

# SENATE APPROPRIATIONS COMMITTEE FISCAL NOTE

**BILL NO.** Senate Bill 576

**PRINTER NO.** 1562

**AMOUNT**

No Fiscal Impact

**FUND**

General Fund

**DATE INTRODUCED**

April 6, 2017

**PRIME SPONSOR**

Senator Dinniman

**DESCRIPTION AND PURPOSE OF BILL**

Senate Bill 576 enacts the Cancer Trial Access for Pennsylvania Patients (TAPP) Act clarifying that the reimbursement of certain expenses of cancer clinical trial patients does not constitute impermissible inducements.

The bill provides that all sponsors of cancer clinical trials shall inform potential patient-subjects of the following:

- Reimbursement for travel and ancillary expenses is available to all enrollees based on financial need;
- Coverage of these expenses is done to eliminate financial barriers to enrollment in order to retain patient-subjects in the clinical trial; and
- Family, friends or chaperones that attend the cancer clinical trials with the patient-subject are eligible for reimbursement for travel and ancillary expenses.

The bill stipulates that reimbursement of travel, ancillary medical costs and other direct patient-incurred expenses related to trial participation is not an inducement to participate nor considered coercive or exerting undue influence to participate in a cancer clinical trial. Reimbursement is considered a means to create parity in clinical trial access and to remove barriers to participation for financially burdened patient-subjects.

The bill provides that government, industry, public and private foundations, corporations and individuals may offer financial support to cover ancillary costs through their support of third-party reimbursement entities.

A third-party reimbursement entity is required to register with a Department of Health-approved Pennsylvania college or university with a school of public health within 30 days of the date the entity first reimburses a patient-subject or a patient-subject's family, friends or chaperones. Registration shall include all of the following: the name of the third-party reimbursement entity, its legal or tax status, its employer identification or other similar identification number, the name of its officers and directors, the names of donors of \$5,000 or more, and other information as the Department of Health deems appropriate. The legislation requires registration to be updated annually, and failure to register shall subject the third-party reimbursement entity to a \$300 fine.

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The bill requires reimbursement programs to be reviewed by an institution's independent ethics review committee (IEC) or institutional review board (IRB), which shall consider whether the reimbursed patient-subjects are recruited fairly, informed adequately, and paid appropriately.

The nature of the ancillary support and general guidelines on financial eligibility must be disclosed in the informed consent process. The reimbursement process must also conform to any applicable State and Federal laws.

This act shall take effect in six month.

### **FISCAL IMPACT:**

Senate Bill 576 will have no fiscal impact to the Commonwealth. The bill provides the authority to the Department of Health to promulgate regulations, which can be accomplished within existing staffing levels and funding provided to the department.