SPONSOR: Sen. Pinkney & Rep. K. Johnson & Rep. Minor-Brown
Sens. Buckson, Hoffner, Mantzavinos, Poore, Seigfried;
Reps. Morrison, Snyder-Hall

DELAWARE STATE SENATE
153rd GENERAL ASSEMBLY

SENATE BILL NO. 320
AS AMENDED BY
SENATE AMENDMENT NO. 2

AN ACT TO AMEND TITLE 16 AND TITLE 24 OF THE DELAWARE CODE RELATING TO PHARMACY AND PHARMACISTS.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF DELAWARE:

Section 1. Amend § 3002G, Title 16 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

§ 3002G. Definitions [For application of this section, see 85 Del. Laws, c. 253, § 23].

For purposes of this chapter:

(1) "Health-care practitioner" means an individual licensed under Title 24 as any of the following:

a. A physician.

b. An advanced practice registered nurse.

c. A physician associate.

<u>d. A pharmacist.</u>

Section 2. Amend § 4701, Title 16 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

§ 4701. Definitions.

As used in this chapter:

(39) "Practitioner" means:

a. A physician, dentist, veterinarian, <u>pharmacist,</u> scientific investigator or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in this State.

Section 3. Amend § 2502, Title 24 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

§ 2502. Definitions [Effective until June 30, 2026].

For purposes of this chapter:

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(23) "Practice of pharmacy" means the interpreting, evaluating, and dispensing of a practitioner's or prescriber's order. The "practice of pharmacy" includes the proper compounding, labeling, packaging, and dispensing of a drug to a patient or the patient's agent, and administering a drug to a patient. The "practice of pharmacy" includes the application of the pharmacist's knowledge of pharmaceutics, pharmacology, pharmacokinetics, drug and food interactions, drug product selection, and patient counseling. The "practice of pharmacy" also includes all of the ~~following:~~ practices that fall within the scope of practice of a pharmacist as established by Subchapter VIII of this chapter.

~~a. Participation in drug utilization and/or drug regimen reviews.~~

~~b. Participation in therapeutic drug selection, substitution of therapeutically equivalent drugproducts.~~

~~c. Advising practitioners and other health-care professionals, as well as patients, regarding the total scope of drug therapy, so as to deliver the best care possible.~~

~~d. Monitoring drug therapy.~~

~~e. Performing and interpreting capillary blood tests to screen and monitor disease risk factors or facilitate patient education, the results of which must be reported to the patient's health-care practitioner; screening results to be reported only if outside normal limits.~~

~~f. Conducting or managing a pharmacy or other business establishment where drugs are compounded or dispensed.~~

~~g. [Repealed.]~~

~~h. Administration of injectable medications, biologicals, and immunizations pursuant to a valid prescription from a practitioner or practitioner-approved protocol approved by a physician duly licensed in the State under subchapter III of Chapter 17 of this title or a nurse duly licensed in the State under Chapter 19 of this title. Upon request, a copy of the protocol will be made available to the designated prescriber or prescribers without cost. All vaccine administrations shall be reported to DelVAX within 72 hours of administration. This report to DelVAX shall include the patient's name, the name of the immunization, inoculations, or vaccinations administered, site of injection, lot and expiration, the facility that provided vaccination, and the date of administration, and shall be submitted electronically. Pharmacists, pharmacy interns, and nationally-certified pharmacy technicians who have completed an accredited training program, are currently trained in CPR, and have notified the Delaware Board of Pharmacy, may administer immunizations via a prescriber's order or protocol for patients 3 years of age and older.~~

~~i. Dispensing contraceptives or dispensing and administering injectable hormonal contraceptives under Chapter 30O of Title 16.~~

~~j. Ordering, performing, and interpreting tests authorized by the Food and Drug Administration, and waived under the federal Clinical Laboratory Improvement Amendments of 1988 [42 U.S.C. § 263a].~~

~~k. Initiating drug therapy for health conditions in accordance with § 2525 of this title.~~

~~*l.* Collaborative pharmacy practice in accordance with a collaborative pharmacy practice agreement.~~

~~m. Initiating, dispensing, or administering medications for human immunodeficiency virus (HIV) pre-exposure prophylaxis and HIV post-exposure prophylaxis under § 2525A of this title, which includes administering laboratory tests, conducting assessments and consultations, and providing referrals.~~

(24)a. "Practitioner" or "prescriber" means an individual who is authorized by law to prescribe drugs in the course of professional practice or by collaborative pharmacy practice agreement or research in any state.

b. A pharmacist licensed under this chapter is deemed a practitioner or prescriber when prescribing drugs or ordering laboratory tests in accordance with Subchapter VIII of this chapter.

Section 4. Amend § 2502, Title 24 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

§ 2502. Definitions [Effective June 30, 2026].

For purposes of this chapter:

(33) "Practice of pharmacy" means the interpreting, evaluating, and dispensing of a practitioner's or prescriber's order. The "practice of pharmacy" includes the proper compounding, labeling, packaging, and dispensing of a drug to a patient or the patient's agent, and administering a drug to a patient. The "practice of pharmacy" includes the application of the pharmacist's knowledge of pharmaceutics, pharmacology, pharmacokinetics, drug and food interactions, drug product selection, and patient counseling. The "practice of pharmacy" also includes all of the ~~following:~~ practices that fall within the scope of practice of a pharmacist as established by Subchapter VIII of this chapter.

~~a. Participation in drug utilization or drug regimen reviews.~~

~~b. Participation in therapeutic drug selection, substitution of therapeutically equivalent drug products.~~

~~c. Advising practitioners and other health-care professionals, as well as patients, regarding the total scope of drug therapy, so as to deliver the best care possible.~~

~~d. Monitoring drug therapy.~~

~~e. Performing and interpreting capillary blood tests to screen and monitor disease risk factors or facilitate patient education, the results of which must be reported to the patient's health-care practitioner. Screening results must be reported only if outside normal limits.~~

~~f. Conducting or managing a pharmacy or other business establishment where drugs are compounded or dispensed.~~

~~g. [Repealed.]~~

~~h. Administration of injectable medications, biologicals, and immunizations pursuant to a valid prescription from a practitioner or practitioner-approved protocol approved by a physician duly licensed in this State under subchapter III of Chapter 17 of this title or a nurse duly licensed in this State under Chapter 19 of this title. Upon request, a copy of the protocol will be made available to the designated prescriber or prescribers without cost. All vaccine administrations shall be reported to DelVAX within 72 hours of administration. This report to DelVAX shall include the patient's name, the name of the immunization, inoculations, or vaccinations administered, site of injection, lot and expiration, the facility that provided vaccination, and the date of administration, and shall be submitted electronically. Pharmacists, pharmacy interns, and nationally-certified pharmacy technicians who have completed an accredited training program, are currently trained in CPR, and have notified the Board, may administer immunizations via a prescriber's order or protocol for patients 3 years of age and older.~~

~~i. Dispensing contraceptives or dispensing and administering injectable hormonal contraceptives under Chapter 30O of Title 16.~~

~~j. Ordering, performing, and interpreting tests authorized by the Food and Drug Administration, and waived under the federal Clinical Laboratory Improvement Amendments of 1988 [42 U.S.C. § 263a].~~

~~k. Initiating drug therapy for health conditions in accordance with § 2525 of this title.~~

~~*l.* Collaborative pharmacy practice in accordance with a collaborative pharmacy practice agreement.~~

~~m. Initiating, dispensing, or administering medications for human immunodeficiency virus (HIV) pre-exposure prophylaxis and HIV post-exposure prophylaxis under § 2525A of this title, which includes administering laboratory tests, conducting assessments and consultations, and providing referrals.~~

(34)a. "Practitioner" or "prescriber" means an individual who is authorized by law to prescribe drugs in the course of professional practice or by collaborative pharmacy practice agreement or research in any state.

b. A pharmacist licensed under this chapter is deemed a practitioner or prescriber when prescribing drugs or ordering laboratory tests in accordance with this chapter's definition of the practice of pharmacy.

Section 5. Amend Chapter 25, Title 24 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

Subchapter VIII. Pharmacist Scope of Practice.

§ 2565. Scope of practice of licensed pharmacists.

A pharmacist licensed under this chapter is authorized to do all of the following:

(1) Participate in drug utilization or drug regimen reviews.

(2) Participate in therapeutic drug selection and substitution of therapeutically equivalent drug products.

(3) Advise other health-care professionals, as well as patients, regarding the total scope of drug therapy, so as to deliver the best care possible.

(4) Monitor drug therapy.

(5) Perform and interpret capillary blood tests to screen and monitor disease risk factors or facilitate patient education. Screening results must be reported to the patient's primary health-care practitioner only if outside normal limits.

(6) Conduct or manage a pharmacy or other business establishment where drugs are compounded or dispensed.

(7)a. Subject to paragraph (7)c. of this section, administer injectable medications, biologicals, and immunizations pursuant to a valid prescription from a practitioner or practitioner-approved protocol approved by a physician duly licensed in this State under Subchapter III of Chapter 17 of this title or by a nurse duly licensed in the State under Chapter 19 of this title. Upon request, a copy of the protocol will be made available to the designated prescriber or prescribers without cost.

b. All vaccine administrations must be reported to DelVAX within 72 hours of administration. This report to DelVAX, which must be submitted electronically, must include all of the following:

1. Patient's name.

2. Name of the immunizations, inoculations, or vaccinations administered.

3. Site of injection.

4. Lot and expiration date.

5. Name of facility that provided the vaccination.

6. The date of administration.

c. Pharmacists, pharmacy interns, and nationally certified pharmacy technicians who have completed an accredited training program, are currently trained in CPR, and have notified the Delaware Board of Pharmacy, may administer immunizations via a prescriber's order or protocol for patients 3 years of age and older.

(8) Dispense contraceptives and dispense and administer injectable hormonal contraceptives under Chapter 30O of Title 16.

(9) Order, perform, and interpret tests authorized by the U.S. Food and Drug Administration, and waived under the federal Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. § 263a. A pharmacist may delegate the performance of a test to an intern or nationally certified pharmacy technician acting under the supervision of the pharmacist.

(10) Initiate drug therapy for health conditions in accordance with § 2525 of this title.

(11) Engage in collaborative pharmacy practice in accordance with a collaborative pharmacy practice agreement.

(12) Initiate, dispense, or administer medications for human immunodeficiency virus (HIV) pre-exposure prophylaxis and HIV post-exposure prophylaxis under § 2525A of this title, which includes administering laboratory tests, conducting assessments and consultations, and providing referrals.

(13) Exercise independent prescriptive authority under § 2566 of this title.

(14) Order and evaluate laboratory tests as related to medication therapy, including medication therapy for the treatment of opioid use disorder under § 2568 of this title.

§ 2566. Independent prescriptive authority.

(a) A pharmacist licensed under this chapter may exercise independent prescriptive authority as follows:

(1) For over-the-counter products.

(2) In accordance with a collaborative pharmacy practice agreement.

(3) For opioid antagonists as permitted under Chapter 30G of Title 16.

(4) Drug categories or devices, except for controlled substances, that are prescribed in accordance with the product's U.S. Food and Drug Administration-approved labeling and that are limited to conditions that meet any of the following criteria:

a. Do not require a new diagnosis.

b. Are minor and generally self-limiting.

c. Have a test that is used to guide diagnosis or clinical decision-making, including any established screening procedures that can be safely performed by a pharmacist and any tests waived under the federal Clinical Laboratory Improvement Amendments of 1988, as amended, or the federal rules adopted under the federal Clinical Laboratory Improvement Amendments of 1988, as amended.

(b) A pharmacist licensed under this chapter may not prescribe controlled substances except as provided for in § 2568 of this title regarding medications for opioid use disorder treatment.

§ 2567. Continuity of care.

A pharmacist licensed under this chapter exercising independent prescriptive authority under § 2566 of this title must comply with rules adopted by the Board to ensure continuity of patient care. The rules adopted by the Board for this purpose must provide for at least the following:

(1) A system, such as the Delaware Health Information Network (DHIN), for documenting the reason for a pharmacist's assessment of a patient, the clinical findings resulting from the assessment, the pharmacist's plan of care, and the treatment provided by the pharmacist, if any.

(2) Systems and processes to allow a pharmacist to communicate with a patient's primary care provider.

(3) Processes that promote continuity of care for patients who do not have a primary care provider or cannot provide contact information for a primary care provider.

§ 2568. Medications for opioid use disorder treatment.

A licensed pharmacist exercising independent prescriptive authority under § 2566 of this title may, under a standing order from the Division of Public Health, prescribe medications, including controlled substances, that are approved by the U.S. Food and Drug Administration for use in the treatment of opioid use disorder.

§ 2569. Malpractice reporting requirement.

A pharmacist practicing under this chapter shall inform the Board in writing of any medical malpractice claim against the pharmacist that has been settled or adjudicated to final judgment ("judgment"). A medical or pharmaceutical insurance carrier who has provided coverage on the malpractice claim shall also inform the Board in writing of the malpractice claim. Notice required to be made under this section must be filed with the Board within 30 days of the settlement or judgment.

§ 2570. Regulations and interpretation.

(a) The Board shall amend and adopt regulations as necessary to implement this subchapter.

(b) Nothing in this subchapter may be construed to prohibit or invalidate the continued use of statewide protocols, standing orders, or collaborative practice agreements authorized elsewhere in this title or under Title 16.

Section 6. This Act takes effect immediately and is to be implemented the earlier of the following:

(1) 1 year from the date of the Act's enactment.

(2) Notice by the Board of Pharmacy published in the Register of Regulations that the final regulations to implement this Act have been promulgated.