Ohio Revised Code

Section 4731.97 Eligible patients.

Effective: March 22, 2020
Legislation: Senate Bill 229 - 132nd General Assembly

(A) As used in this section:

(1) "Investigational drug, product, or device" means a drug, product, or device that has successfully completed phase one of United States food and drug administration clinical trials and remains under clinical investigation, but has not been approved for general use by the United States food and drug administration. "Investigational drug, product, or device" does not include controlled substances in schedule I, as defined in section 3719.01 of the Revised Code.

(2) "Drug" has the same meaning as in section 4729.01 of the Revised Code.

(3) "Product" means a biological product, other than a drug, that is made from a natural human, animal, or microorganism source and is intended to treat a disease or medical condition.

(4) "Device" means a medical device that is intended for use in the diagnosis or treatment of a disease or medical condition.

(5) "Physician" means an individual authorized by this chapter to practice medicine and surgery or osteopathic medicine and surgery.

(6) "Terminal condition" means any of the following conditions, if irreversible, incurable, and untreatable through a method of treatment approved by the United States food and drug administration:

(a) A progressive form of cancer;

(b) A progressive neurological disorder;

(c) A progressive musculoskeletal disorder;

(d) A condition that, based on reasonable medical standards and a reasonable degree of medical certainty, appears likely to cause death within a period of time that is relatively short but does not exceed twelve months.

(7) "Treating physician" means the physician primarily responsible for providing medical care and treating an eligible patient's terminal condition. "Treating physician" does not include the patient's primary care physician unless that physician is treating the patient's terminal condition and no other physician is primarily responsible for treating the terminal condition. The patient may have more than one treating physician.

(B)(1) Subject to division (B)(2) of this section, an individual is an eligible patient if all of the following conditions are met:

(a) The individual has a terminal condition, as determined by the individual's treating physician and by one other physician who has examined the individual.

(b) The individual, as determined by the individual's treating physician, has considered all treatment options for the terminal condition that are approved by the United States food and drug administration and determined that there are no satisfactory or comparable approved treatments and that the risk from the investigational drug, product, or device is no greater than the probable risk from not treating the terminal condition.

(c) The individual's treating physician recommends the use of the investigational drug, product, or device as a last option available for the individual, attests that it represents the individual's best chance at survival, and agrees to either administer or personally furnish it or has issued a prescription to the individual for the investigational drug, product, or device.

(d) The treating physician includes documentation in the patient's medical record that all of the foregoing conditions have been met.

(2) An individual who meets the requirements of division (B)(1) of this section is not an eligible patient if a clinical trial using the investigational drug, product, or device is actively being conducted

within one hundred miles of the individual's residence, unless the individual applied for participation but was denied access to that clinical trial.

(C)(1) A treating physician may treat an eligible patient with an investigational drug, product, or device after securing the patient's informed consent in a signed statement. If the patient is a minor or lacks the capacity to consent, the informed consent must be obtained from a parent, guardian, or other person legally responsible for the patient.

(2) To secure informed consent, the treating physician must do all of the following:

(a) On a form based on the template created by the state medical board under division (I) of this section, record all of the following:

(i) An explanation of the approved treatment options for the terminal condition from which the patient suffers;

(ii) The specific proposed investigational drug, product, or device;

(iii) The potentially best and worst outcomes of using the investigational drug, product, or device with a realistic description of the most likely outcome, including that there is no proof of efficacy and that it is possible new, unanticipated, different, or worse symptoms might result, and that death could be hastened by the investigational drug, product, or device;

(iv) An explanation that the manufacturer of the investigational drug, product, or device may hold the patient liable for all expenses that arise from the patient's use of the investigational drug, product, or device;

(v) An explanation that any health insurance or government program that covers the individual may not include coverage of any charges by the treating physician or another health care provider for any care or treatment resulting from the patient's use of the investigational drug, product, or device;

(vi) A statement explaining that the manufacturer of the investigational drug, product, or device, the pharmacy or other distributor of the drug, and the patient's treating physician or administering

hospital are not liable for or subject to any of the following for an act or omission related to providing, distributing, or treating with, an investigational drug, product, or device, unless the act or omission constitutes willful or wanton misconduct: damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action.

(b) Have the individual giving consent sign the form in the conscious presence of a competent witness;

(c) Have the witness also sign the form and attest that the individual giving consent appeared to do all of the following:

(i) Concur with the treating physician in believing that all approved treatment options would be unlikely to prolong the patient's life;

(ii) Understand the risks involved with using the investigational drug, product, or device;

(iii) Willingly desire to use the investigational drug, product, or device to treat the terminal condition.

(3) An eligible patient, or the patient's parent, guardian, or other person legally responsible for the patient, may revoke consent to treatment with an investigational drug, product, or device at any time and in any manner that communicates the revocation.

(D)(1) Except for actions constituting willful or wanton misconduct, a treating physician who recommends or treats an eligible patient with an investigational drug, product, or device in compliance with this section is not liable for or subject to any of the following for an action or omission related to treatment with the investigational drug, product, or device: damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action.

(2) This section does not create a new cause of action or substantive legal right against a treating physician or hospital related to a physician's not recommending the use of an investigational drug, product, or device.

(E) An official, employee, or agent of this state shall not, solely because an investigational drug, product, or device has not been approved for general use by the United States food and drug administration, prevent or attempt to prevent access by an eligible patient or eligible patient's treating physician to an investigational drug, product, or device that is being provided or is to be provided in accordance with this section or section 4729.89 of the Revised Code.

(F) If an eligible patient dies while being treated with an investigational drug, product, or device and there are any outstanding costs related to treating the patient, the patient's estate, devisees, and heirs shall not be held liable by any person or government entity for those costs.

(G) Nothing in this section requires a health care insurer, the medicaid program or any other government health care program, or any other entity that offers health care benefits to provide coverage for the costs incurred from the use of any investigational drug, product, or device.

(H) Nothing in this section condones, authorizes, or approves of assisted suicide, as defined in section 3795.01 of the Revised Code, or any action that is considered mercy killing or euthanasia.

(I) As soon as practicable after April 6, 2017, the state medical board shall create a template of the form to be used by a treating physician to secure a patient's informed consent under division (C)(2) of this section and make the template available to physicians and hospitals.