HOUSE COMMITTEE ON APPROPRIATIONS

FISCAL NOTE

HOUSE BILL NO. 45 **PRINTERS NO**. 2108 **PRIME SPONSOR**: Godshall

COST / (SAVINGS)

FUND	FY 2017/18	FY 2018/19
General Fund	**$0**	**$0**

SUMMARY: House Bill 45, Printer's Number 2108, creates the Right-to-Try Act which would allow eligible patients to request and use investigational drugs, biological products and medical devices not yet approved by the U.S. Food and Drug Administration (FDA) as long as the patient has a terminal illness and passes other requirements. This legislation is effective in 60 days.

ANALYSIS: This legislation would allow eligible patients to request and use investigational drugs, biological products and medical devices not yet approved for general use by the FDA but which have successfully completed phase one of a clinical trial and remains under investigation by the FDA. An "eligible patient" is defined as a person who has:

- a terminal illness, attested to by the patient's treating physician;
- carefully considered all other treatment options approved by the FDA;
- been unable to participate in a clinical trial for the terminal illness or has not been accepted into a clinical trial;
- received a recommendation from the patient's physician for the product; and
- given written, informed consent for the use of the product.

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

A physician shall not be held liable or be committed for unprofessional conduct for recommending the use of a product to a patient. This immunity extends to the physician's license as well. In addition, this bill does not create a private cause of action against the manufacturer for use of the product by the eligible patient.

HB 45 does not require a drug or device manufacturer to provide the investigational drug, biological product or medical device to the patient, but rather allows them to do so. A manufacturer may require an eligible patient to pay for the costs associated with the drug, product or device or provide them at no cost to the patient.

This legislation does not require health insurers to provide coverage for any health care services including investigational drugs, biological products or medical devices that would not otherwise be a covered benefit under an eligible patient's health insurance policy.

FISCAL IMPACT: This legislation does not place any requirements on Commonwealth agencies or programs and therefore will have no fiscal impact on Commonwealth funds.

PREPARED BY: Ann Bertolino
House Appropriations Committee (R)

DATE: October 2, 2017

Estimates are calculated using the best information available. Actual costs and revenue impact incurred may vary from estimates.