No. 2013-122

AN ACT

SB 1042

Amending the act of September 26, 1951 (P.L.1539, No.389), entitled, as amended, "An act defining clinical laboratory; regulating the operation of the same; requiring such laboratories to obtain permits, and to be operated under the direct supervision of qualified persons; imposing certain duties upon the Department of Health; and providing penalties," further providing for definitions, for inspection, for unlawful conduct and for penalty.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. Section 2 of the act of September 26, 1951 (P.L.1539, No.389), known as The Clinical Laboratory Act, amended December 6, 1972 (P.L.1388, No.297), is amended to read:

Section 2. Definitions.—The **[term]** ***following words and phrases when used in this act shall have the meanings given to them in this section unless the context clearly indicates otherwise:***

"Accept." The act of receiving specimens that are properly collected, separated, labeled, coded, inputted and packaged for shipment or transport to a clinical laboratory operating in accordance with the provisions of this act.

"Clinical Laboratory." **[means any]** *Any* place, establishment or institution organized and operated primarily for the performance of all or any bacteriological, biochemical, microscopical, serological, or parasitological tests by the practical application of one or more of the fundamental sciences to material originating from the human body, by the use of specialized apparatus, equipment and methods, for the purpose of obtaining scientific data which may be used as an aid to ascertain the state of health.

[The term] "Department." **[means the]** *The* Department of Health**[.]** ***of the Commonwealth.***

"Health Care Practitioner." As defined in section 103 of the act of July 19, 1979 (P.L.130, No.48), known as the "Health Care Facilities Act."

"Health Care Provider." As defined in section 103 of the act of July 19, 1979 (P.L.130, No.48), known as the "Health Care Facilities Act."

"Specimen Collection." The instruction, acquisition, separation, labeling, handling, coding or data entry of any material originating from the human body for testing to aid or ascertain a person's state of health.

Section 2. Section 11 of the act, amended August 4, 1961 (P.L.920, No.400), is amended to read:

Section 11. Inspection.—The department **[may at any time visit, enter, examine and inspect the premises occupied, maintained and conducted by any laboratory, and may examine all matters in relation thereto. Periodically the department shall verify the accuracy of the work of each laboratory using such means and standards as the department shall specify by rule or regulation.]** ***shall have the authority to:***

(1) Investigate the facts submitted in an application for permit or renewal of a permit by any person to operate a clinical laboratory and conduct inspections as necessary.

(2) Promulgate regulations for the criteria and manner to investigate or inspect a clinical laboratory.

(3) Maintain access to and enter upon the premises of a clinical laboratory to enforce the provisions of this act.

(4) Exempt or limit out-of-State clinical laboratories from the department's inspection process provided the out-of-State clinical laboratory:

(i) is certified or accredited under section 353 of the Public Health Service Act (58 Stat. 682, 42 U.S.C. § 263a) and, to the extent applicable, by the state that has issued a license or permit to operate a clinical laboratory; and

(ii) provides proof to the department that the clinical laboratory applying for a permit or renewal of a permit has met the requirements for exemption of the inspection process under this section.

Section 3. Sections 13.1 and 14 of the act, amended or added December 6, 1972 (P.L.1388, No.297), are amended to read:

Section 13.1. Unlawful Conduct.—**[It shall be unlawful for any person to solicit, receive, accept, deliver or transmit, by mail or otherwise, material originating from the human body on behalf of any person operating a laboratory not in possession of a permit under this act regardless of whether such laboratory is located in this Commonwealth. The provisions of this section shall not apply to transactions with any person operating a laboratory located in another state, which laboratory has been issued a license or permit in conformity with the "Clinical Laboratories Improvement Act of 1967," and related statutes. Neither shall this section apply to transactions with laboratories operated in this State which are exempt from the permit requirements of this act.]** *(a) Except as provided in section 13, it shall be unlawful for a person or clinical laboratory regardless of whether the person or clinical laboratory is located in this Commonwealth to solicit, collect, process, handle, receive, accept, deliver or transmit, by mail or otherwise, material originating from the human body on behalf of a person or clinical laboratory not in possession of a permit under this act, except that this section may not prohibit a clinical laboratory holding a permit from the department from referring a specimen to another clinical laboratory holding a permit from the department or to a clinical laboratory issued a certificate or accreditation in conformity with section 353 of the Public Health Service Act (58 Stat. 682, 42 U.S.C. § 263a) and related State laws.*

(b) It shall be unlawful for a person or clinical laboratory regardless of whether the person or clinical laboratory is located in this Commonwealth or maintains a permit issued by the department to:

(1) Pay or receive a commission, bonus, kickback or rebate or engage in a split-fee arrangement in any form with a health care provider or health care practitioner, either directly or indirectly, for patients or their specimens referred to any clinical laboratory operating within this