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:

SENATE BILL No. 991

(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.

Legislative Analysis

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EXPERIMENTAL MEDICAL TREATMENTS: RIGHT TO TRY ACT

Senate Bill 991 (Substitute S-3, as passed by the Senate)
Sponsor: Sen. John Pappageorge

House Committee: Health Policy
Senate Committee: Health Policy

Complete to 9-17-14

A SUMMARY OF HOUSE BILL 5649 AND SENATE BILL 991 AS REPORTED BY HOUSE COMMITTEE 9-16-14

In brief, Senate Bill 991 creates the Right to Try Act to do the following:

- Allow eligible patients (defined in the bill) to access yet-unapproved drugs that successfully completed Phase 1 of an FDA-approved clinical trial.
- Allow a manufacturer to provide the investigational drugs, biological products, or devices with or without compensation by the patient.
- Protect a health care provider from licensing sanctions or loss of Medicare certification based solely on recommending treatment with an experimental drug.
- Prohibit governmental officials or agencies from blocking an eligible patient's access to experimental treatments.
- Specify that the act does not create civil liability for a manufacturer or other person or entity providing care to an eligible patient for harm to the patient resulting from the experimental treatment if reasonable care had been exercised and the act had been complied with in good faith.
- Specify that the act does not expand required coverage by health insurers under the Insurance Code, or require health plans, TPAs, or governmental agencies to provide coverage for costs related to experimental treatment.
- Protect the family of eligible patients from incurring costs related to experimental treatments if the patient dies.

BACKGROUND INFORMATION:

According to information available on the website of the Federal Food and Drug Administration, Phase I studies are usually conducted in healthy volunteers. The goal of a Phase 1 study is to determine the drug's most frequent side effects. How the drug is metabolized and excreted may also be studied. Test subjects in a Phase 1 study typically range from 20 to 80.

Phase 2 studies focus on effectiveness in treating a specific disease or condition; safety continues to be studied as well as short-term side effects, and test subjects range from a few dozen to about 300. If at the end of Phase 2, there is evidence of effectiveness (and presumably no safety implications), a Phase 3 study begins. Phase 3 studies collect more information about safety and effectiveness, study different populations and dosages, and uses the drug in combination with other drugs. Test subjects range from several hundred to about 3,000.

DETAILED SUMMARY:

Senate Bill 991 creates a new act—the Right to Try Act. The act would allow, but not require, a manufacturer of an investigational drug, biological product, or device to make its drug, product, or device available, and allow an eligible patient to request the drug, product, or device. An "investigational drug, biological product, or device" (hereinafter "experimental treatment") would mean a drug, biological product, or device that has successfully completed phase 1 of a clinical trial but not yet been approved for general use by the U.S. Food and Drug Administration and remains under investigation in an FDA-approved clinical trial.

"Eligible patient" means an individual who:

- Has an advanced illness, attested to by the patient's treating physician;
- Has considered all other treatment options currently approved by the FDA;
- Has received a recommendation by his or her physician for an experimental treatment;
- Has given written, informed consent for the experimental treatment; and,
- Has documentation of meeting the requirements of being an eligible patient provided by the physician.

Access to experimental treatments

The bill would prohibit an official, employee, or agent of Michigan from blocking or attempting to block an eligible patient's access to an experimental treatment. Counseling, advice, or a recommendation consistent with medical standards of care from a licensed health care provider is not a violation of this provision.

Manufacturers

The bill would allow a manufacturer to provide an investigational drug, biological product, or device to an eligible patient without receiving compensation. The bill also

allows a manufacturer to require an eligible patient to pay the costs of, or the costs associated with, the manufacture of the drug, product, or device.

What the bill does not do

The Right to Try Act **would not**:

- Expand the coverage required of an insurer under the Insurance Code.
- Require a health plan, third party administrator, or governmental agency to provide coverage for the cost of an experimental treatment, or the cost of services related to its use under the act. However, a health plan, TPA, or governmental agency could do so.
- Require any governmental agency to pay costs associated with the use, care, or treatment of a patient with an experimental treatment.
- Require a hospital or facility licensed under Part 215 of the Public Health Code to provide new or additional services, unless approved by the entity.
- 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 person) for any harm done to the eligible patient resulting from the experimental treatment, if the manufacturer or other person or entity is complying with good faith with the terms of the act and has exercised reasonable care.
- Affect any mandatory health care coverage for participation in clinical trials under the Insurance Code.

If a patient dies during treatment

If a patient dies while being treated by an experimental treatment, the patient's heirs would not be liable for any outstanding debt related to the treatment or lack of insurance due to the treatment.

Action against a health care provider

The bill would prohibit a licensing board or disciplinary subcommittee from revoking, failing to renew, suspending, or taking any action against a health care provider's license issued under Articles 15 or 17 of the Public Health Code **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.

Similarly, an entity responsible for Medicare certification could not take action against the provider's Medicare certification based solely on the provider's recommendation that a patient have access to an experimental treatment.

Definitions

The bill would also define the terms "advanced illness" and "written informed consent."

FISCAL IMPACT:

Senate Bill 991 (S-3), as passed by the Senate would not have a significant fiscal impact on the Bureau of Health Care Services (BHCS) within the Department of Licensing and Regulatory Affairs (LARA).

[Note also that Senate Bill 991 says that it does not require any governmental agency to provide coverage for the cost of an investigational drug, biologic product, or device, or the cost of services related to such use. The bill also says a governmental agency is not require to pay costs associated with the use, care, or treatment of a patient with an investigational drug, biologic product, or device.]

BRIEF DISCUSSION OF THE ISSUES:

The current FDA process to test, approve, and bring a new drug to market can take several years to a decade or more. Proponents of this bill say that this is of little comfort to a person who receives a terminal diagnosis today as the person may not live long enough to benefit from a new drug therapy that is currently progressing though the FDA-required clinical trial process. Clinical trials generally take few if any of the more critical cases, only involve a few dozen to a few hundred or thousand at most, and if a controlled trial, only give the new drug to about half of the participants (the others receive a placebo). The bill addresses this concern by creating a process by which a terminally ill patient could access an experimental drug outside of a clinical trial. A patient could not directly access the drug; a prescription from a treating physician would be required, as well as a very detailed written informed consent letter. Manufacturers would be protected from liability if the patient had an adverse reaction or outcome if the bill's provisions were followed, and patients' families would not be responsible for residual costs related to the experimental drug therapy if the patient died. The bill simply allows a dying patient to try, if he or she so wishes, any available option to cure the illness or extend life.

Critics caution that the bill may not do what many think it would. The bill only allows a patient to request a manufacturer to allow them access to a drug currently in a Phase 2 or 3 clinical trial; it does not require the manufacturer to provide that access. In addition, unlike clinical trials, in which the manufacturer covers the cost of treatment, a manufacturer could charge a patient for the whole cost. Many of the new drug therapies, especially the biological products, are extremely expensive – costing thousands for a single dose. Therefore, most terminally ill patients, who most likely are no longer working, may not be able to afford such treatments, even if the bill allows them access.

Another potential negative implications of the bill is that due to unforeseen adverse reactions, a terminally ill patient able to access an experimental drug may be so ill from the harsh effects of the drug, as compared to palliative (or comfort) care available, that the patient may miss the opportunity of remaining quality time with

loved ones and a comfortable and meaningful end-of-life experience. Moreover, apparently, there already is a process in place, on a case-by-case basis, whereby a manufacturer, with FDA approval, may provide access to experimental drug treatment outside of a clinical trial for humanitarian reasons.

POSITIONS:

A representative of the Goldwater Institute testified in support of Senate Bill 991. (9-16-14)

The Hospice and Palliative Care Association of Michigan indicated a neutral position and submitted written testimony listing various concerns with Senate Bill 991. (9-16-14)

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Fiscal Analyst: Paul Holland

■ This analysis was prepared by nonpartisan House staff for use by House members in their deliberations, and does not constitute an official statement of legislative intent.