

By the Committee on Health Policy

588-01081-14

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1                   A bill to be entitled  
2       An act relating to nonresident pharmacies; amending s.  
3       465.0156, F.S.; conforming provisions to changes made  
4       by the act; deleting a requirement that the Board of  
5       Pharmacy refer regulatory issues affecting a  
6       nonresident pharmacy to the state where the pharmacy  
7       is located; creating s. 465.0158, F.S.; requiring  
8       registered nonresident pharmacies to obtain a permit  
9       in order to ship, mail, deliver, or dispense  
10      compounded sterile products into this state; requiring  
11      submission of an application and a nonrefundable fee;  
12      specifying requirements; requiring the Department of  
13      Health to inform permittees of any law or rule  
14      changes; authorizing the board to deny, revoke, or  
15      suspend a permit for certain actions; providing dates  
16      by which certain registered and unregistered  
17      nonresident pharmacies must obtain a permit;  
18      authorizing the Board of Pharmacy to adopt rules;  
19      providing for future repeal; amending s. 465.017,  
20      F.S.; authorizing the department to inspect registered  
21      nonresident pharmacies; requiring nonresident  
22      pharmacies to pay for the costs of such inspections;  
23      providing an effective date.

24  
25   Be It Enacted by the Legislature of the State of Florida:

26  
27       Section 1. Subsections (4) and (5) of section 465.0156,  
28       Florida Statutes, are amended to read:  
29       465.0156 Registration of nonresident pharmacies.—

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30 (4) The board may deny, revoke, or suspend registration of,  
31 or fine or reprimand, a nonresident pharmacy for failure to  
32 comply with s. 465.025, s. 465.0158, or ~~with~~ any requirement of  
33 this section in accordance with ~~the provisions of~~ this chapter.

34 (5) In addition to the prohibitions of subsection (4), the  
35 board may deny, revoke, or suspend registration of, or fine or  
36 reprimand, a nonresident pharmacy in accordance with ~~the~~  
37 ~~provisions of~~ this chapter for conduct that ~~which~~ causes or  
38 could cause serious bodily injury or serious psychological  
39 injury to a human or animal in resident of this state ~~if the~~  
40 ~~board has referred the matter to the regulatory or licensing~~  
41 ~~agency in the state in which the pharmacy is located and the~~  
42 ~~regulatory or licensing agency fails to investigate within 180~~  
43 ~~days of the referral.~~

44 Section 2. Section 465.0158, Florida Statutes, is created  
45 to read:

46 465.0158 Nonresident pharmacy compounded sterile products  
47 permit.—A nonresident pharmacy registered under s. 465.0156 must  
48 also hold a compounded sterile products permit issued under this  
49 section in order to ship, mail, deliver, or dispense, in any  
50 manner, a compounded sterile product into this state.

51 (1) Application for a permit shall be submitted on a form  
52 furnished by the board, together with a nonrefundable permit fee  
53 as provided under s. 465.022(14). The board may require such  
54 information as it deems reasonably necessary to carry out the  
55 purposes of this section, including information pertaining to  
56 registration as an outsourcing facility with the Secretary of  
57 the United States Department of Health and Human Services.

58 (2) As a condition of initial permitting and permit

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59 renewal, the owners, officers, and prescription department  
60 manager or pharmacist in charge of the nonresident pharmacy must  
61 attest in writing that they have read and understand the laws  
62 and rules governing sterile compounding in this state and that  
63 any compounded sterile product shipped, mailed, delivered, or  
64 dispensed into this state will meet or exceed this state's  
65 standards for sterile compounding.

66 (a) The department shall notify all compounded sterile  
67 products permittees when state laws or rules affecting the  
68 standards for sterile compounding in this state are adopted or  
69 revised, along with the effective date of the law or rule.

70 (b) If the department fails to notify a permittee of a  
71 change in state laws or rules, or the permittee does not receive  
72 notification of applicable rules, the permittee remains legally  
73 obligated to meet or exceed this state's standards with respect  
74 to any compounded sterile product shipped, mailed, delivered, or  
75 dispensed into this state. The board may provide an exception to  
76 this requirement by rule if the sterile compounding laws and  
77 rules of the state in which the nonresident pharmacy is located  
78 directly conflict with a board rule for sterile compounding in  
79 this state but provide a comparable standard of product safety  
80 and integrity.

81 (3) A nonresident pharmacy may not ship, mail, deliver, or  
82 dispense any compounded sterile product into this state which:

83 (a) Was compounded in violation of the laws and rules of  
84 the state in which the nonresident pharmacy is located; or

85 (b) Does not meet or exceed this state's sterile  
86 compounding standards as provided in subsection (2).

87 (4) To the extent feasible, biennial permit renewal shall

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88 be timed to coincide with nonresident pharmacies' registration  
89 renewal under s. 465.0156.

90 (5) In accordance with this chapter, the board may deny,  
91 revoke, or suspend the permit of, or fine or reprimand, a  
92 nonresident pharmacy for:

93 (a) Failure to comply with the requirements of this  
94 section; or

95 (b) Conduct that causes or could cause serious bodily  
96 injury or serious psychological injury to a human or animal in  
97 this state.

98 (6) A registered nonresident pharmacy that is currently  
99 shipping, mailing, delivering, or dispensing compounded sterile  
100 products into this state may continue to do so if such products  
101 meet or exceed the standards for sterile compounding in this  
102 state and the pharmacy is issued a nonresident pharmacy  
103 compounded sterile products permit on or before January 31,  
104 2015.

105 (7) A nonresident pharmacy seeking registration in this  
106 state under s. 465.0156 on or after July 1, 2014, may not ship,  
107 mail, deliver, or dispense a compounded sterile product into  
108 this state until it has received the sterile compounded products  
109 permit required under this section.

110 (8) The board shall adopt rules necessary to administer  
111 this section.

112 (9) This section is repealed October 1, 2018, unless  
113 reenacted by the Legislature.

114 Section 3. Section 465.017, Florida Statutes, is amended to  
115 read:

116 465.017 Authority to inspect; disposal.-

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117 (1) Duly authorized agents and employees of the department  
118 ~~may shall have the power to~~ inspect in a lawful manner at all  
119 reasonable hours any pharmacy, including a nonresident pharmacy  
120 registered under s. 465.0156, and any hospital, clinic,  
121 wholesale establishment, manufacturer, physician's office, or  
122 any other place in the state in which drugs and medical supplies  
123 are manufactured, packed, packaged, made, stored, sold, offered  
124 for sale, exposed for sale, or kept for sale for the purpose of:

125 (a) Determining if any provision ~~of the provisions~~ of this  
126 chapter or any rule adopted ~~promulgated~~ under its authority is  
127 being violated;

128 (b) Securing samples or specimens of any drug or medical  
129 supply after paying or offering to pay for such sample or  
130 specimen; or

131 (c) Securing such other evidence as may be needed for  
132 prosecution under this chapter.

133 (2) The cost for inspecting a nonresident pharmacy shall be  
134 reimbursed by the pharmacy. The cost to the pharmacy is limited  
135 to the actual costs incurred by the department.

136 (3) ~~(2) (a)~~ Except as permitted by this chapter, and chapters  
137 406, 409, 456, 499, and 893 or upon the written authorization of  
138 the patient, records maintained in a pharmacy relating to the  
139 filling of prescriptions and the dispensing of medicinal drugs  
140 ~~may shall not~~ be furnished only ~~to any person other than~~ to the  
141 patient for whom the drugs were dispensed, or her or his legal  
142 representative, ~~or~~ to the department pursuant to existing law,  
143 or if, ~~in the event that~~ the patient is incapacitated or unable  
144 to request such ~~said~~ records, her or his spouse ~~except upon the~~  
145 ~~written authorization of such patient.~~

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146       (a) Such records may be furnished in any civil or criminal  
147 proceeding, upon the issuance of a subpoena from a court of  
148 competent jurisdiction and proper notice to the patient or her  
149 or his legal representative by the party seeking such records.

150       (b) The board shall adopt rules establishing ~~to establish~~  
151 practice guidelines for pharmacies to dispose of records  
152 maintained in a pharmacy relating to the filling of  
153 prescriptions and the dispensing of medicinal drugs. Such rules  
154 must ~~shall~~ be consistent with the duty to preserve the  
155 confidentiality of such records in accordance with applicable  
156 state and federal law.

157       Section 4. This act shall take effect July 1, 2014.