

1 Section 1. Section 465.0156, Florida Statutes, is  
2 amended to read:

3 465.0156 Registration of Non-Resident Pharmacies.

4 (1) Any pharmacy which is located outside this state  
5 and which ships, mails, or delivers, in any manner, a  
6 dispensed medicinal drug into this state shall be considered  
7 a non-resident pharmacy, shall be registered with the board,  
8 shall provide pharmacy services at a high level of  
9 protection and competence, and shall disclose to the board  
10 the following specific information:

11 (a) That it maintains at all times a valid, unexpired  
12 license, permit, or registration to operate the pharmacy in  
13 compliance with the laws of the state in which the  
14 dispensing facility is located and from which the medicinal  
15 drugs shall be dispensed;

16 (b) The location, names, and titles of all principal  
17 corporate officers and the pharmacist who serves as the  
18 prescription department manager for dispensing medicinal  
19 drugs to residents of this state. This disclosure shall be  
20 made within 30 days after any change of location, corporate  
21 officer, or pharmacist serving as the prescription  
22 department manager for dispensing medicinal drugs to  
23 residents of this state;

24 (c) That it complies with all lawful directions and  
25 requests for information from the regulatory or licensing  
26 agency of all states in which it is licensed as well as with  
27 all requests for information made by the board pursuant to  
28 this section. It shall respond directly to all

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29 | communications from the board concerning emergency  
30 | circumstances arising from errors in the dispensing of  
31 | medicinal drugs to the residents of this state;

32 |         (d) That it maintains its records of medicinal drugs  
33 | dispensed to patients in this state so that the records are  
34 | readily retrievable from the other business records of the  
35 | pharmacy and from the records of other medicinal drugs  
36 | dispensed; and

37 |         (e) That during its regular hours of operation but not  
38 | less than 6 days per week, for a minimum of 40 hours per  
39 | week, a toll-free telephone service shall be provided to  
40 | facilitate communication between patients in this state and  
41 | a pharmacist at the pharmacy who has access to the patient's  
42 | records. This toll-free number must be disclosed on the  
43 | label affixed to each container of dispensed medicinal  
44 | drugs.

45 |         (2) Applications for non-resident pharmacy registration  
46 | under this section shall be made on a form furnished by the  
47 | board. The board may require such information as the board  
48 | deems reasonably necessary to carry out the purposes of this  
49 | section. The board may grant an exemption from the  
50 | registration requirements of this section to any non-  
51 | resident pharmacy which confines its dispensing activity to  
52 | isolated transactions. The board may define by rule the  
53 | term isolated transactions.

54 |         (3) The registration fee and the biennial renewal fee  
55 | shall be the fee specified in s.465.022.

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56 (4) The board may deny, revoke, or suspend registration  
57 of, or fine or reprimand, a non-resident pharmacy for  
58 failure to comply with s.465.025 or with any requirement of  
59 this section in accordance with the provisions of this  
60 chapter.

61 (5) In addition to the prohibitions of subsection (4)  
62 the board may deny, revoke, or suspend registration of, or  
63 fine or reprimand, a non-resident pharmacy in accordance  
64 with the provisions of this chapter for conduct which causes  
65 or could cause serious bodily injury or serious  
66 psychological injury to a human or animal in ~~resident of~~  
67 ~~this state if the board has referred the matter to the~~  
68 ~~regulatory or licensing agency in the state in which the~~  
69 ~~pharmacy is located and the regulatory or licensing agency~~  
70 ~~fails to investigate within 180 days of the referral.~~

71 (6) It is unlawful for any non-resident pharmacy which  
72 is not registered pursuant to this section to advertise its  
73 services in this state, or for any person who is a resident  
74 of this state to advertise the pharmacy services of a non-  
75 resident pharmacy which has not registered with the board,  
76 with the knowledge that the advertisement will or is likely  
77 to induce members of the public in this state to use the  
78 pharmacy to fill prescriptions.

79 (7) This section does not apply to Internet pharmacies  
80 required to be permitted under s. 465.0197.

81 (8) Notwithstanding s. 465.003(10), for purposes of  
82 this section, the registered pharmacy and the pharmacist  
83 designated by the registered pharmacy as the prescription

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84 department manager or the equivalent must be licensed in the  
85 state of location in order to dispense into this state.

86 Section 2. Section 465.0158, Florida Statutes, is  
87 created to read:

88 465.0158 Non-Resident Sterile Compounding Permit.

89 (1) Any pharmacy which is located outside this state  
90 and which ships, mails, delivers or dispenses, in any  
91 manner, a sterile compounded product into this state shall  
92 be considered a non-resident sterile compounding pharmacy,  
93 shall be registered with the board, shall provide pharmacy  
94 services at a high level of protection and competence and  
95 shall disclose to the board the criteria outlined in this  
96 section:

97 (a) That it maintains at all times a valid, unexpired  
98 license in Florida as a non-resident pharmacy as defined in  
99 Section 465.0156, Florida Statutes.

100 (b) That it maintains at all times a valid, unexpired  
101 and unencumbered license, permit or registration in the  
102 state in which the non-resident pharmacy is located and from  
103 which the sterile compounded products shall be dispensed.

104 (c) That the owners, officers and the prescription  
105 department manager or pharmacist in charge of the non-  
106 resident pharmacy attests at initial licensure that they  
107 have read and understand the laws and rules governing  
108 sterile compounding in Florida.

109 (d) That the owners, officers and the prescription  
110 department manager or pharmacist in charge of the non-  
111 resident pharmacy attest at initial licensure and at each

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112 subsequent licensure renewal that the non-resident pharmacy  
113 is in compliance with all the sterile compounding laws and  
114 rules of the state in which it is physically located.

115 (e) That the owners, officers and the prescription  
116 department manager or pharmacist in charge of the non-  
117 resident pharmacy attest to understanding that they may not  
118 engage in the practice of sterile compounding that exceeds  
119 the laws and rules of the state in which they are physically  
120 located

121 (2) A non-resident pharmacy shall not ship, mail,  
122 deliver, or dispense any sterile compounded product into  
123 Florida that was compounded in violation of the laws and  
124 rules of the state in which the non-resident pharmacy is  
125 physically located.

126 (3) All Florida licensed non-resident pharmacies that  
127 are currently engaging in sterile compounding may continue  
128 to do so as long as they are issued a non-resident sterile  
129 compounding permit by the DOH on or before January 31, 2015.

130 (4) Any non-resident pharmacy seeking licensure in  
131 Florida on or after July 1, 2014 shall not engage in  
132 shipping, mailing, delivering, or dispensing any sterile  
133 compounded product into Florida until it has received a non-  
134 resident sterile compounding permit.

135 (5) The board shall adopt rules which are necessary to  
136 carry out the provisions of this section.

137 Section 3. Section 465.017, Florida Statutes, is  
138 amended to read:

139 465.017 Authority to inspect; Disposal.

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140 (1) Duly authorized agents and employees of the  
141 department shall have the power to inspect in a lawful  
142 manner at all reasonable hours any Florida permitted  
143 pharmacy in and out of state; and any hospital, clinic,  
144 wholesale establishment, manufacturer, physician's offices,  
145 or any other place in the state in which drugs and medical  
146 supplies are manufactured, packed, packaged, made, stored,  
147 sold, offered for sale, exposed for sale, or kept for sale  
148 for the purpose of:

149 (a) Determining if any of the provision of this chapter  
150 or any rule promulgated under its authority is being  
151 violated;

152 (b) Securing samples or specimens of any drug or  
153 medical supply after paying or offering to pay for such  
154 sample or specimen; or

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

157 (2) The cost incurred by the department for inspecting  
158 non-resident pharmacies shall be incurred by the pharmacy.  
159 The cost to the pharmacy is limited to the actual costs  
160 incurred by the department.

161 (3) (a) Except as permitted by this chapter, and  
162 chapters 406, 409, 456, 499, and 893, records maintained in  
163 a pharmacy relating to the filling of prescriptions and the  
164 dispensing of medicinal drugs shall not be furnished to any  
165 person other than to the patient for whom the drugs were  
166 dispensed, or her or his legal representative, or to the  
167 department pursuant to existing law, or, in the event that

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168 | the patient is incapacitated or unable to request said  
169 | records, her or his spouse except upon the written  
170 | authorization of such patient. Such records may be  
171 | furnished in any civil or criminal proceeding, upon the  
172 | issuance of a subpoena from a court of competent  
173 | jurisdiction and proper notice to the patient or her or his  
174 | legal representative by the party seeking such records.

175 |       (b) The board shall adopt rules to establish practice  
176 | guidelines for pharmacies to dispose of records maintained  
177 | in a pharmacy relating to the filling of prescriptions and  
178 | the dispensing of medicinal drugs. Such rules shall be  
179 | consistent with the duty to preserve the confidentiality of  
180 | such records in accordance with applicable state and federal  
181 | law.

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