SUBSTITUTE FOR

SENATE BILL NO. 991

A bill to authorize access to and use of experimental treatments for patients with an advanced 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:

(a) "Advanced illness" means a disease or medical or surgical condition with significant functional impairment that is not reversible even with administration of current federal drug administration approved and available treatments that is expected to result in death or a state of unconsciousness from which recovery is not expected. For purposes of this act only, advanced illness has the same general meaning as terminal illness has in the medical community.

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

(*i*) Has an advanced 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.

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

(*vi*) Is not being treated in a hospital licensed or certified under part 215 of the public health code, 1978 PA 38, MCL 333.21501 to 333.21571, or in a facility subject to 42 CFR 482.25, unless approved by the hospital or facility.

(c) "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.

(d) "Written, informed consent" means a written document that is signed by the patient; parent, if the patient is a minor; legal guardian; or patient advocate designated by the patient under section 5506 of the estates and protected individuals code, 1998 PA 386, MCL 700.5506, and attested to by the patient's physician and a witness and 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 plan or third party administrator 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 with the investigational drug, biological product, or device and that care may be reinstated if this 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 and an eligible patient may request the manufacturer's investigational drug, biological product, or device 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 plan, third party administrator, or governmental agency may, but is not required to, provide coverage for the cost of an investigational drug, biological product, or device, or the cost of services related to the use 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.