

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; providing that certain  
6           medicinal drugs stored in an automated pharmacy system  
7           for outpatient dispensing are part of the inventory of  
8           the pharmacy providing services through such system;  
9           requiring community pharmacies to adopt certain  
10          policies and procedures; authorizing, rather than  
11          requiring, the Board of Pharmacy to adopt specified  
12          rules; deleting an obsolete date; providing an  
13          effective date.

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

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

19          465.0235   Automated pharmacy systems used by long-term care  
20          facilities, hospices, or state correctional institutions, or for  
21          outpatient dispensing.-

22          (1)   A pharmacy may provide pharmacy services to a long-  
23          term care facility or hospice licensed under chapter 400 or  
24          chapter 429 or a state correctional institution operated under  
25          chapter 944 through the use of an automated pharmacy system that

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, places of business where essential goods and  
38 | commodities are sold, rural areas of the state, large employer  
39 | workplaces, and locations where access to a community pharmacy  
40 | is limited.

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

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

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

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

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

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

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

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

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

74            4. Ensuring the sanitary operation of the automated  
75 pharmacy system and the prevention of cross-contamination of

76 | cells, cartridges, containers, cassettes, or packages.

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

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

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

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

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

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

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

100 |       12. Maintaining an ongoing quality assurance program that

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

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

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

125 (5)(4) The Legislature does not intend for this section to

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

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

- 136 |           (a) Recordkeeping requirements.~~†~~  
137 |           (b) Security requirements.~~†~~ and  
138 |           (c) Labeling requirements that permit the use of unit-dose  
139 | medications if the facility, hospice, or institution maintains  
140 | medication-administration records that include directions for  
141 | use of the medication and the automated pharmacy system  
142 | identifies:
- 143 |           1. The dispensing pharmacy.~~†~~
  - 144 |           2. The prescription number.~~†~~
  - 145 |           3. The name of the patient.~~†~~ and
  - 146 |           4. The name of the prescribing practitioner.

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