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BILL ANALYSIS

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Senate Bill 991 (as introduced 6-11-14)
Sponsor: Senator John Pappageorge
Committee: Health Policy

Date Completed: 7-9-14

CONTENT

The bill would create the "Right to Try Act" to provide for access by an eligible terminally ill patient to drugs, biological products, and medical devices not yet approved for general use. Specifically, the proposed Act would do the following:

- **Allow the manufacturer of an investigational drug, biological product, or device to make it available to an eligible patient, either without compensation or at the patient's expense.**
- **Allow a health insurer to provide coverage for the cost of an investigational drug, biological product, or device.**
- **Provide that a governmental agency would not have to pay costs associated with the use, care, or treatment of a patient with an investigational drug, biological product, or device.**
- **Provide that the heirs of a patient who died while being treated by an investigational drug, product, or device would not be liable for any outstanding debt related to the treatment.**
- **Prohibit a regulatory board from taking any action against a health care provider's license or Medicare certification based solely on the provider's recommendations to an eligible patient regarding access to or treatment with an investigational drug, biological product, or device.**
- **Prohibit a State official, employee, or agent from blocking an eligible patient's access to an investigational drug, biological product, or device.**
- **Provide that the proposed Act would not create a private cause of action against a person for any harm resulting from the use of an investigational drug, product, or device, if the person complied with the Act in good faith and exercised reasonable care.**
- **Provide that the Act would not affect any mandatory health care coverage for participation in clinical trials under the Insurance Code.**

Drug, Product, & Device Manufacturers

The proposed Act would allow, but not require, the manufacturer of an investigational drug, biological product, or device to make it available to an eligible patient.

A manufacturer could provide an investigational drug, biological product, or device to an eligible patient without receiving compensation. A manufacturer also could require an eligible patient to pay the costs of or associated with the manufacture of the drug, product, or device.

"Investigational drug, biological product, or device" would mean 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 U.S. Food and Drug Administration (FDA) and remains under investigation in an FDA-approved clinical trial.

"Eligible patient" would mean an individual who meets all of the following conditions:

-- Has a terminal illness, attested to by the patient's treating physician.
-- Has considered all other treatment options currently approved by the FDA.
-- Has received a recommendation from his or her physician for an investigational drug, biological product, or device.
-- Has given written, informed consent for the use of the 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 done so on the patient's behalf.
-- Has documentation from his or her physician that he or she meets all of the eligibility criteria.

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

"Written, informed consent" would mean 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:

-- An explanation of the currently approved products and treatments for the disease or condition from which the patient suffers.
-- 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.
-- Clear identification of the specific proposed investigational drug, biological product, or device that the patient seeks to use.
-- 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, product, or device, unless specifically required to do so by law or contract.
-- 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 treatment ends and the patient meets hospice eligibility requirements.
-- A statement that the patient understands that he or she is liable for all expenses consequent to the use of the drug, product, or device and that the liability extends to the patient's estate, unless a contract between the patient and the manufacturer of the drug, product, or device states otherwise.

The informed consent document also would have to include a description of the potentially best and worst outcomes of using the drug, product, or device and a realistic description of the most likely outcome, as well as the possibility that new, unanticipated, different, or worse symptoms could result and the proposed treatment could hasten death. The description of outcomes would have to be based on the physician's knowledge of the proposed treatment in conjunction with an awareness of the patient's condition.

Health Insurers

The proposed Act would not expand the coverage required of an insurer under the Insurance Code. A health insurer would be allowed, but not required, to provide coverage for the cost of an investigational drug, biological product, or device. The Act would 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.

If a patient died while being treated by an investigational drug, product, or device, his or her heirs would not be liable for any outstanding debt related to the treatment or lack of insurance due to the treatment.

Health Care Providers & Patient Access

Notwithstanding any other law, a licensing board could not revoke, fail to renew, suspend, or take any action against a health care provider's license issued under Article 15 (Occupations) or 17 (Facilities and Agencies) 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, as long as the recommendations were consistent with medical standards of care. A board also could not take action against a health care provider's Medicare certification based solely on the provider's recommendation that a patient have access to such a drug, product, or device.

An official, employee, or agent of the State of Michigan could 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 would not be a violation of this provision.

Private Cause of Action

The proposed Act would 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 drug, product, or device, for any resulting harm to the patient, if the manufacturer or other person or entity were complying in good faith with the Act's terms and had exercised reasonable care.

Legislative Analyst: Julie Cassidy

FISCAL IMPACT

The bill would permit but not require insurers, including governmental programs like Medicaid, to cover the costs of investigational medications. If insurers chose to cover an investigational drug, it could increase costs, but also could decrease costs as an investigational treatment might be less costly than standard treatment. Therefore, the fiscal impact on Medicaid and on State and local governments as providers of employee health insurance is indeterminate.

Fiscal Analyst: Steve Angelotti

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