

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/CS/HB 1115 Dispensing Medicinal Drugs

SPONSOR(S): Health & Human Services Committee, 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 & Human Services Committee	18 Y, 0 N, As CS	Siples	Calamas

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 authorizes a hospital pharmacy to dispense 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 corrects current language to reflect that it is the hospital pharmacy that dispenses the medicinal drug.

Florida law currently authorizes the use of automated pharmacy systems, which are mechanical systems that deliver prescription drugs received from a Florida-permitted pharmacy and maintain related transaction information, in long-term care facilities, hospices, and state correctional institutions. The bill expands current law to authorize the use of automated dispensing systems by community pharmacies for outpatient dispensing. The bill also establishes criteria for such systems and a community pharmacy's responsibilities when employing such a system.

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

Practice of Pharmacy

The Florida Pharmacy Act (Act) regulates Florida pharmacies and imposes 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.²

Dispensing of Medicinal Drugs

Pharmacists, licensed under the Act, are authorized to dispense medicinal drugs³ in this state, and authorized prescribers may dispense medicinal drugs to their patients.⁴ Authorized prescribers include allopathic and osteopathic physicians, podiatrists, dentists, optometrists, advanced practice registered nurses and physician assistants.⁵ A prescriber who dispenses medicinal drugs for a fee or remuneration of any kind, must:⁶

- 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.

Pharmacy Regulation

A person must obtain a DOH-issued permit to operate one of five types of pharmacies:

- **Community pharmacy** – Where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.⁷
- **Institutional pharmacy** – Hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility locations where medicinal drugs are compounded, dispensed, stored, or sold.⁸
- **Nuclear pharmacy** – Where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold, other than hospitals.⁹
- **Special pharmacy** - Locations where medicinal drugs are compounded, dispensed, stored, or sold if that do not otherwise meet an applicable pharmacy definition in s. 465.003, F.S.¹⁰
- **Internet pharmacy** – Locations not otherwise licensed or issued a pharmacy permit within or outside this state, which use the Internet to communicate with or obtain information from

¹ Chapter 465, F.S.

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

³ 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.

⁴ Section 465.0276, F.S.

⁵ 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.

⁶ *Supra* note 4.

⁷ Sections 465.003(11)(a)1. and 465.018, F.S.

⁸ Sections 465.003(11)(a)2. and 465.019, F.S.

⁹ Sections 465.003(11)(a)3. and 465.0193, F.S.

¹⁰ Sections 465.003(11)(a)4. and 465.0196, F.S.

consumers in this state to fill or refill prescriptions or to dispense, distribute, or otherwise practice pharmacy in this state.¹¹

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.¹²

Institutional Pharmacies

All institutional pharmacies must designate a consultant pharmacist of record.¹³ The consultant pharmacist's responsibilities include:¹⁴

- 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;¹⁵
- 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:¹⁶

- 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 homes¹⁷ may purchase medical oxygen for administration to residents.
- Class II Institutional permits are issued to institutional pharmacies that employ 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, a 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.¹⁸

Class III Institutional pharmacies must also maintain policies and procedures which address:¹⁹

- Safe practices for the preparation, dispensing, prepackaging, distribution, and transportation of medicinal drugs and prepackaged drug products;

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

¹² Rule 64B16-28(1)(d), F.A.C.

¹³ Section 465.019(5), F.S., and r. 64B16-28.501, F.A.C.

¹⁴ Section 465.0125, F.S., and r. 64B16-28.501, F.A.C.

¹⁵ 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.

¹⁶ Section 465.019, F.S.

¹⁷ Nursing homes are licensed under part II, ch. 400, F.S.

¹⁸ 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.

¹⁹ Section 465.019(1)(d), F.S.

- 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 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

Automated Pharmacy Systems

An automated pharmacy system is a mechanical system that delivers prescription drugs received from a Florida-permitted pharmacy and maintains related transaction information.²⁵ A Florida-licensed pharmacist must supervise the automated pharmacy system.²⁶ This supervision does not have to be at the same site of the automated pharmacy system and may be provided electronically.²⁷ The pharmacy operating the system must have policies and procedures in place to ensure sufficient security and protect patient confidentiality.²⁸

A pharmacy may use an automated pharmacy system to provide services to a long-term care facility, hospice, or a state correctional institution, and such system does not have to be located at the same location as the pharmacy.²⁹ Current law does not authorize the use of automated pharmacy systems in community pharmacies.

²⁰ Section 465.019(4), F.S.

²¹ Id.

²² Id.

²³ Rule 64B16-28.6021, F.A.C.

²⁴ Id.

²⁵ Section 465.003(17), F.S.

²⁶ Section 465.0235(3), F.S.

²⁷ Id.

²⁸ Rule 64B16-28.607, F.S.

²⁹ Section 465.0235(1), F.S.

However, the Board of Pharmacy adopted rules allowing automated pharmacy systems to be used in community pharmacies. Under these rules, an automated pharmacy system must be located within or adjacent to the prescription department and must collect, control, and maintain all transaction information.³⁰ Such system may not compound or administer medicinal drugs.³¹ All prescriptions dispensed from the system are considered to be certified by the pharmacist.³² The pharmacy operating the automated pharmacy system must:³³

- Have policies and procedures that address, among other things, security, a process for stocking the system, a method for identifying pharmacy personnel involved in the dispensing process, and a method for ensuring patient confidentiality;
- Ensure that each prescription is being dispensed in compliance with law;
- Maintain a readily retrievable electronic record to identify pharmacy personnel involved in the dispensing of a prescription;
- Be able to comply with product recalls;
- Only be stocked or restocked by a Florida-licensed pharmacist; and
- Use two separate verifications, such as a bar code verification, electronic verification, weight verification, or similar process to ensure that the proper medication is being dispensed.

It is unclear whether the Board of Pharmacy has sufficient statutory authority for these rules.

Effect of Proposed Changes

Dispensing by Institutional Pharmacies

CS/HB 1115 expands the authorization to prescribe and dispense medicinal drugs in hospital settings. It allows all prescribers, not just physicians, to prescribe and hospital pharmacies to dispense a limited supply of medicinal drugs when community pharmacy services are unavailable.

The bill authorizes a hospital pharmacy to dispense 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 also authorizes a hospital inpatient, upon discharge, to receive this limited supply of a medicinal drug if community pharmacy services are not available. The bill corrects current language to reflect that it is the hospital pharmacy that dispenses the medicinal drug.

Outpatient Dispensing by Automated Pharmacy Systems

The bill also authorizes Florida-permitted community pharmacies to employ automated pharmacy systems for outpatient dispensing. The bill expands current law regulating automated pharmacy systems located in long-term care facilities, hospices, and state correctional institutions to include automated pharmacy systems employed by community pharmacies.

Under the bill, an automated pharmacy system employed by a community pharmacy does not need to be located at the same location as the community pharmacy if the system:

- Is under the supervision and control of Florida-permitted community pharmacy;
- Is under the supervision of a Florida-licensed pharmacist who is available and accessible for patient counseling prior to the dispensing of any medicinal drug;
- Does not store or dispense any controlled substances; and
- Ensures the confidentiality of personal health information.

The bill requires the community pharmacy to notify the Board of Pharmacy of the location of the system and any time the location of such system changes. The pharmacy must maintain a record of the

³⁰ Rule 64B16-28.141, F.S.

³¹ Id.

³² Id. A pharmacy must certify the accuracy of the final prescription. By doing so, the pharmacist assumes the responsibility for the prescription. (Rule 64B-27.1001, F.A.C.).

³³ Id.

medicinal drugs dispensed by the automated pharmacy system, including the identity of the pharmacist responsible for verifying the accuracy of the dosage and instructions for the prescription, as well as providing patient counseling.

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: Amends s. 465.0235, F.S., relating to automated pharmacy systems used by long-term care facilities, hospices, or state correctional institutions.

Section 3: 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.

DOH will incur costs related to documenting the locations, inspecting, and regulating community pharmacy automated pharmacy systems.³⁴ It is unknown how many community pharmacies will employ an automated pharmacy system; however, it is estimated current resources are adequate to absorb these costs.³⁵

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.

Pharmacies that choose to employ automated pharmacy systems will incur costs associated with obtaining and maintaining those systems.

D. FISCAL COMMENTS:

None.

III. COMMENTS

³⁴ Department of Health, *2019 Agency Legislative Analysis for HB 687*, (Feb. 7, 2019), on file with the Health Quality Subcommittee.

³⁵ *Id.*

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.

On April 9, 2019, the Health and Human Services Committee adopted an amendment and reported the bill favorably as a committee substitute. The amendment:

- Authorized a permitted community pharmacy to employ an automated pharmacy system to dispense medicinal drugs on an outpatient basis;
- Required that an automated pharmacy system be under the supervision and control of a Florida-licensed pharmacist, who must be available for patient counseling;
- Prohibited an automated pharmacy system from dispensing any controlled substance; and
- Required a community pharmacy to notify the Board of Pharmacy of the location of any automated pharmacy system and each time the location changes.

The analysis is drafted to the committee substitute as passed by the Health and Human Services Committee.