

Amendment No. 1

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	<u>    </u>	(Y/N)
ADOPTED AS AMENDED	<u>    </u>	(Y/N)
ADOPTED W/O OBJECTION	<u>    </u>	(Y/N)
FAILED TO ADOPT	<u>    </u>	(Y/N)
WITHDRAWN	<u>    </u>	(Y/N)
OTHER	<u>    </u>	

1 Committee/Subcommittee hearing bill: Health & Human Services  
 2 Committee

3 Representative Willhite offered the following:

4

5 **Amendment (with title amendment)**

6 Remove everything after the enacting clause and insert:

7 Section 1. Section 465.0235, Florida Statutes, is amended  
 8 to read:

9 465.0235 Automated pharmacy systems used by long-term care  
 10 facilities, hospices, or state correctional institutions, or for  
 11 outpatient dispensing.-

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

945897 - h0059-strike.docx

Published On: 2/17/2020 7:56:59 PM

Amendment No. 1

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

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

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

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

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

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

Amendment No. 1

41 (f) The community pharmacy maintains a record of the  
42 medicinal drugs dispensed, including the identity of the  
43 pharmacist responsible for verifying the accuracy of the dosage  
44 and directions and providing patient counseling.

45 (g) The automated pharmacy system ensures the  
46 confidentiality of personal health information.

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

56 1. Maintaining the automated pharmacy system and any  
57 accompanying electronic verification process in good working  
58 order.

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

62 3. Ensuring the accurate filling, stocking, and  
63 verification of the automated pharmacy system.

64 4. Ensuring sanitary operation of the automated pharmacy  
65 system and prevention of cross-contamination of cells,

945897 - h0059-strike.docx

Published On: 2/17/2020 7:56:59 PM

Amendment No. 1

66 cartridges, containers, cassettes, or packages.

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

74 6. Training persons authorized to access, stock, restock,  
75 or use the system.

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

78 8. Removing expired, adulterated, misbranded, or recalled  
79 drugs from the automated pharmacy system.

80 9. Preventing unauthorized persons from accessing the  
81 automated pharmacy system, including assigning, discontinuing,  
82 or modifying security access.

83 10. Identifying and recording persons responsible for  
84 stocking and filling the automated pharmacy system.

85 11. Ensuring compliance with state and federal law,  
86 including, but not limited to, all applicable labeling, storage,  
87 and security requirements.

88 12. Maintaining an ongoing quality assurance program that  
89 monitors performance of the automated pharmacy system and any  
90 accompanying electronic verification process to ensure proper

945897 - h0059-strike.docx

Published On: 2/17/2020 7:56:59 PM

Amendment No. 1

91 and accurate functioning, including tracking and documenting  
92 system errors. A community pharmacy must maintain such  
93 documentation for a minimum of 4 years and must produce it to  
94 the board upon request.

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

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

113 (5)+(4) The Legislature does not intend for this section to  
114 limit the current practice of pharmacy in this state. This  
115 section is intended to allow automated pharmacy systems to

945897 - h0059-strike.docx

Published On: 2/17/2020 7:56:59 PM

Amendment No. 1

116 enhance the ability of a pharmacist to provide pharmacy services  
117 in locations that do not employ a full-time pharmacist. This  
118 section does not limit or replace the use of a consultant  
119 pharmacist.

120 ~~(6)(5)~~ The board may ~~shall~~ adopt rules governing the use  
121 of ~~an~~ automated pharmacy systems. If adopted, such rules ~~system~~  
122 ~~by January 1, 2005~~, which must include all of the following  
123 specify:

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

- 131 1. The dispensing pharmacy.~~†~~  
132 2. The prescription number.~~†~~  
133 3. The name of the patient.~~†~~ and  
134 4. The name of the prescribing practitioner.

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

136

137

138 **T I T L E A M E N D M E N T**

139 Remove everything before the enacting clause and insert:

Amendment No. 1

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