

By the Committees on Rules; and Health Policy; and Senator
Hutson

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1 A bill to be entitled
2 An act relating to automated pharmacy systems;
3 amending s. 465.0235, F.S.; authorizing a community
4 pharmacy to use an automated pharmacy system under
5 certain circumstances; requiring such community
6 pharmacies to adopt, annually review, and maintain a
7 record of, for a specified time period, certain
8 policies and procedures; providing that certain
9 medicinal drugs stored in an automated pharmacy system
10 for outpatient dispensing are part of the inventory of
11 the pharmacy providing services through such system;
12 authorizing, rather than requiring, the Board of
13 Pharmacy to adopt specified rules; deleting an
14 obsolete date; providing an effective date.

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

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

20 465.0235 Automated pharmacy systems used by long-term care
21 facilities, hospices, or state correctional institutions or for
22 outpatient dispensing.-

23 (1) A pharmacy may provide pharmacy services to a long-term
24 care facility or hospice licensed under chapter 400 or chapter
25 429 or a state correctional institution operated under chapter
26 944 through the use of an automated pharmacy system that need
27 not be located at the same location as the pharmacy.

28 (2) A community pharmacy, as defined in s. 465.003(11),
29 which is licensed in this state may provide pharmacy services

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30 for outpatient dispensing through the use of an automated
31 pharmacy system that need not be located at the same location as
32 the community pharmacy if all of the following criteria are met:

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

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

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

45 (d) The automated pharmacy system has a mechanism that
46 provides live, real-time patient counseling by a pharmacist, as
47 defined in s. 465.003(10) and who is licensed in this state,
48 before the dispensing of any medicinal drug.

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

52 (f) The community pharmacy maintains a record of the
53 medicinal drugs dispensed which includes the identity of the
54 pharmacist responsible for verifying the accuracy of the dosage
55 and directions and providing patient counseling.

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

58 (h) The community pharmacy maintains written policies and

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

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

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, and
72 verification of the automated pharmacy system.

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

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

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

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

87 8. Removing expired, adulterated, misbranded, or recalled

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88 drugs from the automated pharmacy system.

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

92 10. Identifying and recording persons responsible for
93 stocking and filling the automated pharmacy system.

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

97 12. Maintaining an ongoing quality assurance program that
98 monitors performance of the automated pharmacy system and any
99 accompanying electronic verification process to ensure proper
100 and accurate functioning, including tracking and documenting
101 system errors. A community pharmacy must maintain such
102 documentation for a minimum of 4 years and must produce it to
103 the board upon request.

104 (3)-(2) Medicinal drugs stored in bulk or unit of use in an
105 automated pharmacy system servicing a long-term care facility,
106 hospice, or correctional institution, or for outpatient
107 dispensing, are part of the inventory of the pharmacy providing
108 pharmacy services to that facility, hospice, or institution, or
109 for outpatient dispensing, and medicinal drugs delivered by the
110 automated pharmacy system are considered to have been dispensed
111 by that pharmacy.

112 (4)-(3) The operation of an automated pharmacy system must
113 be under the supervision of a Florida-licensed pharmacist
114 licensed in this state. To qualify as a supervisor for an
115 automated pharmacy system, the pharmacist need not be physically
116 present at the site of the automated pharmacy system and may

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117 supervise the system electronically. The ~~Florida-licensed~~
118 pharmacist shall be required to develop and implement policies
119 and procedures designed to verify that the medicinal drugs
120 delivered by the automated pharmacy ~~dispensing~~ system are
121 accurate and valid and that the machine is properly restocked.

122 (5) ~~(4)~~ The Legislature does not intend for this section to
123 limit the current practice of pharmacy in this state. This
124 section is intended to allow automated pharmacy systems to
125 enhance the ability of a pharmacist to provide pharmacy services
126 in locations that do not employ a full-time pharmacist. This
127 section does not limit or replace the use of a consultant
128 pharmacist.

129 (6) ~~(5)~~ The board may ~~shall~~ adopt rules governing the use of
130 ~~an~~ automated pharmacy systems. If adopted, such rules ~~system by~~
131 January 1, 2005, which must include all of the following
132 specify:

133 (a) Recordkeeping requirements. ~~†~~

134 (b) Security requirements. ~~†~~ ~~and~~

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

140 1. The dispensing pharmacy. ~~†~~

141 2. The prescription number. ~~†~~

142 3. The name of the patient. ~~†~~ ~~and~~

143 4. The name of the prescribing practitioner.

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