in the best interests of the individual; and
 - (g) the current wishes of the individual.
- (3) When a substitute decision-maker referred to in clause (2)(e) is making a decision about a living donation by an individual, the substitute decision-maker shall
 - (a) where the individual is an adult,
 - (i) act according to what the substitute decision-maker believes the wishes of the individual would be based on what the substitute decision-maker knows of the values and beliefs of the individual and from any other written or oral instructions, or
 - (ii) where the substitute decision-maker does not know the wishes, values and beliefs of the individual, make a decision that the substitute decision-maker believes would be in the best interests of the individual; or
 - (b) where the individual is a minor, make a decision that the substitute decision-maker believes would be in the best interests of the individual.
- (4) Where there is more than one substitute decision-maker who has equal authorization to make health-care decisions, the court may authorize the donation if there is consent from one of those persons.

- (5) Upon application of a party or on its own motion, the court may order that a guardian *ad litem* be appointed for an individual who lacks capacity.
- **26** (1) A consent given pursuant to Sections 23 and 24 or a court authorization pursuant to Section 25 is full authority for any physician to
 - (a) make any examination of the donor that is necessary to assure medical suitability of the organ specified therein; and
 - (b) remove the specified organ from the body of the donor.
- (2) Where for any reason the organ specified in the consent is not removed in the circumstances to which the consent relates, the consent is void.

GENERAL

- 27 (1) Subject to subsection (3), no person shall buy, sell or otherwise deal in, directly or indirectly, for valuable consideration, any human organ, tissue or body for use in transplantation, education or scientific research.
 - (2) For the purpose of subsection (1), valuable consideration does not include
 - (a) reimbursement for reasonable expenses associated with the removal, transplantation, implantation, processing, preservation and quality control, and storage of organs or tissue;
 - (b) remuneration received for participating in or performing a service necessarily incidental to the process whereby a transplant of human tissue is effected or a human body or part of the body is prepared for use for therapeutic purposes or for the purpose of education or scientific research; or
 - (c) the buying and selling of tissues by the tissue bank as approved by a health authority or the Minister.
- (3) Parties who conduct, fund or participate in research involving human organs or tissues donated under this Act may receive payments for products or processes developed for therapeutic purposes as a result of such research.
- 28 (1) Subject to subsections (2) and (3), no person shall disclose or give to any other person, other than the health-care professionals involved in the person's care and in the transplantation process, any information or document that identifies any person, living or dead, including a substitute decision-maker,
 - (a) who has given or refused to give a consent to donation;
 - (b) with respect to whom a consent to donation has been given or refused; or
 - (c) into whose body organs or tissue has been, is being or may be transplanted.
 - (2) Subsection (1) 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 by the person whose identity would be disclosed.
- (3) Subsection (1) does not apply as between the donor and the recipient if
- (a) an organ, a heart valve or a tissue of a type prescribed by the regulations was donated;
- (b) both the recipient of an organ, heart valve or tissue of a type prescribed by the regulations or the recipient's substitute decision-maker and the donor or the donor's substitute decision-maker voluntarily agree in writing to the exchange of identifying information or to a meeting; and
- (c) those agreeing under clause (b) have been informed of the reasonably foreseeable risks of such a meeting or identifying information exchange before they give their consent.
- 29 No action or other proceeding for damages lies against any person in respect of anything done or omitted to be done in good faith and without negligence in the exercise or intended exercise of any authority under this Act.
 - 30 No person shall give false information under this Act.
- 31 No person shall act on a consent given or deemed to be given under this Act if the person has knowledge
 - (a) that the donor subsequently withdrew the consent; or
 - (b) of an objection by the donor.
- 32 No person shall give a consent or refusal under this Act if the person has personal knowledge that the individual for whom the consent or refusal is given would have made a different decision.
- 33 Every person who knowingly contravenes this Act is guilty of an offence and on summary conviction is liable to a fine of not more than \$10,000 or to imprisonment for a term of not more than six months, or to both a fine and imprisonment.
- **34** Except as provided in Sections 18 and 19, nothing in this Act affects the operation of the *Fatality Investigations Act*.
- 35 Nothing in this Act invalidates an authorization made under the *Human Tissue Gift Act* before the coming into force of this Act.
 - **36** (1) The Governor in Council may make regulations
 - (a) prescribing a facility as a continuing-care home for the purpose of clause 2(d);
 - (b) prescribing an entity or entities that are organ-donation programs within the meaning of clause 2(q);

- (c) prescribing an entity or entities that are tissue banks within the meaning of clause 2(w);
 - (d) respecting the Registry, including
 - (i) the process for recording information in the Registry, and
 - (ii) who may access or edit information recorded in the Registry;
- (e) respecting the manner by which individuals may provide information respecting consents or refusals to donation after death to the Registry;
- (f) prescribing information that must be provided in a report from a hospital or the Chief Medical Examiner;
- (g) prescribing additional reports that hospitals, the Chief Medical Examiner, the organ-donation program or the tissue bank must provide;
- (h) excluding or including certain practices from the meaning of valuable consideration;
- (i) setting rates of reimbursement that are not considered valuable consideration;
- (j) respecting the products or processes for which parties who conduct, fund or participate in research are permitted to receive payments;
 - (k) prescribing types of tissues for the purpose of clause 28(3)(a);
 - (l) defining any word or expression used but not defined in this Act;
 - (m) further defining any word or expression defined in this Act; or
- (n) respecting any matter or thing the Governor in Council considers necessary or advisable to carry out effectively the intent and purpose of this Act.
- (2) The exercise by the Governor in Council of the authority contained in subsection (1) is a regulation within the meaning of the *Regulations Act*.
- 37 Section 5 of Chapter 13 of the Revised Statutes, 1989, the *Anatomy Act*, is repealed.
- 38 Subsection 9(1) of Chapter 13 is amended by striking out "Tissue Gift" in the fourth line and substituting "Organ and Tissue Donation".
- 39 Subsection 11(2) of Chapter 13 is amended by striking out "Tissue Gift" in the fifth line and substituting "Organ and Tissue Donation".
- 40 (1) Subsection 14(1) of Chapter 31 of the Acts of 2001, the *Fatality Investigations Act*, is amended by striking out "*Tissue Gift*" in the fourth line and substituting "*Organ and Tissue Donation*".
- (2) Subsection 14(2) of Chapter 31 is amended by striking out "Tissue Gift" in the fourth line and substituting "Organ and Tissue Donation".

- 41 Chapter 36 of the Acts of 2010, the *Human Organ and Tissue Donation Act*, is repealed.
 - 42 Chapter 215 of the Revised Statutes, 1989, Human Tissue Gift Act, is repealed.
- 43 Section 26 of Chapter 379 of the Revised Statutes, 1989, the *Public Trustee Act*, is amended by striking out "*Tissue Gift*" in the last line and substituting "*Organ and Tissue Donation*".
- 44 This Act comes into force on such day the Governor in Council orders and declares by proclamation.