By the Committee on Health Care; and Senator Peaden

587-2189-06

A bill to be entitled

An act relating to drug distribution; amending s. 499.0121, F.S.; removing an expiration date on a provision relating to prescription drug recordkeeping; requiring that certain information be provided by certain prescription drug wholesalers to drug recipients; requiring drug manufacturers to file a list of authorized distributors with the department; requiring the department to publish certain information; providing an effective date.

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

Section 1. Paragraphs (d) and (f) of subsection (6) of section 499.0121, Florida Statutes, are amended to read:

499.0121 Storage and handling of prescription drugs; recordkeeping.--The department shall adopt rules to implement this section as necessary to protect the public health, safety, and welfare. Such rules shall include, but not be limited to, requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.

(6) RECORDKEEPING.--The department shall adopt rules that require keeping such records of prescription drugs as are necessary for the protection of the public health.

(d)1. Each person who is engaged in the wholesale distribution of a prescription drug, and who is not an authorized distributor of record for the drug manufacturer's products, must provide to each wholesale distributor of such drug, before the sale is made to such wholesale distributor, a

written statement under oath identifying each previous sale of the drug back to the last authorized distributor of record, the lot number of the drug, and the sales invoice number of the invoice evidencing the sale of the drug. The written statement must accompany the drug to the next wholesale distributor. The department shall adopt rules relating to the requirements of this written statement. This paragraph does not apply to a manufacturer unless the manufacturer is performing the manufacturing operation of repackaging prescription drugs.

2. Each wholesale distributor of prescription drugs must maintain separate and distinct from other required records all statements that are required under subparagraph 1. and paragraph (e).

3. Each manufacturer of a prescription drug sold in this state must maintain at its corporate offices a current list of authorized distributors and must make such list available to the department upon request.

4. Each manufacturer shall file a written list of all of the manufacturer's authorized distributors of record with the department. A manufacturer shall notify the department not later than 10 days after any change to the list. The department shall publish a list of all authorized distributors of record on its website.

5. For the purposes of this subsection, the term "authorized distributors of record" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's products. Effective March 1, 2004, an ongoing relationship is deemed to exist when a wholesale distributor, including any

affiliated group, as defined in s. 1504 of the Internal Revenue Code, of which the wholesale distributor is a member:

a. Is listed on the manufacturer's current list of authorized distributors of record.

b. Annually purchases not less than 90 percent of all of its purchases of a manufacturer's prescription drug products, based on dollar volume, directly from that manufacturer and has total annual prescription drug sales of $100 million or more.

c. Has reported to the department pursuant to s. 499.012(3)(g)2. that the wholesale distributor has total annual prescription drug sales of $100 million or more, and has a verifiable account number issued by the manufacturer authorizing the wholesale distributor to purchase the manufacturer's drug products directly from that manufacturer and that wholesale distributor makes not fewer than 12 purchases of that manufacturer's drug products directly from the manufacturer using said verifiable account number in 12 months. The provisions of this sub-subparagraph apply with respect to a manufacturer that fails to file a copy of the manufacturer's list of authorized distributors of record with the department by July 1, 2003; that files a list of authorized distributors of record which contains fewer than 10 wholesale distributors permitted in this state, excluding the wholesale distributors described in sub-subparagraph b.; or that, as a result of changes to the list of authorized distributors of record filed with the department, has fewer than 10 wholesale distributors permitted in this state as authorized distributors of record, excluding the wholesale distributors described in sub-subparagraph b.

A wholesale distributor that satisfies the requirements of sub-subparagraph b. or sub-subparagraph c. shall submit to the department documentation substantiating its qualification pursuant to sub-subparagraph b. or sub-subparagraph c. The department shall add those wholesale distributors that the department has determined have met the requirements of sub-subparagraph b. or sub-subparagraph c. to the list of authorized distributors of record on the department's website.

~~6. This paragraph expires July 1, 2006.~~

(f)1. Effective July 1, 2006, each person who is engaged in the wholesale distribution of a prescription drug and who is not the manufacturer of that drug must, before each wholesale distribution of such drug, provide to the person who receives the drug either:

a. A pedigree paper as defined in s. 499.003(31); or

b. Until December 31, 2008, if the prescription drug was purchased directly from the manufacturer, a statement in written or electronic form stating that the wholesale distributor or member of its affiliated group has purchased the specific unit of the prescription drug directly from the manufacturer, as defined in s. 499.012(1)(e), and is an authorized distributor of record as specified in subparagraph (d)5. In accordance with subparagraph (d)5., each manufacturer shall file a written list of all of the manufacturer's authorized distributors of record with the department by July 1, 2006. A manufacturer shall notify the department not later than 10 days after any change to the list. The department shall publish a list of all authorized distributors of record on its website.

2. A repackager must comply with this paragraph.

3. The pedigree paper requirements in this paragraph do not apply to compressed medical gases or veterinary legend drugs.

4. Each wholesale distributor of prescription drugs must maintain separate and distinct from other required records all statements that are required under subparagraph 1.

5. In order to verify compliance with subparagraph (d)1., each manufacturer of a prescription drug sold in this state must make available upon request distribution documentation related to its sales of prescription drugs, regardless of whether the prescription drug was sold directly by the manufacturer to a person in Florida.

Section 2. This act shall take effect on July 1, 2006.

STATEMENT OF SUBSTANTIAL CHANGES CONTAINED IN COMMITTEE SUBSTITUTE FOR Senate Bill 926

The bill revises requirements for certain prescription drug wholesalers to pass a pedigree paper that traces the distribution history of a prescription drug from the manufacturer to the end-user.