AMENDMENTS TO SENATE BILL NO. 576

Sponsor: SENATOR BAKER

Printer's No. 660

Amend Bill, page 1, lines 1 and 2, by striking out all of said lines and inserting

Providing for reimbursement of patient expenses associated with participation in cancer clinical trials and for duties of the Department of Health; and imposing a penalty.

Amend Bill, page 3, by inserting between lines 28 and 29

(11) While the United States Food and Drug Administration recently confirmed to Congress and provided guidance that, in fact, reimbursement of direct patient-incurred expenses is not inducement, many organizations, pharmaceutical companies, philanthropic individuals, charitable organizations, government entities and others still operate under the understanding that such reimbursement could be, in fact, considered inducement.

Amend Bill, page 4, line 12, by striking out all of said line and inserting

"Department." The Department of Health of the Commonwealth.

Amend Bill, page 4, line 15, by striking out all of said line and inserting

"IRB or IEC." An Institutional Review Board (IRB) or an Independent Ethics Review Committee (IEC) that is an appropriately constituted group formally established in accordance with applicable United States Food and Drug Administration regulations or outside the United States by other equivalent and applicable international regulations and guidelines in order to review and monitor biomedical research involving human subjects, and specifically having the authority to approve or disapprove research or to require modifications in research to secure approval.

Amend Bill, page 4, by inserting between lines 17 and 18

"Third-party reimbursement entity." A third-party nonprofit

corporation or public charity that specializes in assisting cancer patients and increasing enrollment, retention and minority participation in cancer clinical trials.

Amend Bill, page 5, line 8, by striking out the comma after "trial" and inserting a semicolon

Amend Bill, page 5, lines 12 and 13, by striking out all of said lines and inserting

(c) Expenses and registration.--The following apply:

(1) Government, industry, public and private foundations,

Amend Bill, page 5, lines 17 through 20, by striking out "third party nonprofit corporations and public charities that" in line 17 and all of lines 18 through 20 and inserting

a third-party reimbursement entity.

(2) A third-party reimbursement entity shall register with a department-approved Pennsylvania college or university with a school of public health. Registration must occur within 30 days of the date the third-party reimbursement entity first reimbursed a patient-subject, or the patient-subject's family, friends or chaperones, for travel or ancillary expenses related to a cancer clinical trial conducted within this Commonwealth.

(3) Registration under paragraph (2) shall include:

(i) The name of the third-party reimbursement entity.

(ii) The third-party reimbursement entity's legal and tax status.

(iii) The third-party reimbursement entity's employer or other similar identification number.

(iv) The names of the third-party reimbursement entity's principal officers and directors.

(v) The names of donors of $5,000 or more to the third-party reimbursement entity.

(vi) Appropriate identifying information, as determined by the department, regarding other sources of funding from a source of $5,000 or more.

(vii) Other information as the department deems necessary or appropriate.

(4) A third-party reimbursement entity registering under paragraph (2) shall update the registration no less than once annually utilizing forms and regulations developed by the department.

(5) A third-party reimbursement entity that fails to register as required by this subsection shall be subject to a

penalty of no more than $300 imposed by the department.

Amend Bill, page 6, line 5, by striking out "90 days" and inserting

six months