AMENDMENTS TO HOUSE BILL NO. 126

Sponsor: SENATOR DINNIMAN

Printer's No. 2004

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

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

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

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

CHAPTER 54

CANCER TRIAL ACCESS FOR PENNSYLVANIA PATIENTS

Sec.

5401. Scope.

5402. Legislative findings and intent.

5403. Definitions.

5404. Improving access to cancer clinical trials.

§ 5401. Scope.

This chapter relates to cancer trial access for Pennsylvania patients.

§ 5402. Legislative findings and intent.

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

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

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

(3) A low participation rate or a homogenous participant

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

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

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

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

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

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

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

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

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

(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.

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

§ 5403. Definitions.

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

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

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

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

"IRB." An Institutional Review Board 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.

"IEC." An Independent Ethics Review Committee 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.

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

"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.

§ 5404. Improving access to cancer clinical trials.

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

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

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

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

(b) Reimbursement.--

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

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

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

(1) Government, industry, public and private foundations, corporations and individuals may offer financial support to patient-subjects, or the family, friends or chaperones of patient-subjects, to cover ancillary costs through their support of 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.

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

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

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

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

CHAPTER 55
EPINEPHRINE AUTO-INJECTOR ENTITIES

Sec.
5501. Scope.
5502. Definitions.
5503. Epinephrine auto-injectors for authorized entities.

§ 5501. Scope.

This chapter relates to epinephrine auto-injector entities.

§ 5502. Definitions.

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

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

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

(1) recreation camps;

(2) colleges and universities;

(3) day-care facilities;

(4) youth sports leagues;

(5) amusement parks;

(6) restaurants;
(7) places of employment; and
(8) sports arenas.
"Department." The Department of Health of the Commonwealth.
"Epinephrine auto-injector." A single-use device used for the automatic injection of a premeasured dose of epinephrine into the human body.
"Health care practitioner." An individual who is authorized to practice some component of the healing arts by a license, permit, certificate or registration issued by a Commonwealth licensing agency or board.
§ 5503. Epinephrine auto-injectors for authorized entities.
(a) Prescribing and dispensing.--Notwithstanding any provision of law to the contrary, a health care practitioner with prescriptive authority may prescribe epinephrine auto-injectors in the name of an authorized entity for use in accordance with this section. Pharmacists and health care practitioners may dispense epinephrine auto-injectors pursuant to a prescription issued in the name of an authorized entity.
(b) Supply.--
(1) An authorized entity may acquire and stock a supply of epinephrine auto-injectors pursuant to a prescription issued in accordance with this section. The epinephrine auto-injectors shall be stored:
(i) in a location readily accessible in an emergency; and
(ii) in accordance with:
(A) the epinephrine auto-injector's instructions for use; and
(B) any additional requirements that may be established by the department.
(2) An authorized entity shall designate employees or agents who have completed the training required under subsection (d) to be responsible for the storage, maintenance, control and general oversight of epinephrine auto-injectors acquired by the authorized entity.
(c) Use.--An employee or agent of an authorized entity or other individual associated with the entity who has completed the training required under subsection (d) may use epinephrine auto-injectors prescribed under subsection (a) to do any of the following:
(1) Provide an epinephrine auto-injector for immediate administration to any individual, or the parent, guardian or caregiver of the individual, who the employee, agent or other individual associated with the entity believes, in good faith, is experiencing anaphylaxis, regardless of whether the individual has a prescription for an epinephrine auto-injector or has previously been diagnosed with an allergy.
(2) Administer an epinephrine auto-injector to any individual who the employee, agent or other individual believes, in good faith, is experiencing anaphylaxis,

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

(d) Training.--

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

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

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

(iii) emergency follow-up procedures.

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

(e) Good Samaritan protections.--

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

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

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

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

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

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

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

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

Samaritan civil immunity).

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

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

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

Section 2. This act shall take effect as follows:

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

(2) This section shall take effect immediately.

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