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: Judiciary Committee

BILL:	CS/CS/SB 926
INTRODUCER:	Judiciary Committee, Health Care Committee, and Senator Peaden
SUBJECT:	Prescription Drugs/Sale/Distribution
DATE:	April 27, 2006 REVISED:

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

I. Summary:

This bill reduces the amount of information a prescription drug wholesaler must include in a pedigree paper for drugs purchased directly from a manufacturer. For such distributions, the pedigree paper needs to state only that the drug was purchased directly from its manufacturer and whether the wholesaler is part of an affiliated group. A more detailed pedigree paper, however, must accompany subsequent distributions of those drugs. Additionally, a pedigree paper is not required for prescription drugs owned by a wholesaler but shipped directly by a manufacturer to certain persons or entities.

The bill also creates a limited prescription drug veterinary wholesaler permit. Under the bill, a person with a limited prescription drug veterinary wholesaler permit generally is not required to use pedigree papers.

This bill substantially amends the following sections of the Florida Statutes: 499.003, 499.005, 499.006, 499.01, 499.012, 499.0121, 499.0122, 499.041, 499.065, 499.0661, and 499.067.

II. Present Situation:

Seventeenth Statewide Grand Jury

The Governor petitioned the Florida Supreme Court to impanel a grand jury to investigate the theft and diversion of high-end prescription drugs and the manufacture of counterfeit prescription

drugs.[1] On February 27, 2003, the grand jury released its first interim report. The grand jury found that drugs flowing through the wholesale market had been illegally acquired.

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 a report that highlighted the problems with counterfeit and diverted drugs in Florida.[2] 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 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.

Pedigree Papers

Under existing law, and until July 1, 2006, wholesalers that are not authorized distributors of record of a prescription drug manufacturer must provide a pedigree paper for a prescription drug distributed to another wholesaler. That pedigree paper must contain the following information:

- A statement tracing the chain of custody of the drug back to the last authorized distributor of record;
- The lot number of the drug; and
- The sales invoice number of the drug.[3]

However, for specified drugs, which are drugs that are susceptible to counterfeiting or diversion, *all* prescription drug wholesalers must provide a pedigree paper. This pedigree paper must be a statement that the drug was purchased directly from the manufacturer. Alternatively, the pedigree paper must include:

- A statement tracing the chain of custody of the drug back to the manufacturer;
- The lot number of the drug; and
- The sales invoice number from previous sales of the drug.[4]

Beginning on July 1, 2006, *all* prescription drug wholesalers must provide a pedigree paper for wholesale distributions of *any* drug. Additionally, the pedigree paper must contain more information than was previously required. That pedigree paper must contain the following information:

- Chain of ownership back to the manufacturer;
- Amount;

[1] See Petition for Order to Impanel a Statewide Grand Jury, *In Re: Statewide Grand Jury*, No. SC02-2645 (December 20, 2002).
[2] See OFFICE OF PROGRAM POLICY ANALYSIS AND GOVERNMENT ACCOUNTABILITY, REPORT NO. 03-18, COUNTERFEIT AND DIVERTED DRUGS THREATEN PUBLIC HEALTH AND WASTE STATE DOLLARS (February, 2003).
[3] Section 499.0121(6)(d), F.S.
[4] Section 499.0121(6)(e), F.S.

- Dosage, form, and strength;
- Lot number;
- Name and address of each owner and his or her signature;
- Shipping information; and
- Contact information for each wholesaler in the chain of ownership.[5]

III. Effect of Proposed Changes:

This bill reduces the amount of information a prescription drug wholesaler must include in a pedigree paper for drugs purchased directly from a manufacturer. For such distributions, the pedigree paper needs to state only that the drug was purchased directly from its manufacturer and whether the wholesaler is part of an affiliated group. A more detailed pedigree paper, however, must accompany subsequent distributions of those drugs. Additionally, a pedigree paper is not required for prescription drugs owned by a wholesaler but shipped directly by a manufacturer to certain persons or entities.

The bill also creates a limited prescription drug veterinary wholesaler permit. The bill requires the permit to distribute wholesale veterinary drugs in this state. Additionally, no more than 30 percent of a permitted person's drug sales may be prescription drugs approved for human use.

Pedigree Paper for Certain Distributions

Under the bill, after a wholesaler distributes drugs that were purchased directly from a manufacturer, further distributions must be accompanied by a pedigree paper containing a certain minimum amount of information. That information must include:

- The amount of the drug;
- The form of the drug and strength;
- The lot number of the drug;
- The name and address of each former owner of the drug and his or her signature;
- Shipping information, including the name of each person certifying delivery or receipt of the drug since it left the manufacturer;
- An invoice number, shipping document number, or another unique number identifying the transaction;
- Certification that other pedigree papers were authenticated; and
- Other information.

Special rules apply for drugs in which title is in a wholesaler, but that are sent by a manufacturer to:

- A person authorized by law to administer or dispense prescription drugs; or
- A member of an affiliated group, except a repackager.

[5] Sections 499.003(31) and 499.0121(6)(f), F.S.

Under this scenario, the purchaser must receive an invoice from the wholesaler and shipping information and identification of the shipment by the manufacturer.

Limited Prescription Drug Veterinary Wholesaler Permit

The bill requires veterinary drug wholesalers to obtain a limited prescription drug veterinary wholesaler permit. These wholesalers generally are not required to use pedigree papers as are required of wholesalers of drugs for human consumption. However, veterinary drug wholesalers must comply with other requirements of law applicable to other prescription drug wholesalers.

Effective Date

The bill takes effect on July 1, 2006.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

The annual fee for a limited prescription drug veterinary wholesaler permit may not be less than $300 or exceed $500.

B. Private Sector Impact:

The bill may provide a competitive advantage to prescription drug wholesalers that can purchase a drug directly from a manufacturer. These wholesalers will not have to supply a detailed pedigree paper. Other wholesalers will incur the expense of supplying and creating pedigree papers. Additionally, the requirements of the bill may discourage the sale of prescription drugs between wholesalers.

C. Government Sector Impact:

The Department of Health is required to adopt rules.

VI. Technical Deficiencies:

None.

VII. Related Issues:

Chapter 499, F.S., contains cross-references that do not expire to provisions of law that expire on the effective date of the bill, July 1, 2006. The existence of cross-references to expired provisions of law may create confusion in the future. An example of such a cross-reference exists in s. 499.003(31), F.S., which defines the term "pedigree paper." Paragraph (a) of subsection (31) of s. 499.003, F.S., defines the term as "[a] document required pursuant to s. 499.0121(6)(d) or (e)." Paragraphs (d) and (e) of subsection (6) of s. 499.0121, F.S., expire on July 1, 2006. Paragraph (b) of subsection (31) of s. 499.0121, F.S., creates an additional definition of "pedigree paper" that takes effect on July 1, 2006. For clarity, the Legislature may wish to repeal cross-references in paragraph (a) to provisions of law that expire on the effective date of the bill.

VIII. Summary of Amendments:

None.