As Introduced

134th General Assembly
Regular Session
2021-2022

H. B. No. 680

Representatives Young, T., Stein
Cosponsors: Representatives Ferguson, Johnson

A BILL

To amend sections 4729.88 and 4731.97 and to enact section 3902.63 of the Revised Code regarding certain off-label use of drugs, products, and devices approved or authorized by the United States Food and Drug Administration and to name this act the Preventative Care Act.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF OHIO:

Section 1. That sections 4729.88 and 4731.97 be amended and section 3902.63 of the Revised Code be enacted to read as follows:

Sec. 3902.63. As used in this section, "off-label drug, product, or device" has the same meaning as in section 4731.97 of the Revised Code.

(A) On and after the effective date of this section, and notwithstanding section 3901.71 of the Revised Code, a health plan issuer shall cover an off-label drug, product, or device prescribed in accordance with section 4731.97 of the Revised Code if the drug, product, or device is already covered under the health benefit plan in question.

(B) Division (A) of this section shall not be construed as doing either of the following:

(1) Requiring a health plan issuer to provide coverage for a drug, product, or device that is not already covered under the health benefit plan in question;

(2) Prohibiting the health plan issuer from imposing cost-sharing amounts, as required by the health benefit plan.

Sec. 4729.88. (A) Notwithstanding any provision of this chapter or rule adopted by the state board of pharmacy, a pharmacist may dispense epinephrine autoinjectors pursuant to a prescription issued under section 4723.483, 4730.433, or 4731.96 of the Revised Code.

A pharmacist who in good faith dispenses epinephrine autoinjectors under this division is not liable for or subject to any of the following for any action or omission of an entity to which an epinephrine autoinjector is dispensed: damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action.

(B) Notwithstanding any provision of this chapter or rule adopted by the state board of pharmacy, a pharmacist may dispense injectable or nasally administered glucagon pursuant to a prescription issued under section 4723.4811, 4730.437, or 4731.92 of the Revised Code.

A pharmacist who in good faith dispenses injectable or nasally administered glucagon under this division is not liable for or subject to any of the following for any action or omission of an entity to which the drug is dispensed: damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action.

(C)(1) Notwithstanding any provision of this chapter or rule adopted by the state board of pharmacy, a pharmacist shall dispense an off-label drug pursuant to a prescription issued under section 4731.97 of the Revised Code, if the drug is available to the pharmacist.

A pharmacist who in good faith dispenses a drug under this division is not liable for or subject to any of the following for any injury, death, or loss to person or property related to dispensing the drug: damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action.

(2) As used in this section:

(a) "Off-label drug" means a drug that has been fully approved by or received emergency use authorization from the United States food and drug administration to treat or prevent a condition that is different from a patient's other qualifying condition.

(b) "Other qualifying condition" has the same meaning as in section 4731.97 of the Revised Code.

Sec. 4731.97. (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) "Off-label drug, product, or device" means a drug, product, or device that has been fully approved by or received emergency use authorization from the United States food and drug administration to prevent or treat a condition that is different from a patient's other qualifying condition.

(6) "Other qualifying condition" means a preventable, acute, or chronic health condition caused by a contagion that has resulted in the death of at least one person in this state.

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

~~(6)~~ (8) "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)~~ (9) "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)~~ (B)(3) of this section, an individual is an eligible patient for treatment with an investigational drug, product, or device 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~~ An individual is an eligible patient for treatment with an off-label drug, product, or device if all of the following conditions are met:

(a) The individual has or is at risk of having an other qualifying condition, as determined by the individual's treating physician and by one other physician who has examined the individual.

(b) The individual's treating physician recommends the use of the off-label drug, product, or device after consultation with the individual and the individual's family and agrees to either administer or personally furnish it or has issued a prescription to the individual for the off-label drug, product, or device.

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

(3) 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 or an off-label 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 or other qualifying condition from which the patient suffers;

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

(iii) The potentially best and worst outcomes of using the investigational drug, product, or device or off-label drug, product, or device with a realistic description of the most likely outcome, including, in the case of an investigational drug, product, or device, 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~~ In the case of an investigational drug, product, or device, 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~~ In the case of an investigational drug, product, or device, 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 or off-label 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 or off-label 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~~ If the individual is being treated with an investigational drug, product, or device, 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 or off-label drug, product, or device;

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

off-label drug, product, or device to prevent or treat the other qualifying 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 or off-label 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 or off-label 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 or off-label use of the 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 or off-label 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 the case of an investigational drug, product, or device, 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~~ the 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 effective date of this amendment, 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 to prevent or treat a patient's other qualifying condition with an off-label drug, product, or device and make the template available to physicians and hospitals.

Section 2. That existing sections 4729.88 and 4731.97 of the Revised Code are hereby repealed.

Section 3. This act shall be known as the Preventative Care Act.