THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 511

Session of 2021

INTRODUCED BY J. WARD, FONTANA, ARGALL, COLLETT, VOGEL, MARTIN, PHILLIPS-HILL, PITTMAN, YUDICHAK, HUTCHINSON, MENSCH, BAKER, BROWNE, STEFANO, MUTH, AUMENT, HAYWOOD, STREET, SANTARSIERO, BROOKS, BREWSTER, TARTAGLIONE AND A. WILLIAMS, APRIL 13, 2021

SENATOR TOMLINSON, CONSUMER PROTECTION AND PROFESSIONAL LICENSURE, AS AMENDED, JUNE 22, 2022

AN ACT

Amending the act of September 27, 1961 (P.L.1700, No.699), entitled "An act relating to the regulation of the practiceof pharmacy, including the sales, use and distribution of drugs and devices at retail; and amending, revising, consolidating and repealing certain laws relating thereto," 5 further providing for authority to administer injectable medications, biologicals and immunizations. AMENDING THE ACT OF SEPTEMBER 27, 1961 (P.L.1700, NO.699), 8 <--ENTITLED "AN ACT RELATING TO THE REGULATION OF THE PRACTICE 9 OF PHARMACY, INCLUDING THE SALES, USE AND DISTRIBUTION OF 10 11 DRUGS AND DEVICES AT RETAIL; AND AMENDING, REVISING, CONSOLIDATING AND REPEALING CERTAIN LAWS RELATING THERETO," 12 FURTHER PROVIDING FOR AUTHORITY TO ADMINISTER INJECTABLE 13 MEDICATIONS, BIOLOGICALS AND IMMUNIZATIONS; AND ABROGATING 14 INCONSISTENT REGULATIONS. 15 16 The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows: 17 18 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 19 20 read: 21 Section 9.2. Authority to Administer Injectable Medications, Biologicals and Immunizations. (a) The board shall by regulation establish education and training standards and 23

- 1 practice guidelines pursuant to which pharmacists shall be
- 2 authorized to administer injectable medications, biologicals and
- 3 immunizations to persons who are more than eighteen years of age
- 4 and influenza immunizations by injectable or needle free
- 5 delivery methods to persons nine years of age and older. Such
- 6 standards and guidelines shall include, but not be limited to,
- 7 the following:
- 8 (1) Satisfactory completion of an academic and practical
- 9 curriculum approved by the board that includes the current-
- 10 guidelines and recommendations of the Centers for Disease
- 11 Control and Prevention in the Public Health Service of the
- 12 United States Department of Health and Human Services, the
- 13 American Council on Pharmaceutical Education or a similar health
- 14 authority or professional body and includes, but is not limited
- 15 to, disease epidemiology, vaccine characteristics, injection
- 16 technique, emergency response to adverse events and related
- 17 topics.
- (2) Maintenance of a current cardiopulmonary resuscitation
- 19 (CPR) certificate acceptable to the board.
- 20 (3) That the administration of injectable medications,
- 21 biologicals and immunizations be in accordance with a definitive
- 22 set of treatment guidelines established by a physician and the
- 23 Centers for Disease Control and Prevention, Advisory Committee
- 24 on Immunization Practices guidelines or another competent-
- 25 authority approved by the board.
- 26 (4) That a minimum of two hours of the thirty hour
- 27 requirement for continuing education for license renewal be-
- 28 dedicated to this area of practice.
- (5) For individuals under eighteen years of age, that
- 30 parental consent be obtained prior to administration.

- 1 Administration of influenza immunizations by injectable or
- 2 needle free delivery methods shall be in accordance with the
- 3 immunization schedule established by the Centers for Disease
- 4 Control and Prevention.
- 5 (6) Maintenance of a level of professional liability
- 6 insurance coverage in the minimum amount of one million dollars
- 7 (\$1,000,000) per occurrence or claims made. Failure to maintain
- 8 insurance coverage as required shall subject the licensees to
- 9 disciplinary proceedings. The board shall accept as satisfactory
- 10 evidence of insurance coverage any of the following:
- (i) personally purchased liability insurance;
- (ii) professional liability insurance coverage provided by
- 13 the individual licensee's employer; or
- (iii) similar insurance coverage acceptable to the board.
- (7) Notification of the individual's primary care provider,
- 16 if known, within forty eight hours of administration.
- 17 (a.1) The board shall by regulation establish education and
- 18 training standards and practice guidelines pursuant to which
- 19 pharmacists shall be authorized to administer:
- 20 (1) injectable medications, biologicals and immunizations to
- 21 persons who are more than eighteen years of age; and
- 22 (2) the following immunizations by injectable or needle free
- 23 delivery methods to persons who are three years of age and
- 24 older:
- 25 (i) A vaccine listed in the United States Centers for
- 26 Disease Control and Prevention's Recommended Immunization
- 27 <u>Schedule recommended by the Federal Advisory Committee on</u>
- 28 Immunization Practices; or
- 29 (ii) A vaccine recommended in the United States Centers for
- 30 Disease Control and Prevention's Health Information for

- 1 International Travel; or
- 2 (iii) A vaccine listed on the Food and Drug Administration's
- 3 Vaccines Licensed for Use in the United States; or
- 4 (iv) A vaccine authorized through Emergency Use
- 5 Authorization by the Food and Drug Administration.
- 6 (a.2) The standards and quidelines to be established by the
- 7 board shall include, but not be limited to, the following:
- 8 <u>(1) Satisfactory completion of an academic and practical</u>
- 9 <u>curriculum approved by the board that includes the current</u>
- 10 guidelines and recommendations of the Centers for Disease
- 11 Control and Prevention in the Public Health Service of the
- 12 United States Department of Health and Human Services, the
- 13 Accreditation Council for Pharmacy Education or a similar health
- 14 <u>authority or professional body and includes, but is not limited</u>
- 15 to, disease epidemiology, vaccine characteristics, injection
- 16 <u>technique</u>, <u>emergency response to adverse events and related</u>
- 17 topics.
- 18 (2) Registration with the board or certification as a
- 19 certified pharmacy technician from either the Pharmacy
- 20 Technician Certification Board or National Healthcareer
- 21 Association and satisfactory completion of a practical training
- 22 program that is approved by the Accreditation Council for
- 23 Pharmacy Education or a similar health authority and a minimum
- 24 of two hours of approved immunization related continuing
- 25 pharmacy education. The practical training program must include,
- 26 but is not limited to, hands on injection technique and the
- 27 <u>recognition and treatment of emergency reactions to vaccines.</u>
- 28 (3) Acceptable proof of education and training standards as
- 29 evidenced by the immunization credentials or a license of an-
- 30 <u>individual who, at the time of filing an application is licensed</u>

- 1 as a pharmacist and has immunization credentials or a license,
- 2 if applicable, in another state or territory of the United
- 3 States.
- 4 <u>(4) Maintenance of a current cardiopulmonary resuscitation</u>
- 5 (CPR) certificate acceptable to the board.
- 6 (5) That the administration of injectable medications,
- 7 biologicals and immunizations be in accordance with a definitive
- 8 set of treatment guidelines established by a physician and the
- 9 <u>Centers for Disease Control and Prevention, Advisory Committee</u>
- 10 on Immunization Practices guidelines or another competent
- 11 authority approved by the board.
- 12 (6) That a minimum of two hours of the thirty hour
- 13 requirement for continuing education for license renewal be
- 14 <u>dedicated to this area of practice.</u>
- 15 (7) For individuals under eighteen years of age, that
- 16 parental consent be obtained prior to administration.
- 17 Administration of influenza immunizations by injectable or
- 18 needle-free delivery methods shall be in accordance with the-
- 19 immunization schedule established by the Centers for Disease
- 20 Control and Prevention, the Advisory Committee on Immunization
- 21 Practices or another competent authority.
- 22 (8) Maintenance of a level of professional liability
- 23 insurance coverage in the minimum amount of one million dollars
- 24 (\$1,000,000) per occurrence or claims made. Failure to maintain
- 25 insurance coverage as required shall subject the licensees to
- 26 <u>disciplinary proceedings</u>. The board shall accept as satisfactory
- 27 <u>evidence of insurance coverage any of the following:</u>
- 28 <u>(i) personally purchased liability insurance;</u>
- 29 (ii) professional liability insurance coverage provided by
- 30 the individual licensee's employer; or

- 1 (iii) similar insurance coverage acceptable to the board.
- 2 <u>(9) Notification of the individual's primary care provider,</u>
- 3 if known, within forty-eight hours of administration.
- 4 (b) A pharmacist's authority to administer injectable
- 5 medications, biologicals and immunizations [shall not] may be
- 6 delegated to [any other person] a pharmacy technician or
- 7 pharmacy intern trained in accordance with this section. A
- 8 pharmacy intern who has completed a course of education and
- 9 training which meets the requirements of subsection [(a)(1) and
- 10 (2)] (a.2) (1) and (4) and a pharmacy technician who meets the
- 11 requirements of subsection (a.2) (2) and (4) may administer
- 12 injectable medications, biologicals and immunizations to persons-
- 13 who are more than eighteen years of age and [influenza] the
- 14 immunizations <u>listed in subsection (a.1)(2)</u> by injectable or
- 15 needle-free delivery methods to persons [nine] who are three
- 16 years of age and older only under the direct, immediate and
- 17 personal supervision of a pharmacist holding the authority to
- 18 administer injectable medications, biologicals and
- 19 immunizations.
- 20 (c) A supervising pharmacist shall report the administration
- 21 of vaccines under this section to the immunization registry
- 22 <u>maintained by the Department of Health within seventy two hours</u>
- 23 of vaccine administration and to the patient's primary care
- 24 physician in accordance with subsection (a.2)(9).
- 25 (d) A pharmacist, pharmacy intern and pharmacy technician
- 26 who administers an immunization to a person under eighteen years
- 27 of age in accordance with this section shall inform the parent
- 28 or adult caregiver on the importance of a well child visit with
- 29 a pediatrician or other licensed primary care provider and refer-
- 30 the patient as appropriate.

- 1 (e) Nothing in this section shall be construed to prohibit a
- 2 supervising pharmacist from delegating the reporting of vaccine
- 3 administration in subsection (c) to a pharmacy technician or
- 4 pharmacy intern.
- 5 Section 2. This act shall take effect in 60 days.
- 6 SECTION 1. SECTION 9.2(A) INTRODUCTORY PARAGRAPH AND (5) AND <--
- 7 (B) OF THE ACT OF SEPTEMBER 27, 1961 (P.L.1700, NO.699), KNOWN
- 8 AS THE PHARMACY ACT, ARE AMENDED AND THE SECTION IS AMENDED BY
- 9 ADDING SUBSECTIONS TO READ:
- 10 SECTION 9.2. AUTHORITY TO ADMINISTER INJECTABLE MEDICATIONS,
- 11 BIOLOGICALS AND IMMUNIZATIONS.--(A) THE BOARD SHALL BY
- 12 REGULATION ESTABLISH EDUCATION AND TRAINING STANDARDS AND
- 13 PRACTICE GUIDELINES PURSUANT TO WHICH PHARMACISTS SHALL BE
- 14 AUTHORIZED TO ADMINISTER INJECTABLE MEDICATIONS, BIOLOGICALS AND
- 15 IMMUNIZATIONS TO PERSONS WHO ARE MORE THAN EIGHTEEN YEARS OF AGE
- 16 AND INFLUENZA AND COVID-19 IMMUNIZATIONS BY INJECTABLE OR
- 17 NEEDLE-FREE DELIVERY METHODS TO PERSONS [NINE] FIVE YEARS OF AGE
- 18 AND OLDER. SUCH STANDARDS AND GUIDELINES SHALL INCLUDE, BUT NOT
- 19 BE LIMITED TO, THE FOLLOWING:
- 20 * * *
- 21 (5) FOR INDIVIDUALS UNDER EIGHTEEN YEARS OF AGE, THAT
- 22 PARENTAL CONSENT BE OBTAINED PRIOR TO ADMINISTRATION.
- 23 ADMINISTRATION OF INFLUENZA AND COVID-19 IMMUNIZATIONS BY
- 24 INJECTABLE OR NEEDLE-FREE DELIVERY METHODS SHALL BE IN
- 25 ACCORDANCE WITH THE IMMUNIZATION SCHEDULE ESTABLISHED BY THE
- 26 CENTERS FOR DISEASE CONTROL AND PREVENTION.
- 27 * * *
- 28 (B) [A] EXCEPT AS PROVIDED UNDER SUBSECTION (E), A
- 29 PHARMACIST'S AUTHORITY TO ADMINISTER INJECTABLE MEDICATIONS,
- 30 BIOLOGICALS AND IMMUNIZATIONS SHALL NOT BE DELEGATED TO ANY

- 1 OTHER PERSON. A PHARMACY INTERN WHO HAS COMPLETED A COURSE OF
- 2 EDUCATION AND TRAINING WHICH MEETS THE REQUIREMENTS OF
- 3 SUBSECTION (A) (1) AND (2) MAY ADMINISTER INJECTABLE MEDICATIONS,
- 4 BIOLOGICALS AND IMMUNIZATIONS TO PERSONS WHO ARE MORE THAN
- 5 EIGHTEEN YEARS OF AGE AND INFLUENZA AND COVID-19 IMMUNIZATIONS
- 6 BY INJECTABLE OR NEEDLE-FREE DELIVERY METHODS TO PERSONS [NINE]
- 7 FIVE YEARS OF AGE AND OLDER ONLY UNDER THE DIRECT, IMMEDIATE AND
- 8 PERSONAL SUPERVISION OF A PHARMACIST HOLDING THE AUTHORITY TO
- 9 ADMINISTER INJECTABLE MEDICATIONS, BIOLOGICALS AND IMMUNIZATIONS
- 10 OR A PHYSICIAN, PHYSICIAN ASSISTANT OR CERTIFIED REGISTERED
- 11 NURSE PRACTITIONER.
- 12 (C) A SUPERVISING PHARMACIST SHALL REPORT THE
- 13 <u>ADMINISTRATION OF IMMUNIZATIONS UNDER THIS SECTION TO THE</u>
- 14 IMMUNIZATION REGISTRY MAINTAINED BY THE DEPARTMENT OF HEALTH
- 15 WITHIN SEVENTY-TWO HOURS OF IMMUNIZATION ADMINISTRATION AND TO
- 16 THE INDIVIDUAL'S PRIMARY CARE PROVIDER IN ACCORDANCE WITH
- 17 SUBSECTION (A) (7). NOTHING IN THIS SUBSECTION SHALL BE CONSTRUED
- 18 TO PROHIBIT A SUPERVISING PHARMACIST FROM DELEGATING THE
- 19 REPORTING OF IMMUNIZATION ADMINISTRATION TO A PHARMACY INTERN.
- 20 (D) A PHARMACIST OR PHARMACY INTERN WHO ADMINISTERS AN
- 21 INFLUENZA OR COVID-19 IMMUNIZATION TO AN INDIVIDUAL UNDER
- 22 EIGHTEEN YEARS OF AGE SHALL INFORM THE PARENT OR ADULT CAREGIVER
- 23 OF THE IMPORTANCE OF A WELL-CHILD VISIT WITH A PEDIATRICIAN OR
- 24 OTHER LICENSED PRIMARY CARE PROVIDER AND REFER THE PATIENT AS
- 25 APPROPRIATE.
- 26 (E) A PHARMACIST WHO HOLDS THE AUTHORITY TO ADMINISTER
- 27 <u>INJECTABLE MEDICATIONS, BIOLOGICALS AND IMMUNIZATIONS MAY</u>
- 28 DELEGATE THE AUTHORITY TO ADMINISTER INFLUENZA AND COVID-19
- 29 <u>IMMUNIZATIONS TO A CERTIFIED REGISTERED NURSE PRACTITIONER</u>,
- 30 PHYSICIAN ASSISTANT, REGISTERED NURSE OR LICENSED PRACTICAL

- 1 NURSE.
- 2 SECTION 2. THE PROVISIONS OF 49 PA. CODE §§ 27.12(C)(1) AND
- 3 27.403(B) ARE ABROGATED INSOFAR AS THEY ARE INCONSISTENT WITH
- 4 THE AMENDMENT OR ADDITION OF SECTION 9.2(A) INTRODUCTORY
- 5 PARAGRAPH AND (5), (B), (C) AND (D) OF THE ACT.
- 6 SECTION 3. THIS ACT SHALL TAKE EFFECT IMMEDIATELY.