

By Senator Latvala

16-00907-12

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1 A bill to be entitled

2 An act relating to prescription drug wholesale  
3 regulations; amending s. 499.01, F.S.; requiring the  
4 Department of Health to issue a permit by endorsement  
5 to an out-of-state prescription drug wholesale  
6 distributor that meets certain requirements;  
7 authorizing out-of-state wholesale distributors  
8 holding a valid permit to continue to operate under  
9 that permit until its expiration; providing an  
10 effective date.

11  
12 Be It Enacted by the Legislature of the State of Florida:

13  
14 Section 1. Paragraph (e) of subsection (2) of section  
15 499.01, Florida Statutes, is amended to read:

16 499.01 Permits.—

17 (2) The following permits are established:

18 (e) *Out-of-state prescription drug wholesale distributor*  
19 *permit.*—An out-of-state prescription drug wholesale distributor  
20 is a wholesale distributor located outside this state which  
21 engages in the wholesale distribution of prescription drugs into  
22 this state and which must be permitted by the department and  
23 comply with all the provisions required of a wholesale  
24 distributor under this part. An out-of-state prescription drug  
25 wholesale distributor that applies to the department for a new  
26 permit or the renewal of a permit must submit a bond of  
27 \$100,000, or other equivalent means of security acceptable to  
28 the department, such as an irrevocable letter of credit or a  
29 deposit in a trust account or financial institution, payable to

16-00907-12

20121006\_\_

30 the Florida Drug, Device, and Cosmetic Trust Fund. The purpose  
31 of the bond is to secure payment of any administrative penalties  
32 imposed by the department and any fees and costs incurred by the  
33 department regarding that permit which are authorized under  
34 state law and which the permittee fails to pay 30 days after the  
35 fine or costs become final. The department may make a claim  
36 against such bond or security until 1 year after the permittee's  
37 license ceases to be valid or until 60 days after any  
38 administrative or legal proceeding authorized in this part which  
39 involves the permittee is concluded, including any appeal,  
40 whichever occurs later.

41 1. The out-of-state prescription drug wholesale distributor  
42 must maintain at all times a license or permit to engage in the  
43 wholesale distribution of prescription drugs in compliance with  
44 laws of the state in which it is a resident. The department  
45 shall issue an out-of-state permit by endorsement to an  
46 applicant who, upon applying to the department and remitting a  
47 filing fee, set by the board, demonstrates to the board that the  
48 applicant satisfies the requirements of this chapter and holds a  
49 valid drug wholesale distributor license or permit from another  
50 state. An out-of state prescription drug wholesale distributor  
51 that holds a valid permit under this chapter on the effective  
52 date of this act may continue to operate under that permit until  
53 its expiration, after which the distributor may apply for a  
54 permit by endorsement as provided in this subparagraph.

55 2. An out-of-state prescription drug wholesale distributor  
56 permit is not required for an intracompany sale or transfer of a  
57 prescription drug from an out-of-state establishment that is  
58 duly licensed as a prescription drug wholesale distributor, in

16-00907-12

20121006\_\_

59 its state of residence, to a licensed prescription drug  
60 wholesale distributor in this state, if both wholesale  
61 distributors conduct wholesale distributions of prescription  
62 drugs under the same business name. The recordkeeping  
63 requirements of ss. 499.0121(6) and 499.01212 must be followed  
64 for this transaction.

65 Section 2. This act shall take effect July 1, 2012.