Senate Fiscal Agency
P. O. Box 30036
Lansing, Michigan 48909-7536

BILL ANALYSIS

Telephone: (517) 373-5383
Fax: (517) 373-1986

Senate Bill 991 (Substitute S-1 as reported)
Sponsor: Senator John Pappageorge
Committee: Health Policy

CONTENT

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

-- Allow an eligible patient to request an investigational drug, biological product, or device.
-- 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 plan, third-party administrator, or governmental agency to provide coverage for the cost of an investigational drug, biological product, or device, or related services.
-- 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.

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

-- Has an advanced illness, attested to by the patient's treating physician.
-- Has considered all other treatment options currently approved by the U.S. Food and Drug Administration (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.
-- Has documentation from his or her physician that he or she meets all of the eligibility criteria.
-- Is not being treated in a hospital licensed or certified under the Public Health Code or in a facility subject to 42 CFR 482.25 (which establishes pharmaceutical services

requirements for hospitals that participate in Medicare), unless approved by the hospital or facility.

"Advanced illness" would mean a disease or medical or surgical condition with significant 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 the proposed Act, "advanced illness" would have the same general meaning as "terminal illness" has in the medical community.

"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 FDA and remains under investigation in an FDA-approved clinical trial.

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.

Date Completed: 7-22-14 Fiscal Analyst: Steve Angelotti