CHAPTER 2020-7

Committee Substitute for House Bill No. 389

An act relating to the practice of pharmacy; amending s. 381.0031, F.S.; requiring specified licensed pharmacists to report certain information relating to public health to the Department of Health; amending s. 465.003, F.S.; revising the definition of the term "practice of the profession of pharmacy"; creating s. 465.1865, F.S.; providing definitions; providing requirements for pharmacists to provide services under a collaborative pharmacy practice agreement; requiring the terms and conditions of such agreement to be appropriate to the training of the pharmacist and the scope of practice of the physician; requiring notification to the board upon practicing under a collaborative pharmacy practice agreement; requiring pharmacists to submit a copy of the signed collaborative pharmacy practice agreement to the Board of Pharmacy; providing for the maintenance of patient records for a certain period of time; providing for renewal of such agreement; requiring a pharmacist and the collaborating physician to maintain on file and make available the collaborative pharmacy practice agreement; prohibiting certain actions relating to such agreement; requiring specified continuing education for a pharmacist who practices under a collaborative pharmacy practice agreement; requiring the Board of Pharmacy to adopt rules in consultation with the Board of Medicine and the Board of Osteopathic Medicine; creating s. 465.1895, F.S.; requiring the Board of Pharmacy to identify minor, nonchronic health conditions that a pharmacist may test or screen for and treat; providing requirements for a pharmacist to test or screen for and treat minor, nonchronic health conditions; requiring the board to develop a formulary of medicinal drugs that a pharmacist may prescribe; providing requirements for the written protocol between a pharmacist and a supervising physician; prohibiting a pharmacist from providing certain services under certain circumstances; requiring a pharmacist to complete a specified amount of continuing education; providing additional requirements for pharmacists and pharmacies providing testing and screening services; providing for applicability; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsection (2) of section 381.0031, Florida Statutes, is amended to read:

381.0031 Epidemiological research; report of diseases of public health significance to department.—

(2) Any practitioner licensed in this state to practice medicine, osteopathic medicine, chiropractic medicine, naturopathy, or veterinary medicine; <u>any licensed pharmacist authorized under a protocol with a supervising physician under s. 465.1895, or a collaborative pharmacy practice agreement, as defined in s. 465.1865, to perform or order and evaluate laboratory</u>

and clinical tests; any hospital licensed under part I of chapter 395; or any laboratory appropriately certified by the Centers for Medicare and Medicaid Services under the federal Clinical Laboratory Improvement Amendments and the federal rules adopted thereunder which diagnoses or suspects the existence of a disease of public health significance shall immediately report the fact to the Department of Health.

Section 2. Subsection (13) of section 465.003, Florida Statutes, is amended to read:

465.003 Definitions.—As used in this chapter, the term:

(13) "Practice of the profession of pharmacy" includes compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of any medicinal drug; consulting concerning therapeutic values and interactions of patent or proprietary preparations, whether pursuant to prescriptions or in the absence and entirely independent of such prescriptions or orders; and conducting other pharmaceutical services. For purposes of this subsection, "other pharmaceutical services" means the monitoring of the patient's drug therapy and assisting the patient in the management of his or her drug therapy, and includes review of the patient's drug therapy and communication with the patient's prescribing health care provider as licensed under chapter 458, chapter 459, chapter 461, or chapter 466, or similar statutory provision in another jurisdiction, or such provider's agent or such other persons as specifically authorized by the patient, regarding the drug therapy; and initiating, modifying, or discontinuing drug therapy for a chronic health condition under a collaborative pharmacy practice agreement. ~~However,~~ Nothing in this subsection may be interpreted to permit an alteration of a prescriber's directions, the diagnosis or treatment of any disease, the initiation of any drug therapy, the practice of medicine, or the practice of osteopathic medicine, unless otherwise permitted by law or specifically authorized by s. 465.1865 or s. 465.1895. "Practice of the profession of pharmacy" also includes any other act, service, operation, research, or transaction incidental to, or forming a part of, any of the foregoing acts, requiring, involving, or employing the science or art of any branch of the pharmaceutical profession, study, or training, and shall expressly permit a pharmacist to transmit information from persons authorized to prescribe medicinal drugs to their patients. The practice of the profession of pharmacy also includes the administration of vaccines to adults pursuant to s. 465.189, the testing or screening for and treatment of minor, nonchronic health conditions pursuant to s. 465.1895, and the preparation of prepackaged drug products in facilities holding Class III institutional pharmacy permits.

Section 3. Section 465.1865, Florida Statutes, is created to read:

465.1865 Collaborative pharmacy practice for chronic health conditions.

(1) For purposes of this section, the term:

(a) "Collaborative pharmacy practice agreement" means a written agreement between a pharmacist who meets the qualifications of this section and a physician licensed under chapter 458 or chapter 459 in which a collaborating physician authorizes a pharmacist to provide specified patient care services to the collaborating physician's patients.

(b) "Chronic health condition" means:

1. Arthritis;

2. Asthma;

3. Chronic obstructive pulmonary diseases;

4. Type 2 diabetes;

5. Human immunodeficiency virus or acquired immune deficiency syndrome;

6. Obesity; or

7. Any other chronic condition adopted in rule by the board, in consultation with the Board of Medicine and Board of Osteopathic Medicine.

(2) To provide services under a collaborative pharmacy practice agreement, a pharmacist must be certified by the board, according to the rules adopted by the board in consultation with the Board of Medicine and the Board of Osteopathic Medicine. To be certified, a pharmacist must, at a minimum:

(a) Hold an active and unencumbered license to practice pharmacy in this state.

(b) Have earned a degree of doctor of pharmacy or have completed 5 years of experience as a licensed pharmacist.

(c) Have completed an initial 20-hour course approved by the board, in consultation with the Board of Medicine and Board of Osteopathic Medicine, that includes, at a minimum, instruction on the following:

1. Performance of patient assessments.

2. Ordering, performing, and interpreting clinical and laboratory tests related to collaborative pharmacy practice.

3. Evaluating and managing diseases and health conditions in collaboration with other health care practitioners.

4. Any other area required by board.

(d) Maintain at least $250,000 of professional liability insurance coverage. However, a pharmacist who maintains professional liability insurance coverage pursuant to s. 465.1895 satisfies this requirement.

(e) Have established a system to maintain records of all patients receiving services under a collaborative pharmacy practice agreement for a period of 5 years from each patient's most recent provision of service.

(3) The terms and conditions of the collaborative pharmacy 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. A copy of the certification issued under subsection (2) must be included as an attachment to the collaborative pharmacy practice agreement.

(a) A collaborative pharmacy practice agreement must include the following:

1. Name of the collaborating physician's patient or patients for whom a pharmacist may provide services.

2. Each chronic health condition to be collaboratively managed.

3. Specific medicinal drug or drugs to be managed by the pharmacist for each patient.

4. Circumstances under which the pharmacist may order or perform and evaluate laboratory or clinical tests.

5. Conditions and events upon which the pharmacist must notify the collaborating physician and the manner and timeframe in which such notification must occur.

6. Beginning and ending dates for the collaborative pharmacy practice agreement and termination procedures, including procedures for patient notification and medical records transfers.

7. A statement that the collaborative pharmacy practice agreement may be terminated, in writing, by either party at any time.

(b) A collaborative pharmacy practice agreement shall automatically terminate 2 years after execution if not renewed.

(c) The pharmacist, along with the collaborating physician, must maintain on file the collaborative pharmacy practice agreement at his or her practice location, and must make such agreements available to the department or board upon request or inspection.

(d) A pharmacist who enters into a collaborative pharmacy practice agreement must submit a copy of the signed agreement to the board before the agreement may be implemented.

(4) A pharmacist may not:

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

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

(5) A physician may not delegate the authority to initiate or prescribe a controlled substance as described in s. 893.03 or 21 U.S.C. s. 812 to a pharmacist.

(6) A pharmacist who practices under a collaborative pharmacy practice agreement must complete an 8-hour continuing education course approved by the board that addresses issues related to collaborative pharmacy practice each biennial licensure renewal in addition to the continuing education requirements under s. 465.009. A pharmacist must submit confirmation of having completed such course when applying for licensure renewal. A pharmacist who fails to comply with this subsection shall be prohibited from practicing under a collaborative pharmacy practice agreement under this section.

(7) The board, in consultation with the Board of Medicine and the Board of Osteopathic Medicine, shall adopt rules pursuant to ss. 120.536(1) and 120.54 to implement this section.

Section 4. Section 465.1895, Florida Statutes, is created to read:

465.1895 Testing or screening for and treatment of minor, nonchronic health conditions.—

(1) A pharmacist may test or screen for and treat minor, nonchronic health conditions within the framework of an established written protocol with a supervising physician licensed under chapter 458 or chapter 459. For purposes of this section, a minor, nonchronic health condition is typically a short-term condition that is generally managed with minimal treatment or self-care, and includes:

(a) Influenza.

(b) Streptococcus.

(c) Lice.

(d) Skin conditions, such as ringworm and athlete's foot.

(e) Minor, uncomplicated infections.

(2) A pharmacist who tests or screens for and treats minor, nonchronic health conditions under this section must:

(a) Hold an active and unencumbered license to practice pharmacy in the state.

(b) Hold a certification issued by the board to test and screen for and treat minor, nonchronic health conditions, in accordance with requirements established by the board in rule in consultation with the Board of Medicine and Board of Osteopathic Medicine. The certification must require a pharmacist to complete, on a one-time basis, a 20-hour education course approved by the board in consultation with the Board of Medicine and the Board of Osteopathic Medicine. The course, at a minimum, must address patient assessments; point-of-care testing procedures; safe and effective treatment of minor, nonchronic health conditions; and identification of contraindications.

(c) Maintain at least $250,000 of liability coverage. A pharmacist who maintains liability coverage pursuant to s. 465.1865 satisfies this requirement.

(d) Report a diagnosis or suspected existence of a disease of public health significance to the department pursuant to s. 381.0031.

(e) Upon request of a patient, furnish patient records to a health care practitioner designated by the patient.

(f) Maintain records of all patients receiving services under this section for a period of 5 years from each patient's most recent provision of service.

(3) The board shall adopt, by rule, a formulary of medicinal drugs that a pharmacist may prescribe for the minor, nonchronic health conditions approved under subsection (1). The formulary must include medicinal drugs approved by the United States Food and Drug Administration which are indicated for treatment of the minor, nonchronic health condition. The formulary may not include any controlled substance as described in s. 893.03 or 21 U.S.C. s. 812.

(4) A pharmacist who tests or screens for and treats minor, nonchronic health conditions under this section may use any tests that may guide diagnosis or clinical decisionmaking which the Centers for Medicare and Medicaid Services has determined qualifies for a waiver under the federal Clinical Laboratory Improvement Amendments of 1988, or the federal rules adopted thereunder, or any established screening procedures that can safely be performed by a pharmacist.

(5) The written protocol between a pharmacist and supervising physician under this subsection 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 under this section. 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 board.

(a) At a minimum, the protocol shall include:

1. Specific categories of patients who the pharmacist is authorized to test or screen for and treat minor, nonchronic health conditions.

2. 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.

3. 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.

4. A process and schedule for the physician to review the pharmacist's actions under the protocol.

5. A process and schedule for the pharmacist to notify the physician of the patient's condition, tests administered, test results, and course of treatment.

6. Any other requirements as established by the board in consultation with the Board of Medicine and the Board of Osteopathic Medicine.

(b) A pharmacist authorized to test and screen for and treat minor, nonchronic conditions under a protocol shall provide evidence of current certification by the board to the supervising physician. A supervising physician shall review the pharmacist's actions in accordance with the protocol.

(6) A pharmacist providing services under this section may not perform such services while acting as an employee without the written approval of the owner of the pharmacy.

(7) A pharmacist providing services under this section must complete a 3-hour continuing education course approved by the board addressing issues related to minor, nonchronic health conditions each biennial licensure renewal in addition to the continuing education requirements under s. 465.009. Each pharmacist must submit confirmation of having completed the course when applying for licensure renewal. A pharmacist who fails to comply with this subsection may not provide testing, screening, or treatment services.

(8) A pharmacist providing services under this section must provide a patient with written information to advise the patient to seek followup care from his or her primary care physician. The board, by rule, shall adopt guidelines for the circumstances under which the information required under this subsection shall be provided.

(9) The pharmacy in which a pharmacist tests and screens for and treats minor, nonchronic health conditions must prominently display signage

indicating that any patient receiving testing, screening, or treatment services under this section is advised to seek followup care from his or her primary care physician.

(10) A pharmacist providing services under this section must comply with applicable state and federal laws and regulations.

(11) The requirements of the section do not apply with respect to minor, nonchronic health conditions when treated with over-the-counter products.

Section 5. This act shall take effect July 1, 2020.

Approved by the Governor March 11, 2020.

Filed in Office Secretary of State March 11, 2020.