

By Senator Latvala

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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.

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

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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

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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

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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.