847704

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
02/26/2016	.	
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The Committee on Appropriations (Grimsley) recommended the following:

Senate Amendment (with title amendment)

Delete lines 2374 - 2421

and insert:

(a) The following persons must maintain business records that include the information specified in paragraph (b) ~~Wholesale distributors must establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records must provide a complete audit trail from receipt to sale~~

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~~or other disposition, be readily retrievable for inspection, and include, at a minimum, the following information~~:

1. Persons permitted or required to be permitted under chapter 499 to engage in the manufacture, repackaging, or distribution of active pharmaceutical ingredients or prescription drugs. ~~The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;~~

2. Persons other than those set forth in subparagraph 1. that engage in the receipt of active pharmaceutical ingredients or prescription drugs. ~~The name, principal address, and state license permit or registration number of the person authorized to purchase prescription drugs;~~

~~3. The name, strength, dosage form, and quantity of the drugs received and distributed or disposed of;~~

~~4. The dates of receipt and distribution or other disposition of the drugs; and~~

~~5. Any financial documentation supporting the transaction.~~

(b) Business records for persons specified in paragraph (a) must include:

1. The name and address of the seller, and the Florida permit number of the seller if such seller is not exempt from Florida permitting requirements, of the active pharmaceutical ingredient or prescription drug.

2. The address of the location the active pharmaceutical ingredient or prescription drug was shipped from.

3. The distribution date of the active pharmaceutical ingredient or prescription drug.

4. The name, strength, and quantity, and the National Drug

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Code if such code has been assigned, of the distributed active pharmaceutical ingredient or prescription drug.

5. The name and Florida permit number of the person that purchased the active pharmaceutical ingredient or prescription drug.

6. The financial data, including the unit type and unit price, for the distributions involving active pharmaceutical ingredients or prescription drugs.

7. The date and method of disposition of the active pharmaceutical ingredient or prescription drug. ~~Inventories and records must be made available for inspection and photocopying by authorized federal, state, or local officials for a period of 2 years following disposition of the drugs or 3 years after the creation of the records, whichever period is longer.~~

(c) Each manufacturer or repackager of medical devices, over-the-counter drugs, or cosmetics must maintain business records that include:

1. The name and address of the seller or transferor of the product.

2. The address of the location the product was shipped from.

3. The date of the sale or distribution of the product.

4. The name and quantity of the product involved.

5. The name and address of the person who purchased the product ~~Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means must be readily available for authorized inspection during the retention period. Records that are kept at a central location outside of this state and that~~

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~~are not electronically retrievable must be made available for inspection within 2 working days after a request by an authorized official of a federal, state, or local law enforcement agency. Records that are maintained at a central location within this state must be maintained at an establishment that is permitted pursuant to this part and must be readily available~~.

(d) Persons permitted, or required to be permitted, under this chapter to engage in the manufacture, repackaging, or distribution of active pharmaceutical ingredients or prescription drugs; or the manufacture or repackaging of medical devices, over-the-counter drugs, and cosmetics; must establish, maintain, or have the capability to create a current inventory of the active pharmaceutical ingredients, prescription drugs, over-the-counter drugs, cosmetics, and devices at an establishment where activities specified in this paragraph are undertaken and must be able to produce such inventory for inspection by the department within 2 business days ~~Each manufacturer or repackager of medical devices, over-the-counter drugs, or cosmetics must maintain records that include the name and principal address of the seller or transferor of the product, the address of the location from which the product was shipped, the date of the transaction, the name and quantity of the product involved, and the name and principal address of the person who purchased the product~~.

(e) Business records required to be kept pursuant to this section, and that are kept at the inspection site or can be immediately retrieved by computer or other electronic means, must be readily available for authorized inspection during the

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retention period. Records kept at a central location outside of this state which are not electronically retrievable must be made available for inspection within 2 working days after a request by an authorized official of a federal, state, or local law enforcement agency. Records maintained at a central location within this state must be maintained at an establishment that is permitted pursuant to this part and such records must be readily available for inspection ~~When pedigree papers are required by this part, a wholesale distributor must maintain the pedigree papers separate and distinct from other records required under this part~~.

(f) Records required to be kept pursuant to this subsection must be maintained as specified for a period of not less than 6 years from the date of disposition of the active pharmaceutical ingredients, prescription drugs, over-the-counter drugs, medical devices, or cosmetics.

(g) To the extent that prescription drugs are also products as defined in the federal act, as amended, and the information required by the business records requirements of this section are also included in the tracking and tracing requirements of the federal act, as amended, and departmental rules, the manufacturer, wholesale distributor, repackager, or dispenser must follow both the requirements of the federal act, as amended, and departmental rules.

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

And the title is amended as follows:

Delete lines 64 - 66

and insert:

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recordkeeping requirements; specifying recordkeeping requirements for manufacturers and repackagers of medical devices, over-the-counter drugs, and cosmetics; increasing the quantity of unit doses of