This Bill Analysis reflects the contents of the bill as it was presented in committee.

HOUSE BILL 652:
Right to Try Act for Terminally Ill Patients

2015-2016 General Assembly

Committee:	House Health	**Date:**	April 15, 2015
Introduced by:	Reps. Blackwell, Hager, Lambeth, Reives	**Prepared by:**	Amy Jo Johnson Committee Counsel
Analysis of:	PCS to First Edition H652-CSTK-12		

SUMMARY: The PCS to House Bill 652 would establish a process by which eligible patients who are terminally ill could obtain access to investigational drugs, biological products, and devices so long as various requirements are met. The PCS makes technical and clarifying changes.

CURRENT LAW: Generally, non-US Food and Drug Administration (FDA) approved prescription drugs are not available for patient use. Patients may participate, if eligible, in FDA approved clinical trials. If a patient is not eligible for a clinical trial, the FDA has an expanded access program for unapproved drugs; however the patient must be approved to obtain access by the FDA.

BILL ANALYSIS:

The PCS to House Bill 652 would allow the manufacturer of an investigational drug, biological product, or device to make available to an eligible patient that manufacturer's investigational drug, biological product, or device. The manufacturer may provide this investigational drug, biological product, or device with or without a cost to the patient. The phrase "investigational drug, biological product, or device" is defined as "a drug, biological product, or device that has successfully completed Phase I of a clinical trial but has not yet been approved for general use by the [FDA] and remains under investigation in a clinical trial approved by the [FDA]."

In order for a person to be eligible to receive the investigation drug, biological product, or device, the following criteria must be met:

- The person must have a progressive medical or surgical condition that (i) entails significant functional impairment, (ii) is not considered by a treating physician to be reversible even with the administration of available treatments approved by the FDA, and (iii) will soon result in death without life-sustaining procedures. This diagnosis of a terminal illness must be attested by a physician.
- The person must have, in consultation with the treating physician, considered all other treatment options currently approved by the FDA.
- The person must have received a recommendation by the treating physician for use of the investigational drug, biological product, or device.
- The person must have given written, informed consent to use of the investigational drug, biological product, or device.
- There must be documentation from the treating physician that the person meets all of the criteria above. This documentation must include an attestation from the treating physician that the treating physician was consulted in the creation of the required written, informed consent.

With regards to the required written informed consent, House Bill 652 would require that the informed consent must be a written document that is signed by an eligible patient; or if the patient is a minor, by a parent or legal guardian; or if the patient is incapacitated, by a designated health care agent pursuant to a health care power of attorney. The written informed consent must include the following:

- An explanation of the currently approved products and treatments for the eligible patient's terminal illness.
- An attestation that the eligible patient concurs with the treating physician in believing that all currently approved treatments are unlikely to prolong the eligible patient's life.
- Clear identification of the specific investigational drug, biological product, or device proposed for treatment of the eligible patient's terminal illness.
- A description of the potentially best and worst outcomes resulting from use of the investigational drug, biological product, or device to treat the eligible patient's terminal illness, along with a realistic description of the most likely outcome.
- A statement that eligibility for hospice care may be withdrawn if the eligible patient begins treatment of the terminal illness with an investigational drug, biological product, or device, and that hospice care may be reinstated if such treatment ends and the eligible patient meets hospice eligibility requirements.
- A statement that the eligible patient's health benefit plan or third party administrator and provider are not obligated to pay for any care or treatments consequent to the use of the investigational drug, biological product, or device, unless specifically required to do so by law or contract.
- A statement that the eligible patient understands that he or she is liable for all expenses consequent to the use of the investigational drug, biological product, or device and that this liability extends to the eligible patient's estate, unless a contract between the patient and the manufacturer of the drug, biological product, or device states otherwise.
- A statement that the eligible patient or, for an eligible patient who is a minor or lacks capacity to provide informed consent, that the parent or legal guardian consents to the use of the investigational drug, biological product, or device for treatment of the terminal condition.

House Bill 652 would also prohibit any liability to the heirs of the eligible patient for any outstanding debt related to the use of investigational drugs, biological products, or devices.

House Bill 652 also contains provisions that would prohibit certain punitive actions from being taken against health care providers based upon a recommendation to an eligible patient regarding investigational drugs, biological products, or devices. No official, employee, or agent of the State would be able to take action to block or attempt to block an eligible patient's access to investigational drugs, biological products, or devices.

Under House Bill 652, no private right of action would be able to be brought 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 an investigational drug, biological product, or device, for any harm caused to the eligible patient resulting from use of the investigational drug, biological product, or device as long as the manufacturer or other person or entity has made a good faith effort to comply with the provisions of the act and has exercised reasonable care in undertaking his or her actions.

EFFECTIVE DATE: This act becomes effective October 1, 2015.