Amendment No. (for drafter's use only)

CHAMBER ACTION

Senate House

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Representative(s) Homan offered the following:

Amendment (with title amendment)

On page 2, between line(s) 5-6, insert:

Section 1. Subsections (28) and (31) of section 499.003, Florida Statutes, are 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:

(28) "Manufacturer" means a person who prepares, derives, manufactures, or produces a drug, device, or cosmetic. The term excludes pharmacies that are operating in compliance with pharmacy practice standards as defined in chapter 465 and rules adopted under that chapter. This term also means the holder of an approved new drug application, abbreviated new drug application, or new animal drug application; a private label distributor if the private label distributor's prescription drugs are originally manufactured and labeled for the

distributor and have not been repackaged; or the distribution point establishment for the manufacturer, contract manufacturer, or private label distributor, whether the establishment is a member of the manufacturer's affiliated group or is a contract distribution site, only to the extent that the contract distribution distributes the drugs of the manufacturer.

(31) "Pedigree paper" means:

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

(b)1. Effective July 1, 2006, a document or electronic 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; or.

2. Effective July 1, 2006, a statement, under oath, in written or electronic form, given when a wholesale distribution company purchases and receives the specific unit of the prescription drug directly from the manufacturer of the prescription drug, and distributes the prescription drug directly to a chain pharmacy warehouse or a person authorized by law to purchase prescription drugs, for the purpose of administering or dispensing the drug pursuant to s. 465.003.

a. For purposes of this subparagraph, the term "wholesale distribution company" means a wholesale distributor, as defined in s. 499.012(1)(b), that performs intracompany transfers of specific units of prescription drugs to another wholesale

distributor that is a member of its affiliated group as described in s. 499.012(1)(d)2.b.

b. For purposes of this subparagraph, the term "intracompany transfers" may not include transfers of prescription drugs if those specific units of the prescription drugs were not purchased directly from the manufacturer.

c. For purposes of this subparagraph, "chain pharmacy warehouse" means a wholesale distributor permitted pursuant to s. 499.012 that maintains a physical location for prescription drugs that functions solely as a central warehouse to perform intra-company transfers of such drugs to a member of its affiliated group, as described in s. 499.0121(6)(h)1.

(c) The information required to be included on the form approved by the department pursuant to subparagraph (b)1. ~~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; an invoice number, a shipping document number, or another number uniquely identifying the transaction; and a certification that the recipient wholesaler has authenticated the pedigree papers. If the manufacturer or repackager has uniquely serialized the individual legend drug unit, that identifier must also be included on the form approved by the department pursuant to subparagraph (b)1. ~~pedigree.~~ 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.~~

(d)1. The information required to be included pursuant to subparagraph (b)2. must include:

a. A written statement that states: "This wholesale distribution company purchased the specific unit of the prescription drug directly from the manufacturer."

b. The manufacturer's National Drug Code identifier that provides the name of the manufacturer and the name and address of the wholesaler and the purchaser of the prescription drug.

c. The name of the prescription drug as it was provided by the manufacturer.

d. The quantity, dosage form, and strength of the prescription drug.

2. The wholesale distribution company shall also maintain and make available to the department, upon request, the name and shipping address of the manufacturer from whom the prescription drugs were purchased; the dates of shipment and invoice numbers from the manufacturer to the wholesale distribution company for such prescription drugs; lot numbers of such prescription drugs received by the wholesale distribution company; and any records of any intracompany transfers within the wholesale distribution company of such prescription drugs.

(e) The department may adopt rules and forms relating to the requirements of this subsection.

Section 2. Subsection (29) of section 499.005, Florida Statutes, is amended to read:

499.005 Prohibited acts.--It is unlawful for a person to perform or cause the performance of any of the following acts in this state:

(29) The receipt of a prescription drug pursuant to a wholesale distribution without either first receiving a pedigree paper that was attested to as accurate and complete by the wholesale distributor or complying with the provisions of s. 499.0121(6)(f)6.

Section 3. Paragraph (f) of subsection (6) of section 499.0121, Florida Statutes, is 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.

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

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.

6. The provisions of subparagraph (f)1. are satisfied when a wholesale distributor takes title to, but not possession of, a prescription drug, and the prescription drug's manufacturer ships the prescription drug directly to a person authorized by law to purchase prescription drugs for the purpose of administering or dispensing the drug pursuant to s. 465.003 or a member of an affiliated group, as described in subparagraph (h)1.

a. The wholesale distributor must deliver to the recipient of the prescription drug, within 14 days of the shipment notification from the manufacturer, an invoice and the following sworn statement: "This wholesale distribution company purchased the specific unit of the prescription drug, listed on the invoice, directly from the manufacturer and has been notified by the manufacturer that the specific unit of prescription drug was shipped by the manufacturer directly to a person authorized by law to administer or dispense the legend drug pursuant to s. 465.003, Florida Statutes, or a member of an affiliated group, as described in s. 499.0121(6)(h)1., Florida Statutes." The invoice must contain a clear cross-reference to the shipping

document sent by the manufacturer to the recipient of the prescription drug.

b. The recipient of the prescription drug must acquire, within 14 days of receipt of the prescription drug, a shipping document from the manufacturer that contains, at a minimum:

(I) The name and address of the manufacturer, including the point of origin of the shipment, the wholesaler, and such purchaser.

(II) The name of the prescription drug as it appears on the label.

(III) The quantity, dosage form, and strength of the prescription drug.

(IV) The date of the shipment from the manufacturer.

c. The wholesale distributor must also maintain and make available to the department, upon request, the lot number of such drug if the applicable lot numbers are provided to the wholesale distributor by the manufacturer and are not contained in the shipping document received by such recipient.

7. Failure of the purchaser to acquire, or the wholesale distributor or manufacturer to deliver, the documentation required under subparagraph (f)6. shall constitute failure to acquire or deliver a pedigree paper under s. 499.0051. Forgery by the purchaser, wholesale distributor, or manufacturer of the documentation required to be acquired or delivered under subparagraph (f)6. shall constitute forgery of a pedigree paper under s. 499.0051.

8. The department may by rule define alternatives to compliance with subparagraph (f)1. for a prescription drug in the inventory of a permitted prescription drug wholesaler as of

June 30, 2006, and the return of a prescription drug purchased prior to July 1, 2006. The department may specify time limits for such alternatives.

========= T I T L E A M E N D M E N T =========

On page 1, line(s) 2-3,

remove: all of said lines

and insert:

An act relating to drug distribution; amending s. 499.003, F.S.; revising definitions; authorizing the Department of Health to adopt rules and forms relating to pedigree paper requirements; amending s. 499.005, F.S.; revising a provision relating to prohibited acts; amending s. 499.0121, F.S.; revising requirements relating to the storage and handling of prescription drugs; amending s. 499.006, F.S.;