



SPONSOR: Sen. S. McBride & Rep. Harris & Rep. Morrison
Sens. Hoffner, Huxtable, Pinkney, Sokola, Sturgeon,
Townsend; Rep. Baumbach

DELAWARE STATE SENATE
152nd GENERAL ASSEMBLY

SENATE BILL NO. 194

AN ACT TO AMEND TITLE 24 OF THE DELAWARE CODE RELATING TO PRACTICE OF PHARMACY.

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

Section 1. Amend Chapter 25, Title 24 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underlines as follows and by redesignating accordingly:

§ 2502. Definitions.

For purposes of this chapter:

(21) "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 pharmaceuticals, pharmacology, pharmacokinetics, drug and food interactions, drug product selection, and patient counseling. The "practice of pharmacy" also includes all of the following:

- a. Participation in drug utilization and/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 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- g. [Repealed.]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 adult immunizations pursuant to a valid prescription or physician-approved protocol approved by a physician duly licensed in the State under subchapter

III of Chapter 17 of this title. Pharmacists shall request which physician or physicians and notify the physician or physicians as designated by the patient of such administration within 72 hours. The notice shall include the patient's name, the name of the immunizations, inoculations or vaccinations administered, and the date of administration and may be submitted by phone, fax, post or electronically. Upon request a copy of the protocol will be made available to the designated physician or physicians without costs.

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. 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.

§2525A. Human immunodeficiency virus (HIV) pre-exposure prophylaxis and HIV post-exposure prophylaxis.

(a) Pursuant to a statewide written protocol approved by the Division of Public Health, a pharmacist may initiate, dispense, or administer medications for HIV pre-exposure prophylaxes and for HIV post-exposure prophylaxis, which includes administering laboratory tests, conducting assessments and consultations, and providing referrals.

(b) When initiating therapy for and administering or dispensing HIV pre-exposure prophylaxis or HIV post-exposure prophylaxis under a statewide protocol, a pharmacist must complete a training program approved by the Board within 1 year of the first time initiating therapy and administering or dispensing HIV pre-exposure prophylaxis or HIV post-exposure prophylaxis. The training program must include information about all of the following:

(1) Financial assistance programs for HIV pre-exposure prophylaxis and HIV post-exposure prophylaxis.

(2) Relevant federal guidelines regarding HIV pre-exposure prophylaxis or HIV post-exposure prophylaxis.

(c) When initiating therapy for and administering or dispensing HIV pre-exposure prophylaxis or HIV post-exposure prophylaxis to a new patient, a pharmacist may not allow the patient to waive consultation for HIV pre-exposure prophylaxis or HIV post-exposure prophylaxis.

(d) HIV pre-exposure prophylaxis.

(1) Under a statewide protocol, a pharmacist may dispense between a 30-day and 60-day supply of HIV pre-exposure prophylaxis if the all of the following apply:

a. The patient is HIV-negative as documented by a negative HIV test result obtained within the previous 7 days from one of the following:

1. An HIV antigen/antibody test.

2. An HIV antibody-only test.

3. A rapid, point-of-care fingerstick blood test approved by the U.S. Food and Drug Administration.

b. The patient does not report any of the following:

1. Any signs or symptoms of acute HIV infection on a self-reported checklist of acute HIV infection signs and symptoms.

2. Usage of any contraindicated medication.

c. The pharmacist provides counseling to the patient on the ongoing use of HIV pre-exposure prophylaxis, which must include education about all of the following:

1. Side effects.

2. Safety during pregnancy and breastfeeding.

3. Adherence to recommended dosing.

4. The importance of timely testing and treatment for HIV, renal function, hepatitis B, hepatitis C, sexually transmitted infections, and pregnancy for individuals of childbearing capacity.

5. The requirement for subsequent prescriptions for HIV pre-exposure prophylaxis issued by a primary care provider.

d. To the extent possible, the pharmacist documents the services provided by the pharmacist in the patient record system shared with the primary care provider.

(2) If the test results from a test under paragraph (1)a. of this subsection are not sent directly to the pharmacist, the pharmacist must verify the test results.

(3) If the patient tests positive for HIV infection from a test under paragraph (1)a. of this subsection, the pharmacist shall direct the primary care provider and provide a list of providers and clinics in the region.

(4) If the patient does not provide evidence of a negative HIV test under paragraph (1)a. of this subsection, the pharmacist shall initiate and administer an HIV test and interpret the test results prior to initiating any treatment under this subsection.

(e) HIV post-exposure prophylaxis.

(1) Under a statewide protocol, a pharmacist may dispense a course of HIV post-exposure prophylaxis if the pharmacist does all of the following:

- a. Screens the patient and determines that the exposure to HIV occurred within the previous 72 hours.
- b. Provides HIV testing or determines that the patient is one of the following:
 - 1. Willing to undergo HIV testing consistent with federal guidelines.
 - 2. Unwilling to undergo HIV testing but otherwise eligible for HIV post-exposure prophylaxis.
- c. Provides counseling to the patient on the ongoing use of HIV post-exposure prophylaxis, which must include education about all of the following:
 - 1. Side effects.
 - 2. Safety during pregnancy and breastfeeding.
 - 3. Adherence to recommended dosing.
 - 4. The importance of timely testing and treatment for HIV, renal function, hepatitis B, hepatitis C, sexually transmitted infections, and pregnancy for individuals of childbearing capacity.
 - 5. The availability of HIV pre-exposure prophylaxis for a person who is at a substantial risk of acquiring HIV.
- d. To the extent possible, documents the services provided by the pharmacist in the patient record system shared with the primary care provider.

SYNOPSIS

This Act allows pharmacists, under protocol approved by the Division of Public Health, to provide HIV pre-exposure and post-exposure prophylaxis treatments.

Author: Senator S. McBride