

ENROLLED

CS/CS/HB 59, Engrossed 1

2020 Legislature

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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

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26 | need not be located at the same location as the pharmacy.

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

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

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

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

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

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

50 | (f) The community pharmacy maintains a record of the

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51 medicinal drugs dispensed, including the identity of the
52 pharmacist responsible for verifying the accuracy of the dosage
53 and directions and providing patient counseling.

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

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

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

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

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

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

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

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

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

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

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

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

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

99 12. Maintaining an ongoing quality assurance program that
 100 monitors and records performance of the automated pharmacy

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101 system and any accompanying electronic verification process to
 102 ensure proper and accurate functioning, including tracking and
 103 documenting system errors. A community pharmacy must maintain
 104 such records for a minimum of 4 years and must make such records
 105 available to the board upon request.

106 (3)-(2) Medicinal drugs stored in bulk or unit of use in an
 107 automated pharmacy system servicing a long-term care facility,
 108 hospice, or correctional institution, or for outpatient
 109 dispensing, are part of the inventory of the pharmacy providing
 110 pharmacy services to that facility, hospice, or institution, or
 111 for outpatient dispensing, and medicinal drugs delivered by the
 112 automated pharmacy system are considered to have been dispensed
 113 by that pharmacy.

114 (4)-(3) The operation of an automated pharmacy system must
 115 be under the supervision of a ~~Florida-licensed~~ pharmacist
 116 licensed in this state. To qualify as a supervisor for an
 117 automated pharmacy system, the pharmacist need not be physically
 118 present at the site of the automated pharmacy system and may
 119 supervise the system electronically. The ~~Florida-licensed~~
 120 pharmacist shall be required to develop and implement policies
 121 and procedures designed to verify that the medicinal drugs
 122 delivered by the automated pharmacy ~~dispensing~~ system are
 123 accurate and valid and that the machine is properly restocked.

124 (5)-(4) The Legislature does not intend for this section to
 125 limit the current practice of pharmacy in this state. This

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126 section is intended to allow automated pharmacy systems to
 127 enhance the ability of a pharmacist to provide pharmacy services
 128 in locations that do not employ a full-time pharmacist. This
 129 section does not limit or replace the use of a consultant
 130 pharmacist.

131 (6)~~(5)~~ The board may~~shall~~ adopt rules governing the use
 132 of ~~an~~ automated pharmacy systems. If adopted, such rules ~~system~~
 133 ~~by January 1, 2005, which~~ must include all of the following
 134 ~~specify:~~

- 135 (a) Recordkeeping requirements.~~.~~
- 136 (b) Security requirements.~~.~~~~and~~
- 137 (c) Labeling requirements that permit the use of unit-dose
 138 medications if the facility, hospice, or institution maintains
 139 medication-administration records that include directions for
 140 use of the medication and the automated pharmacy system
 141 identifies:

- 142 1. The dispensing pharmacy.~~.~~
- 143 2. The prescription number.~~.~~
- 144 3. The name of the patient.~~.~~~~and~~
- 145 4. The name of the prescribing practitioner.

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