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LEGISLATIVE ACTION

| Senate | . | House |
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| Comm: RCS | . | |
| 02/27/2020 | . | |
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The Committee on Rules (Hutson) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause
and insert:

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



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12 429 or a state correctional institution operated under chapter
13 944 through the use of an automated pharmacy system that need
14 not be located at the same location as the pharmacy.

15 (2) A community pharmacy, as defined in s. 465.003(11),
16 which is licensed in this state may provide pharmacy services
17 for outpatient dispensing through the use of an automated
18 pharmacy system that need not be located at the same location as
19 the community pharmacy if:

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

22 (b) The automated pharmacy system is housed in an indoor
23 environment area and in a location that increases patients'
24 access to their prescriptions, including, but not limited to,
25 medical facilities, places of business where essential goods and
26 commodities are sold, rural areas of the state, large employer
27 workplaces, and locations where access to a community pharmacy
28 is limited.

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

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

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

39 (f) The community pharmacy maintains a record of the
40 medicinal drugs dispensed which includes the identity of the



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41 pharmacist responsible for verifying the accuracy of the dosage
42 and directions and providing patient counseling.

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

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

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

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

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

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

63 5. Testing the accuracy of the system and any accompanying
64 electronic verification process. The automated pharmacy system
65 and accompanying electronic verification process must, at a
66 minimum, be tested before the first use of the system, upon
67 restarting the system, and after a modification of the system or
68 electronic verification process which alters the filling or
69 electronic verification process.



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

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

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

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

79 10. Identifying and recording persons responsible for
80 stocking and filling the automated pharmacy system.

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

84 12. Maintaining an ongoing quality assurance program that
85 monitors performance of the automated pharmacy system and any
86 accompanying electronic verification process to ensure proper
87 and accurate functioning, including tracking and documenting
88 system errors. A community pharmacy must maintain such
89 documentation for a minimum of 4 years and must produce it to
90 the board upon request.

91 (3)(2) Medicinal drugs stored in bulk or unit of use in an
92 automated pharmacy system servicing a long-term care facility,
93 hospice, or correctional institution, or for outpatient
94 dispensing, are part of the inventory of the pharmacy providing
95 pharmacy services to that facility, hospice, or institution, or
96 for outpatient dispensing, and medicinal drugs delivered by the
97 automated pharmacy system are considered to have been dispensed
98 by that pharmacy.



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99 (4)~~(3)~~ The operation of an automated pharmacy system must
100 be under the supervision of a ~~Florida-licensed~~ pharmacist
101 licensed in this state. To qualify as a supervisor for an
102 automated pharmacy system, the pharmacist need not be physically
103 present at the site of the automated pharmacy system and may
104 supervise the system electronically. The ~~Florida-licensed~~
105 pharmacist shall be required to develop and implement policies
106 and procedures designed to verify that the medicinal drugs
107 delivered by the automated pharmacy ~~dispensing~~ system are
108 accurate and valid and that the machine is properly restocked.

109 (5)~~(4)~~ The Legislature does not intend for this section to
110 limit the current practice of pharmacy in this state. This
111 section is intended to allow automated pharmacy systems to
112 enhance the ability of a pharmacist to provide pharmacy services
113 in locations that do not employ a full-time pharmacist. This
114 section does not limit or replace the use of a consultant
115 pharmacist.

116 (6)~~(5)~~ The board may ~~shall~~ adopt rules governing the use of
117 ~~an~~ automated pharmacy systems. If adopted, such rules ~~system by~~
118 ~~January 1, 2005, which~~ must include all of the following
119 specify:

- 120 (a) Recordkeeping requirements.~~†~~
121 (b) Security requirements.~~†~~ ~~and~~
122 (c) Labeling requirements that permit the use of unit-dose
123 medications if the facility, hospice, or institution maintains
124 medication-administration records that include directions for
125 use of the medication and the automated pharmacy system
126 identifies all of the following:

- 127 1. The dispensing pharmacy.~~†~~



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- 128 2. The prescription number.~~†~~
129 3. The name of the patient.~~†~~~~and~~
130 4. The name of the prescribing practitioner.
131 Section 2. This act shall take effect July 1, 2020.
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133 ===== T I T L E A M E N D M E N T =====

134 And the title is amended as follows:

135 Delete everything before the enacting clause
136 and insert:

137 A bill to be entitled

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