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 1654
SPONSOR:	Regulated Industries Committee and Senator Fasano
SUBJECT:	Veterinary Drug Distribution
DATE:	April 7, 2005 REVISED:

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

I. Summary:

The committee substitute (CS) establishes the limited veterinary prescription drug wholesaler permit 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 the s. 503(b) of the Federal Food, Drug, and Cosmetic Act (s. 503(b))[1] to veterinarians. The CS provides several permit requirements and conditions under the permit, including a $20,000 bond or equivalent surety requirement, and provides permissible transactions under the permit.

The committee substitute defines any prescription drug subject to, defined by, or described by s. 503(b) which has been returned by a veterinarian to a limited veterinary prescription drug wholesaler as an adulterated drug.

The CS provides that no more than 30 percent of drug sales by limited veterinary prescription drug wholesaler a may be prescription drugs prescribed for human use. It also requires that a limited veterinary prescription drug wholesaler must 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 CS provides that any drug subject to, defined by, or described by the act which has been returned by a veterinarian may not be returned to inventory for subsequent wholesale distribution.

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

[1] 21 U.S.C. s. 301, et. seq., relating to drugs approved or intended for human use or consumption.

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

The CS provides an effective date of July 1, 2005.

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 the Department of Health (DOH or department) 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.[2]

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.[3] In addition, each prescription drug wholesaler must have a designated representative who has successfully passed an examination on federal and state laws, and department rules,

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

relating to wholesale distribution of prescription drugs.[4] Before purchasing any prescription drugs from another wholesaler 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 or s. 465.003(8), F.S., s. 499.007(12), F.S.,[5] or s. 499.0122(1)(b) or (c), F.S.[6]

Section 499.0122(1)(c), 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 that any person that engages in the distribution of veterinary prescription drugs in, or into, Florida obtain a permit.

A veterinary prescription drug wholesaler also distributes prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act[7] (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 requirements in paragraphs (6)(d), (e), or (f) of s. 499.0121, F.S.

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. According to an industry

[4] *See* s. 499.012(9) and (11), F.S.
[5] Relating to the use of drugs that intended for humans that are habit forming or harmful.
[6] 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."
[7] 21 U.S.C. s. 301, et. seq.

representative, 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 that the department 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 the department, 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 the department, 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 veterinary prescription drug wholesaler as an adulterated drug.

Section 2 amends s. 499.01(1), F.S., to require a permit for any person or establishment that intends to operate as a limited veterinary drug wholesaler. The CS provides that the limited veterinary drug wholesaler permit may not be issued to the address of a health care entity or pharmacy licensed under ch. 465, except as provided in s. 499.01(2)(d), F.S.,

Section 3 amends s. 499.012, F.S., to establish the limited veterinary prescription drug wholesaler permit. The CS 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. The CS provides the following permit requirements and conditions under the permit:

- The permitholder must be engaged in the business of wholesaling prescription and veterinary legend drugs on a full-time basis.
- No more than 30 percent of 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.
- 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 resident.
- The permitholder must 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 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 CS permits an intracompany sale or transfer of prescription drug from an out of state establishment licensed as a limited veterinary prescription drug wholesaler to a licensed prescription drug wholesaler. Both wholesalers must operate under the same name, and comply with the recordkeeping requirements of s. 499.0121(6), F.S.

Section 4 amends s. 499.0122(1)(d), F.S., to delete veterinarians from group of persons or entities to whom a veterinary legend drug retail establishment may sell veterinary legend drug. The CS 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 veterinary prescription drug wholesaler's permit. The CS provides the fee may not be less than $300 or no more than $500.

Section 6 amends s. 499.065, F.S., to require department inspection of each limited veterinary prescription drug wholesaler. The bill also permits the department to order the immediate closure of a limited veterinary prescription drug 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, 2005.

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:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Summary of Amendments:

None.