

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/CS/HB 59 Automated Pharmacy Systems

SPONSOR(S): Health & Human Services Committee, Health Quality Subcommittee, Willhite

TIED BILLS: **IDEN./SIM. BILLS:** SB 708

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	13 Y, 0 N, As CS	Siples	McElroy
2) Health Care Appropriations Subcommittee	11 Y, 0 N	Mielke	Clark
3) Health & Human Services Committee	16 Y, 0 N, As CS	Siples	Calamas

SUMMARY ANALYSIS

An automated pharmacy system is a mechanical system that dispenses prescription drugs received from a Florida-permitted pharmacy and maintains related transaction information. Such a system offers some mechanism, either videoconferencing or teleconferencing, by which a pharmacist may counsel a patient at the time of dispensing. Florida law currently authorizes the use of automated pharmacy systems in long-term care facilities, hospices, and state correctional institutions. The Board of Pharmacy has adopted rules regulating the use of such systems.

CS/CS/HB 59 expands current law to authorize a community pharmacy to provide outpatient dispensing through the use of an automated pharmacy system. The bill establishes criteria for such systems and a community pharmacy's responsibilities when employing such a system.

The bill has an indeterminate, but likely 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, 2020.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

The Florida Pharmacy Act (Act) regulates Florida pharmacies and contains the minimum requirements for safe practice.¹ The Board of Pharmacy 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 an inspection is also required any time a pharmacy changes its ownership or address.⁸

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.⁹ A Florida-licensed pharmacist must supervise the automated pharmacy system.¹⁰ This supervision does not have to be at the same site of the automated pharmacy system and may be provided electronically.¹¹ The pharmacy operating the system must have policies and procedures in place to ensure sufficient security and protect patient confidentiality.¹²

Current law authorizes a pharmacy to use an automated pharmacy system to provide services to a long-term care facility, hospice, or a state correctional institution, and does not require such system to be located at the same location as the pharmacy.¹³

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 465.003(17), F.S.

¹⁰ Section 465.0235(3), F.S.

¹¹ Id.

¹² Rule 64B16-28.607, F.S.

¹³ Section 465.0235(1), F.S.

Current law does not explicitly authorize the use of automated pharmacy systems in community pharmacies. 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.¹⁴ Such system may not compound or administer medicinal drugs.¹⁵ All prescriptions dispensed from the system are considered to be certified by the pharmacist.¹⁶ A pharmacy operating an automated pharmacy system must:¹⁷

- 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

CS/CS/HB 59 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 housed in an accessible indoor environment, such as a medical facility, place of business where essential goods and services are sold, rural area, large employer workplace, or location where access to a community pharmacy is limited;
- Has a mechanism that allows a Florida-licensed pharmacist to provide live, real-time 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 a 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 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.

A community pharmacy must also maintain and annually review written policies and procedures that ensure the safety and security of the automated pharmacy system. The policies and procedures must address:

¹⁴ Rule 64B16-28.141, F.S.

¹⁵ Id.

¹⁶ 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.).

¹⁷ Id.

- Maintaining of the automated pharmacy system and any accompanying electronic verification process in good working order;
- Ensuring the integrity of the drug identifier database and its ability to identify the person responsible for making database entries;
- Ensuring the accurate filling, stocking, and verification of the automated pharmacy system;
- Ensuring sanitary operation of the automated pharmacy system and prevention of cross-contamination of cells, cartridges, containers, cassettes, or packages;
- Testing the accuracy of the automated pharmacy system and any accompanying electronic verification process;
- Training individuals who are authorized to access, stock, or use the system;
- Conducting routine and preventative maintenance, including calibration;
- Preventing unauthorized persons from accessing the system;
- Identifying and recording persons responsible for stocking and filing the automated pharmacy system;
- Ensuring compliance with state and federal law; and
- Maintaining an ongoing quality assurance program that monitors performance of the automated pharmacy system and accompanying electronic verification process to ensure proper and accurate functioning.

The bill requires a community pharmacy to test the system before its first use, upon restarting the system, and after any modification to the system which alters the filling or electronic verification process. The community pharmacy must also maintain track and document any system errors and maintain such documentation for four years and must produce it upon the request of the Board.

Current law requires the Board of Pharmacy to adopt rules for automated pharmacy systems. The bill authorizes the Board of Pharmacy to adopt rules on automated pharmacy systems, rather than require such action.

The bill provides an effective date of July 1, 2020.

B. SECTION DIRECTORY:

Section 1: Amends s. 465.0235, F.S., relating to automated pharmacy systems used by long-term care facilities, hospices, and state correctional institutions.

Section 2: Provides an effective date of July 1, 2020.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

DOH will experience a recurring increase in workload related to documenting the locations, inspecting, and regulating community pharmacy automated pharmacy systems.¹⁸ 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.¹⁹

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

¹⁸ Department of Health, *2020 Agency Legislative Analysis for HB 59*, on file with the Health Quality Subcommittee.

¹⁹ *Id.*

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

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

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The Board of Pharmacy has sufficient rulemaking authority to implement the bill under s. 465.0235, F.S.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On February 18, 2020, the Health and Human Services Committee adopted a strike-all amendment and reported the bill favorably as a committee substitute. The strike-all amendment:

- Required that an automated pharmacy system be located in an easily accessible indoor environment;
- Required that an automated pharmacy system provide live, real-time patient counseling with a Florida-licensed pharmacist;
- Required a pharmacy to maintain written policies and procedures that address maintenance, security, sanitation, quality control, training, and compliance with state and federal law;
- Authorized, rather than required, the Board of Pharmacy to adopt rules.

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