

Right to Try Act

Preamble

Whereas the process of approval for life-saving treatments to terminally ill patients in Canada often takes many years;

And whereas patients who have a terminal illness do not have the luxury of waiting until a life-saving treatment receives final approval for its use;

And whereas patients who have a terminal illness have a fundamental right to attempt to pursue the preservation of their own lives by accessing all available potential life-saving treatments;

And whereas the use of a potential life-saving treatment is a decision that should be made by the patient with a terminal illness in consultation with the patient's physician;

Now, therefore, Her Majesty, by and with the advice and consent of the Senate and House of Commons of Canada, enacts as follows:

Title

1. This Act shall be known as the Right to Try Act.

Definitions

2. In this Act:

- a. "approving physician" means a licensed physician, certified as a specialist by the Royal College of Physicians and Surgeons of Canada, whose practice includes the treatment and care of the eligible patient's terminal illness;
- b. "eligible patient" means a person who meets all of the following:
 - i. has a terminal illness;
 - ii. has considered all other treatment options currently approved by Health Canada;
 - iii. has received a prescription or recommendation from an approving physician for a potential life-saving treatment;
 - iv. has given informed consent by any means appropriate to their condition or, if the patient is a minor or lacks the mental capacity to provide informed consent, a parent or legal guardian has given informed consent on the patient's behalf in accordance with any laws of the respective jurisdictions governing substitute decisions; and

- v. has documentation from a physician that the person has met the requirements of this subsection;
- c. “informed consent” is given when an eligible patient confirms their understanding of all of the following:
 - i. a general explanation of the currently approved products and treatments, if any, for the terminal illness from which the eligible patient suffers;
 - ii. a description of the specific proposed potential life-saving treatment that the eligible patient is seeking to use;
 - iii. a general description of the best and worst potential outcomes of using the potential life-saving treatment and any known risks and side-effects associated with such treatment. If applicable, the description shall include the possibility that new, unanticipated, different, or worse symptoms may result and that death could be hastened by the administration of the proposed potential life-saving treatment;
 - iv. any costs for which the eligible patient may be responsible.
- d. “person” includes a corporation;
- e. “potential life-saving treatment” means a drug, biological product, device or process, or any combination of the foregoing, which, in the reasonable professional opinion of an approving physician in their absolute discretion, has the potential or possibility, whether or not remote, to:
 - i. treat or cure an eligible patient's terminal illness or assist in the alleviation of the symptoms associated with the terminal illness;
 - ii. extend or prolong an eligible patient's life;
 - iii. stop, delay or reverse the progression of the terminal illness and its symptoms;
 - iv. improve an eligible patient's quality of life; or
 - v. advance the research in the treatment of, or the alleviation of the symptoms associated with, the terminal illness;
- f. “provider of a potential life-saving treatment” means:
 - i. a research facility, hospital or other medical institution engaged in investigating a treatment or cure of a terminal illness;

ii. a person who manufactures, imports or distributes a drug, biological product, or device which could be used in the treatment of a terminal illness; or

iii. any;

A. physician, nurse, pharmacist or other regulated health provider; or

B. other person as prescribed by the regulations

who is involved, either directly or indirectly, in the administration, dispensing, prescribing or delivery of the potential life-saving treatment; and

g. “terminal illness” means an irremediable and incurable disease for which there is no life-saving treatment. For greater certainty, the natural death of a patient suffering from a terminal illness must be reasonably foreseeable.

Provision of Potential Life-Saving Treatment

3. A provider of a potential life-saving treatment may make available or administer a potential life-saving treatment to eligible patients under this Act. This Act does not require that a provider of a potential life-saving treatment make available its potential life-saving treatment to an eligible patient.

4. A provider of a potential life-saving treatment shall have the discretion to devise the conditions, processes and parameters of the administration and delivery of the potential life-saving treatment to an eligible patient. Such conditions, processes and parameters shall include, but not be limited to, the determination of the proper dosing and method of delivery of the potential life-saving treatment, the performance of any necessary tests or examinations and the proper monitoring of the eligible patient’s health. A provider of a potential life-saving treatment may administer and deliver a potential life-saving treatment to one or more eligible patients, in accordance with this Act, in the form of an experimental trial to evaluate the safety, tolerability, efficacy and therapeutic benefit of a potential life-saving treatment.

5. A provider of a potential life-saving treatment may:

a. provide a potential life-saving treatment to an eligible patient without receiving compensation; or

b. require an eligible patient to pay the costs of or associated with the manufacture, administration or delivery of the potential life-saving treatment.

This section does not require a health care insurer to provide coverage for the cost of any potential life-saving treatment. A health care insurer may provide coverage for a potential life-saving treatment.

No Liability

[ntd - provinces may have to amend legislation regulating the practice of medicine to ensure that professional licences won't be revoked when acting in accordance with this Law]

6. Except in the case of gross negligence or willful misconduct, any provider of a potential-life saving treatment to an eligible patient with a terminal illness in accordance with this Act shall not be:
 - a. liable in any civil action; or
 - b. held criminally responsible pursuant to any law or regulation

for any loss, damage, injury or death arising out of, relating to, or resulting from advice given or recommendations made to an eligible patient, the design, development, clinical testing and investigation, manufacturing, labeling, distribution, sale, purchase, donation, dispensing, prescription, administration or use of the potential life-saving treatment or for the safety or effectiveness thereof.

[ntd - provinces may have to amend legislation regulating the practice of medicine to address exemption from malpractice claims and provincial offences when acting in accordance with this Law]

Filing of Information

7. A provider of a potential life-saving treatment must, in accordance with the regulations, provide the information described in section 4 respecting the administration, delivery and use of a potential life-saving treatment, together with such other information required by those regulations, to the recipient designated in those regulations.

Approval for General Use

8. A potential life-saving treatment of a terminal illness may be approved for general use in Canada, subject to and in accordance with any conditions prescribed by the regulations.

Conflict

9. In the event of a conflict between this Act and any other law enacted by the Parliament of Canada, including, but not limited to, the Food and Drug Act, R.S. c. F-27, the Canada Health Act, 1984 c. 6 and the Criminal Code, R.S. C-34, the provisions of this Act shall prevail.

Regulations

10. The Minister of Health must make regulations:
 - a. prescribing additional persons as providers of potential life-saving treatment for the purposes of subparagraph 2(d)(iii)(B) and the conditions under which they may provide treatment; and

- b. respecting the filing of information by a provider of a potential life-saving treatment pursuant to section 7; and
- c. prescribing the conditions under which a potential life-saving treatment may be approved for general use in Canada pursuant to section 8.

Offence and Punishment

- 11.** Any provider of a potential life-saving treatment who knowingly fails to comply with this Act or the regulations,
- a. is guilty of an indictable offence and liable to a term of imprisonment of not more than two years;
 - b. is guilty of an offence punishable on summary conviction; or
 - c. is liable to pay a fine which shall not exceed * * * dollars (\$* * *).

[ntd - to determine amount of fine]