Amendment No. (for drafter's use only)

CHAMBER ACTION

Senate	House
.	
.	
.	

Representative(s) Benson offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

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)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. The information required to be included on the form approved by the department pursuant to this subparagraph ~~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 pursuant to this subparagraph ~~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; or

2. A statement, under oath, in written or electronic form, confirming that a wholesale distributor 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, as defined in s. 465.003. For purposes of this paragraph, the term "chain pharmacy warehouse" means a wholesale distributor permitted pursuant to s. 499.01 that maintains a physical location for prescription drugs that functions solely as a central warehouse

to perform intracompany transfers of such drugs to a member of its affiliated group as described in s. 499.0121(6)(h)1.

a. The following information must be included on the form approved by the department pursuant to this subparagraph:

(I) The following statement: "This wholesale distributor purchased the specific unit of the prescription drug directly from the manufacturer."

(II) The names and addresses of the manufacturer, the wholesaler, and the purchaser of the prescription drug.

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

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

b. The wholesale distributor must also maintain and make available to the department, upon request, the point of origin of the prescription drug, including intracompany transfers; the date of the shipment from the manufacturer to the wholesale distributor; the lot number of such drug; and the invoice number from the manufacturer.

The department may ~~shall~~ adopt rules and forms ~~a form~~ relating to the requirements of this subsection ~~paragraph no later than 90 days after the effective date of this act~~.

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. Subparagraph 1. is 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, as defined in s. 465.003, or a member of an affiliated group, as described in paragraph (h), with the exception of a repackager.

a. The wholesale distributor must deliver to the recipient of the prescription drug, within 14 days after the shipment notification from the manufacturer, an invoice and the following sworn statement: "This wholesale distributor purchased the specific unit of the prescription drug listed on the invoice directly from the manufacturer, and 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, as defined in s. 465.003, Florida Statutes, or a member of an affiliated group, as described in s. 499.0121(6)(h), Florida Statutes, with the exception of a repackager." The invoice must contain a unique 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 after 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, and the names and addresses of the wholesaler and the 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 not contained in the shipping document acquired by the recipient.

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

8. The department may, by rule, specify alternatives to compliance with subparagraph 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.

Section 4. This act shall take effect July 1, 2006.

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

Remove the entire title and insert:

A bill to be entitled

An act relating to drug distribution; amending s. 499.003, F.S.; revising the definition of the term "pedigree paper"; authorizing the Department of Health to adopt rules and forms relating to pedigree paper requirements; amending s. 499.005, F.S.; revising a prohibited acts provision relating to pedigree papers; amending s. 499.0121, F.S.; requiring certain wholesale distributors taking title to a prescription drug to provide an invoice to the recipient containing certain information; requiring a recipient of a prescription drug to acquire from the manufacturer a shipping document containing specified information; requiring wholesale distributor to make certain information available to the department; providing for penalties; authorizing the department to adopt certain rules relating to the inventory and return of certain prescription drugs; providing an effective date.