Legislative Analysis

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EXPERIMENTAL MEDICAL TREATMENTS: RIGHT TO TRY ACT

House Bill 5649
Sponsor: Rep. Nancy E. Jenkins

Senate Bill 991 (Substitute S-3)
Sponsor: Sen. John Pappageorge

House Committee: Health Policy
Senate Committee: Health Policy

Complete to 9-15-14

A SUMMARY OF HOUSE BILL 5649 AS INTRODUCED 6-11-14 AND SENATE BILL 991 AS PASSED BY THE SENATE 8-13-14

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, 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 the Department of Licensing and Regulatory Affairs (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.

The bill is tie-barred to a bill that has not yet been introduced.

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.]

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