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

(a) Recordkeeping requirements.
(b) Security requirements.
(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.
4. The name of the prescribing practitioner.

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