

CHAPTER 2020-124

Committee Substitute for Committee Substitute for House Bill No. 59

An act relating to automated pharmacy systems; amending s. 465.0235, F.S.; authorizing a community pharmacy to use an automated pharmacy system under certain circumstances; providing that certain medicinal drugs stored in an automated pharmacy system for outpatient dispensing are part of the inventory of the pharmacy providing services through such system; requiring community pharmacies to adopt certain policies and procedures; authorizing, rather than requiring, the Board of Pharmacy to adopt specified rules; deleting an obsolete date; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 465.0235, Florida Statutes, is amended to read:

465.0235 Automated pharmacy systems used by long-term care facilities, hospices, or state correctional institutions, or for outpatient dispensing.—

(1) A pharmacy may provide pharmacy services to a long-term care facility or hospice licensed under chapter 400 or chapter 429 or a state correctional institution operated under chapter 944 through the use of an automated pharmacy system that need not be located at the same location as the pharmacy.

(2) A community pharmacy, as defined in s. 465.003 and licensed in this state, may provide pharmacy services for outpatient dispensing through the use of an automated pharmacy system that need not be located at the same location as the community pharmacy if:

(a) The automated pharmacy system is under the supervision and control of the community pharmacy.

(b) The automated pharmacy system is housed in an indoor environment area and in a location to increase patients' access to their prescriptions, including, but not limited to, medical facilities or places of business where essential goods and commodities are sold or large employer workplaces or locations where access to a community pharmacy is limited.

(c) The community pharmacy providing services through the automated pharmacy system notifies the board of the location of the automated pharmacy system and any changes in such location.

(d) The automated pharmacy system has a mechanism that provides live, real-time patient counseling by a pharmacist, as defined in s. 465.003 and licensed in this state, before the dispensing of any medicinal drug.

(e) The automated pharmacy system does not contain or dispense any controlled substance listed in s. 893.03 or 21 U.S.C. s. 812.

(f) The community pharmacy maintains a record of the medicinal drugs dispensed, including the identity of the pharmacist responsible for verifying the accuracy of the dosage and directions and providing patient counseling.

(g) The automated pharmacy system ensures the confidentiality of personal health information.

(h) The community pharmacy maintains written policies and procedures to ensure the proper, safe, and secure functioning of the automated pharmacy system. The community pharmacy shall annually review the policies and procedures and maintain a record of such policies and procedures for a minimum of 4 years. The annual review must be documented in the community pharmacy's records and must be made available to the board upon request. The policies and procedures must, at a minimum, address all of the following:

1. Maintaining the automated pharmacy system and any accompanying electronic verification process in good working order.

2. Ensuring the integrity of the automated pharmacy system's drug identifier database and its ability to identify the person responsible for making database entries.

3. Ensuring the accurate filling, stocking, restocking, and verification of the automated pharmacy system.

4. Ensuring the sanitary operation of the automated pharmacy system and the prevention of cross-contamination of cells, cartridges, containers, cassettes, or packages.

5. Testing the accuracy of the automated pharmacy system and any accompanying electronic verification process. The automated pharmacy system and accompanying electronic verification process must, at a minimum, be tested before the first use of the system, upon restarting the system, and after a modification of the system or electronic verification process which alters the filling, stocking, or restocking of the system or the electronic verification process.

6. Training of persons authorized to access, stock, restock, or use the system.

7. Conducting routine and preventative maintenance of the automated pharmacy system, including calibration of the system, if applicable.

8. Removing expired, adulterated, misbranded, or recalled medicinal drugs from the automated pharmacy system.

9. Preventing unauthorized persons from accessing the automated pharmacy system, including assigning, discontinuing, or modifying security access.

10. Identifying and recording persons responsible for filling, stocking, and restocking the automated pharmacy system.

11. Ensuring compliance with state and federal law, including, but not limited to, all applicable labeling, storage, and security requirements.

12. Maintaining an ongoing quality assurance program that monitors and records performance of the automated pharmacy system and any accompanying electronic verification process to ensure proper and accurate functioning, including tracking and documenting system errors. A community pharmacy must maintain such records for a minimum of 4 years and must make such records available to the board upon request.

~~(3)~~(2) Medicinal drugs stored in bulk or unit of use in an automated pharmacy system servicing a long-term care facility, hospice, or correctional institution, or for outpatient dispensing, are part of the inventory of the pharmacy providing pharmacy services to that facility, hospice, or institution, or for outpatient dispensing, and medicinal drugs delivered by the automated pharmacy system are considered to have been dispensed by that pharmacy.

~~(4)~~(3) The operation of an automated pharmacy system must be under the supervision of a ~~Florida-licensed~~ pharmacist licensed in this state. To qualify as a supervisor for an automated pharmacy system, the pharmacist need not be physically present at the site of the automated pharmacy system and may supervise the system electronically. The ~~Florida-licensed~~ pharmacist shall be required to develop and implement policies and procedures designed to verify that the medicinal drugs delivered by the automated pharmacy dispensing system are accurate and valid and that the machine is properly restocked.

~~(5)~~(4) The Legislature does not intend for this section to limit the current practice of pharmacy in this state. This section is intended to allow automated pharmacy systems to enhance the ability of a pharmacist to provide pharmacy services in locations that do not employ a full-time pharmacist. This section does not limit or replace the use of a consultant pharmacist.

~~(6)~~(5) The board may ~~shall~~ adopt rules governing the use of an automated pharmacy systems. If adopted, such rules system by January 1, 2005, which must include all of the following specify:

- (a) Recordkeeping requirements.;
 - (b) Security requirements.;
- and

(c) Labeling requirements that permit the use of unit-dose medications if the facility, hospice, or institution maintains medication-administration records that include directions for use of the medication and the automated pharmacy system identifies:

1. The dispensing pharmacy;[;]
2. The prescription number;[;]
3. The name of the patient;[;]~~and~~
4. The name of the prescribing practitioner.

Section 2. This act shall take effect July 1, 2020.

Approved by the Governor June 29, 2020.

Filed in Office Secretary of State June 29, 2020.