

SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: Health Care Committee

BILL: CS/SB 926

INTRODUCER: Health Care Committee and Senator Peaden

SUBJECT: Prescription Drugs/Sale/Distribution

DATE: April 6, 2006

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HE	Fav/CS
2.			JU	
3.			HA	
4.			WM	
5.			RC	
6.				

I. Summary:

The bill amends the statutory provision which requires a pedigree paper that traces the distribution history of a prescription drug *not specified* by the Department of Health (DOH or department) in rule back to the last authorized distributor of record (ADR). The pedigree paper is provided by the selling wholesaler to a purchasing wholesaler upon the wholesale distribution of a non-specified prescription drug. This provision is set to expire on July 1, 2006, when different criteria already established in statute take effect. The bill deletes the expiration date of July 1, 2006, thus continuing the existing distribution history requirements for nonspecified drugs for entities that are not ADRs.

The bill amends the statutory provision that takes effect July 1, 2006, which specifies that whenever a prescription drug wholesaler distributes a prescription drug, the wholesaler must provide a pedigree for each unit of such prescription drug that traces the distribution history of each such unit from the manufacturer to wholesalers and to any end-users, such as pharmacies, health care practitioners or hospitals. The bill revises this provision to give wholesalers an option, until December 31, 1008, to either:

- Provide a pedigree for each unit of a prescription drug; or
- Provide a statement in written or electronic form stating the wholesale distributor or member of its affiliated group has purchased the specific unit of the prescription drug *directly from the manufacturer*, as defined in paragraph 499.012(1)(e), F.S., and is an ADR. Each manufacturer must file a written list of all of the manufacturer's ADRs with DOH by July 1, 2006. A manufacturer must notify DOH not later than 10 days after any change to the list. The department must publish a list of all ADRs on its website.

This bill amends section 499.0121(6)(d) and (f), Florida Statutes.

II. Present Situation:

Seventeenth Statewide Grand Jury

The Governor petitioned the Florida Supreme Court to impanel a grand jury to examine issues relating to the sale and resale of counterfeit drugs in the wholesale market in Florida. On February 27, 2003, the Seventeenth Statewide Grand Jury released a report that examined the sale and resale of counterfeit prescription drugs in the pharmaceutical wholesale market in Florida. The grand jury made various findings in its report regarding the flow of drugs through the wholesale market that had been illegally acquired or diverted.

Office of Program Policy Analysis and Government Accountability Report No. 03-18

In February 2003, the Office of Program Policy Analysis and Government Accountability issued Report No. 03-18, which highlighted the problems with counterfeit and diverted drugs in Florida. The findings of the report indicated that millions of dollars are lost due to the counterfeit and diverted drugs in Florida's prescription drug wholesale industry. The report found a rise in drug cases involving counterfeit and diverted drugs in Florida's prescription drug industry. The report concluded that Florida law did not provide adequate controls over wholesale drug market practices, and that administrative and criminal penalties failed to provide an adequate deterrent.

2003 Wholesale Drug Legislation

In 2003, the Florida Legislature passed legislation (ch. 2003-155, Laws of Florida), which revised the Florida Drug and Cosmetic Act to impose more stringent regulations on prescription drug wholesalers. The list of prohibited acts relating to drugs, devices, and cosmetics was expanded to include additional prohibitions relating to prescription drugs. The legislation created criminal offenses relating to illicit activities involving diversion from the wholesale distribution of prescription drugs. The legislation also revised recordkeeping requirements for prescription drug wholesalers for a wholesaler that is an authorized distributor of record (ADR) of a drug manufacturer. Each person who is engaged in wholesale drug distribution and who is not an ADR must provide to each wholesale drug distributor of such drug, before the sale is made, a written statement under oath identifying each previous sale of the drug back to the last ADR, 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 drug distributor and no longer needs to identify all sales of such drug in the "pedigree papers." The 2003 legislation provided for a phased-in implementation of the recordkeeping requirements for the wholesale distribution of drugs in Florida.

Pedigree Paper Requirements

The Bureau of Statewide Pharmaceutical Services of the Department of Health (DOH) is responsible for regulating the wholesale distribution of drugs intended for human consumption and veterinary prescription drugs in Florida under the Florida Drug and Cosmetic Act. The Florida Drug and Cosmetic Act is codified at ch. 499, F.S. The Act defines "wholesale distribution" to mean distribution of prescription drugs to persons other than a consumer or

patient, but does not include specified activities. Under s. 499.012, F.S., the activities exempt from “wholesale distribution” include: purchases or acquisitions by a hospital or other health care entity of prescription drugs for its own use from a group purchasing organization of which it is a member; the sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug by a charitable organization; the sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug among hospitals or other health care entities that are under common control; the sale, purchase, trade, or other transfer of a prescription drug from or for any federal, state, or local government agency or entity eligible to purchase drugs at public health service prices under federal law to a contract provider or its subcontractor for eligible patients under specified conditions; and certain activities conducted in accordance with rules of DOH.

The Act requires prescription drug wholesalers to maintain records that provide a complete audit trail of prescription drugs from purchase to sale or other disposition. Such records known as “pedigree papers” must include a written statement of all previous sales of the drug that is being sold in a wholesale market. Section 499.003, F.S., defines “pedigree paper” to mean a document required under paragraph 499.012(6)(d) or (e), F.S., or effective July 1, 2006, a document or electronic form approved by DOH 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 pedigree paper is specified in s. 499.003(31)(b), F.S.

Paragraph 499.0121(6)(d), F.S., requires a pedigree paper that traces the distribution history of a prescription drug *not specified* in DOH rule¹ back to the last ADR. The pedigree paper is provided by the selling wholesaler to a purchasing wholesaler upon the wholesale distribution of a non-specified prescription drug. An ADR does not have to meet the requirements of paragraph 499.0121(6)(d), F.S. A wholesale distributor or affiliated group with whom a manufacturer has established an ongoing relationship to distribute the manufacturer’s products can be designated as an ADR. An ongoing relationship is defined to exist between a manufacturer and a wholesaler when:

- The wholesaler is on the manufacturer’s list of ADRs;
- The wholesaler buys at least 90 percent of all the manufacturer’s products handled by the wholesaler directly from the manufacturer and has total annual prescription sales of \$100 million or more; and
- The wholesaler has reported to DOH sales of \$100 million or more, has a verifiable account number issued by the manufacturer authorizing the wholesale distributor to purchase the manufacturer’s drug product directly from that manufacturer, and that wholesale distributor makes not fewer than 12 purchases of that manufacturer’s drug product directly from the manufacturer.

¹ A specified prescription drug is one that has been listed by DOH rule as a high-risk drug because it has been counterfeited or diverted from the legal channels and meets certain criteria set forth in paragraph 499.0121(6)(e), F.S. According to DOH there are 34 drugs on the list of “specified drugs.” See Rule 64F-12.001(2)(x), Florida Administrative Code.

Paragraph 499.0121(6)(d), F.S., expires on July 1, 2006, when different criteria, set forth in paragraph 499.0121(6)(f), F.S., go into effect.

Paragraph 499.0121(6)(e), F.S., requires that a pedigree trace the distribution history of a prescription drug *specified* in DOH rule back to the manufacturer. The pedigree paper is given by the selling wholesaler to a purchasing wholesaler upon the wholesale distribution of a specified prescription drug. Paragraph 499.0121(6)(e) expires on July 1, 2006, when different criteria, set forth in paragraph 499.0121(6)(f), F.S., go into effect.

Paragraph 499.0121(6)(f), F.S., requires that, whenever a prescription drug wholesaler distributes a prescription drug, the wholesaler must give a pedigree for each unit of such prescription drug that traces the distribution history of each such unit from the manufacturer to wholesalers and to any end-users, such as pharmacies, health care practitioners or hospitals.

Under paragraph 499.0121(6)(h), F.S., chain drug store warehouses and repackaging operations that distribute drugs only to members of their affiliated group are exempt from passing the pedigree papers required for specified and non-specified drugs. Under subparagraph 499.0121(6)(h)3., F.S., a repackager that is a member of a chain drugstore's affiliated group must provide a written statement in lieu of the pedigree paper history required by paragraph 499.0121(6)(d), F.S., paragraph 499.0121(6)(e), or paragraph 499.0121(6)(f) F.S.

III. Effect of Proposed Changes:

The bill amends paragraph 499.0121(6)(d), F.S., which requires a pedigree paper that traces the distribution history of a prescription drug not specified² in DOH rule back to the last authorized distributor of record (ADR). The pedigree paper is provided by the selling wholesaler to a purchasing wholesaler upon the wholesale distribution of a non-specified prescription drug. The bill deletes the expiration date of July 1, 2006, for paragraph 499.0121(6)(d), F.S., thus continuing the existing distribution history requirements for nonspecified drugs for entities that are not ADRs.

The bill amends paragraph 499.0121(6)(f), F.S., which requires effective July 1, 2006, that whenever a prescription drug wholesaler distributes a prescription drug, the wholesaler must provide a pedigree for each unit of such prescription drug that traces the distribution history of each such unit from the manufacturer to wholesalers and to any end-users, such as pharmacies, health care practitioners or hospitals. The bill revises paragraph 499.0121(6)(f), F.S., to give wholesalers an option, until December 31, 2008, to either:

- Provide a pedigree for each unit of a prescription drug; or
- Provide a statement in written or electronic form stating the wholesale distributor or member of its affiliated group has purchased the specific unit of the prescription drug *directly from the manufacturer*, as defined in paragraph 499.012(1)(e), F.S., and is an ADR. Each manufacturer must file a written list of all of the manufacturer's ADRs with

² A specified prescription drug is one that has been listed by DOH rule as a high-risk drug because it has been counterfeited or diverted from the legal channels and meets certain criteria set forth in paragraph 499.0121(6)(e), F.S. According to DOH there are 34 drugs on the list of "specified drugs." See Rule 64F-12.001(2)(x), Florida Administrative Code.

DOH by July 1, 2006. A manufacturer must notify DOH not later than 10 days after any change to the list. The department must publish a list of all ADRs on its website.

The effective date of the bill is July 1, 2006.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Art. I, s. 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill provides an option for drug wholesalers, in lieu of passing a pedigree paper to trace history, to provide a statement in written or electronic form stating the wholesale distributor or member of its affiliated group has purchased the specific unit of the prescription drug, *directly from the manufacturer*, as defined in paragraph 499.012(1)(e), F.S., and is an ADR. The wholesaler or member of its affiliated group is not required to attest to the veracity of the statement, identify each previous sale of the drug back to the last ADR, provide the lot number of the drug, and the sales invoice number of the invoice evidencing the sale of the drug which is

currently required by paragraph 499.0121(6)(d), F.S. The department, which regulates drug wholesale distribution may have difficulty in tracing any drugs which are diverted into the possession of such wholesalers or any member of its affiliated group.

This Senate staff analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

VIII. Summary of Amendments:

None.

This Senate staff analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.
