

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 1115 Dispensing Medicinal Drugs

SPONSOR(S): Health Quality Subcommittee, Willhite

TIED BILLS: **IDEN./SIM. BILLS:** SB 1124

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	10 Y, 0 N, As CS	Siples	McElroy
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Currently, a physician is authorized to dispense up to a 24-hour supply of a medicinal drug to a patient the physician is treating in an emergency department of a hospital that holds an appropriate institutional pharmacy permit. The physician must determine that the medicinal drug is needed and that community pharmacy services are not readily accessible to the patient. If the patient needs more than a 24-hour supply of a drug, the physician must provide the patient with a prescription for use after the initial 24-hour period.

CS/HB 1115 expands this authorization to allow all prescribers, not just physicians, to prescribe medicinal drugs under these circumstances and extends patient eligibility to include a hospital inpatient upon discharge. The bill also increases the supply limit of what may be dispensed to the greater of a 24-hour supply of a medicinal drug or a supply of a medicinal drug that is sufficient to last a patient until the next business day. The bill updates current language to reflect that it is the hospital pharmacy would be dispensing the medicinal drug.

The bill has an insignificant, negative fiscal impact on the Department of Health, which current resources are adequate to absorb. The bill has no fiscal impact on local governments.

The bill provides an effective date of July 1, 2019.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Pharmacy Regulation

The Florida Pharmacy Act (Act) regulates Florida pharmacies and contains the minimum requirements for safe practice.¹ The Board of Pharmacy (board) within the Department of Health (DOH) is tasked with adopting rules to implement the provisions of the Act and setting standards of practice within the state.² A person must obtain a DOH-issued permit to operate a pharmacy:

- **Community pharmacy** - A permit is required for each location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.³
- **Institutional pharmacy** - A permit is required for every location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility where medicinal drugs are compounded, dispensed, stored, or sold.⁴
- **Nuclear pharmacy** - A permit is required for every location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold. The term “nuclear pharmacy” does not include hospitals licensed under chapter 395 or the nuclear medicine facilities of such hospitals.⁵
- **Special pharmacy** - A permit is required for every location where medicinal drugs are compounded, dispensed, stored, or sold if the location does not otherwise meet an applicable pharmacy definition in s. 465.003, F.S.⁶
- **Internet pharmacy** - A permit is required for a location not otherwise licensed or issued a permit under chapter 465, F.S., within or outside this state, which uses the Internet to communicate with or obtain information from consumers in this state to fill or refill prescriptions or to dispense, distribute, or otherwise practice pharmacy in this state.⁷

All permitted pharmacies must pass an on-site inspection before DOH will issue an initial permit and is also required any time a pharmacy changes its ownership or address.⁸

Institutional Pharmacies

All institutional pharmacies must designate a consultant pharmacist of record.⁹ The consultant pharmacist’s responsibilities include:¹⁰

- Maintaining all drug records required by law;
- Establishing drug handling procedures for the safe handling and storage of drugs;
- Ordering and evaluating laboratory and clinical testing when necessary for the proper performance of the consultant pharmacist’s responsibilities;¹¹

¹ Chapter 465, F.S.

² Sections 465.005, 465.0155(1), and 465.022, F.S.

³ Sections 465.003(11)(a)1. and 465.018, F.S.

⁴ Sections 465.003(11)(a)2. and 465.019, F.S.

⁵ Sections 465.003(11)(a)3. and 465.0193, F.S.

⁶ Sections 465.003(11)(a)4. and 465.0196, F.S.

⁷ Sections 465.003(11)(a)5. and 465.0197, F.S.

⁸ Rule 64B16-28(1)(d), F.A.C.

⁹ Section 465.019(5), F.S., and r. 64B16-28.501, F.A.C.

¹⁰ Section 465.0125, F.S., and r. 64B16-28.501, F.A.C.

- Conducting drug regimen reviews as required by state or federal law; and
- Inspecting the facility and preparing a written report to be filed at the permitted facility monthly.

There are four types of institutional pharmacy permits issued by the board to institutional pharmacies:¹²

- Class I Institutional permits are issued to institutional pharmacies in which all medicinal drugs are administered from individual prescription containers to individual patients; and in which medicinal drugs are not dispensed on the premises, except licensed nursing homes¹³ may purchase medical oxygen for administration to residents.
- Class II Institutional permits are issued to institutional pharmacies that employs the services of a registered pharmacist who dispenses to and consults with patients on the premises of the institution and for use on the premises of the institution.
- Modified Class II Institutional permits are issued to institutional pharmacies in a short-term, primary care treatment center that meet all the requirements for a Class II permit, except space and equipment requirements.
- Class III Institutional permits are issued to institutional pharmacies, including central distribution facilities, affiliated with a hospital that provide the same services that are authorized by a Class II institutional pharmacy permit. Additionally, an Class III Institutional pharmacy 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 appropriately permitted;
 - Provide the above-listed services to an entity under common control which holds an active health care clinic establishment permit.¹⁴

Class III Institutional pharmacies must also maintain policies and procedures which address:¹⁵

- 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.

Dispensing of Medicinal Drugs

Pharmacists, licensed under the Act, are authorized to dispense medicinal drugs¹⁶ in this state, and authorized prescribers may dispense medicinal drugs to their patients.¹⁷ Authorized prescribers include allopathic and osteopathic physicians, podiatrists, dentists, optometrists, advanced practice registered

¹¹ A consultant pharmacist may only order these tests for patients residing in a nursing home facility and when authorized by the nursing home facility's medical director. The consultant pharmacist must complete additional training and meet additional qualifications in the practice of institutional pharmacy, as required by the board.

¹² Section 465.019, F.S.

¹³ Nursing homes are licensed under part II, ch. 400, F.S.

¹⁴ A health care clinic establishment permit is required for the purchase of a prescription drug by a place of business at one general physical location that provides health care or veterinary services, which is owned or operated by a business entity. See s. 499.01(2)(r), F.S.

¹⁵ Section 465.019(1)(d), F.S.

¹⁶ A medicinal drug is a substance or preparation commonly known as a prescription or legend drug, which by federal or state law may only be dispensed pursuant to a prescription. See s. 465.003(8), F.S.

¹⁷ Section 465.0276, F.S.

nurses and physician assistants.¹⁸ A prescriber who dispenses medicinal drugs for a fee or remuneration of any kind, must:¹⁹

- Register with his or her professional licensing board as a dispensing practitioner and pay the fee established by the board;
- Comply with and be subject to all state and federal laws, rules, and regulations applicable to pharmacists and pharmacies;
- Give each patient a written prescription and advise the patient that the prescription may be filled in the practitioner's office or at any pharmacy, orally or in writing; and
- Verify the identity of a patient who is not known to the dispenser before dispensing a controlled substance.

Dispensing of Medicinal Drugs by Institutional Pharmacies

An institutional pharmacy must hold a community pharmacy permit to dispense medicinal drugs to outpatients.²⁰ However, an authorized prescriber 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 that the treating practitioner determines that the medicinal drug is warranted and community pharmacy services are not readily accessible.²¹ If the patient needs more than a 24-hour supply of a medicinal drug, the treating practitioner must dispense a 24-hour supply of the medicinal drug and provide the patient with a prescription for use after the initial 24-hour period.²² Such dispensing must be in accordance with the hospital's procedures.

For any drug dispensed from the emergency department of a hospital, the prescriber must create, and the consultant pharmacist of record must maintain, a patient record which includes the following:²³

- Patient name and address;
- Drug and strength of the prescribed and/or dispensed;
- Quantity prescribed and/or dispensed;
- Directions for use;
- Prescriber/Dispenser;
- Prescriber DEA registration, if applicable; and
- Reason community pharmacy services were not readily accessible;

Any dispensed medications must be properly labeled and may not exceed the greater of a 24-hour supply or the minimal dispensable quantity.²⁴

Effect of Proposed Changes

CS/HB 1115 expands the authorization to prescribe and dispense medicinal drugs in hospital settings. It allows all prescribers, not just physicians, to prescribe medicinal drugs under these circumstances and extends patient eligibility to include a hospital inpatient upon discharge. The bill also increases the supply limit of what may be dispensed to the greater of a 24-hour supply of a medicinal drug or a supply of a medicinal drug that is sufficient to last a patient until the next business day. The bill updates current language to reflect that it is the hospital pharmacy would be dispensing the medicinal drug.

¹⁸ For limitations on an optometrist's authority to prescribe or dispense a medicinal drug, see s. 463.0055, F.S.; for an advanced practice registered nurse's limitations, see s. 464.012 ; and for a physician assistant's limitations, see ss. 458.347(4)(e) or 459.022(4)(e), F.S.

¹⁹ *Supra* note 17.

²⁰ Section 465.019(4), F.S.

²¹ *Id.*

²² *Id.*

²³ Rule 64B16-28.6021, F.A.C.

²⁴ *Id.*

The bill provides an effective date of July 1, 2019.

B. SECTION DIRECTORY:

Section 1: Amends s. 465.019, F.S., relating to institutional pharmacies; permits.

Section 2: Provides an effective date of July 1, 2019.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

DOH may incur insignificant, non-recurring costs associated with amending adopted rules, which may be absorbed within current resources.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill may prevent patients who have difficulty accessing a community pharmacy after visiting an emergency department of a hospital or being discharged from inpatient care at a hospital, from returning to the emergency department or hospital to obtain additional relief.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

DOH has sufficient rulemaking authority to implement the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 26, 2019, the Health Quality Subcommittee adopted a strike-all amendment and reported the bill favorably as a committee substitute. The strike-all amendment authorizes a hospital pharmacy to dispense the greater of a 24-hour supply or a supply of medicine sufficient to last until the next business day to a patient in an emergency room or a hospital inpatient upon discharge. The strike-all amendment also authorizes all prescribers, not just physicians, to prescribe medicinal drugs to be dispensed under these circumstances.

The analysis is drafted to the committee substitute as passed by the Health Quality Subcommittee.