

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

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

56 2. An out-of-state prescription drug wholesale distributor

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57 | permit is not required for an intracompany sale or transfer of a
58 | prescription drug from an out-of-state establishment that is
59 | duly licensed as a prescription drug wholesale distributor, in
60 | its state of residence, to a licensed prescription drug
61 | wholesale distributor in this state, if both wholesale
62 | distributors conduct wholesale distributions of prescription
63 | drugs under the same business name. The recordkeeping
64 | requirements of ss. 499.0121(6) and 499.01212 must be followed
65 | for this transaction.

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