By Senator Peaden

2-593-05

A bill to be entitled

An act relating to the sale and distribution of prescription drugs; amending s. 499.003, F.S.; redefining the term "pedigree paper"; amending s. 499.0121, F.S.; deleting the expiration dates of provisions governing recordkeeping and reporting which apply to wholesale distributors of prescription drugs, drug repackagers, and chain drug entities that are part of an affiliated group; providing an effective date.

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

Section 1. Subsection (31) of section 499.003, Florida Statutes, is amended to read:

499.003 Definitions of terms used in ss. 499.001-499.081.--As used in ss. 499.001-499.081, the term:

(31) "Pedigree paper" means:

(a) A document required pursuant to s. 499.0121(6)(d) or (e); or

(b) Effective July 1, 2006, a document or electronic ~~in a~~ form approved by the Department of Health and containing information that records each distribution of any given legend drug, from sale by a pharmaceutical manufacturer, through acquisition and sale by any wholesaler or repackager~~, until final sale to a pharmacy or other person administering or dispensing the drug~~. The information required to be included on a legend drug's pedigree paper must at least detail the amount of the legend drug, its dosage form and strength, its lot numbers, the name and address of each owner of the legend drug and his or her signature, its shipping information,

including the name and address of each person certifying delivery or receipt of the legend drug, and a certification that the recipient has authenticated the pedigree papers. It must also include the name, address, telephone number and, if available, e-mail contact information of each wholesaler involved in the chain of the legend drug's custody. The department shall adopt rules and a form relating to the requirements of this paragraph no later than 90 days after the effective date of this act.

Section 2. Paragraphs (d), (e), and (h) 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.~~

(e)1. Notwithstanding paragraph (d), each person who is engaged in the wholesale distribution of a specified drug must provide to each wholesale distributor of such specified drug:

a. Upon any sale, a written statement that:

(I) If the establishment is not a member of an affiliated group: "This establishment purchased the specific unit of the specified drug directly from the manufacturer"; or

(II) If the establishment is a member of an affiliated group: "This establishment or a member of my affiliated group purchased the specific unit of the specified drug directly from the manufacturer"; or

b. Before the wholesale distribution, a written statement, under oath, that identifies each previous sale of the specific unit of the specified drug back to the manufacturer of the specified drug, the lot number of the specific unit of the specified prescription drug, and the sales invoice number of the invoice evidencing each previous sale of the specific unit of the specified drug. The written statement identifying all sales of such specific unit of the specified drug must accompany the specific unit of the specified drug for each subsequent wholesale distribution of the specific unit of the specified drug to a wholesale distributor.

The department shall adopt rules to administer the requirements of these written statements.

2. As used in this paragraph, the term "specified drug" means a specific prescription drug on the list of drugs adopted by the department by rule.

3.a. A drug may be placed on the list of specified drugs if the department has seized or issued a stop sale notice on the prescription drug because of the adulteration, counterfeiting, or diversion of the prescription drug from the legal channels of distribution for prescription drugs, or the United States Food and Drug Administration, a manufacturer, a wholesale distributor, a law enforcement agency, or a government agency responsible for regulating the sale or distribution of prescription drugs in another state has notified the department in writing or through a website operated by one of said entities that the prescription drug has been adulterated, counterfeited, or diverted from the legal channels of distribution for prescription drugs; and the prescription drug satisfies one of the following criteria:

(I) The prescription drug is included among the top 150 prescription drugs for which the state has incurred the highest amount of Medicaid claims in the most recently ended state fiscal year;

(II) The prescription drug is available for normal prescription use in dosages or strengths that have a wholesale cost of $200 or more;

(III) The prescription drug is used extensively for patients with human immunodeficiency virus, acquired immune deficiency syndrome, cancer, or other serious, life-threatening conditions, where drug nonresponsiveness would not be considered to be medically unusual;

(IV) The prescription drug is an injectable drug;

(V) The prescription drug is subject to a special, limited distribution process and is not generally sold to wholesale distributors by the manufacturer of the prescription drug;

(VI) The department has found not less than five instances where statements required pursuant to paragraph (d) for the prescription drug were not passed on other than because of unintentional oversight, or have been passed on by or to a wholesale distributor and such statements were fraudulent; or

(VII) A shipment of a prescription drug has been reported to a law enforcement agency as having been stolen or as missing.

b. A prescription drug may be placed on the list of specified drugs if the prescription drug satisfies any three of the seven criteria set forth in sub-sub-subparagraphs (I)-(VII). However, a prescription drug may not be included on the list of specified drugs if the prescription drug is unlikely to be counterfeited or diverted from the legal channels of distribution for prescription drugs.

c. Before the department begins the rulemaking process to place a drug on the list of specified drugs, except when the department files a rule under the procedure specified in sub-subparagraph e., the Drug Wholesaler Advisory Council created in s. 499.01211 shall consider whether a prescription drug should be included on or added to the list of specified drugs using the criteria enumerated in sub-subparagraph a. or sub-subparagraph b. and provide a written recommendation adopted by majority vote to the secretary of the department concerning each such drug. This paragraph does not apply to

any list of prescription drugs on which the department has begun rulemaking prior to this paragraph becoming law.

d. When a prescription drug is added to the list of specified drugs, the requirements of this paragraph shall be effective as to the prescription drug beginning 60 days after the effective date of the rule adding the prescription drug to the list, except when the department files a rule under the procedure specified in sub-subparagraph e.

e.(I) Notwithstanding chapter 120, if the Attorney General or Statewide Prosecutor certifies to the secretary of the department that a prescription drug should be added to the list of specified drugs by emergency rule, the department may proceed to add such drug to the list of specified drugs and the emergency rule shall be effective for a period of 1 year from the date on which the emergency rule is filed, if the department begins the rulemaking process to adopt a permanent rule to place the drug on the list of specified drugs not later than 90 days after the date on which the emergency rule was filed. An emergency rule adding a drug to the list of specified drugs may not be renewed.

(II) A prescription drug may be placed on the list of specified drugs through the procedure provided in this sub-subparagraph when:

(A) The prescription drug satisfies any two of the criteria specified in sub-subparagraph a. or sub-subparagraph b.; or

(B) The prescription drug satisfies any one of the criteria specified in sub-subparagraph a. or sub-subparagraph b. if the prescription drug has not yet become available for wholesale distribution or has been available for wholesale distribution for not more than 60 days.

(III) Notwithstanding chapter 120, any emergency rule that places a prescription drug on the list of specified drugs may be challenged as being an invalid exercise of the delegated legislative authority only if the department lacks any substantial competent evidence that the prescription drug satisfied the criteria required pursuant to sub-sub-subparagraph (I) or sub-sub-subparagraph (II). Not later than 7 days after any request by any person, the department shall provide such person with the substantial competent evidence that justifies the department's adoption of an emergency rule placing a prescription drug on the list of specified drugs.

(IV) The department shall notify all prescription drug wholesalers and out-of-state prescription drug wholesalers by electronic means, facsimile, or United States mail and on the bureau's website when any emergency rule is adopted which places a prescription drug on the list of specified drugs. Not later than 7 days after the department adopts an emergency rule placing a prescription drug on the list of specified drugs, wholesalers shall provide the department with the lot numbers and quantities of such prescription drug which the wholesaler owns or has in transit on the date that the department adopted the emergency rule placing the prescription drug on the list of specified drugs.

(V) The requirements of subparagraph 1. do not apply to those lot numbers and quantities of a prescription drug which are included on a report filed pursuant to sub-sub-subparagraph (IV), and paragraph (d) shall apply to those lot numbers and quantities of the prescription drug. In addition to the requirements of paragraph (d), any wholesale distributor selling a prescription drug included on a report

filed pursuant to sub-sub-subparagraph (IV) shall provide any wholesaler purchasing the prescription drugs with a statement under oath that the prescription drugs are among those included on a report filed pursuant to sub-sub-subparagraph (IV) and with a copy of the report filed by the wholesale distributor with the department for those prescription drugs.

f. Not less than annually, the council and department shall evaluate whether each prescription drug included on the list of specified drugs should remain on the list. In determining whether a prescription drug should remain on the list of specified drugs, the council and department must consider:

(I) The availability of generic forms of the drug.

(II) Changes in the price of the drug since the prescription drug was placed on the list.

(III) The current status of the drug that caused the department to place the prescription drug on the list of specified drugs.

The council shall provide a written recommendation adopted by majority vote to the secretary of the department concerning each drug that the council recommends be removed from the list of specified drugs.

4. This paragraph does not apply to a manufacturer; however, a repackager must comply with this paragraph.

~~5. This paragraph expires July 1, 2006.~~

(h)1. This paragraph applies only to an affiliated group, as defined by s. 1504 of the Internal Revenue Code of 1986, as amended, which is composed of chain drug entities, including at least 50 retail pharmacies, warehouses, or

repackagers, which are members of the same affiliated group, if the affiliated group:

a. Discloses to the department the names of all its members; and

b. Agrees in writing to provide records on prescription drug purchases by members of the affiliated group not later than 48 hours after the department requests such records, regardless of the location where the records are stored.

2. Each warehouse within the affiliated group must comply with all applicable federal and state drug wholesale permit requirements and must purchase, receive, hold, and distribute prescription drugs only to a retail pharmacy or warehouse within the affiliated group. Such a warehouse is exempt from providing a pedigree paper in accordance with paragraphs (d) and (e) to its affiliated group member warehouse, provided that:

a. Any affiliated group member that purchases or receives a prescription drug from outside the affiliated group must receive a pedigree paper if the prescription drug is distributed in or into this state and a pedigree paper is required under this section and must authenticate the documentation as required in subsection (4), regardless of whether the affiliated group member is directly subject to regulation under this chapter; and

b. The affiliated group makes available to the department on request all records related to the purchase or acquisition of prescription drugs by members of the affiliated group, regardless of the location where the records are stored, if the prescription drugs were distributed in or into this state.

3. If a repackager repackages prescription drugs solely for distribution to its affiliated group members for the exclusive distribution to and among retail pharmacies that are members of the affiliated group to which the repackager is a member:

a. The repackager must:

(I) In lieu of the written statement required by paragraph (d) or paragraph (e), for all repackaged prescription drugs distributed in or into this state, state in writing under oath with each distribution of a repackaged prescription drug to an affiliated group member warehouse or repackager: "All repackaged prescription drugs are purchased by the affiliated group directly from the manufacturer or from a prescription drug wholesaler that purchased the prescription drugs directly from the manufacturer.";

(II) Purchase all prescription drugs it repackages:

(A) Directly from the manufacturer; or

(B) From a prescription drug wholesaler that purchased the prescription drugs directly from the manufacturer; and

(III) Maintain records in accordance with this section to document that it purchased the prescription drugs directly from the manufacturer or that its prescription drug wholesale supplier purchased the prescription drugs directly from the manufacturer.

b. All members of the affiliated group must provide to agents of the department on request records of purchases by all members of the affiliated group of prescription drugs that have been repackaged, regardless of the location where the records are stored or where the repackager is located.

~~4. This paragraph expires July 1, 2006.~~

Section 3. This act shall take effect upon becoming a law.

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SENATE SUMMARY

Redefines the term "pedigree paper" for purposes of the Florida Drug and Cosmetic Act. Deletes the expiration dates of provisions governing the wholesale distribution of prescription drugs.