

## AMENDMENTS TO HOUSE BILL NO. 126

Sponsor: SENATOR DINNIMAN

Printer's No. 2004

1 Amend Bill, page 1, line 1, by striking out "Providing" and  
2 inserting

3 Amending Title 35 (Health and Safety) of the Pennsylvania  
4 Consolidated Statutes, providing for reimbursement of patient  
5 expenses associated with participation in cancer clinical  
6 trials and for duties of the Department of Health; imposing a  
7 penalty; providing

8 Amend Bill, page 1, lines 6 through 15; pages 2 through 5,  
9 lines 1 through 30; page 6, lines 1 through 6; by striking out  
10 all of said lines on said pages and inserting

11 Section 1. Title 35 of the Pennsylvania Consolidated  
12 Statutes is amended by adding chapters to read:

13 CHAPTER 54

14 CANCER TRIAL ACCESS FOR PENNSYLVANIA PATIENTS

15 Sec.

16 5401. Scope.

17 5402. Legislative findings and intent.

18 5403. Definitions.

19 5404. Improving access to cancer clinical trials.

20 § 5401. Scope.

21 This chapter relates to cancer trial access for Pennsylvania  
22 patients.

23 § 5402. Legislative findings and intent.

24 (a) Findings and declarations.--The General Assembly finds  
25 and declares as follows:

26 (1) A Pennsylvanian will be diagnosed with cancer  
27 approximately every four minutes, and a Pennsylvanian will  
28 die of cancer every 10 minutes. African-American  
29 Pennsylvanians in particular face higher rates of cancer  
30 incidence and mortality compared to other races and  
31 ethnicities.

32 (2) The ability to translate medical findings from  
33 research to practice relies largely on having robust and  
34 diverse patient participation in cancer clinical trials.

35 (3) A low participation rate or a homogenous participant

1 group prevents segments of the population from benefiting  
2 from advances achieved through clinical research, creates  
3 uncertainties over the applicability of research findings and  
4 has proven to develop lifesaving drugs that work for some  
5 ethnic populations but not others.

6 (4) Conversely, some drug trials are canceled because  
7 they do not show promise for the current homogenous study  
8 population of patients but could be beneficial to other  
9 ethnicities who are not receiving the trial drug because of  
10 poor participation rates.

11 (5) Diverse patient participation in cancer clinical  
12 trials depends, in part, on whether a participant can afford  
13 ancillary medical and other costs, including transportation  
14 for clinical visits required by trial participation, which  
15 are not covered by standard of care, or lodging during the  
16 course of his or her participation. A national study in 2015  
17 found that patient households making less than \$50,000  
18 annually were almost 30% less likely to participate in  
19 clinical trials.

20 (6) Another barrier to cancer clinical trial  
21 participation is the cost of travel, lodging and other  
22 expenses for a patient's travel companion, including a family  
23 member, friend, health care provider or chaperones that  
24 attend cancer clinical trial treatments to provide emotional,  
25 physical and mental support to the trial participant. Some  
26 trial participants are too old, too young or too ill to  
27 simply travel on their own.

28 (7) Cancer clinical trials often only cover the actual  
29 cost of the drug being tested and very rarely the direct  
30 costs of participation by a patient-subject. There are often  
31 significant expenses associated with enrollment in a clinical  
32 trial that are not covered by the clinical trial site or  
33 sponsor. These include travel expenses to and from the  
34 clinical sites whether by air, car, bus, train, taxi or  
35 public transportation along with the travel costs of parking,  
36 car rental, gas, tolls and lodging.

37 (8) This disparity threatens one of the most basic  
38 ethical underpinnings of clinical research, the requirement  
39 that the benefits of research be made available equitably  
40 among all eligible individuals.

41 (9) According to the National Cancer Institute, Cancer  
42 Clinical Trials Resource Guide, some of the barriers  
43 preventing individuals, with cancer or at high risk of  
44 developing cancer, from participating in clinical trials are  
45 direct and indirect financial and personal costs, including  
46 travel.

47 (10) Some corporations, individuals, public and private  
48 foundations, health care providers and other stakeholders are  
49 hesitant to contribute to or accept funds from programs that  
50 are organized to alleviate financial burdens faced by  
51 patients who wish to participate in clinical trials and their

1 caregivers due to concerns that the United States Food and  
2 Drug Administration or other Federal regulators would view  
3 the payments made from those funds as prohibited inducements  
4 for patients to receive the health care services provided  
5 during clinical trials.

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

14 (b) Intent.--It is the intent of the General Assembly to  
15 enact legislation to define and establish a clear difference  
16 between what is considered inducement for a patient to  
17 participate in a clinical trial and direct reimbursement of  
18 patient-incurred expenses for participating in a cancer clinical  
19 trial.

20 § 5403. Definitions.

21 The following words and phrases when used in this chapter  
22 shall have the meanings given to them in this section unless the  
23 context clearly indicates otherwise:

24 "Cancer clinical trials." Research studies that test new  
25 cancer treatments on people, including chemotherapies, stem cell  
26 therapies and other new treatments.

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

28 "Inducement." Paying a person money, including a lump sum or  
29 salary payment, to participate in a cancer clinical trial.

30 "IRB." An Institutional Review Board that is an  
31 appropriately constituted group formally established in  
32 accordance with applicable United States Food and Drug  
33 Administration regulations or outside the United States by other  
34 equivalent and applicable international regulations and  
35 guidelines in order to review and monitor biomedical research  
36 involving human subjects, and specifically having the authority  
37 to approve or disapprove research or to require modifications in  
38 research to secure approval.

39 "IEC." An Independent Ethics Review Committee that is an  
40 appropriately constituted group formally established in  
41 accordance with applicable United States Food and Drug  
42 Administration regulations or outside the United States by other  
43 equivalent and applicable international regulations and  
44 guidelines in order to review and monitor biomedical research  
45 involving human subjects, and specifically having the authority  
46 to approve or disapprove research or to require modifications in  
47 research to secure approval.

48 "Patient-subject." A person participating in a cancer  
49 clinical trial.

50 "Third-party reimbursement entity." A third-party nonprofit  
51 corporation or public charity that specializes in assisting

1 cancer patients and increasing enrollment, retention and  
2 minority participation in cancer clinical trials.

3 § 5404. Improving access to cancer clinical trials.

4 (a) Inducement.--All sponsors of cancer clinical trials  
5 shall inform potential patient-subjects at the time of the  
6 informed consent process of the following:

7 (1) Reimbursement for travel and ancillary costs is  
8 available to all enrollees based on financial need.

9 (2) Coverage of the travel and other ancillary costs is  
10 done to eliminate financial barriers to enrollment in order  
11 to retain patient-subjects in the clinical trial.

12 (3) Family, friends or chaperones that attend the cancer  
13 clinical trial treatments to support the patient-subject are  
14 eligible for reimbursement of their travel and ancillary  
15 expenses.

16 (b) Reimbursement.--

17 (1) Reimbursement of travel, ancillary medical costs and  
18 other direct patient-incurred expenses related to trial  
19 participation shall not be considered an inducement to  
20 participate in a cancer clinical trial.

21 (2) Reimbursement for travel and ancillary expenses  
22 shall not be considered coercive or exerting undue influence  
23 to participate in a trial; instead reimbursement shall be  
24 considered a means to create parity in clinical trial access  
25 and remove a barrier to participation for financially  
26 burdened patient-subjects.

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

28 (1) Government, industry, public and private  
29 foundations, corporations and individuals may offer financial  
30 support to patient-subjects, or the family, friends or  
31 chaperones of patient-subjects, to cover ancillary costs  
32 through their support of a third-party reimbursement entity.

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

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

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

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

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

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

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

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

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

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

10 (5) A third-party reimbursement entity that fails to  
11 register as required by this subsection shall be subject to a  
12 penalty of no more than \$300 imposed by the department.

13 (d) Reimbursement programs.--Reimbursement programs must  
14 comply with the following:

15 (1) Reimbursement programs that cover ancillary medical  
16 and travel expenses must be reviewed and approved by the IRB  
17 or IEC in conjunction with their review of the proposed  
18 clinical trial. The IRB or IEC must consider whether the  
19 reimbursed patient-subjects are recruited fairly, informed  
20 adequately and paid appropriately.

21 (2) The nature of the ancillary support and general  
22 guidelines on financial eligibility must be disclosed in the  
23 informed consent process.

24 (3) The reimbursement process must conform to Federal  
25 and State laws and guidance.

#### 26 CHAPTER 55

#### 27 EPINEPHRINE AUTO-INJECTOR ENTITIES

28 Sec.

29 5501. Scope.

30 5502. Definitions.

31 5503. Epinephrine auto-injectors for authorized entities.

32 § 5501. Scope.

33 This chapter relates to epinephrine auto-injector entities.

34 § 5502. Definitions.

35 The following words and phrases when used in this chapter  
36 shall have the meanings given to them in this section unless the  
37 context clearly indicates otherwise:

38 "Administer." The direct application of an epinephrine auto-  
39 injector to the body of an individual.

40 "Authorized entity." Any entity or organization, other than  
41 a school entity or a nonpublic school under section 1414.2 of  
42 the act of March 10, 1949 (P.L.30, No.14), known as the Public  
43 School Code of 1949, which has an employee or agent who has  
44 completed the required training and at which allergens capable  
45 of causing anaphylaxis may be present, including, but not  
46 limited to:

47 (1) recreation camps;

48 (2) colleges and universities;

49 (3) day-care facilities;

50 (4) youth sports leagues;

51 (5) amusement parks;

- 1           (6) restaurants;
- 2           (7) places of employment; and
- 3           (8) sports arenas.

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

5           "Epinephrine auto-injector." A single-use device used for  
6 the automatic injection of a premeasured dose of epinephrine  
7 into the human body.

8           "Health care practitioner." An individual who is authorized  
9 to practice some component of the healing arts by a license,  
10 permit, certificate or registration issued by a Commonwealth  
11 licensing agency or board.

12 § 5503. Epinephrine auto-injectors for authorized entities.

13           (a) Prescribing and dispensing.--Notwithstanding any  
14 provision of law to the contrary, a health care practitioner  
15 with prescriptive authority may prescribe epinephrine auto-  
16 injectors in the name of an authorized entity for use in  
17 accordance with this section. Pharmacists and health care  
18 practitioners may dispense epinephrine auto-injectors pursuant  
19 to a prescription issued in the name of an authorized entity.

20           (b) Supply.--

21           (1) An authorized entity may acquire and stock a supply  
22 of epinephrine auto-injectors pursuant to a prescription  
23 issued in accordance with this section. The epinephrine auto-  
24 injectors shall be stored:

25           (i) in a location readily accessible in an  
26 emergency; and

27           (ii) in accordance with:

28           (A) the epinephrine auto-injector's instructions  
29 for use; and

30           (B) any additional requirements that may be  
31 established by the department.

32           (2) An authorized entity shall designate employees or  
33 agents who have completed the training required under  
34 subsection (d) to be responsible for the storage,  
35 maintenance, control and general oversight of epinephrine  
36 auto-injectors acquired by the authorized entity.

37           (c) Use.--An employee or agent of an authorized entity or  
38 other individual associated with the entity who has completed  
39 the training required under subsection (d) may use epinephrine  
40 auto-injectors prescribed under subsection (a) to do any of the  
41 following:

42           (1) Provide an epinephrine auto-injector for immediate  
43 administration to any individual, or the parent, guardian or  
44 caregiver of the individual, who the employee, agent or other  
45 individual associated with the entity believes, in good  
46 faith, is experiencing anaphylaxis, regardless of whether the  
47 individual has a prescription for an epinephrine auto-  
48 injector or has previously been diagnosed with an allergy.

49           (2) Administer an epinephrine auto-injector to any  
50 individual who the employee, agent or other individual  
51 believes, in good faith, is experiencing anaphylaxis,

1 regardless of whether the individual has a prescription for  
2 an epinephrine auto-injector or has previously been diagnosed  
3 with an allergy.

4 (d) Training.--

5 (1) An employee or agent of the authorized entity or  
6 other individual associated with the entity shall complete an  
7 anaphylaxis training program as required by the department.  
8 The training shall be conducted by a nationally recognized  
9 organization experienced in training laypersons in emergency  
10 health treatment, a health care practitioner employed or  
11 contracted by the authorized entity or an entity or  
12 individual approved by the department. The department may  
13 approve specific entities or individuals or may approve  
14 classes of entities or individuals to conduct the training.  
15 Training may be conducted online or in person and, at a  
16 minimum, shall cover:

17 (i) how to recognize signs and symptoms of severe  
18 allergic reactions, including anaphylaxis;

19 (ii) standards and procedures for the storage and  
20 administration of an epinephrine auto-injector; and

21 (iii) emergency follow-up procedures.

22 (2) The entity or individual that conducts the training  
23 shall issue a certificate, on a form developed or approved by  
24 the department, to each individual who successfully completes  
25 the anaphylaxis training program.

26 (e) Good Samaritan protections.--

27 (1) The following shall not be liable for any injuries  
28 or related damages that result from any act or omission taken  
29 under this section:

30 (i) An authorized entity that possesses and makes  
31 available epinephrine auto-injectors and its employees,  
32 agents and other individuals associated with the entity;

33 (ii) a health care practitioner that prescribes or  
34 dispenses epinephrine auto-injectors to an authorized  
35 entity;

36 (iii) a pharmacist or health care practitioner that  
37 dispenses epinephrine auto-injectors to an authorized  
38 entity; and

39 (iv) an individual or entity that conducts the  
40 training described under subsection (d).

41 (2) The immunity provided under paragraph (1) shall not  
42 apply to acts or omissions constituting intentional  
43 misconduct or gross negligence.

44 (3) The administration of an epinephrine auto-injector  
45 in accordance with this section shall not be considered the  
46 practice of medicine or any other profession that otherwise  
47 requires licensure.

48 (4) This subsection shall not eliminate, limit or reduce  
49 any other immunity or defense that may be available under  
50 law, including that provided under 42 Pa.C.S. § 8332  
51 (relating to emergency response provider and bystander good

1 Samaritan civil immunity).

2 (5) An entity located in this Commonwealth shall not be  
3 liable for any injuries or related damages that result from  
4 the provision or administration of an epinephrine auto-  
5 injector outside of this Commonwealth if the entity:

6 (i) would not have been liable for the injuries or  
7 related damages had the provision or administration  
8 occurred within this Commonwealth; or

9 (ii) is not liable for the injuries or related  
10 damages under the law of the state in which the provision  
11 or administration occurred.

12 Section 2. This act shall take effect as follows:

13 (1) The addition of 35 Pa.C.S. Ch. 54 shall take effect  
14 in six months.

15 (2) This section shall take effect immediately.

16 (3) The remainder of this act shall take effect in 60  
17 days.