

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 Judiciary

BILL: CS/CS/SB 1222

INTRODUCER: Judiciary Committee; Health Policy Committee; and Senator Bean, and others

SUBJECT: Acute and Post-acute Hospital Care

DATE: February 8, 2022

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Rossitto-Vanwinkle</u>	<u>Brown</u>	<u>HP</u>	<u>Fav/CS</u>
2.	<u>Ravelo</u>	<u>Cibula</u>	<u>JU</u>	<u>Fav/CS</u>
3.	_____	_____	<u>RC</u>	_____

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/CS/SB 1222 authorizes paramedics and Class III institutional pharmacies, a type of hospital pharmacy, to serve hospital patients at their homes. Under the bill, a paramedic, under the supervision of a physician or acting under other standing orders, may provide basic life support services and advanced life support services to a patient receiving acute and post-acute hospital care at his or her permanent residence through a program approved by the Centers for Medicare and Medicaid Services and the Agency for Health Care Administration. A Class III institutional pharmacy may dispense, distribute, compound, and fill prescriptions for medicinal drugs for these same patients.

The bill provides an effective date of July 1, 2022.

II. Present Situation:

Florida's Department of Health (DOH)

The Legislature created the Department of Health (DOH) to protect and promote the health, safety and welfare of all residents and visitors in the state.¹ The DOH is charged with the regulation of health practitioners for the preservation of the health, safety, and welfare of the

¹ Sections 20.43 and 456.003, F.S.

public. The Division of Medical Quality Assurance (MQA) is responsible for the boards² and professions within the DOH.³

Boards of Medicine and Osteopathic Medicine

The Board of Medicine regulates allopathic physicians (MD). An MD is a person who is licensed to practice medicine in Florida. Practicing medicine includes the diagnosis, treatment, operation, or prescription for any human disease, pain, injury, deformity, or other physical or mental condition.⁴ Allopathic standards of practice and standards of care for a particular practice setting include, but are not limited to, education and training, equipment and supplies, medications including anesthetics, assistance of and delegation to other personnel, transfer agreements, sterilization, records, performance of complex or multiple procedures, informed consent, and policy and procedure manuals.⁵

The Board of Osteopathic Medicine regulates osteopathic physicians (DO). A DO is a person who is licensed to practice osteopathic medicine Florida. The practice of osteopathic medicine includes the diagnosis, treatment, operation, or prescription for any human disease, pain, injury, deformity, or other physical or mental condition, which practice is based in part upon educational standards and requirements that emphasize the importance of the musculoskeletal structure and manipulative therapy in the maintenance and restoration of health.⁶

Emergency Medical Services (EMS)

The Legislature created ch. 401, F.S., in 1973 with the intent to establish a statewide organized and regulated system of regional EMS providers with two major objectives:

- To develop a statewide system of emergency medical telecommunications to maximize the use of existing radio channels to provide faster and more effective EMS to the general population;⁷ and
- To protect and enhance the public health, safety, and welfare with the establishment a statewide EMS plan to:
 - Monitor the quality of patient care delivered by each licensed service;
 - Certify EMS personnel;
 - Create an EMS advisory council;
 - Develop a comprehensive statewide injury-prevention program; and
 - Development minimum standards for EMS providers, personnel, vehicles, services, medical direction, and inspections.⁸

The Legislature further recognized that a major impediment to meeting its two legislative objectives for s. 401, F.S., was the inability of governmental and private agencies to respond

² Under s. 456.001(1), F.S., “board” is defined as any board, commission, or other statutorily created entity, to the extent such entity is authorized to exercise regulatory or rulemaking functions within the DOH or, in some cases, within the MQA.

³ Section 20.43, F.S.

⁴ Section 458.305, F.S.

⁵ Section 458.331(1)(v), F.S.

⁶ Section 459.003, F.S.

⁷ Section 401.013, F.S.

⁸ Section 401.211, F.S.

cooperatively in order to finance a system of regional EMS. In response, the Legislature found it in the public interest to foster the development of a statewide EMS provider system and created the Florida Emergency Medical Services Grant Act.⁹ This law authorizes the DOH to make grants to local agencies, EMS organizations, and youth athletic organizations to provide EMS, including emergency medical dispatch, and work with local EMS organizations to expand the use of automated external defibrillator (AED) devices.¹⁰

Emergency Medical Service Providers

Before a person or entity, including a government entity, provides prehospital or interfacility advanced life support (ALS) services or basic life support (BLS) transportation services to the public, the person or entity must be licensed as a BLS service or an ALS service. Every ALS ambulance transporting a person who is sick, injured, wounded, incapacitated, or helpless must have a least two persons on-board: one who is a certified paramedic or licensed physician and one who is a certified emergency medical technician (EMT), certified paramedic, or licensed physician and also meets the requirements of an ambulance driver. The person having the highest medical certification must be in charge of patient care.¹¹

Paramedic

A certified paramedic may perform both BLS and ALS.¹² ALS includes the assessment or treatment by a certified paramedic qualified in the use of techniques such as endotracheal intubation, the administration of drugs or intravenous fluids, telemetry, cardiac monitoring, cardiac defibrillation, and other techniques described in the EMT-Paramedic National Standard Curriculum or the National EMS Education Standards, pursuant to DOH administrative rules.¹³

Qualifications for Certification

To be qualified for certification as a paramedic, an individual must either successfully complete an initial Florida paramedic training program that was conducted in accordance with the January 2009 U.S. DOT National EMS Education Standards; or if the individual is from out of state or military trained in accordance with the 1998 U.S. DOT EMT-Paramedic (EMT-P) NSC or the January 2009 U.S. DOT National EMS Education Standards, if he or she currently holds a valid paramedic certification from the National Registry of Emergency Medical Technicians (NR-EMT).

Each applicant must submit an application to the DOH. If the applicant completed his or her initial paramedic training program in Florida, then he or she must pass the DOH-required paramedic certification examination within two years after completing the initial Florida training program. The DOH will accept a passing score for this exam if taken within the 2-year period, whether the exam is taken before or after the application is filed.

⁹ See ss. 401.101 and 401.104, F.S.

¹⁰ Section 401.111, F.S.

¹¹ Section 401.25(1), F.S.

¹² Section 401.23(17), F.S.

¹³ Section 401.23(1), F.S.

To maintain an active certificate, a paramedic must pay the recertification fee and complete 30 hours of paramedic refresher training based on criteria in the January 2009 U.S. DOT National EMS Education Standards which includes adult and pediatric education with a minimum of two hours in pediatric emergencies, and maintain a current Advanced Cardiac Life Support (ACLS) card.¹⁴ The DOH accepts either the affirmation of a licensed EMS provider's medical director, a certificate of completion of refresher training from a DOH-approved Florida training program, or a DOH-approved CE provider's proof of compliance with the CE requirements.

EMS Services in Community Health Care

Section 401.272, F.S., was enacted by the Legislature to encourage more effective use of the skills of EMTs and paramedics by enabling them to perform, in partnership with local county health departments, specific additional health care tasks that are consistent with the public health and welfare. Notwithstanding any other provision of law to the contrary, a paramedic or an EMT may perform "health promotion and wellness"¹⁵ activities and blood pressure screenings in a nonemergency environment, within the scope of his or her training, and under the direction of a medical director.

A paramedic may administer immunizations in a nonemergency environment, within the scope of his or her training, and under the direction of a medical director. There must be a written agreement between the paramedic's medical director and the county health department located in each county in which the paramedic administers immunizations. This agreement must establish the protocols, policies, and procedures under which the paramedic must operate. Each medical director under whose direction a paramedic administers immunizations must verify and document that the paramedic has received sufficient training and experience to administer immunizations. The verification must be documented on forms developed by the DOH, and the forms must be maintained at the service location of the licensee and made available to the DOH upon request.

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.¹⁶ 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.¹⁷

The Practice of Pharmacy

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

¹⁴ See s 401.27(4)(e)2., F.S., and Fla. Admin. Code R. 64J-1.022, (2021).

¹⁵ "Health promotion and wellness" means the provision of public health programs pertaining to the prevention of illness and injury. Section 401.272(2)(a), F.S.

¹⁶ See ss. 465.002, and 465.0155, F.S.

¹⁷ Fla. Admin. Code R. 64B16-28.100(1) (2021).

- Community pharmacy;¹⁸
- Institutional pharmacy;¹⁹
- Nuclear pharmacy;²⁰
- Special pharmacy;²¹
- Internet pharmacy;²²
- Non-resident sterile compounding pharmacy;²³ and
- Special sterile compounding pharmacy.²⁴

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.²⁵ Institutional pharmacy permits are required for any pharmacy located in any health care institution.²⁶

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.²⁷

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 homes²⁸ may purchase medical oxygen for administration to residents.²⁹

Institutional Class II Pharmacy

A Class II institutional pharmacy is a pharmacy that employs the services of a registered pharmacist who, in practicing institutional pharmacy, provide dispensing and consulting services

¹⁸ 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.

¹⁹ *See* ss. 465.003(11)(a)2., and 465.019, F.S.

²⁰ 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.

²¹ 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.

²² 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.

²³ 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.

²⁴ *See* Fla. Admin. Code R. 64B16-28.100 and 64B16-28.802 (2021). An outsourcing facility is considered a pharmacy and must hold a special sterile compounding permit if it engages in sterile compounding.

²⁵ Section 465.003(11)(a)2., F.S.

²⁶ Fla. Admin. Code R. 64B16-28.100(3) (2021).

²⁷ Section 465.019, F.S.

²⁸ *See* part II, ch. 400, F.S., relating to nursing homes.

²⁹ Section 465.019(2)(a), F.S.

on the premises to patients of the institution, for use on the premises of the institution.³⁰ A Class II institutional pharmacy is required to be open sufficient hours to meet the needs of the hospital facility.³¹ The consultant pharmacist of record is responsible for establishing a written policy and procedure manual.³²

Modified Institutional Class II Pharmacy Permits

Modified Institutional Class II pharmacies are institutional pharmacies in short-term, primary care treatment centers which meet all the requirements for a Class II permit, except space and equipment requirements.³³ 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.³⁴

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:

- 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.^{35, 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

³⁰ 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.

³¹ Fla. Admin. Code R. 64B16-28.603 (2021).

³² Section 465.019(5), F.S.

³³ Section 465.019(2)(c), F.S.

³⁴ Fla. Admin. Code R. 64B16-28.702(2) (2021). 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.

³⁵ Section 465.019(2)(d)1., F.S.

³⁶ See s. 499.01(2)(r), F.S.

DOH.³⁷ However, medicinal drugs may 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 that community pharmacy services are not readily accessible, geographically or otherwise, to the patient. Such prescribing and dispensing must be for a supply of the drug that will last for the greater of the following:

- Up to 48 hours; or
- Through the end of the next business day.³⁸

Notwithstanding those limits, if a state of emergency has been declared and is in effect for a specific area of the state, a supply of a medicinal drug which will last up to 72 hours may be prescribed and dispensed to persons in that area. A prescriber prescribing medicinal drugs in a state of emergency may also provide the patient with a prescription for the drug for use beyond the initial prescription period if the prescriber determines that such use is warranted. Any prescribing or dispensing of a controlled substance during a state of emergency must comply with the applicable requirements of ss. 456.44 and 465.0276, F.S.

III. Effect of Proposed Changes:

CS/CS/SB 1222 amends s. 401.272, F.S., to authorize a paramedic to provide basic and advanced life support to a patient receiving acute and post-acute hospital care at his or her permanent residence through a program approved by the Centers for Medicare and Medicaid Services and the Agency for Health Care Administration.

Moreover, the physician who supervises or provides medical direction to a paramedic who administers the basic life support services or advanced life support services is liable for any act or omission of the paramedic.

The Department of Health is authorized to adopt and enforce rules relating to the expanded scope of services that may be provided by a paramedic under the bill.

The bill amends s. 465.019, F.S., to expand the scope of Class III institutional pharmacies to authorize them to dispense, distribute, compound, and fill prescriptions for medicinal drugs to a patient receiving acute and post-acute hospital care at his or her permanent residence through a program approved by the Centers for Medicare and Medicaid Services and the Agency for Health Care Administration.

The bill makes technical and conforming changes to ss. 401.23, 14.33, 252.515, 395.1027, and 401.245 F.S.

The bill provides an effective date of July 1, 2022.

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.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

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:

By allowing private hospitals to serve patients at their homes through the use of paramedics and hospital pharmacies, CS/CS/SB 1222 may allow health care services to be provided in a more cost effective manner. Moreover, the ability to treat a hospital patient at his or her home may make additional hospital beds available for patients having more serious conditions.

C. Government Sector Impact:

By allowing government hospitals or private hospitals receiving government funding to serve patients at their homes through the use of paramedics and hospital pharmacies, the bill may allow health care services to be provided in a more cost effective manner. Moreover, the ability to treat a hospital patient at his or her home may make additional hospital beds available for patients having more serious conditions.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 401.23, 401.272, 465.019, 14.33, 252.515, 395.1027, and 401.245.

IX. Additional Information:**A. Committee Substitute – Statement of Substantial Changes:**

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS/CS by Judiciary on February 7, 2022:

The committee substitute limits the expansion of the additional authority granted to paramedics and Class III institutional pharmacies in the underlying committee substitute. The underlying committee substitute would have allowed paramedics and Class III institutional pharmacies to serve patients in a “nonemergent community setting.” Under the committee substitute, the services may be provided only at a patient’s residence through a program approved by both CMS and AHCA. Additionally, the committee substitute no longer authorizes a Class II or Class III institutional pharmacy to provide medicines to a patient where community pharmacy services are not readily accessible.

CS by Health Policy on January 19, 2022:

The CS:

- Authorizes paramedics to perform BLS services, ALS services, and additional health care services to acute care at-home patients in a nonemergent community setting under the supervision of a physician in partnership with specific hospitals;
- Requires a physician supervising a paramedic who provides BLS, ALS, or additional health care services to acute care at home patients under the bill, to be liable for any act or omission of the paramedic when performing the acts or services;
- Authorizes Class III institutional pharmacies to dispense, distribute, compound, and fill prescriptions for medicinal drugs to acute care at home patients and inpatients; and
- Authorizes Class II and III institutional pharmacies that do not have community pharmacy permits to dispense to an acute care at-home patient in a nonemergent community setting if a prescriber treating the patient in the hospital determines that the medicinal drug is warranted and that community pharmacy services are not readily accessible, geographically or otherwise.

B. Amendments:

None.