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THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 2461 Session of 2020

INTRODUCED BY GROVE, APRIL 29, 2020

REFERRED TO COMMITTEE ON PROFESSIONAL LICENSURE, APRIL 29, 2020

AN ACT

Amending the act of September 27, 1961 (P.L.1700, No.699), entitled "An act relating to the regulation of the practice of pharmacy, including the sales, use and distribution of drugs and devices at retail; and amending, revising, consolidating and repealing certain laws relating thereto," further providing for authority to administer injectable medications, biologicals and immunizations.

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

Section 1. Section 9.2 of the act of September 27, 1961 (P.L.1700, No.699), known as the Pharmacy Act, is amended to read:

Section 9.2. Authority to Administer Injectable Medications, Biologicals [and], Immunizations and Clinical Tests.--(a) The board shall by regulation establish education and training standards and practice guidelines pursuant to which pharmacists shall be authorized to administer injectable medications, biologicals and immunizations to persons who are more than [eighteen] nine years of age [and influenza immunizations] by injectable or needle-free delivery methods [to persons nine years of age and older]. Such standards and guidelines shall

include, but not be limited to, the following:

(1) Satisfactory completion of an academic and practical curriculum approved by the board that includes the current guidelines and recommendations of the Centers for Disease Control and Prevention in the Public Health Service of the United States Department of Health and Human Services, the American Council on Pharmaceutical Education or a similar health authority or professional body and includes, but is not limited to, disease epidemiology, vaccine characteristics, injection technique, emergency response to adverse events and related topics.

(1.1) Accept as proof of education and training standards the immunization credentials or a license of an individual who, at the time of filing an application is licensed as a pharmacist and has immunization credentials or a license, if applicable, in another state or territory of the United States.

(2) Maintenance of a current cardiopulmonary resuscitation (CPR) certificate acceptable to the board.

(3) That the administration of injectable medications, biologicals and immunizations be in accordance with a definitive set of treatment guidelines established by a physician and the Centers for Disease Control and Prevention, Advisory Committee on Immunization Practices guidelines or another competent authority approved by the board.

(4) That a minimum of two hours of the thirty-hour requirement for continuing education for license renewal be dedicated to this area of practice.

(5) For individuals under eighteen years of age, that parental consent be obtained prior to administration. Administration of [influenza] immunizations by injectable or

needle-free delivery methods shall be in accordance with the immunization schedule established by the Centers for Disease Control and Prevention, the Advisory Committee on Immunization Practices or another competent authority.

(6) Maintenance of a level of professional liability insurance coverage in the minimum amount of one million dollars ($1,000,000) per occurrence or claims made. Failure to maintain insurance coverage as required shall subject the licensees to disciplinary proceedings. The board shall accept as satisfactory evidence of insurance coverage any of the following:

(i) personally purchased liability insurance;

(ii) professional liability insurance coverage provided by the individual licensee's employer; or

(iii) similar insurance coverage acceptable to the board.

(7) Notification of the individual's primary care provider, if known, within forty-eight hours of administration.

(b) A pharmacist's authority to administer injectable medications, biologicals and immunizations shall not be delegated to any other person. A pharmacy intern who has completed a course of education and training which meets the requirements of subsection (a)(1) and (2) may administer injectable medications, biologicals and immunizations to persons who are more than [eighteen] nine years of age [and influenza immunizations] by injectable or needle-free delivery methods [to persons nine years of age and older] and only under the direct, immediate and personal supervision of a pharmacist holding the authority to administer injectable medications, biologicals and immunizations.

(c) On and after the effective date of this subsection, a pharmacist shall be authorized to order and administer the

following for COVID-19:

(1) Injectable medications, biologicals or immunizations authorized or approved by the United States Food and Drug Administration for COVID-19 in a manner which complies with the rules, regulations or guidelines established by the Centers for Disease Control and Prevention.

(2) Injectable medications, biologicals or immunizations consistent with the United States Food and Drug Administration's approved labeling for the injectable medications, biologicals or immunizations.

(3) In vitro diagnostic tests authorized or approved by the United States Food and Drug Administration or the Centers for Disease Control and Prevention. Tests ordered and administered under this paragraph shall comply with existing rules, regulations or guidelines for the administration of the test to determine if a an individual has contracted COVID-19.

(d) A pharmacy may order and administer any tests waived by the United States Food and Drug Administration under the Clinical Laboratory Improvement Amendments of 1988 (Public Law 100-578, 102 Stat. 2903) for the duration of a declaration of a disaster emergency issued by the Governor under 35 Pa.C.S. § 7301(c) (relating to general authority of Governor) for a communicable disease and for ninety days after the termination or expiration of the disaster emergency under 35 Pa.C.S. § 7301(c) unless rescinded, superseded, amended or revised by additional orders of the Governor.

(e) A pharmacy or pharmacist that orders or administers a test under this subsection shall be exempt from the two years from all of the following:

(1) The laboratory experience requirement under section

3(1) of the act of September 26, 1951 (P.L.1539, No.389), known as "The Clinical Laboratory Act."

(2) Any regulation promulgated by the Department of Health which would prevent the administration of a test waived by the United States Food and Drug Administration under the Clinical Laboratory Improvement Amendments of 1988.

(f) A pharmacy or pharmacist that orders or administers a test under this subsection shall only be required to apply to the Department of Health for one (1) screening site permit for multiple screening sites.

(g) As used in this section, the following words and phrases shall have the meanings given to them in this subsection:

"Communicable disease." An illness which is capable of being spread to a susceptible host through the direct or indirect transmission of an infectious agent or its toxic product by an infected person, animal or arthropod or through the inanimate environment.

"COVID-19." The novel coronavirus as identified in the proclamation of disaster emergency issued by the Governor on March 6, 2020, published at 50 Pa.B. 1644 (March 21, 2020).

Section 2. This act shall take effect immediately.