SENATE BILL No. 991

June 11, 2014, Introduced by Senators PAPPAGEORGE, NOFS, JONES, BRANDENBURG, COLBECK, KAHN, ROBERTSON and MARLEAU and referred to the Committee on Health Policy.

A bill to authorize access to and use of experimental treatments for patients with a terminal illness; to establish conditions for use of experimental treatment; to prohibit sanctions of health care providers solely for recommending or providing experimental treatment; to clarify duties of a health insurer with regard to experimental treatment authorized under this act; to prohibit certain actions by state officials, employees, and agents; and to restrict certain causes of action arising from experimental treatment.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

Sec. 1. This act shall be known and may be cited as the "right to try act".

Sec. 2. As used in this act, and unless the context otherwise requires:

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(a) "Eligible patient" means an individual who meets all of the following conditions:

(*i*) Has a terminal illness, attested to by the patient's treating physician.

(*ii*) Has considered all other treatment options currently approved by the United States food and drug administration.

(*iii*) Has received a recommendation from his or her physician for an investigational drug, biological product, or device.

(*iv*) Has 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 has given written, informed consent on the patient's behalf.

(*v*) Has documentation from his or her physician that he or she meets the requirements of this subdivision.

(b) "Investigational drug, biological product, or device" means a drug, biological product, or device that has successfully completed phase 1 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 United States food and drug administration-approved clinical trial.

(c) "Terminal illness" means a disease that, without life-sustaining procedures, will soon result in death or a state of unconsciousness from which recovery is unlikely.

(d) "Written, informed consent" means a written document signed by the patient and attested to by the patient's physician and a witness that, at a minimum, includes all of the following:

(*i*) An explanation of the currently approved products and treatments for the disease or condition from which the patient suffers.

(*ii*) An attestation that the patient concurs with his or her physician in believing that all currently approved and conventionally recognized treatments are unlikely to prolong the patient's life.

(*iii*) Clear identification of the specific proposed investigational drug, biological product, or device that the patient is seeking to use.

(*iv*) A description of the potentially best and worst outcomes of using the investigational drug, biological product, or device and a realistic description of the most likely outcome. The description shall include the possibility that new, unanticipated, different, or worse symptoms might result and that death could be hastened by the proposed treatment. The description shall be based on the physician's knowledge of the proposed treatment in conjunction with an awareness of the patient's condition.

(*v*) A statement that the patient's health insurer and provider are not obligated to pay for any care or treatments consequent to the use of the investigational drug, biological product, or device, unless they are specifically required to do so by law or contract.

(*vi*) A statement that the patient's eligibility for hospice care may be withdrawn if the patient begins curative treatment and that care may be reinstated if the curative treatment ends and the patient meets hospice eligibility requirements.

(*vii*) A statement that the patient understands that he or she

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 drug, biological product, or device states otherwise.

Sec. 3. (1) A manufacturer of an investigational drug, biological product, or device may make available the manufacturer's investigational drug, biological product, or device to an eligible patient under this act. This act does not require that a manufacturer make available an investigational drug, biological product, or device to an eligible patient.

(2) A manufacturer may do all of the following:

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

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

Sec. 4. (1) This act does not expand the coverage required of an insurer under the insurance code of 1956, 1956 PA 218, MCL 500.100 to 500.8302.

(2) A health insurer may, but is not required to, provide coverage for the cost of an investigational drug, biological product, or device under this act.

(3) This act does not require any governmental agency to pay costs associated with the use, care, or treatment of a patient with an investigational drug, biological product, or device.

Sec. 5. If a patient dies while being treated by an

investigational drug, biological product, or device, the patient's heirs are not liable for any outstanding debt related to the treatment or lack of insurance due to the treatment.

Sec. 6. Notwithstanding any other law, a licensing board shall not revoke, fail to renew, suspend, or take any action against a health care provider's license issued under article 15 or 17 of the public health code, 1978 PA 368, MCL 333.16101 to 333.18838 and 333.20101 to 333.22260, based solely on the 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. A board shall not take action against a health care provider's medicare certification based solely on the health care provider's recommendation that a patient have access to an investigational drug, biological product, or device.

Sec. 7. An official, employee, or agent of this state shall not block or attempt to block an eligible patient's access to an investigational drug, biological product, or device. Counseling, advice, or a recommendation consistent with medical standards of care from a licensed health care provider is not a violation of this section.

Sec. 8. (1) This act does not create 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 the investigational drug, biological product, or device for any harm done to the eligible patient resulting from the investigational drug, biological

product, or device, if the manufacturer or other person or entity is complying in good faith with the terms of this act and has exercised reasonable care.

(2) This act does not affect any mandatory health care coverage for participation in clinical trials under the insurance code of 1956, 1956 PA 218, MCL 500.100 to 500.8302.