By the Committees on Appropriations; and Health Policy; and Senator Diaz

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A bill to be entitled

An act relating to the practice of pharmacy; amending s. 381.0031, F.S.; requiring certain licensed pharmacists to report specified 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"; amending s. 465.0125, F.S.; requiring a pharmacist to complete additional training to be licensed as a consultant pharmacist; authorizing a consultant pharmacist to perform specified services under certain circumstances and within the scope of a written collaborative practice agreement with certain health care practitioners; providing requirements for the agreement; prohibiting a consultant pharmacist from modifying or discontinuing medicinal drugs prescribed by a health care practitioner without a written collaborative practice agreement; revising the responsibilities of a consultant pharmacist; requiring written collaborative practice agreements to be made available upon request from or upon inspection by the Department of Health; prohibiting a consultant pharmacist from diagnosing any disease or condition; defining the term "health care facility"; creating s. 465.1865, F.S.; defining the terms "collaborative pharmacy practice agreement" and "chronic health condition"; specifying criteria a pharmacist must meet to provide services under a collaborative pharmacy practice agreement; providing requirements for

collaborative pharmacy practice agreements; providing for the renewal of such agreements; requiring collaborating pharmacists and physicians to maintain a copy of the collaborative pharmacy practice agreements at their practices and make such agreements available upon request or inspection; requiring pharmacists to submit a copy of the signed collaborative pharmacy practice agreement to the Board of Pharmacy before implementing it; prohibiting pharmacists from engaging in specified activities without a collaborative pharmacy practice agreement; prohibiting pharmacists from entering into collaborative pharmacy practice agreements under certain circumstances; prohibiting collaborating physicians from delegating to pharmacists the authority to initiate or prescribe a controlled substance; providing continuing education requirements for pharmacists practicing under collaborative pharmacy practice agreements; requiring the Board of Medicine in consultation with the Board of Osteopathic Medicine and the Board of Pharmacy to adopt rules; 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; any licensed pharmacist authorized under a collaborative pharmacy practice agreement, as defined in s. 465.1865, to perform or order and evaluate laboratory 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, the term "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; reviewing and making recommendations regarding~~, and includes review of~~ the patient's drug therapy and health care status in communication with the patient's prescribing health care provider as licensed under chapter 458, chapter 459, chapter 461, or chapter 466, or a similar statutory provision in

another jurisdiction, or such provider's agent or such other persons as specifically authorized by the patient; and initiating, modifying, or discontinuing drug therapy for a chronic health condition under a collaborative pharmacy practice agreement~~, regarding the drug therapy~~. ~~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. The term "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 and the preparation of prepackaged drug products in facilities holding Class III institutional pharmacy permits. The term also includes ordering and evaluating any laboratory or clinical testing; conducting patient assessments; and modifying, discontinuing, or administering medicinal drugs pursuant to s. 465.0125 by a consultant pharmacist.

Section 3. Section 465.0125, Florida Statutes, is amended to read:

465.0125 Consultant pharmacist license; application, renewal, fees; responsibilities; rules.—

(1) The department shall issue or renew a consultant pharmacist license upon receipt of an initial or renewal application that ~~which~~ conforms to the requirements for consultant pharmacist initial licensure or renewal as adopted ~~promulgated~~ by the board by rule and a fee set by the board not to exceed $250. To be licensed as a consultant pharmacist, a pharmacist must complete additional training as required by the board.

(a) A consultant pharmacist may provide medication management services in a health care facility within the framework of a written collaborative practice agreement between the pharmacist and a health care facility medical director or a physician licensed under chapter 458 or chapter 459, a podiatric physician licensed under chapter 461, or a dentist licensed under chapter 466 who is authorized to prescribe medicinal drugs. A consultant pharmacist may provide medication management services, conduct patient assessments, and order and evaluate laboratory or clinical testing only for patients of the health care practitioner with whom the consultant pharmacist has a written collaborative practice agreement.

(b) A written collaborative practice agreement must outline the circumstances under which the consultant pharmacist may:

1. Order and evaluate any laboratory or clinical tests to promote and evaluate patient health and wellness, and monitor drug therapy and treatment outcomes.

2. Conduct patient assessments as appropriate to evaluate and monitor drug therapy.

3. Modify or discontinue medicinal drugs as outlined in the agreed-upon patient-specific order or preapproved treatment

protocol under the direction of a physician. However, a consultant pharmacist may not modify or discontinue medicinal drugs prescribed by a health care practitioner who does not have a written collaborative practice agreement with the consultant pharmacist.

4. Administer medicinal drugs.

(c) A ~~The~~ consultant pharmacist shall maintain ~~be responsible for maintaining~~ all drug, patient care, and quality assurance records as required by law and, with the collaborating practitioner, maintain written collaborative practice agreements that must be available upon request from or upon inspection by the department.

(d) This subsection does not authorize a consultant pharmacist to diagnose any disease or condition.

(e) For purposes of this subsection, the term "health care facility" means an ambulatory surgical center or hospital licensed under chapter 395, an alcohol or chemical dependency treatment center licensed under chapter 397, an inpatient hospice licensed under part IV of chapter 400, a nursing home licensed under part II of chapter 400, an ambulatory care center as defined in s. 408.07, or a nursing home component licensed under chapter 400 within a continuing care facility licensed under chapter 651 ~~for establishing drug handling procedures for the safe handling and storage of drugs. The consultant pharmacist may also be responsible for ordering and evaluating any laboratory or clinical testing when, in the judgment of the consultant pharmacist, such activity is necessary for the proper performance of the consultant pharmacist's responsibilities. Such laboratory or clinical testing may be ordered only with~~

~~regard to patients residing in a nursing home facility, and then only when authorized by the medical director of the nursing home facility. The consultant pharmacist must have completed such additional training and demonstrate such additional qualifications in the practice of institutional pharmacy as shall be required by the board in addition to licensure as a registered pharmacist~~.

(2) Notwithstanding ~~the provisions of~~ subsection (1), a consultant pharmacist or a doctor of pharmacy licensed in this state may also be responsible for ordering and evaluating any laboratory or clinical testing for persons under the care of a licensed home health agency when, in the judgment of the consultant pharmacist or doctor of pharmacy, such activity is necessary for the proper performance of his or her responsibilities and only when authorized by a practitioner licensed under chapter 458, chapter 459, chapter 461, or chapter 466. In order for the consultant pharmacist or doctor of pharmacy to qualify and accept this authority, he or she must receive 3 hours of continuing education relating to laboratory and clinical testing as established by the board.

(3) The board shall adopt ~~promulgate~~ rules necessary to implement and administer this section.

Section 4. 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; or

6. Obesity.

(2) To provide services under a collaborative pharmacy practice agreement, a pharmacist must be certified according to rules of the Board of Medicine that he or she:

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

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

(c) Has completed an initial 20-hour course approved by the Board of Medicine in consultation with the Board of Osteopathic Medicine and the Board of Pharmacy which includes, at a minimum, instruction on all of 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 of Medicine rule,

adopted in consultation with the Board of Osteopathic Medicine and the Board of Pharmacy.

(d) Maintains at least $250,000 of professional liability insurance coverage. However, a pharmacist who maintains professional liability insurance coverage of at least $250,000 under a written protocol with a supervising physician for the testing for and treatment of minor nonchronic health conditions satisfies this requirement.

(e) Has established a system to maintain records of all patients receiving services under a collaborative pharmacy practice agreement for a period of 5 years.

(3) The terms and conditions of the collaborative pharmacy practice agreement must be appropriate to the pharmacist's education and 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.

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 must be renewed at least every 2 years.

(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 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 of Pharmacy 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 to a pharmacist the authority to initiate or prescribe a controlled substance as described in s. 893.03 or 21 U.S.C. s. 812.

(6) In addition to the continuing education requirements

under s. 465.009, a pharmacist who practices under a collaborative pharmacy practice agreement must, for each biennial licensure renewal, complete an 8-hour continuing education course approved by the Board of Medicine in consultation with the Board of Osteopathic Medicine and the Board of Pharmacy which addresses issues related to the chronic conditions to be collaboratively managed. Such 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 of Medicine in consultation with the Board of Osteopathic Medicine and the Board of Pharmacy shall adopt rules pursuant to ss. 120.536(1) and 120.54 to implement this section.

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