

FOR CONSIDERATION By the Committee on Health Policy

588-00653A-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          amending s. 465.017, F.S.; authorizing the department  
20          to inspect registered nonresident pharmacies;  
21          requiring nonresident pharmacies to pay for the costs  
22          of such inspections; providing an effective date.

23  
24 Be It Enacted by the Legislature of the State of Florida:

25  
26           Section 1. Subsections (4) and (5) of section 465.0156,  
27 Florida Statutes, are amended to read:

28           465.0156 Registration of nonresident pharmacies.—

29           (4) The board may deny, revoke, or suspend registration of,

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30 or fine or reprimand, a nonresident pharmacy for failure to  
31 comply with s. 465.025, s. 465.0158, or ~~with~~ any requirement of  
32 this section in accordance with ~~the provisions of~~ this chapter.

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

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

45 465.0158 Nonresident pharmacy compounded sterile products  
46 permit.—A nonresident pharmacy registered under s. 465.0156 must  
47 also hold a compounded sterile products permit issued under this  
48 section in order to ship, mail, deliver, or dispense, in any  
49 manner, a compounded sterile product into this state.

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

57 (2) As a condition of initial permitting and permit  
58 renewal, the owners, officers, and prescription department

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

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

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

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

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

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

86 (4) To the extent feasible, biennial permit renewal shall  
87 be timed to coincide with nonresident pharmacies' registration

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88 renewal under s. 465.0156.

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

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

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

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

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

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

111 Section 3. Section 465.017, Florida Statutes, is amended to  
112 read:

113 465.017 Authority to inspect; disposal.—

114 (1) Duly authorized agents and employees of the department  
115 ~~may shall have the power to~~ inspect in a lawful manner at all  
116 reasonable hours any pharmacy, including a nonresident pharmacy

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117 registered under s. 465.0156, and any hospital, clinic,  
118 wholesale establishment, manufacturer, physician's office, or  
119 any other place in the state in which drugs and medical supplies  
120 are manufactured, packed, packaged, made, stored, sold, offered  
121 for sale, exposed for sale, or kept for sale for the purpose of:

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

125 (b) Securing samples or specimens of any drug or medical  
126 supply after paying or offering to pay for such sample or  
127 specimen; or

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

130 (2) The cost for inspecting a nonresident pharmacy shall be  
131 reimbursed by the pharmacy. The cost to the pharmacy is limited  
132 to the actual costs incurred by the department.

133 (3) ~~(2)(a)~~ Except as permitted by this chapter, and chapters  
134 406, 409, 456, 499, and 893 or upon the written authorization of  
135 the patient, records maintained in a pharmacy relating to the  
136 filling of prescriptions and the dispensing of medicinal drugs  
137 may ~~shall not~~ be furnished only ~~to any person other than~~ to the  
138 patient for whom the drugs were dispensed, or her or his legal  
139 representative, ~~or~~ to the department pursuant to existing law,  
140 or if, ~~in the event that~~ the patient is incapacitated or unable  
141 to request such ~~said~~ records, her or his spouse ~~except upon the~~  
142 ~~written authorization of such patient.~~

143 (a) Such records may be furnished in any civil or criminal  
144 proceeding, upon the issuance of a subpoena from a court of  
145 competent jurisdiction and proper notice to the patient or her

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146 or his legal representative by the party seeking such records.

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

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