

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Rules

BILL: SB 294

INTRODUCER: Senator Harrell

SUBJECT: Collaborative Pharmacy Practice for Chronic Health Conditions

DATE: March 11, 2025

REVISED: 02/19/25

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Smith</u>	<u>Brown</u>	<u>HP</u>	Favorable
2.	<u>Gerbrandt</u>	<u>McKnight</u>	<u>AHS</u>	Favorable
3.	<u>Smith</u>	<u>Yeatman</u>	<u>RC</u>	Pre-meeting

I. Summary:

SB 294 amends s. 465.1865, F.S., relating to collaborative pharmacy practice agreements. Under current law, collaborative pharmacy practice describes an arrangement in which a physician authorizes a pharmacist to provide specified patient care services relating to chronic health conditions to one or more of the physician's patients. The bill provides that the term "chronic health condition" does not include heart failure, coronary heart disease, and cardiac rhythm disorder.

In practice, this would ensure that those conditions remain excluded from any definition of the term that may be adopted in rule by the Board of Pharmacy.

The bill has no fiscal impact on state revenues or expenditures.

The bill takes effect July 1, 2025.

II. Present Situation:

Pharmacist Licensure

Pharmacy is the third largest health profession behind nursing and medicine.¹ The Board of Pharmacy (BOP), in conjunction with the Department of Health (DOH), regulates the practice of pharmacists pursuant to ch. 465, F.S.² To be licensed as a pharmacist, a person must:³

- Complete an application and remit an examination fee;

¹ American Association of Colleges of Pharmacy, *About AACP*, available at <https://www.aacp.org/about-aacp> (last visited Feb. 13, 2025).

² Sections 465.004 and 465.005, F.S.

³ Section 465.007, F.S. The DOH may also issue a license by endorsement to a pharmacist who is licensed in another state upon meeting the applicable requirements set forth in law and rule. *See* s. 465.0075, F.S.

- Be at least 18 years of age;
- Hold a degree from an accredited and approved school or college of pharmacy;⁴
- Have completed a BOP-approved internship; and
- Successfully complete the BOP-approved examination.

A pharmacist must complete at least 30 hours of BOP-approved continuing education during each biennial renewal period.⁵

Pharmacist Scope of Practice

In Florida, the practice of the profession of pharmacy includes:⁶

- Compounding, dispensing, and consulting concerning the contents, therapeutic values, and uses of any medicinal drug;
- Consulting concerning therapeutic values and interactions of patent or proprietary preparations;
- Monitoring a patient's drug therapy and assisting the patient in the management of his or her drug therapy, including the review of the patient's drug therapy and communication with the patient's prescribing health care provider or other persons specifically authorized by the patient;
- Transmitting information from prescribers to their patients;
- Administering specified vaccines to adults and influenza vaccines to persons seven years of age or older;⁷
- Administering epinephrine autoinjections;⁸
- Administering antipsychotic medications by injection;⁹ and
- Screen an adult for Human Immunodeficiency Syndrome (HIV) exposure.¹⁰

A pharmacist may not alter a prescriber's directions, diagnose or treat any disease, initiate any drug therapy, or practice medicine or osteopathic medicine, unless permitted by law.¹¹

Pharmacists may order and dispense drugs that are included in a formulary developed by a committee composed of members of the Board of Medicine (BOM), the Board of Osteopathic Medicine (BOOM), and the BOP.¹² The formulary may only include:¹³

- Any medicinal drug of single or multiple active ingredients in any strengths when such active ingredients have been approved individually or in combination for over-the-counter sale by the U.S. Food and Drug Administration (FDA);

⁴ If the applicant has graduated from a 4-year undergraduate pharmacy program of a school or college of pharmacy located outside the U.S., the applicant must demonstrate proficiency in English, pass the board-approved Foreign Pharmacy Graduate Equivalency Examination, and complete a minimum of 500 hours in a supervised work activity program within Florida under the supervision of a DOH licensed pharmacist.

⁵ Section 465.009, F.S.

⁶ Section 465.003(13), F.S.

⁷ See s. 465.189, F.S.

⁸ *Id.*

⁹ Section 465.1893, F.S.

¹⁰ Section 465.1861, F.S.

¹¹ Section 465.003(22), F.S.

¹² Section 465.186, F.S.

¹³ *Id.*

- Any medicinal drug recommended by the FDA Advisory Panel for transfer to over-the-counter status pending approval by the FDA;
- Any medicinal drug containing any antihistamine or decongestant as a single active ingredient or in combination;
- Any medicinal drug containing fluoride in any strength;
- Any medicinal drug containing lindane in any strength;
- Any over-the-counter proprietary drug under federal law that has been approved for reimbursement by the Florida Medicaid Program; and
- Any topical anti-infectives, excluding eye and ear topical anti-infectives.

A pharmacist may order the following, within his or her professional judgment and subject to the following conditions:

- Certain oral analgesics for mild to moderate pain. The pharmacist may order these drugs for minor pain and menstrual cramps for patients with no history of peptic ulcer disease. The prescription is limited to a six-day supply for one treatment of:
 - Magnesium salicylate/phenyltoloxamine citrate;
 - Acetylsalicylic acid (zero order release, long acting tablets);
 - Choline salicylate and magnesium salicylate;
 - Naproxen sodium;
 - Naproxen;
 - Ibuprofen;
 - Phenazopyridine, for urinary pain; and
 - Antipyrine 5.4 percent, benzocaine 1.4 percent, glycerin, for ear pain if clinical signs or symptoms of tympanic membrane perforation are not present;
- Anti-nausea preparations;
- Certain antihistamines and decongestants;
- Certain topical antifungal/antibacterials;
- Topical anti-inflammatory preparations containing hydrocortisone not exceeding 2.5 percent;
- Certain otic antifungal/antibacterial;
- Salicylic acid 16.7 percent and lactic acid 16.7 percent in flexible collodion, to be applied to warts, except for patients under 2 years of age, and those with diabetes or impaired circulation;
- Vitamins with fluoride, excluding vitamins with folic acid in excess of 0.9 mg.;
- Medicinal drug shampoos containing lindane for the treatment of head lice;
- Ophthalmic. Naphazoline 0.1 percent ophthalmic solution;
- Certain histamine H2 antagonists;
- Acne products; and
- Topical antiviral for herpes simplex infections of the lips.¹⁴

Collaborative Pharmacy Practice Agreements

Under s. 465.1865, F.S., a collaborative pharmacy practice agreement (CPPA) is a formal agreement in which a physician licensed under ch. 458 or 459, F.S., makes a diagnosis, supervises patient care, and refers patients to a pharmacist under a protocol that allows the

¹⁴ Fla. Admin. Code R. 64B16-27.220 (2025).

pharmacist to provide specified patient care services for certain chronic medical conditions. A CPPA specifies what functions beyond the pharmacist's typical scope of practice can be delegated to the pharmacist by the collaborating physician. Common tasks include initiating, modifying, or discontinuing medication therapy and ordering and evaluating tests.

Pharmacist Training for Collaborative Practice

To provide services under a CPPA, a pharmacist must be certified by the BOP. To obtain certification a pharmacist must complete a 20-hour course approved by the BOP, in consultation with the BOM and the BOOM, and:

- Hold an active and unencumbered license to practice pharmacy;
- Have a Ph.D. in pharmacy or have five years of experience as a licensed pharmacist;
- Have completed the BOP-approved, 20-hour course, eight hours of which must be live or live video conference that includes instruction in:
 - Performance of patient assessments;
 - Ordering, performing, and interpreting clinical and laboratory tests;
 - Evaluating and managing diseases and health conditions in collaboration with other health care practitioners; and
 - Writing and entering into a CPPA.
- Maintains at least \$250,000 of professional liability insurance coverage; and
- Has established a system to maintain patient records of patients receiving services under a CPPA for five years from the patient's most recent service.¹⁵

Required Contents of CPPA

The terms and conditions of the CPPA must be appropriate to the pharmacist's training, and the services delegated to the pharmacist must be within the collaborating physician's scope of practice. A copy of the certification received from the BOP must be included as an attachment to the CPPA. A CPPA must include the following:

- The name of the collaborating physician's patient(s) for whom a pharmacist may provide services;
- Each chronic health condition to be collaboratively managed;
- The specific medicinal drug(s) to be managed for each patient;
- Material terms defined as those terms enumerated in s. 465.1865(3)(a), F.S.;
- Circumstances under which the pharmacist may order or perform and evaluate laboratory or clinical tests;
- Conditions and events in which the pharmacist must notify the collaborating physician and the manner and timeframe in which notification must occur;
- The start and ending dates of the CPPA and termination procedures, including procedures for patient notification and medical records transfers;
- A statement that the CPPA may be terminated, in writing, by either party at any time; and
- In the event of an addendum to the material terms of an existing CPPA, a copy of the addendum and the initial agreement.

¹⁵ Section 465.1865(2), F.S.

A CPPA will automatically terminate two years after execution if not renewed. The pharmacist, along with the collaborating physician, must maintain the CPPA on file at his or her practice location and must make the CPPA available to the DOH or BOP upon request or inspection. A pharmacist who enters into a CPPA must submit a copy of the signed agreement to the BOP before the agreement may be implemented.¹⁶

Allowable Chronic Health Conditions

CPPAs in Florida allow a pharmacist to provide specific patient care services for chronic health conditions. Section 465.1865(1)(b), F.S., establishes that the term “chronic health condition” means:

- Arthritis;
- Asthma;
- Chronic obstructive pulmonary diseases;
- Type 2 diabetes;
- Human immunodeficiency virus or acquired immune deficiency syndrome;
- Obesity; or
- Any other chronic condition adopted in rule by the board, in consultation with the BOM and the BOOM.

The BOP has adopted the following list of chronic health conditions for which a pharmacist certified pursuant to s. 465.1865, F.S., can provide specified patient care services to patients of a collaborating physician pursuant to a pending CPPA:

- Hyperlipidemia;
- Hypertension;
- Anti-coagulation management;
- Nicotine Dependence;
- Opioid use disorder;
- Hepatitis C
- Those chronic health conditions enumerated in s. 465.1865(1)(b), F.S.¹⁷

On May 23, 2024, the Boards of Pharmacy, Medicine, and Osteopathic Medicine held a Joint Rules Committee meeting to discuss adding heart disease to the list of chronic health conditions.¹⁸ The committee ultimately decided not to proceed with the proposed rule language.¹⁹

Prohibited Acts Regarding a CPPA

A pharmacist may not:

- Modify or discontinue medicinal drugs prescribed by a health care practitioner with whom he or she does not have a CPPA; or
- Enter into a CPPA while acting as a pharmacy employee without the written approval of the owner of the pharmacy.

¹⁶ Section 465.1865(3), F.S. and Fla. Admin. Code R. 64B16-31.003 (2025).

¹⁷ Fla. Admin. Code R. 64B16-31.007, F.A.C. (2025).

¹⁸ Florida Department of Health, *Senate Bill 294 Analysis* (Feb. 17, 2025) (on file with Senate Committee on Health Policy).

¹⁹ *Id.*

A physician may not delegate the authority to initiate or prescribe a controlled substance listed in s. 893.03, F.S. or 21 U.S.C. s. 812, to a pharmacist.

Continuing Education

A pharmacist who practices under a CPPA must complete an eight-hour continuing education (CE) course approved by the BOP that addresses CPPA-related issues each biennial licensure renewal, in addition to the CE requirements under s. 465.009, F.S. A pharmacist wishing to maintain CPPA certification must submit confirmation of having completed such course when applying for licensure renewal. A pharmacist who fails to complete this CE is prohibited from practicing under a CPPA.

CPPAs in Effect

According to the DOH 2023-2024 Annual Report, there are 39,486 licensed pharmacists in Florida.²⁰ In fiscal year 2023-2024, 87 pharmacists became certified to provide care under a CPPA.²¹

III. Effect of Proposed Changes:

Section 1 amends s. 465.1865, F.S., to exclude heart failure, coronary heart disease, and cardiac rhythm disorders from the definition of “chronic health condition.” This would remove the authority of the Board of Pharmacy (BOP) to include those conditions as “chronic health conditions” in rule.

Under current law and rule, pharmacists are not authorized to “collaboratively manage” heart failure, coronary heart disease, and cardiac rhythm disorders with a collaborating physician under a collaborative pharmacy agreement (CPPA). This would not change upon the enactment of the bill, but it would prevent the BOP from classifying those conditions by rule as chronic health conditions that may be included in a CPPA prospectively.

Section 2 provides an effective date of July 1, 2025.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

²⁰ Florida Department of Health, Division of Medical Quality Assurance, *Annual Report and Long-Range Plan, Fiscal Year 2023-2024*, at pg. 4, available at <https://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/annual-reports.html> (last visited Feb. 13, 2025).

²¹ *Id.*

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

The bill has no fiscal impact on state revenues or expenditures.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 465.1865 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.