HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 685 CS Veterinary Drug Distribution
SPONSOR(S): Coley and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 1540

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Committee	9 Y, 0 N, w/CS	Bell	Mitchell
2) Agriculture Committee		Kaiser	Reese
3) Health Care Appropriations Committee			
4) Health & Families Council			
5)			

SUMMARY ANALYSIS

HB 685 w/ CS establishes a new type of prescription drug wholesaler permit, the "limited prescription drug veterinary wholesaler permit" (permit). The permit is required for any person who engages in the distribution, in or into the state to veterinarians, of veterinary prescription drugs and prescription drugs regulated by the Federal Food, Drug, and Cosmetic Act (act).[1] The bill provides several permit requirements, including a $20,000 bond or equivalent surety requirement, and provides parameters for permit holders.

The bill defines any human prescription drug, regulated under the act, as an adulterated drug if it has been returned by a veterinarian to a limited prescription drug veterinary wholesaler.

The bill provides that no more than 30 percent of drug sales by limited prescription drug veterinary wholesalers may be prescription drugs prescribed for human use. It also requires a limited prescription drug veterinary wholesaler to comply with pedigree paper tracking requirements except under certain circumstances. The bill provides a fee for a limited prescription drug veterinary wholesaler's permit of not less than $300 or more than $500 annually.

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

The DOH estimates that, with the creation of the permit, there will be a yearly loss of $3,000. According to DOH, this loss of revenue will have no effect on current operations.

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

[1] Section 503(b) of the Federal Food, Drug, and Cosmetic Act regulates pharmaceutical drugs intended for human consumption.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide Limited Government – HB 685 w/ CS creates a new prescription drug wholesaler permit. The new permit allows veterinary wholesalers to provide legend drugs intended for human use but limits the sales to no more than 30 percent. The bill decreases requirements for veterinary wholesalers that wish to provide legend drugs intended for human use. The creation of the permit will result in a yearly loss of $3,000 in regulatory fees, according to the Department of Health (DOH).

B. EFFECT OF PROPOSED CHANGES:

HB 685 w/ CS establishes a new type of prescription drug wholesaler permit, the "limited prescription drug veterinary wholesaler permit" (permit). The permit is required for any person who engages in the distribution in or into the state of veterinarian prescription drugs and prescription drugs subject to, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act[2] to veterinarians. The bill also allows limited veterinary drug wholesalers to sell drugs to:

- Licensed veterinarians practicing on a full-time basis;
- Veterinary medicine instructors;
- Law enforcement personnel with service animals;
- Researchers, not involved in clinical use; or
- For use in chemical analysis or physical testing, for the purposes of instruction in law enforcement, research, or testing.

The bill provides several permit requirements, including a $20,000 bond or equivalent surety requirement, and provides parameters for permit holders. The bill defines any prescription drug subject to, defined by, or described by s. 503(b), which has been returned by a veterinarian to a limited prescription drug veterinary wholesaler as an adulterated drug.

The bill specifies that no more than 30 percent of drug sales[3] by limited prescription drug veterinary wholesalers may be prescription drugs prescribed for human use. It also requires a limited prescription drug veterinary wholesaler to comply with pedigree paper tracking requirements under s. 499.0121, F.S., except that the permit holder 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 permits 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 veterinarian wholesaler. Both wholesalers must operate under the same name, and comply with the recordkeeping requirements of s. 499.0121(6), F.S.

The bill provides a fee for a permit of not less than $300 or more than $500 annually. It also requires the Department of Health (DOH) to inspect each limited prescription drug wholesaler. It authorizes DOH to order immediate closures of a limited prescription drug veterinary wholesaler if DOH determines that it presents an immediate danger to the public health safety and welfare.

[2] Section 503(b) of the Federal Food, Drug, and Cosmetic Act regulates pharmaceutical drugs intended for human consumption.

[3] According to a survey conducted by the American Veterinary Distributors Association (AVDA), human drug sales comprise approximately 30% of the annual sales volume of veterinary wholesalers who sell all types of veterinary products to veterinarians.

Limited Veterinarian Prescription Drug Wholesaler Permit Requirements
The bill provides the following permit requirements and conditions under the permit:

- The permit holder 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 permit holder may not be licensed in any state to wholesale prescription drugs subject to s. 503(b) of the Federal Food, Drug, and Cosmetic Act to any person who is authorized to sell, distribute, purchase, trade, or use these drugs on or for humans;
- The permit holder must submit a $20,000 bond or equivalent surety;
- The permit holder must maintain a license or permit to engage in wholesale distribution of prescription drugs at all times in compliance with the laws of the state in which it is a resident;
- The permit holder must comply with s. 499.0121, F.S., except that the permit holder is not required to comply with the pedigree paper requirements of s. 499.0121(6)(f), F.S., for wholesale distribution of a prescription drug to a veterinarian; and
- The permit holder may not return to inventory for subsequent wholesale distribution any drug federally regulated under s. 503(b) which has been returned by a veterinarian.

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

Overview
The Bureau of Statewide Pharmacy Services of DOH is responsible for regulating the wholesale distribution of drugs intended for human consumption[4] and veterinary legend drugs[5] in Florida under the Florida Drug and Cosmetic Act. The Florida Drug and Cosmetic Act is codified in ch. 499, F.S.

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.

Currently, wholesalers that distribute drugs to veterinarians must have a prescription drug wholesaler's permit, an out-of-state wholesaler's permit, a retail pharmacy wholesaler's permit, or a veterinary prescription drug wholesaler permit. However, most often wholesalers that distribute drugs to veterinarians register as a prescription drug wholesaler or a veterinary prescription drug wholesaler.

Veterinary prescription drug wholesalers are limited to only distributing prescription drugs developed and intended for animal use. According to an industry representative, some prescription drugs intended for human use do not have an equivalent prescription drug intended for animal use. Because of this deficiency, veterinarians may prescribe human drugs to animals. According to DOH, human medications sold by veterinarians are not on any list of adulterated, counterfeit, or diverted drugs. The human drugs sold by veterinarians include eye ointment, antibiotics, allergy medications, and topical anesthetics.

Existing Regulations:
Veterinary Prescription Drug Wholesaler Permits
Section 499.01, F.S., requires a permit for any person or establishment that wishes to operate as a veterinary prescription drug wholesaler. Veterinary prescription drug wholesaler is defined as any person engaged in the wholesale distribution of veterinary prescription drugs in or into Florida.[6]

Prescription Drug Wholesalers
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. In addition, each prescription drug wholesaler must have a designated representative who has successfully passed an

[4] Section 499.003(25), F.S.
[5] Section 499.0122(1)(c), F.S.
[6] Section 499.003(40), F.S.

examination on federal and state laws, and department rules, relating to the wholesale distribution of prescription drugs.

	Prescription Drug Wholesaler	Limited Veterinary Prescription Drug Wholesaler (proposed permit)	Veterinary Prescription Drug Wholesaler
Type of Prescription Drugs Dispensed	Legend drugs defined or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act.	May dispense up to 30% of sales from legend drugs.	Veterinarian legend drugs only.
Required Deposit	$100,000 bond, certificate of deposit, or letter of credit	$20,000 bond, certificate of deposit, or letter of credit	None required.
Authorized yearly fees	$800 Annually s. 499.041(2)(a), F.S.	$300-$500 Annually (proposed legislation)	$500 s. 499.041(g), F.S.

Pedigree Papers

Pedigree papers are the key standard for control of the wholesale drug industry designed to prevent drug diversion, fraud, and counterfeiting. They require wholesalers to provide purchasers with a written sales history tracing each drug back to its initial manufacturer. These written histories, commonly referred to as pedigree papers, provide an audit trail and contain specific information about each sales transaction, such as the name and address of each previous purchaser of the drug.

Beginning July 1, 2006, prescription drug wholesalers will be required to pass pedigree papers down to the retail level. Wholesalers who pass pedigree papers to veterinarians are included in this provision.

Florida Drug & Cosmetic Act

Pursuant to the Florida Drug and Cosmetic Act, part I, chapter 499, Florida Statutes, DOH is responsible for administering and enforcing efforts to prevent fraud, adulteration, misbranding, or false advertising in the preparation, manufacture, repackaging, or distribution of drugs, devices and cosmetics. Wholesalers, manufacturers and distributors of drugs or devices must be permitted by the department or otherwise be exempt.[7]

Under the Florida Drug and Cosmetic Act (act), any person who is at least 18 years of age or older, pays a permit fee, and submits specified information may, with certain exceptions, obtain a permit as a prescription drug wholesaler.[8] The applicant must not have been found guilty of a violation of a law that directly relates to a drug, device, or cosmetic, regardless of adjudication. The applicant must submit information on contact persons for each facility used by the applicant for the storage, handling and distribution of prescription drugs. The permit, once granted, may be renewed biennially.

An out-of-state prescription drug wholesaler distributor located outside of Florida must be permitted by DOH. DOH is authorized to adopt rules that allow out-of-state drug wholesalers to obtain a drug wholesale permit on the basis of reciprocity in Florida to the extent that an out-of-state drug wholesaler possesses a valid permit from another state with requirements that are comparable to those of Florida and can show that the other state from which the wholesaler holds a permit would extend reciprocity under its laws to a Florida-permitted drug wholesaler. According to DOH, there are approximately 450

[7] Drug marketing is also subject to regulation under the Federal Prescription Drug Marketing Act of 1987, which establishes minimum standards for the prescription drug industry including requirements for an audit trail of sales transactions.

[8] See ss. 499.01 and 499.012, F.S. The permitting requirements for a number of establishments licensed or permitted by the Department of Health to engage in activities regulated under the Florida Drug and Cosmetic Act are the same. Such establishments include: prescription drug manufacturer; over-the-counter drug manufacturer; compressed medical gas manufacturer; device manufacturer; cosmetic manufacturer; prescription drug wholesaler; compressed medical gas wholesaler; out-of state prescription drug wholesaler; retail pharmacy drug wholesaler; veterinary legend drug retail establishment; medical oxygen retail establishment; complimentary drug distributor; or restricted prescription drug distributor.

prescription drug wholesalers located in Florida and 900[9] out-of-state wholesalers, of which less than 10 percent are one of the three large full-line wholesalers or their distribution centers, or major full-line regional wholesalers. The remaining wholesalers are secondary wholesalers that primarily buy and sell among other prescription drug wholesalers rather than to end-users such as hospitals or other health care entities, which include physicians or pharmacies.

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 sold in a wholesale market.

The act specifies criminal penalties for violations relating to activities regulated by DOH under the act. Such criminal offenses are, with few exceptions, punishable as a second-degree misdemeanor.

C. SECTION DIRECTORY:

Section 1. – Amends s. 499.006, F.S., to define a prescription drug returned by a veterinarian to a limited prescription drug veterinary wholesaler as an adulterated drug. Prescription drugs are those regulated by s. 503(b) of the Federal Food, Drug, and Cosmetic Act.

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 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 a limited prescription drug veterinary wholesaler permit. The bill 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.

Section 4. – Amends s. 499.01221(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 permits 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 more than $500 annually.

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

Section 7. – Provides an effective date of July 1, 2006.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

[9] According to Department of Health records from 2003.

Estimated Revenue	1st Year	2nd Year (Annualized/Recurring)
Decrease in permit fee revenue $300 for est. 10 permits	-3,000	-3,000
Total Estimated Revenue	- $3,000	- $3,000

2. Expenditures:

   None

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None

2. Expenditures:

   None

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Under the proposed legislation veterinary wholesalers who wish to offer some legend drugs intended for human use have the option of obtaining a limited veterinary prescription drug wholesaler permit instead of a prescription drug wholesaler permit. Because the limited veterinary prescription drug wholesaler has fewer requirements than the prescription drug wholesaler permit, some cost savings may be realized. Wholesalers who choose to obtain the newly created permit may pass their savings on to their customers.

D. FISCAL COMMENTS:

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

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   This bill does not require counties or municipalities to spend funds or take action requiring the expenditure of funds. This bill does not reduce the percentage of state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

   None

B. RULE-MAKING AUTHORITY:

The Department of Health has the necessary rulemaking authority to carry out the provisions in the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

On February 22, 2006, the Health Care Regulation Committee adopted one amendment to HB 685. The amendment specifies that limited prescription drug veterinary wholesalers can sell prescription drugs to:

- Licensed veterinarians practicing on a full-time basis;
- Veterinary medicine instructors;
- Law enforcement personnel with service animals;
- Researchers, not involved in clinical use; or
- For use in chemical analysis or physical testing, for the purposes of instruction in law enforcement, research, or testing.

The analysis is drafted to the committee substitute.