Amendment No. (for drafter's use only)

CHAMBER ACTION

Senate House

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Representative Bean offered the following:

Amendment (with title amendment)

On page 3, between lines 19 and 20,

insert:

Section 3. 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 4. 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 requirement of 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 under s. 465.003, or a member of an affiliated group, as described in paragraph (h), except 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 a sworn statement that "This wholesale distributor purchased the specific unit of the prescription drug listed in 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 pursuant to s. 465.003, Florida Statutes, or a member of an affiliated group, as described in s. 499.0121(6)(h), Florida Statutes, except 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; 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.

The wholesale distributor must also maintain and make available to the department, upon request, the lot number of the prescription drug if the lot number is 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 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 define 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.

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

On page 1, lines 2-10,

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remove: all of said lines

and insert:

An act relating to pharmacy; amending s. 465.026, F.S.; deleting a provision authorizing certain community pharmacies to transfer prescriptions for Schedule II medicinal drugs under certain conditions; creating s. 465.0266, F.S.; authorizing the dispensing or refilling of a prescription without a transferred prescription under specified conditions; amending s. 499.005, F.S.; revising a prohibition 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 purchaser containing certain information; requiring a recipient of a prescription drug to acquire from the manufacturer a shipping document containing specified information; requiring a 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