SENATE AMENDED

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THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 1104 Session of 2015

INTRODUCED BY GODSHALL, BOBACK, MILLARD, JAMES, MURT, D. COSTA, O'BRIEN, PASHINSKI, BARRAR, MARSHALL, KOTIK, QUIGLEY, HARHAI, BARBIN, DeLUCA, LEWIS, COHEN, ROZZI, CAUSER, RAVENSTAHL, PETRI, MILNE, ZIMMERMAN, GABLER, COX, WATSON, GIBBONS, KORTZ AND SANTARSIERO, MAY 4, 2015

SENATOR VANCE, PUBLIC HEALTH AND WELFARE, IN SENATE, AS AMENDED, SEPTEMBER 28, 2016

AN ACT

Providing for the use of investigational drugs, biological products and devices by terminally ill patients.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. Short title.

This act shall be known and may be cited as the Right-to-Try Act.

Section 2. Legislative findings and intent.

(a) Findings and declarations.--The General Assembly finds and declares as follows:

(1) The process of approval for investigational drugs, biological products and devices in the United States protects future patients from premature, ineffective and unsafe medications and treatments over the long run, but the process often takes many years.

(2) Patients who have a terminal illness do not have the luxury of waiting until an investigational drug, biological product or device receives final approval from the United States Food and Drug Administration.

(3) Patients who have a terminal illness have a fundamental right to attempt to pursue the preservation of their lives by accessing available investigational drugs, biological products and devices.

(4) The use of available investigational drugs, biological products and devices is a decision that should be made by the patient with a terminal illness in consultation with the patient's health care provider and the patient's health care team, if applicable.

(5) The decision to use an investigational drug, biological product or device should be made with full awareness of the potential risks, benefits and consequences to the patient and the patient's family.

(b) Intent.--It is the intent of the General Assembly to allow terminally ill patients to use potentially life-saving investigational drugs, biological products and devices.

Section 3. Definitions.

The following words and phrases when used in this act shall have the meanings given to them in this section unless the context clearly indicates otherwise:

"Eligible patient." As follows:

(1) A person who has:

(i) a terminal illness, attested to by the patient's treating ~~physician~~ HEALTH CARE PROVIDER; <--

(ii) carefully considered all other treatment options approved by the United States Food and Drug

Administration;

(iii) been unable to participate in a clinical trial for the terminal illness that is located within 100 miles of the patient's home address or has not been accepted to the clinical trial within one week of completion of the clinical trial application process;

(iv) received a recommendation from the patient's treating ~~physician~~ HEALTH CARE PROVIDER for an investigational drug, biological product or device; <--

(v) given written, informed consent for the use of the investigational drug, biological product or device, or, if the patient is a minor or lacks the mental capacity to provide informed consent, a parent or ~~legal guardian~~ LEGALLY AUTHORIZED REPRESENTATIVE has given written, informed consent on the patient's behalf; and <-- <--

(vi) documentation from the patient's treating ~~physician~~ HEALTH CARE PROVIDER that the patient meets the requirements of this paragraph. <--

(2) The term does not include a person being treated as an inpatient in any hospital.

~~"Hospital." As defined in section 802.1 of the act of July 19, 1979 (P.L.130, No.48), known as the Health Care Facilities Act.~~ "HEALTH CARE PROVIDER." A LICENSED HOSPITAL OR HEALTH CARE FACILITY, MEDICAL EQUIPMENT SUPPLIER OR PERSON WHO IS LICENSED, CERTIFIED OR OTHERWISE REGULATED TO PROVIDE HEALTH CARE SERVICES UNDER THE LAWS OF THIS COMMONWEALTH, INCLUDING A PHYSICIAN, PODIATRIST, OPTOMETRIST, PSYCHOLOGIST, PHYSICAL THERAPIST, CERTIFIED NURSE PRACTITIONER, REGISTERED NURSE, NURSE MIDWIFE, PHYSICIAN'S ASSISTANT, CHIROPRACTOR, DENTIST, PHARMACIST OR AN INDIVIDUAL ACCREDITED OR CERTIFIED TO PROVIDE BEHAVIORAL HEALTH <--

SERVICES.

"Investigational drug, biological product or device." A drug, biological product or device that has successfully completed phase one of a clinical trial but has not yet been approved for general use by the United States Food and Drug Administration and remains under investigation in a clinical trial approved by the United States Food and Drug Administration.

~~"Physician." As defined in section 2 of the act of December 20, 1985 (P.L.457, No.112), known as the Medical Practice Act of 1985.~~ <--

"Terminal illness." A disease or condition that, without life-sustaining procedures, will soon result in death or a state of permanent unconsciousness from which recovery is unlikely.

"Written, informed consent." A written document PLACED IN THE PATIENT'S MEDICAL RECORD signed by the patient and attested to by the patient's treating ~~physician~~ HEALTH CARE PROVIDER and a witness that, at a minimum: <--

(1) Explains the currently approved products and treatments for the disease or condition from which the patient suffers.

(2) Attests to the fact that the patient concurs with the patient's treating ~~physician~~ HEALTH CARE PROVIDER in believing that all currently approved and conventionally recognized treatments are unlikely to prolong the patient's life. <--

(3) Clearly identifies the specific proposed investigational drug, biological product or device that the patient is seeking to use.

(4) Describes the potentially best and worst outcomes of

using the investigational drug, biological product or device with a realistic description of the most likely outcome, including the possibility that new, unanticipated, different or worse symptoms might result, and that death could be hastened by the proposed treatment, based on the ~~physician's~~ HEALTH CARE PROVIDER'S knowledge of the proposed treatment in conjunction with an awareness of the patient's condition.

(5) Makes clear that the patient's health insurer and HEALTH CARE provider are not obligated to pay for THE USE OF THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE OR any care or treatments consequent to the use of the investigational drug, biological product or device.

(6) Makes clear that the patient's eligibility for hospice care may be withdrawn if the patient begins curative treatment and care may be reinstated if the curative treatment ends and the patient meets hospice eligibility requirements.

(7) Makes clear that in-home health care may be denied if treatment begins.

(8) States that the patient understands that the patient is liable for all expenses consequent to the use of the investigational drug, biological product or device, and that this liability extends to the patient's estate, unless a contract between the patient and the manufacturer of the investigational drug, biological product or device states otherwise.

Section 4. Access.

(a) General rule.--A manufacturer of an investigational drug, biological product or device may make available the manufacturer's investigational drug, biological product or

device to eligible patients in accordance with this act.

(b) Costs.--A manufacturer may:

(1) Provide an investigational drug, biological product or device to an eligible patient without receiving compensation.

(2) Require an eligible patient to pay the costs of, or the costs associated with, the manufacture of the investigational drug, biological product or device.

(c) Insurers.--~~A health insurer may:~~ <--

~~(1) In its discretion, provide coverage for the cost of an investigational drug, biological product or device.~~

~~(2) Except as set forth in subsection (d), deny coverage to an eligible patient from the time the eligible patient begins use of the investigational drug, biological product or device through a period not to exceed six months from the time the investigational drug, biological product or device is no longer used by the eligible patient.~~

~~(d) Limitation.--Coverage may not be denied for a preexisting condition or in cases where coverage commenced prior to the time the eligible patient begins use of the investigational drug, biological product, or device.~~ NOTHING IN <-- THIS ACT SHALL BE CONSTRUED TO REQUIRE A HEALTH INSURER TO PROVIDE COVERAGE FOR ANY HEALTH CARE SERVICES, INCLUDING INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS OR DEVICES, THAT WOULD NOT OTHERWISE BE A COVERED BENEFIT UNDER AN ELIGIBLE PATIENT'S HEALTH INSURANCE POLICY.

Section 5. Unprofessional conduct.

(a) ~~Physician~~ HEALTH CARE PROVIDER immunity.--No ~~physician~~ <-- HEALTH CARE PROVIDER who in good faith recommends or <-- participates in the use of an investigational drug, biological

product or device under this act shall be subject to criminal or civil liability, nor shall a ~~physician~~ HEALTH CARE PROVIDER be found to have committed an act of unprofessional conduct under ~~the act of October 5, 1978 (P.L.1109, No.261), known as the Osteopathic Medical Practice Act, or the act of December 20, 1985 (P.L.457, No.112), known as the Medical Practice Act of 1985.~~ ANY LAW OF THIS COMMONWEALTH RELATING TO LICENSURE. <--

(b) ~~Physician~~ HEALTH CARE PROVIDER licensure not affected.-- Notwithstanding any other law to the contrary, ~~the State Board of Medicine and the State Board of Osteopathic Medicine may not~~ NO LICENSURE BOARD MAY revoke, suspend or otherwise take any action against an individual holding a license issued ~~under the Osteopathic Medical Practice Act or the Medical Practice Act of 1985,~~ BY A COMMONWEALTH LICENSURE BOARD based solely on the ~~individual's~~ HEALTH CARE PROVIDER'S recommendations to an eligible patient regarding access to or treatment with an investigational drug, biological product or device, as long as the recommendations are consistent with medical standards of care. ~~Any action against an individual or entity's Medicare certification based solely on recommendations that a patient have access to an investigational drug, biological product or device is prohibited.~~

Section 6. Construction.

Nothing in this act shall be construed as creating a private cause of action against a manufacturer of an investigational drug, biological product or device, or against any other person or entity involved in the care of an eligible patient using an investigational drug, biological product or device for any injury suffered by the eligible patient resulting from the investigational drug, biological product or device, as long as

the manufacturer or other person or entity acted in accordance with this act, except when the injury results from a failure to exercise reasonable care.

Section 7. Effective date.

This act shall take effect in 60 days.