

THE FLORIDA SENATE
2020 SUMMARY OF LEGISLATION PASSED
Committee on Health Policy

CS/HB 389 — Practice of Pharmacy

by Health and Human Services Committee and Rep. Sirois and others (CS/SB 714 by Health Policy Committee and Senator Hutson)

The bill (Chapter 2020-7, L.O.F.) expands the scope of practice for pharmacists in two ways, by creating specified parameters under which pharmacists may:

- Enter into a collaborative pharmacy practice agreement with a physician to treat that physician's patients for chronic health conditions; and
- Test or screen for and treat minor, nonchronic health conditions for any patient who qualifies for such testing and treatment under the provisions and requirements of a written protocol with a supervising physician.

Collaborative Pharmacy Practice for Chronic Health Conditions

Under the bill, a “collaborative pharmacy practice agreement” (collaborative agreement) means a written agreement between a pharmacist who meets qualifications specified in the bill and a Florida-licensed allopathic or osteopathic physician in which the collaborating physician authorizes the pharmacist to provide specified patient care to the physician's patients named in the agreement.

The bill defines “chronic health condition” to mean arthritis, asthma, chronic obstructive pulmonary diseases, type 2 diabetes, HIV/AIDS, obesity, or any other chronic condition adopted in rule by the Board of Pharmacy (BOP) in consultation with the Board of Medicine (BOM) and the Board of Osteopathic Medicine (BOOM).

Before providing services under a collaborative agreement, a pharmacist must be certified by the BOP according to rules adopted by the BOP in consultation with the BOM and BOOM. Requirements for certification include minimum standards for experience and education, including completion of an initial 20-hour course providing instruction on topics such as performing patient assessments, ordering and interpreting laboratory tests, evaluating and managing diseases and health conditions, and other subjects required by the BOP. Certification also requires a pharmacist to maintain at least \$250,000 in professional liability insurance coverage and to establish a system to maintain patient records for five years.

The terms and conditions of a collaborative agreement must be appropriate to the pharmacist's training, and services delegated to the pharmacist must be within the collaborating physician's scope of practice. A copy of the pharmacist's certification issued BOP must be included as an attachment to the collaborative agreement. A collaborative agreement must, among other requirements, include:

- The names of the physician's patient(s) who may be treated by the pharmacist;
- Each chronic health condition to be collaboratively managed;
- Specific drugs to be managed by the pharmacist for each patient;

- Circumstances under which the pharmacist may order, perform, or evaluate lab or clinical tests; and
- Conditions that require the pharmacist to notify the collaborating physician.

A pharmacist who enters into a collaborative agreement must submit a copy of the signed agreement to the BOP before the agreement may be implemented. A collaborative agreement will automatically terminate two years after execution if not renewed.

The bill prohibits a pharmacist from:

- Modifying or discontinuing drugs prescribed by a health care practitioner with whom he or she does not have a collaborative agreement; or
- Entering into a collaborative agreement while acting as an employee of a pharmacy without the written approval of the pharmacy owner.

The bill prohibits a physician from delegating the authority to initiate or prescribe controlled substances to a pharmacist.

A pharmacist who practices under a collaborative agreement must complete an eight-hour continuing education course approved by the BOP that addresses issues related to collaborative pharmacy practice with each biennial renewal of the pharmacist's license, in addition to continuing education requirements he or she must meet under preexisting law.

The bill requires the BOP, in consultation with the BOM and BOOM, to adopt rules to implement the bill's provisions for collaborative pharmacy practice.

Testing and Screening for and Treatment of Minor, Nonchronic Health Conditions by Pharmacists

The bill authorizes pharmacists who meet qualifications specified in the bill to test or screen for and treat minor, nonchronic health conditions within the framework of a written protocol with a supervising allopathic or osteopathic physician licensed in Florida. Under the bill, a minor, nonchronic health condition is typically a short-term condition that is generally managed with minimal treatment or self-care and includes:

- Influenza;
- Streptococcus;
- Lice;
- Skin conditions, such as ringworm and athlete's foot; and
- Minor, uncomplicated infections.

To qualify under the bill, a pharmacist must be certified by the BOP to have met certain educational requirements, including completion of a 20-hour education program approved by the BOP in consultation with the BOM and BOOM which must address patient assessments, point-of-care testing procedures, safe and effective treatments, and identification of contraindications.

A pharmacist so certified by the BOP must provide evidence of the certification to the supervising physician.

A pharmacist who tests and treats under the bill must also maintain at least \$250,000 in liability coverage; furnish a patient's records, upon the patient's request, to a health care practitioner designated by a patient; and maintain patient records for five years from each patient's most recent provision of service.

The BOP is required to adopt by rule a formulary of drugs that a pharmacist may prescribe under a test-and-treat protocol for minor, nonchronic health conditions covered under the protocol. Such drugs must be approved by the federal Food and Drug Administration which are indicated for the treatment of such conditions. The formulary may not include controlled substances.

The bill provides that a pharmacist who tests and treats may use any tests that guide the diagnosis or clinical decision-making which the federal Centers for Medicare & Medicaid Services has determined qualify for a waiver under the federal Clinical Laboratory Improvement Amendments of 1988, or federal rules adopted thereunder, or any established screening procedures that can safely be performed by a pharmacist.

A written protocol between a pharmacist and supervising physician must include particular terms and conditions imposed by the supervising physician relating to the testing and screening for and treatment of minor, nonchronic health conditions. The terms and conditions must be appropriate to the pharmacist's training. A pharmacist who enters into such a protocol with a supervising physician must submit the protocol to the BOP. The protocol must include:

- Specific categories of patients who the pharmacist is authorized to test or screen for and treat minor, nonchronic health conditions;
- The physician's instructions for obtaining relevant patient medical history for the purpose of identifying disqualifying health conditions, adverse reactions, and contraindications to the approved course of treatment;
- The physician's instructions for the treatment of minor, nonchronic health conditions based on the patient's age, symptoms, and test results, including negative results;
- A process and schedule for the physician to review the pharmacist's actions under the protocol;
- A process and schedule for the pharmacist to notify the physician of the patient's condition, tests administered, test results, and course of treatment; and
- Any other requirements as established by the BOP in consultation with the BOM and BOOM.

A pharmacist certified by the BOP to test and treat under the bill must complete a three-hour continuing education course approved by the BOP that addresses issue related to minor, nonchronic health conditions with each biennial renewal of the pharmacist's license, in addition to continuing education requirements he or she must meet under preexisting law.

A pharmacist providing test-and-treat services under the bill may not perform such services while acting as an employee of a pharmacy without the written approval of the pharmacy owner.

A pharmacist who tests and treats under the bill must provide a patient with written information to advise the patient to seek follow-up care from his or her primary care physician. The BOP must adopt rules for the circumstances under which such information must be provided.

A pharmacy in which a pharmacist tests and treats under the bill must prominently display signage indicating that any patient receiving testing, screening, or treatment services as authorized under the bill is advised to seek follow-up care from his or her primary care physician.

The bill provides that its test-and-treat provisions do not apply with respect to minor, nonchronic health conditions when treated with over-the-counter products.

Other Provisions

The bill:

- Provides that its two requirements for \$250,000 in professional liability coverage (the first for collaborative pharmacy practice and the second for testing for and treating minor, nonchronic health conditions) are not duplicative and that coverage for either satisfies both requirements;
- Adds pharmacists who are authorized to perform or order and evaluate laboratory or clinical tests under a collaborative pharmacy practice or test-and-treat protocol, to the list of health care practitioners and facilities that, upon the diagnosis or suspicion of the existence of a disease of public health significance, must immediately report that fact to the Department of Health; and
- Amends the statutory definition of “practice of the profession of pharmacy” to conform to the bill’s provisions.

These provisions became law upon approval by the Governor on March 11, 2020, and take effect July 1, 2020.

Vote: Senate 28-12; House 98-17