SENATE OF PENNSYLVANIA
BILL SUMMARY

House Bill 45
Printer's No. 1264

Prime Sponsor: Godshall
Committee: Health and Human Services

SYNOPSIS:

Enacts the "Right-to-Try Act" (the "Act") which allows terminally ill patients to elect to use investigational drugs, biological products and medical devices which have yet to receive final approval by the Federal Food and Drug Administration (the "FDA"). The Act also provides certain immunities to health care providers and manufacturers.

SUMMARY:

The Act finds that while the process for receiving FDA approval of investigational drugs, biological products and medical devices protects patients, it often takes many years. It also finds that terminally ill patients do not have the time to wait for final approval. As a result, the FDA has, among other efforts, created a more streamlined process for patient access to investigational drugs, biological products and medical devices. It is the intent of the Act to allow terminally ill patients to use such drugs, products and devices before final FDA approval under certain circumstances.

Definitions:

An "eligible patient" is defined by the Act as an individual who, among other requirements, has:

- A terminal illness
- Carefully considered all other treatment approved options
- Under circumstances defined in the Act, been unable to participate in a clinical trial for the terminal illness
- Received a recommendation from the treating physician for the use of the drug, product or device
- Given written, informed consent
- Documentation from the treating physician stating that the patient meets the above requirements

An "eligible patient" cannot, however, be an inpatient in any hospital.

A "health care provider" is defined as a licensed health care facility under the Health Care Facilities Act or a person licensed, certified or otherwise regulated to provide health care services.

An "investigational drug, biological product or medical device" is any such drug, product or device that has completed phase one of a clinical trial but has not yet been approved for general use by the FDA.

A "terminal illness" is a condition that, without life-sustaining procedures, will soon result in death or a state of permanent unconsciousness from which recovery is unlikely.

The Act defines "written, informed consent" as a written document signed by a patient and attested to by a treating physician that, at a minimum:

- Explains currently approved products and treatments
- Attests to the fact that the patient concurs with the treating physician that those treatments are unlikely to prolong the patient's life
- Identifies the proposed drug, product or device
- Describes the potentially best and worst outcomes
- Makes clear that the patient's insurer is not obligated to pay for the use of the drug, product or device
- Makes clear that the patient's eligibility for hospice care or in-home care may be withdrawn or denied
- States that the patient understands that the patient (and his or her estate) is liable for all expenses

Access:

Manufacturers may make available the investigational drug, biological product or medical device, with or with out cost, to eligible patients in accordance with the Act.

Nothing in the Act, however, will require an insurer to provide coverage for a drug, product or device not otherwise covered by a patient's health insurance policy.

Unprofessional Conduct:

A health care provider who in good faith recommends an investigational drug, biological product or medical device under the Act may not be subject to criminal or civil liability nor be found to have committed an act of unprofessional conduct.

In addition, a licensure board may not revoke, suspend, or otherwise take any action against:

- An individual holding a license 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 medical device, as long as the recommendations are consistent with medical standards of care
- Any other licensee solely for participating in the use of an investigational drug, biological product or medical device in good faith in accordance with the Act.

Legislative Construction

Nothing in the Act may be construed to create a private cause of action against a manufacturer or against any other person or entity involved in the care of an eligible patient, except when the injury results from a failure to exercise reasonable care.

Effective Date: 60 days

BILL HISTORY:

In the House:

Referred to HUMAN SERVICES, Jan. 23, 2017
Reported as amended, March 22, 2017
First consideration, March 22, 2017
Laid on the table, March 22, 2017
Removed from table, April 4, 2017
Second consideration, with amendments, April 5, 2017
Re-committed to APPROPRIATIONS, April 5, 2017
Re-reported as committed, April 18, 2017
Third consideration and final passage, April 18, 2017 (193-0)

In the Senate

Referred to HEALTH AND HUMAN SERVICES, April 20, 2017

Prepared by: Cortez 6/19/2017