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 Military and Veterans Affairs, Space, and Domestic Security

BILL:	CS/SB 262
INTRODUCER:	Military and Veterans Affairs, Space, and Domestic Security Committee and Senator Harrell
SUBJECT:	Dispensing Medicinal Drugs
DATE:	March 23, 2021 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Brown	Brown	HP	**Favorable**
2.	Brown	Caldwell	MS	**Fav/CS**
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 262 amends s. 465.019, F.S., to authorize medicinal drugs to be dispensed by a hospital that operates a Class II or Class III institutional pharmacy to a patient of the hospital's emergency department or a hospital inpatient upon discharge if a prescriber treating the patient in the hospital determines that:

- The medicinal drug is warranted; and
- Community pharmacy services are not readily accessible to the patient, geographically or otherwise.

If prescribing and dispensing occurs, the bill requires that a supply of the drug must be dispensed that will last for the greater of up to 48 hours or through the end of the next business day, and that during a declared state of emergency, a 72-hour supply may be dispensed by a hospital located in an area affected by the emergency.

Any of these new circumstances that authorize the prescription of a controlled substance must comply with existing regulations and restrictions on the prescribing of a controlled substance.

The bill has an insignificant fiscal impact on the Department of Health (DOH) that can be absorbed within existing resources.

The bill takes effect July 1, 2021.

II. Present Situation:

Medicinal Prescribing and Dispensing Practitioners

There are several professions in Florida that have prescriptive authority at various levels, including:

- Allopathic physicians;
- Osteopathic physicians;
- Podiatrists;
- Dentists;
- Advanced practice registered nurses;[1]
- Physician assistants;[2] and
- Pharmacists.[3]

A person may not dispense medicinal drugs unless licensed as a pharmacist, except that a practitioner authorized by law to prescribe drugs may dispense medicinal drugs to patients in the regular course of practice.[4] A practitioner who dispenses medicinal drugs for human consumption for a fee or remuneration of any kind, whether directly or indirectly, must:

- Register with the professional licensing board as a dispensing practitioner and pay a board-established fee at the time of registration and upon renewal of his or her license;
- Comply with, and be subject to, all laws and rules applicable to pharmacists and pharmacies, including, chs. 456, 499, and 893, F.S., and all applicable federal laws and federal regulations; and
- Give each patient a written prescription and, orally or in writing, advise the patient that the prescription may be filled in the practitioner's office or at any pharmacy, before dispensing any drug.[5]

Pharmacy

The practice of pharmacy and the licensure of pharmacies are regulated under ch. 465, F.S. The "practice of the profession of pharmacy" includes:

- Compounding, dispensing, and consulting the consumer concerning the contents, therapeutic values, and uses of any medicinal (prescription)[6] drug; and
- Other pharmaceutical services.[7, 8]

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[1] Section 464.012(3)(a), F.S.
[2] *See* ss. 458.347(4)(e)4., and 459.022(4)(e)4., F.S.
[3] *See* s. 465.186, F.S., and Fla. Admin. Code R. 64B8-36.001 (2019).
[4] Section 465.0276(1)(a), F.S.
[5] Section 465.0276(2)(a), (b), and (c), F.S.
[6] Under s. 465.003(8), F.S., "medicinal drugs" means substances commonly known as "prescription" or "legend" drugs required by law to be dispensed by prescription only.
[7] Section 465.003(13), F.S.
[8] In the context of pharmacy practice, "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 chs. 458, 459, 461, or 466, F.S., 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. The "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

The Board of Pharmacy

The Board of Pharmacy (BOP) is created within the DOH and is authorized to make rules to regulate the practice of professional pharmacy in pharmacies meeting minimum requirements for safe practice.[9] All pharmacies must obtain a permit before operating, unless exempt by law. This is true whether opening a new establishment or simply changing locations or owners.[10]

The Practice of Pharmacy

Florida law recognizes seven types of pharmacies as eligible for various operating permits to be issued by the DOH:

- Community pharmacy;[11]
- Institutional pharmacy;[12]
- Nuclear pharmacy;[13]
- Special pharmacy;[14]
- Internet pharmacy;[15]
- Non-resident sterile compounding pharmacy;[16] and
- Special sterile compounding pharmacy.[17]

Institutional Pharmacies

An "institutional pharmacy" includes any pharmacy located in a health care institution, which includes a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility where medicinal drugs are compounded, dispensed, stored, or sold.[18] Institutional pharmacy permits are required for any pharmacy located in any health care institution.[19]

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employing the science or art of any branch of the pharmaceutical profession, study, or training, expressly permits a pharmacist to transmit information from persons authorized to prescribe medicinal drugs to their patients, and includes the administration of vaccines to adults. *See* s. 465.003(13), F.S.

[9] *See ss.* 465.002, and 465.0155, F.S.

[10] Fla. Admin. Code R. 64B16-28.100(1) (2019).

[11] The term "community pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis. *See* ss. 465.003(11)(a)1. and 465.018, F.S.

[12] *See* ss. 465.003(11)(a)2., and 465.019, F.S.

[13] The term "nuclear pharmacy" includes every location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold, but does not include hospitals licensed under ch. 395, F.S., or the nuclear medicine facilities of such hospitals. *See* ss. 465.003(11)(a)3. and 465.0193, F.S.

[14] The term "special pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold if such locations are not otherwise defined by law. *See* ss. 465.003(11)(a)4. and 465.0196, F.S.

[15] The term "internet pharmacy" includes locations not otherwise licensed or issued a permit under ch. 465, F.S., whether or not in Florida, which use the Internet to communicate with or obtain information from consumers in this state and use such communication or information to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy in this state. *See* ss. 465.003(11)(a)5. and 465.0197, F.S.

[16] The term "nonresident sterile compounding pharmacy" includes a pharmacy that ships, mails, delivers, or dispenses, in any manner, a compounded sterile product into Florida, and a nonresident pharmacy registered under s. 465.0156, F.S., or an outsourcing facility, must hold a nonresident sterile compounding permit. *See* s. 465.0158(1), F.S.

[17] *See* Fla. Admin. Code R. 64B16-28.100 and 64B16-28.802 (2019). An outsourcing facility is considered a pharmacy and must hold a special sterile compounding permit if it engages in sterile compounding.

[18] Section 465.003(11)(a)2., F.S.

[19] Fla. Admin. Code R. 64B16-28.100(3) (2019).

All institutional pharmacies must designate a consultant pharmacist[20] who is responsible for maintaining all drug records required by law, and 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 tests when these tests are necessary.[21] These laboratory or clinical tests may be ordered only for patients residing in a nursing home, when authorized by the facility's medical director. The consultant pharmacist must complete additional training and demonstrate additional qualifications in the practice of institutional pharmacy, as required by the BOP, and be licensed as a registered pharmacist.[22, 23]

Currently there are four types of institutional pharmacy permits issued by the BOP to institutional pharmacies: Institutional Class I, Class II, Modified Class II, and Class III.[24]

Institutional Class I Pharmacy

A Class I institutional pharmacy is an institutional pharmacy in which all medicinal drugs are administered from individual prescription containers to an individual patient and in which medicinal drugs are not dispensed on the premises, except that licensed nursing homes[25] may purchase medical oxygen for administration to residents.[26]

Institutional Class II Pharmacy

A Class II institutional pharmacy is a pharmacy that employs the services of a registered pharmacist or pharmacists who, in practicing institutional pharmacy, provide dispensing and consulting services on the premises to patients of the institution, for use on the premises of the institution.[27] A Class II institutional pharmacy is required to be open sufficient hours to meet the needs of the hospital facility.[28] The consultant pharmacist of record is responsible for establishing a written policy and procedure manual.[29] An institutional Class II pharmacy may elect to participate in the Cancer Drug Donation Program within the Department of Business and Professional Regulation.[30]

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[20] *See* ss. 465.003(11), and 465.0125, F.S.
[21] *Id*.
[22] Section 465.0125, F.S.
[23] As required by Fla. Admin. Code R. 64B16-28.501(1), (2), and (3) (2019), the consultant pharmacist must also "conduct Drug Regimen Reviews required by Federal or State law, inspect the facility and prepare a written report to be filed at the permitted facility at least monthly, . . . monitor the facility system for providing medication administration records and physician order sheets to ensure that the most current record of medications is available for the monthly drug regimen review, and may utilize additional consultant pharmacists to assist in this review and in the monthly facility inspection." A licensed consultant pharmacist may "remotely access a facility or pharmacy's electronic database from outside the facility or pharmacy to conduct any services additional or supplemental to regular drug regimen reviews, subject to the pharmacy or facility establishing policies and procedures to ensure the security and privacy of confidential patient records, including compliance with applicable Federal HIPAA regulations." The BOP must be notified in writing within ten days of any change in the consultant pharmacist of record, pursuant to Fla. Admin. Code R. 64B16-28.501(1)(b) (2019).
[24] Section 465.019, F.S.
[25] *See* part II, ch. 400, F.S., relating to nursing homes.
[26] Section 465.019(2)(a), F.S.
[27] *See* s. 465.019(2)(b), F.S. Exceptions apply when there is a state of emergency and for single doses of a drug ordered by physicians in limited circumstances.
[28] Fla. Admin. Code R. 64B16-28.603 (2019).
[29] Section 465.019(5), F.S.
[30] *See* s. 499.029, F.S., relating to the Cancer Drug Donation Program Act.

Modified Institutional Class II Pharmacy Permits

Modified Institutional Class II pharmacies are institutional pharmacies in short-term, primary care treatment centers that meet all the requirements for a Class II permit, except space and equipment requirements.[31] Modified Class II Institutional pharmacies are designated as Type A, Type B, and Type C according to the specialized type of the medicinal drug delivery system utilized at the facility, either a patient-specific or bulk drug system, and the quantity of the medicinal drug formulary at the facility.[32]

All Modified Class II institutional pharmacies must be under the control and supervision of a certified consultant pharmacist. The consultant pharmacist of record is responsible for developing and maintaining a current policy and procedure manual. The permittee must make available the policy and procedure manual to the appropriate state or federal agencies upon inspection.[33]

Institutional Class III Pharmacies

Class III institutional pharmacies are pharmacies, including central distribution facilities, that are affiliated with a hospital that provide the same services authorized by a Class II institutional pharmacy permit. Class III institutional pharmacies may also:

- Dispense, distribute, compound, and fill prescriptions for medicinal drugs;
- Prepare prepackaged drug products;
- Conduct other pharmaceutical services for the affiliated hospital and for entities under common control that are each permitted under ch. 465, F.S., to possess medicinal drugs; and
- Provide the services in Class I institutional pharmacies, Class II institutional pharmacies, and Modified Class II institutional pharmacies that hold an active health care clinic establishment permit.[34, 35]

A Class III institutional pharmacy must also maintain policies and procedures addressing the following:

- The consultant pharmacist responsible for pharmaceutical services;

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[31] Section 465.019(2)(c), F.S.

[32] Fla. Admin. Code R. 64B16-28.702(2) (2019). Modified Class II Institutional Pharmacies provide the following pharmacy services: (1) Type "A" Modified Class II Institutional Pharmacies provide pharmacy services in a facility which has a formulary of not more than 15 medicinal drugs, excluding those medicinal drugs contained in an emergency box, and in which the medicinal drugs are stored in bulk and in which the consultant pharmacist provides on-site consultations not less than once every month, unless otherwise directed by the BOP after review of the policy and procedure manual; (2) Type "B" Modified Class II Institutional Pharmacies provide pharmacy services in a facility in which medicinal drugs are stored in the facility in patient specific form and in bulk form and which has an expanded drug formulary, and in which the consultant pharmacist provides on-site consultations not less than once per month, unless otherwise directed by the BOP after review of the policy and procedure manual; and (3) Type "C" Modified Class II Institutional Pharmacies provide pharmacy services in a facility in which medicinal drugs are stored in the facility in patient specific form and which has an expanded drug formulary, and in which the consultant pharmacist provides onsite consultations not less than once per month, unless otherwise directed by the BOP after review of the policy and procedure manual.

[33] *See* Florida Board of Pharmacy, *Institutional Pharmacy Permit*, *available at* http://floridaspharmacy.gov/licensing/institutional-pharmacy-permit/ (last visited March 19, 2021).

[34] Section 465.019(2)(d)1., F.S.

[35] *See* s. 499.01(2)(r), F.S.

- Safe practices for the preparation, dispensing, prepackaging, distribution, and transportation of medicinal drugs and prepackaged drug products;
- Recordkeeping to monitor the movement, distribution, and transportation of medicinal drugs and prepackaged drug products;
- Recordkeeping of pharmacy staff responsible for each step in the preparation, dispensing, prepackaging, transportation, and distribution of medicinal drugs and prepackaged drug products; and
- Medicinal drugs and prepackaged drug products that may not be safely distributed among Class III institutional pharmacies.[36]

Institutional Pharmacies – Dispensing Medicinal Drugs

Class II and Class III institutional pharmacies are permitted to dispense medicinal drugs to outpatients only when that institution has been issued a community pharmacy permit from the DOH.[37] An individual licensed to prescribe medicinal drugs may dispense up to a 24-hour supply of a medicinal drug to any patient of an emergency department of a hospital that operates a Class II or Class III institutional pharmacy, provided the physician treating the patient in such hospital's emergency department determines the following:

- The medicinal drug is warranted; and
- Community pharmacy services are not readily accessible, geographically or otherwise, to the patient.[38]

Such dispensing from the emergency department must be in accordance with the procedures of the hospital. For any patient for whom a medicinal drug is determined to be warranted by the treating emergency department physician for a period to exceed 24 hours, an individual licensed to prescribe the drug must dispense a 24-hour supply of the drug to the patient and provide the patient with a prescription for the drug for use after the initial 24-hour period.[39] The BOP is authorized to adopt rules necessary to carry out these provisions.

III. Effect of Proposed Changes:

The bill permits medicinal drugs to be dispensed by a hospital that operates a Class II or Class III institutional pharmacy to a patient of the hospital's emergency department or a hospital inpatient upon discharge if a prescriber treating the patient in the hospital determines that:

- The medicinal drug is warranted; and
- Community pharmacy services are not readily accessible to the patient, geographically or otherwise.

If such prescribing and dispensing occurs, the bill requires that a supply of the drug must be dispensed that will last for the greater of up to 48 hours or through the end of the next business day; however, a supply lasting up to 72 hours may be dispensed during a declared state of emergency by a hospital located in an area affected by the emergency.

[36] Section 465.019(2)(d)2., F.S.
[37] *See* s. 465.019(2)(a), F.S., which prohibits a Class I institutional pharmacy from dispensing medicinal drugs.
[38] Section 465.019(4), F.S.
[39] *Id.*

A prescriber who prescribes medicinal drugs under the above circumstances may provide the patient with a prescription for such drug for use beyond the initial prescription period if the prescriber determines that use is warranted.

A prescription authorized under any of these conditions must comply with existing regulations on controlled substances provided in ss. 456.44 and 465.0276, F.S.[40]

The Board of Pharmacy, Department of Health is authorized to adopt rules to implement the bill.

The bill takes effect July 1, 2021.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The bill does not appear to require cities and counties to expend funds or limit their authority to raise revenue or receive state-shared revenues as specified by Article VII, Section 18 of the State Constitution.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None identified.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

[40] Sections 456.44 and 465.0276, F.S., impose restrictions and limitations on controlled substance prescribing, such as what may be prescribed and how often.

C. Government Sector Impact:

The Department of Health expects to incur a non-recurring cost based on rulemaking, and anticipates that the cost can be absorbed within current budget authority.[41]

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 465.019 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Military and Veterans Affairs, Space, and Domestic Security on March 23, 2021:
The committee substitute provides that the new conditions that authorize the prescribing of a controlled substance are subject to ss. 456.44 and 465.0276, F.S., which regulate the prescribing of controlled substances.

B. Amendments:

None.

[41] Department of Health, *2021 Agency Legislative Bill Analysis, SB 262* (Jan. 25, 2021) (on file with the Senate Committee on Military and Veterans Affairs, Space, and Domestic Security).