Legislative Analysis

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EXPERIMENTAL MEDICAL TREATMENTS: RIGHT TO TRY ACT

House Bill 5649 (Substitute H-1) *(Enacted as PA 346 of 2014)*
Sponsor: Rep. Nancy E. Jenkins

Senate Bill 991 (Substitute S-3, as passed by the Senate) *(Enacted as PA 345 of 2014)*
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.

House Bill 5649 specifies that recommending or providing experimental treatment by a health care provider or a health facility's cooperation in a recommended experimental treatment under the Right to Try Act is not grounds for the Department of Licensing and Regulatory Authority to investigate or take action against a health professional or health facility, except in the case of gross negligence or willful misconduct.

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."

House Bill 5649 adds two new sections to the Public Health Code (MCL 333.16221a and 333.20165a). Except in the case of gross negligence or willful misconduct as determined by the Department of Licensing and Regulatory Affairs (LARA), a health care provider's

recommendation or treatment for an eligible patient under provisions of the Right to Try Act would not be grounds for LARA to investigate under Section 16221 or grounds for disciplinary action against a licensee under Section 16226.

Similarly, a health facility's cooperation in a treatment recommended by a health professional as authorized under the Right to Try Act, alone, would not be grounds for LARA to take action against a licensee under Section 20165, except in the case of gross negligence or willful misconduct.

"Gross negligence" would mean conduct so reckless as to demonstrate a substantial lack of concern for whether serious injury to a person would result.

"Willful misconduct" would mean conduct committed with an intentional or reckless disregard for the safety of others, as by failing to exercise reasonable care to prevent a known danger.

The bill is tie-barred to Senate Bill 991, meaning it could not take effect unless SB 991 were also enacted.

FISCAL IMPACT:

Senate Bill 991 (S-3), as passed by the Senate, and House Bill 5649, as introduced, 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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■ 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.