

AMENDMENTS TO SENATE BILL NO. 576

Sponsor: SENATOR BAKER

Printer's No. 660

1 Amend Bill, page 1, lines 1 and 2, by striking out all of
2 said lines and inserting
3 Providing for reimbursement of patient expenses associated with
4 participation in cancer clinical trials and for duties of the
5 Department of Health; and imposing a penalty.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

14 a third-party reimbursement entity.

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

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

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

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

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

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

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

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

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

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

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

1 penalty of no more than \$300 imposed by the department.
2 Amend Bill, page 6, line 5, by striking out "90 days" and
3 inserting
4 six months