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LEGISLATIVE ACTION

Senate

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House

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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.