Senate Public Health and Welfare Committee

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Summary
HB 1104 PN 1420

This legislation creates the Right-to-Try Act. It permits manufacturers which have investigational drugs, biological products, and devices that have completed phase one of a clinical trial the ability to make their products available to eligible patients prior to approval by the United States Food and Drug Administration (USFDA).

An eligible patient is defined as someone, other than a patient being treated as an inpatient in a hospital, who has:

- A terminal illness verified by the patient's physician;
- Carefully considered other treatment options which have been approved by the USFDA;
- Been unable to participate in a clinical trial within 100 miles of the patient's home or not been accepted into a trial within once week of completion of the clinical trial application;
- Received a recommendation from the treating physician;
- Given written, informed consent or if the patient is a minor, a parent or legal guardian has given written, informed consent; and
- Documentation from the treating physician that the patient is eligible

Written, informed consent is a written document signed by the patient and attested to by the treating physician and a witness that:

- Explains the approved treatments and products for the patient's diagnosis,
- Attests to the fact that the patient agrees with the treating physician that all approved treatments are unlikely to prolong the patient's life,
- Identifies the investigational drug, biological product, or device the patient is seeking to use,
- Describes the risks and possible outcomes as well as that death may be hastened by the treatment,

- States that the patient's health insurer and provider are not obligated to pay for any care or treatment consequent to the use of the investigational drug, biological product, or device,
- States that hospice care may be withdrawn if the patient begins curative treatment and reinstated if such treatment ends and the hospice requirements are again met,
- States that in-home-health care may be denied if treatment begins, and
- States that the patient is liable for all costs consequent to 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 states otherwise.

A manufacturer may provide the investigational drug, biological product, or device without compensation or may charge the patient the costs associated with the manufacture. An insurer may provide coverage or deny coverage to a patient for a term not to exceed six months after the patient is no longer using the investigational drug, biological product, or device except that coverage may not be denied for a preexisting condition in which coverage began prior to the use of the investigational drug, biological product, or device.

Physicians acting in good faith under this act will not be subject to criminal or civil liability or be found guilty of unprofessional conduct. Similarly, the State Board of Medicine may not take action against a physician's license based solely on recommendations or treatment so long as they are consistent with medical standards of care. Actions against a physician or hospital's Medicare certification are prohibited.

The act does not create any private cause of action against a manufacturer or anyone involved in the care of an eligible patient except when the injury results from a failure to exercise reasonable care.

Effective Date
This act shall take effect in 60 days.

Amendment A10302 –Clarifies the responsibilities of insurance companies, adds a new definition of health care provider, deletes the definitions of hospital and physician, and replaces the term legal guardian with legally authorized representative. It also requires the written informed consent to be placed in the patient's medical record and deletes language regarding actions against Medicare certification.