FMA
FLORIDA MEDICAL ASSOCIATION
1430 Piedmont Drive E., Tallahassee, FL 32308

# Summary of HB 389

## HB 389: AN ACT RELATING TO THE PRACTICE OF PHARMACY

A rather unexpected addition to Speaker Jose Oliva's desire to expand the scope of practice for all mid-level providers is HB 389, which passed the Senate, the House and was signed by the Governor on the same day (March 11, 2020).

This bill started as the "test and treat the flu and strep" bill, but unfortunately was expanded later in the session. To best understand how this bill expands the scope of practice of pharmacy, it is necessary to examine the two main sections separately, as different conditions apply. First, the bill allows pharmacists to treat chronic health conditions under certain circumstances. Second, the bill allows pharmacists to test, screen for and treat minor, nonchronic health conditions.

**Collaborative Pharmacy Practice for Chronic Health Conditions**

HB 389 will effectively allow pharmacists to practice medicine without any requirement that they receive the requisite education and training required to do so safely and effectively. With the completion of a mere 20-hour course, HB 389 will allow pharmacists to provide medical care for patients with **chronic health conditions** such as:

- Arthritis
- Asthma
- Chronic obstructive pulmonary disease
- HIV/AIDS
- Obesity
- Any other condition that the Board of Pharmacy decides pharmacists should be able to treat.

To provide services to patients with chronic health conditions, a pharmacist must enter into a "collaborative pharmacy practice agreement" with an MD or a DO. The agreement must limit the pharmacist to providing such services to the collaborating physician's patients only.

To be eligible to provide services under a collaborative pharmacy practice agreement, a pharmacist must be certified by the Board of Pharmacy (BOP) under rules it adopts. At a minimum, these rules must require the pharmacist to:

- Hold an active and unencumbered license to practice pharmacy in Florida.

- Have earned a degree of doctor of pharmacy or have completed five years of experience as a licensed pharmacist.
- Maintain at least $250,000 of professional liability insurance coverage.
- Have a system to maintain patient records for a period of five years.
- Have completed an initial 20-hour course approved by the board (in consultation with the Board of Medicine and Board of Osteopathic Medicine). The course must include instruction on:
    - Performance of patient assessments
    - Ordering, performing and interpreting clinical and lab tests related to collaborative pharmacy practice
    - Evaluating and managing diseases and health conditions in collaboration with other health care practitioners
    - Any other area required by the Board of Pharmacy

The collaborative practice agreement between a pharmacist and the supervising physician must include the following:

- The name of the collaborating physician's patient or patients for whom a pharmacist may provide services
- Each chronic health condition to be collaboratively managed
- The specific medicinal drug or drugs to be managed by the pharmacist for each patient
- The circumstances under which the pharmacist may order or perform and evaluate lab or clinical tests
- Conditions and events upon which the pharmacist must notify the collaborating physician and the manner and timeframe in which such notification must occur
- Beginning and ending dates for the collaborative agreement and termination procedures
- A statement that the agreement may be terminated, in writing, by either party at any time

The bill provides that the collaborative practice agreement 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. As the Board of Pharmacy is responsible for promulgating rules to implement this bill, it is doubtful there will be much guidance, if any, as to what this provision means.

The bill does specifically state that a pharmacist <u>may not</u>:

1. Modify or discontinue medicinal drugs prescribed by a health care practitioner with whom he or she does not have a collaborative practice agreement.

2. Enter into a collaborative practice agreement while acting as an employee without the written approval of the owner of the pharmacy.

3. Initiate or prescribe a controlled substance under a collaborative practice agreement.

Pharmacists who practice under a collaborative practice agreement must complete an eight-hour CE course every two years approved by the Board of Pharmacy.

It is unclear exactly what a supervising physician can allow a pharmacist to do under a collaborative practice agreement. The bill changes the practice of pharmacy to include the "initiating, modifying, or discontinuing drug therapy for a chronic health condition under a collaborative pharmacy practice agreement," and appears to allow pharmacists to diagnose or treat any disease, initiate any drug therapy and practice medicine as specifically authorized by the new sections created by HB 389. The section on chronic health conditions specifically authorizes pharmacists to provide "specified patient care services" but never defines what those specified patient care services are.

It is important to note that, unlike the next section on minor, nonchronic health conditions, any services the pharmacist provides must be for the patients of the collaborating physician only. This will require a pharmacist to enter into multiple collaborative agreements if he or she wants to provide services to patients with different treating physicians. A pharmacist will not be able to provide services to any person who is not already under the care of a physician.

**Testing or Screening for and Treatment of Minor, Nonchronic Health Conditions**

HB 389 allows pharmacists to test, screen for and treat minor nonchronic health conditions under the framework of an established written protocol with an MD or DO. The bill defines a minor, nonchronic health condition as 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
- Minor uncomplicated infections

Unlike for chronic conditions, there is no authority for the Board of Pharmacy to add other conditions by rule. The FMA will argue that pharmacists can only test for and treat the enumerated conditions. Exactly which skin conditions and minor infections a pharmacist can test/treat will have to be worked out via rule and/or litigation.

To test, screen for and treat minor, nonchronic health conditions, a pharmacist must:

- Hold an active and unencumbered license to practice pharmacy in Florida
- Maintain at least $250,000 of liability coverage
- Report a diagnosis or suspected existence of a disease of public health significance to the department
- Furnish patient records to a health care practitioner designated and requested by the patient
- Maintain records of all patients receiving services for five years
- Hold a certification from the Board of Pharmacy

The requirements for certification must be established by the BOP (in "consultation" with the BOM and the BOOM) and must require a pharmacist to complete a one-time, 20-hour education course approved by the BOP (again in "consultation" with the BOM and BOOM). The course must, at a minimum, address patient assessments, point-of-care testing procedures, safe and effective treatment of minor, nonchronic health conditions, and identification of contraindications.

The BOP shall also adopt a formulary of medicinal drugs a pharmacist may prescribe for the minor nonchronic conditions listed above. The formulary must include drugs approved by the FDA that are indicated for treatment of each minor, nonchronic condition. Controlled substances are specifically excluded.

HB 389 specifically allows any pharmacist who tests/treats under this section to use any test that CMS has determined qualifies for a waiver under the Clinical Laboratory Improvement Amendments of 1988, or any screening procedure that can be safely performed by a pharmacist. This is obviously open to a wide range of interpretation.

The bill requires the written protocol between the pharmacist and the supervising physician to include the particular terms and conditions imposed by the supervising physician appropriate to the pharmacist's training. At a minimum, the protocol must include:

- The specific categories of patients that the pharmacist is authorized to test and treat.
- The supervising physician's instructions for obtaining a patient's medical history to identify disqualifying health conditions, adverse reactions and contraindications to the approved course of treatment.
- The supervising physician's instructions for how the pharmacist is to treat minor, nonchronic health conditions.
- A process and schedule for how the supervising physician is to review the actions of the pharmacist, and how the pharmacist is to notify the supervising physician of the patient's condition, the tests the pharmacist has administered, the test results and the course of treatment.
- Any other requirements established by the Board of Pharmacy (in consultation with the BOM and the BOOM).

HB 389 deleted the major safeguards adopted by the Senate in committee but did retain a few minor ones.

The supervising physician is required to review the pharmacist's actions in accordance with the protocol. Absent rules implementing this provision, a physician could presumably conduct the review at his or her discretion, even months after the care has been provided.

The pharmacist may not enter into a protocol while acting as an employee without written approval of the owner of the pharmacy. This will not be a problem, as it most likely will be the pharmacy owner requiring the pharmacist to provide these services.

Pharmacists who enter into a protocol to test/treat minor, nonchronic conditions must complete a BOP-approved three-hour continuing education course every two years.

Any pharmacy that has a pharmacist who tests/treats minor, nonchronic health conditions must prominently display a sign stating that any patient who receives such services is advised to seek follow-up care from his/her primary care physician. The pharmacist providing such testing/treatment must provide patients with written information advising them to seek follow-up care from their primary care provider per guidelines to be adopted by the BOP.

HB 389 provides that requirements for a pharmacist to test/treat minor, nonchronic conditions do not apply when treated with over-the-counter products. Presumably then, a pharmacist can test and treat the flu, strep, etc. without entering into a physician protocol if he or she only treats such conditions with over-the-counter products. The FMA will maintain that a pharmacist without a protocol cannot test for minor, nonchronic conditions.

Unlike for chronic conditions, as explained in the section above, a pharmacist will be able to test/treat for minor, nonchronic conditions by entering into a single protocol agreement with an MD or DO. Pharmacists are not limited to testing/treating only the patients of physicians that they have a protocol agreement with.

It should be noted that autonomous APRNs (as provided for in HB 607) are not authorized to enter into collaborative practice agreements with pharmacists or enter into protocols with pharmacists to test/treat minor, nonchronic conditions.

This act takes effect July 1, 2020.