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: Regulated Industries Committee

BILL:	CS/SB 1540
SPONSOR:	Regulated Industries Committee and Senator Baker
SUBJECT:	Veterinary Drug Distribution
DATE:	March 20, 2006 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Oxamendi	Imhof	RI	**Fav/CS**
2.			HE	
3.				
4.				
5.				
6.				

I. Summary:

The bill establishes the limited prescription drug veterinary wholesaler permit (permittee) for any person that engages in the distribution, in or into this state, of veterinary prescription drugs and prescription drugs for human use to veterinarians.

It provides that any prescription drug for human that has been returned by a veterinarian to a permittee is an adulterated drug under s. 499.006, F.S.

The bill provides several permit requirements and conditions for the permit. The bill provides that a permittee must be engaged in the business of wholesaling veterinary prescription or legend drugs full-time, must limit prescription drugs prescribed for human use to no more than 30 percent of total annual drug sales, must not otherwise be authorized to wholesale prescription drugs for human use, must provide a $20,000 bond or equivalent surety requirement, and must maintain a valid limited prescription drug veterinary wholesaler permit.

The bill provides that any human use drug which has been returned by a veterinarian may not be returned to inventory for subsequent wholesale distribution. It provides that an out-of-state prescription drug wholesale permit or a limited prescription drug veterinary wholesaler permit is not required for an intercompany sale or drug transfer from a licensed out-of-state establishment.

The bill also requires a limited prescription drug veterinary wholesaler to comply with s. 499.0121, F.S., except that the permitholder is not required to comply with the pedigree paper requirements of s. 499.0121(6)(f), F.S., upon the wholesale distribution of a prescription drug to a veterinarian.

The bill provides a fee for a limited prescription drug veterinary wholesaler's permit of not less than $300 or no more than $500 annually.

The bill requires the Department of Health (DOH or department) to inspect each limited prescription drug veterinary wholesaler, and it authorizes the department to order the immediate closure of a limited prescription drug veterinary wholesaler if the department determines that it presents an immediate danger to the public health, safety, or welfare.

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

II. Present Situation:

The Bureau of Statewide Pharmaceutical Services of 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.

Wholesale Distribution and Distributors

Section 499.012, F.S., provides a definition of "wholesale distribution" to mean the distribution of prescription drugs to persons other than the consumer or patient and specifies exceptions to the definition for:

- Purchases by a hospital or other health care entity from a group purchasing organization;
- The sale, purchase or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug by a not-for-profit charitable organization to a not-for-profit affiliate;
- 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; and
- The sale, purchase, trade, or other transfer of a prescription drug from or for any federal, state, or local government agency or any entity eligible to purchase prescription drugs at public health services prices under federal law.

Under s. 499.012, F.S., "wholesale distributor" is defined to mean any person engaged in wholesale distribution of prescription drugs. Persons or entities which distribute wholesale veterinary prescription drugs must obtain a permit under the Florida Drug and Cosmetic Act, as a prescription drug wholesaler, or if located outside of Florida, as an out-of-state prescription drug wholesaler.[1]

All prescription drug wholesalers are required to post a $100,000 bond and to file an extensive permit application that includes the submission of fingerprint cards for all key individuals associated with the wholesaler's operations in order for a criminal history check to be performed.[2] In addition, each prescription drug wholesaler must have a designated representative

[1] *See* s. 499.012, F.S.
[2] *See* s. 499.012(2), (3), and (4), F.S.

who has successfully passed an examination on federal and state laws, and department rules, relating to wholesale distribution of prescription drugs.[3] Before purchasing any prescription drugs from another wholesale drug distributor, a wholesale drug distributor must meet due diligence requirements.

Definitions

Section 499.003(25), F.S., defines the terms "legend drug," "prescription drug," or "medicinal drug" to mean "any drug, including, but not limited to, finished dosage forms, or active ingredients subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act (the federal act) or s. 465.003(8), F.S., s. 499.007(12), F.S.,[4] or s. 499.0122(1)(b) or (c), F.S.[5]

Section 499.0122(1)(c), F.S., defines "veterinary legend drug" to mean "a legend drug intended solely for veterinary use." This definition also provides that the label of the drug must bear the statement, "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian."

Section 499.0122, F.S., defines a "veterinary drug retail establishment" to mean, "A person permitted to sell veterinary legend drugs to the public or to veterinarians, but does not include a pharmacy licensed under [ch. 465, F.S.]."

Veterinary Prescription Drug Wholesaler

Section 499.01, F.S., requires a permit for any person or establishment that wishes to operate as a veterinary prescription drug wholesaler. Section 499.003(40), F.S., defines a "veterinary prescription drug wholesaler" to mean any person engaged in wholesale distribution of veterinary prescription drugs in or into Florida.

Section 499.012(2), F.S., establishes several types of wholesaler permits. Specifically, s. 499.012(2)(g), F.S., provides a permit classification for a veterinary prescription drug wholesaler. It also requires any person that engages in the distribution of veterinary prescription drugs in, or into, Florida to obtain a permit.

A veterinary prescription drug wholesaler that also distributes prescription drugs subject to, defined by, or described by the federal act[6] (approved or intended for human use or consumption), which the wholesaler did not manufacture, must obtain a permit as a prescription drug wholesaler or out-of-state prescription drug wholesaler instead of the veterinary prescription drug wholesaler permit. A veterinary prescription drug wholesaler must comply with the requirements for wholesale distributors under s. 499.0121, F.S., except the pedigree paper

[3] *See* s. 499.012(9) and (11), F.S.
[4] Relating to the use of drugs that are intended for humans that are habit forming or harmful.
[5] Relating to prescription medical oxygen, which is a compressed medical gas and which can only be sold on the order or prescription of a practitioner authorized by law to prescribe, and veterinary legend drugs. "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian."
[6] 21 U.S.C. s. 301, et. seq.

requirements in paragraphs (6)(d), (e), or (f) of s. 499.0121, F.S. Pedigree paper requirements are record requirements for tracking the prescription drugs from manufacturers to retail pharmacies.

However, this classification is not applicable to a wholesaler that distributes human and veterinary drugs. A wholesaler that distributes human and veterinary drugs must continue to meet the licensure requirements for wholesale distributors. A veterinary drug wholesale industry representative maintains that the permit requirements for wholesale distributors are too stringent for veterinary wholesalers who also sell human drugs for animal use.

Recordkeeping Requirements

Section 499.0121, F.S., requires the department to adopt rules that require the keeping of such records as are necessary for the protection of the public health. Section 499.0121(6)(f), F.S., provides a record requirement for pedigree of prescription drugs intended for human use. Specifically, s. 499.0121(6)(f), F.S., requires:

> 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.

According to DOH, the purpose of the pedigree paper requirement is to protect the drug supply from counterfeit or diverted prescription drugs that pose a danger to the public health. According to DOH, veterinarians ordinarily purchase prescription drugs that are labeled and approved for veterinary use. It is also common practice for a veterinarian to purchase a prescription drug labeled and intended for human use to use on an animal when a veterinary legend drug is not available on the market. According to an animal-health industry representative, 98 of the approximately 10,000 drugs approved for human use are also used on animals.

III. Effect of Proposed Changes:

Section 1. Amends s. 499.006, F.S., to define a prescription drug subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act (s. 503(b)) which has been returned by a veterinarian to a limited prescription drug veterinary wholesaler as an adulterated drug.

Section 2. Amends s. 499.01, F.S., to require a permit for any person or establishment that intends to operate as a limited prescription drug veterinary wholesaler. The bill provides that the limited prescription drug veterinary wholesaler permit may not be issued to the address of a health care entity or pharmacy licensed under ch. 465, F.S., except as provided in s. 499.01(2)(d), F.S.

Section 3. Amends s. 499.012, F.S., to establish the limited prescription drug veterinary wholesaler permit. The bill provides that this permit is required for any person that engages in the distribution, in or into this state, of veterinary prescription drugs and prescription drugs subject to, or described by s. 503(b) to veterinarians. Section 499.012(2)(h), F.S., provides that the limited prescription dug wholesaler permit is required to engage in the distribution of prescription veterinary drugs "unless engaging in the activities of and permitted as a prescription drug manufacturer, nonresident prescription drug manufacturer, prescription drug wholesaler, or out-of-state prescription drug wholesaler." For example, a licensed prescription drug wholesaler, which can currently distribute human and veterinary drugs to, is not required to have a limited prescription drug veterinary wholesaler permit to distribute human and veterinary drugs under the conditions stated in this section.

The bill provides the following permit requirements and conditions:

- The permitholder must be engaged in the business of wholesaling prescription and veterinary legend drugs to persons:
    - Licensed as veterinarians practicing on full time basis;
    - Regularly and lawfully engaged in instruction in veterinary medicine;
    - Regularly and lawfully engaged in law enforcement activities;
    - For use in research not involving clinical use; or
    - For use in chemical analysis or physical testing, for the purpose of instruction in law enforcement activities, research, or testing;
- No more than 30 percent of total annual drug sales may be prescription drugs prescribed for human use.
- The permitholder may not be licensed in any state to wholesale prescription drugs subject to s. 503(b) to any person who is authorized to sell, distribute, purchase, trade, or use these drugs on or for humans. For example, a limited prescription drug veterinary wholesaler permitholder cannot distribute human drugs for use on humans.
- The permitholder must submit a $20,000 bond or equivalent surety.
- The permitholder must maintain at all times a license or permit to engage in wholesale distribution of prescription drugs in compliance with the laws of the state in which it is a resident.
- The permitholder must comply with s. 499.0121, F.S., storage labeling, and recordkeeping requirements, except that the permitholder is not required to comply with the pedigree paper requirements of s. 499.0121(6)(f), F.S., upon the wholesale distribution of a prescription drug to a veterinarian.
- The permitholder may not return to inventory for subsequent wholesale distribution any drug subject to, defined by, or described by s. 503(b) which has been returned by a veterinarian.

The bill permits an intracompany sale or transfer of prescription drugs from an out-of-state establishment that is duly licensed to engage in the wholesale distribution of prescription drugs in its state of residence to a licensed limited prescription drug veterinary wholesaler. Both wholesalers must operate under the same name, and comply with the recordkeeping requirements of s. 499.0121(6), F.S., for the transaction.

Section 4. Amends s. 499.0122(1)(d), F.S., to delete veterinarians from the group of persons or entities to whom a veterinary legend drug retail establishment may sell veterinary legend drugs. The bill would permit a veterinary legend drug retail establishment to only sell veterinary legend drugs to the public.

Section 5. Amends s. 499.041, F.S., to require a fee for a limited prescription drug veterinary wholesaler's permit. The bill provides the fee may not be less than $300 or no more than $500 annually.

Section 6. Amends s. 499.065, F.S., to require department inspection of each limited prescription drug veterinary wholesaler. The bill also permits the department to order the immediate closure of a limited prescription drug veterinary wholesaler if the department determines that it presents an immediate danger to the public health, safety, or welfare.

Section 7. Provides an effective date of 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 bill establishes a fee for a limited prescription drug veterinary wholesaler's permit of not less than $300 or more than $500 annually.

B. Private Sector Impact:

The bill requires a limited prescription drug veterinary wholesale permitholder to submit a bond of $20,000 or equivalent surety to DOH.

C. Government Sector Impact:

According to the Department of Health, the department estimates that no more that 10 establishments will apply and qualify to become limited veterinary wholesalers. If each is currently permitted as a prescription drug wholesaler or out-of-state prescription drug wholesaler, there would be a decrease in revenue of $3,000 annually. According to DOH, the $3,000 loss in revenue will have no effect on operations.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Summary of Amendments:

None.