

## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

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

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REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Committee	9 Y, 0 N, w/CS	Bell	Mitchell
2) Agriculture Committee	10 Y, 0 N	Kaiser	Reese
3) Health Care Appropriations Committee	14 Y, 0 N	Money	Massengale
4) Health & Families Council	10 Y, 0 N, w/CS	Bell	Moore
5) _____	_____	_____	_____

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### SUMMARY ANALYSIS

House Bill 685 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).<sup>1</sup> 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 also specifies 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 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 the department determines that it presents an immediate danger to the public health, safety, or welfare.

The bill provides a fee for a limited prescription drug veterinary wholesaler's permit of not less than \$300 or more than \$500 annually. DOH estimates that, with the creation of the permit, there will be a yearly loss of \$3,000 in trust fund revenue, but will have no effect on current operations.

The bill expands the options available to meet the prescription drug pedigree paper tracking requirements. The bill provides alternative pedigree paper requirements for prescription drugs purchased directly from the manufacturer and prescription drugs shipped directly from the manufacturer to an end user. The bill also authorizes DOH to revoke a permittee's permit in an emergency situation. The bill directs DOH to publish a list of current revoked permits on their website.

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

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<sup>1</sup> 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** - The bill 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.

#### B. EFFECT OF PROPOSED CHANGES:

The bill 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 section 503(b) of the Federal Food, Drug, and Cosmetic Act<sup>2</sup> to veterinarians. The bill also allows limited veterinary drug wholesalers to sell drugs to the following:

- Licensed veterinarians practicing on a full-time basis.
- Veterinary medicine instructors.
- Law enforcement personnel with service animals.
- Researchers, not involved in clinical use.
- 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 section 503(b) of the Federal Food, Drug, and Cosmetic Act, 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<sup>3</sup> 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 section 499.0121, Florida Statutes, except that the permit holder is not required to comply with the pedigree paper requirements of section 499.0121(6)(f), Florida Statutes, upon the wholesale distribution of a prescription drug to a veterinarian.

The bill permits intra-company 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 section 499.0121(6), Florida Statutes.

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 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.

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<sup>2</sup> Section 503(b) of the Federal Food, Drug, and Cosmetic Act regulates pharmaceutical drugs intended for human consumption.

<sup>3</sup> According to a survey conducted by the American Veterinary Distributors Association (AVDA), human drug sales comprise approximately 30 percent 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 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 section 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 section 499.0121, Florida Statutes, except that the permit holder is not required to comply with the pedigree paper requirements of section 499.0121(6)(f), Florida Statutes, 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 section 503(b) of the Federal Food, Drug, and Cosmetic Act, which has been returned by a veterinarian.

## New Pedigree Paper Requirements

The bill expands the options available to meet the prescription drug pedigree paper tracking requirements. The bill amends s. 499.003, F.S., to create an alternative to the pedigree paper requirements scheduled to implement July 1, 2006. The bill allows for the alternative pedigree requirements when the prescription drug is directly purchased from the manufacturer. The purchaser must provide the invoice and a certificate under oath in written or electronic form stating that:

- If the establishment is not a member of an affiliated group: "This establishment purchased the specific unit of the legend drug directly from the manufacturer;" or
- If the establishment is a member of an affiliated group: "This establishment or a member of its affiliated group purchased the specific unit of the legend drug directly from the manufacturer."

According to s. 499.0121, F.S., "affiliated groups" are composed of chain drug entities, including at least 50 retail pharmacies, warehouses, or repackagers.

## Drop Ship Provision

The bill exempts wholesalers that receive the title for a direct shipment of prescription drugs from the manufacturer to end user (hospital, doctor, or physician) or a member of an affiliated group from full pedigree paper requirements.

The purchaser of the prescription drug must obtain a shipping document from the manufacturer that contains at least:

- The name and address of the manufacturer, including the point of origin of the shipment; and the purchaser;
- The name of the prescription drug as it appears on the label;
- The quantity, dosage form, and strength of the prescription drug; and
- The date of the shipment.

The bill authorizes Department of Health to develop rules for the inventory of a permitted prescription drug wholesaler as of June 30, 2006, and the return of a prescription drug purchase prior to July 1, 2006.

## Emergency Suspension of Permit

The bill amends s. 499.0661, F.S., to authorize the Department of Health (DOH) to enter an emergency order suspending the permittee's permit. The bill requires DOH to post notice of opportunity for a hearing pursuant to ss. 120.569 and 120.57, F.S.

The bill requires DOH to publish a list of permittees on their website who DOH has issued an emergency order to or a permanent order.

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<sup>4</sup> and veterinary legend drugs<sup>5</sup> in Florida under the Florida Drug and Cosmetic Act. The Florida Drug and Cosmetic Act is codified in chapter 499, Florida Statutes.

Under section 499.012, Florida Statutes, "wholesale distributor" is defined to mean any person engaged in wholesale distribution of prescription drugs. Persons or entities that 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, Florida Statutes, 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.<sup>6</sup>

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

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<sup>4</sup> Section 499.003(25), F.S.

<sup>5</sup> Section 499.0122(1)(c), F.S.

<sup>6</sup> Section 499.003(40), F.S.

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

## CURRENT SITUATION – PEDIGREE PAPERS

The 2003 Legislature passed comprehensive reforms to the Florida Drug and Cosmetic Act to address drug fraud and diversion. The law currently provides for two implementation phases. Phase I was implemented on July 1, 2003 and is scheduled to sunset July 1, 2006. Phase II, full pedigree paper requirements, is set to be implemented July 1, 2006.

Currently there are two different record keeping requirements for prescription drugs in Florida. If a prescription drug is on the specified drug list wholesalers must follow one set of requirements, and if a prescription drug not listed on the “specified drug list” another set of requirements must be followed.

According to the Department of Health there are approximately 450 prescription drug wholesalers located in Florida and 900<sup>7</sup> out-of-state wholesalers, of which less than ten percent are one of the three large full-line wholesalers or their distribution centers, or major full-line regional wholesalers. The remainders 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, including physicians or pharmacies.

### **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.

The 2003 Legislature passed pedigree paper reforms in SB 2312. The reforms currently provide for two implementation phases. Phase I was implemented on July 1, 2003 and is scheduled to sunset July 1, 2006. Phase II is set to be implemented July 1, 2006.

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.

### Pedigree Requirements for “Specified Drugs”

The Department of Health (DOH) determines “specified drugs” by rule. DOH publishes a “specified drug list” on their website. Specified drugs are the drugs most likely to be adulterated. There are currently 34 drugs on the “specified drug list.”

There are three different regulatory options when engaged in the wholesale distribution of a specified drug. Each person who is engaged in the wholesale distribution of a specified drug must provide each

<sup>7</sup> According to the Department of Health 2003 records.

wholesale distributor, upon any sale, a written statement that :

1. If the establishment is not a member of an affiliated group: "This establishment purchased the specific unit of the specified drug directly from the manufacturer"; or
2. If the establishment is a member of an affiliated group: "This establishment or a member of my affiliated group purchased the specific unit of the specified drug directly from the manufacturer"; or
3. Before the wholesale distribution (sale of the prescription drug), a written statement, under oath, that identifies each previous sale of the specific unit of the specified drug back to the manufacturer of the specified drug, the lot number of the specific unit of the specified prescription drug, and a sales invoice number of the invoice evidencing each specific unit of the specified drug.

#### Pedigree Requirements for drugs not listed on the "Specified Drug List"

Wholesalers, who do not qualify as an "authorized distributor of record" (see below) purchasing prescription drugs not listed on the "specified drug list," must provide a pedigree paper, under oath, that traces the prescription drug back to the last authorized distributor of record (rather than back to the manufacturer of the drug).

#### "Authorized Distributor of Record"

Authorized Distributor of Record (ADR) is defined by s. 499.0121, F.S., as a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's products. An ongoing relationship exists when a wholesale distributor (including an affiliated group) meets the following requirements:

- Is listed on the manufacturer's current list of authorized distributors of record;
- Annually purchases at least 90 percent of all its prescription drugs directly from one manufacturer and has at least \$100 million in total annual prescription drug sales;
- Makes at least 12 yearly purchases from the wholesale distributor; and
- Meets Department of Health (DOH) reporting requirements.

Pursuant to s. 499.0121, F.S., DOH publishes a list of wholesale distributors that qualify as an authorized distributor of record. Currently, there are 525 wholesalers listed.<sup>8</sup> Currently, each person engaged in wholesale distribution who does not meet ADR specification must prepare and provide a pedigree paper for the distribution of a prescription drug (not listed on the "specified drug list"<sup>9</sup>) back to the last ADR (rather than back to the manufacturer of the drug). ADR wholesalers do not have to meet this provision.

#### "Affiliated Group" Designation

Affiliated groups are defined by s. 1504 of the Internal Revenue Code of 1986. According to s. 499.0121, F.S., "affiliated groups" are composed of chain drug entities, including at least 50 retail pharmacies, warehouses, or repackagers. Affiliated groups must:

- Disclose to the Department of Health (DOH) the names of all the members; and
- Agree in writing to provide records on prescription drug purchases by members of the same affiliated group not later than 48 hours after DOH requests such records, regardless of where the records are stored.

Warehouses within the affiliated group must comply with all federal and state wholesale permit requirements and must purchase, receive, hold, and distribute prescription drugs to only a retail pharmacy or warehouse within the affiliated group. Prescription drug wholesalers within an affiliated

<sup>8</sup> See Department of Health Website, <http://www.doh.state.fl.us/pharmacy/drugs/index.html>

<sup>9</sup> The specified drug list is a list of prescription drugs that are most likely to be diverted. The Department of Health places drugs that meet certain requirements on the list. There are currently 34 drugs on the specified drug list.

group are exempt from pedigree paper requirements as long as the drugs do not leave the affiliated group. The Department of Health may request all records related to purchase or acquisition of prescription drugs, and the affiliated group must make them available.

The affiliated group designation was scheduled to sunset July 1, 2006. However, the 2005 Legislature removed the sunset provision, thus during phase II of the pedigree paper reforms the affiliated group exemption will continue indefinitely.

### **Pedigree Papers Requirements**

Currently, on July 1, 2006 the special provisions for “authorized distributor of record” will phase out and all players will be required to meet the same pedigree paper requirements.

On July 1, each person who is engaged in the wholesale distribution of a prescription drug and who is not the manufacturer of that drug, must provide a pedigree paper defined in s. 499.003(31), F.S., to the person who receives the drug.

The Department of Health (DOH) is currently in final stages of the rule-development process regarding pedigree papers, including provisions for digital pedigree papers. Recently, DOH sent out a letter to all companies that currently have an active permit to distribute wholesale prescription drugs in Florida to remind them of the full implementation of pedigree papers July 1, 2006.

During the 2005 Legislative Session, the definition of pedigree paper was amended to clarify that a pedigree paper may be in either paper or electronic form.<sup>10</sup> A pedigree paper must include an invoice number, shipping document number, or other number uniquely identifying the transaction. Additionally, if the manufacturer or repackager has uniquely serialized the individual legend drug unit in a generally recognized standardized method, that identifier must also be included on the pedigree paper.

### **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.<sup>11</sup>

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.<sup>12</sup> 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

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<sup>10</sup> Section 499.003(31), Florida Statutes.

<sup>11</sup> 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.

<sup>12</sup> 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<sup>13</sup> 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. 499.003, F.S., to provide for an alternative to the full pedigree paper requirements set to implement July 1, 2006.

**Section 2.** – Amends s. 499.005, F.S., to create a pedigree paper exemption for direct shipments of prescription drugs.

**Section 3.** – Amends s. 499.006, F. S., defining a prescription drug returned by a veterinarian to a limited prescription drug veterinary wholesaler as an adulterated drug. Prescription drugs are those regulated by section 503(b) of the Federal Food, Drug, and Cosmetic Act.

**Section 4.** - Amends s. 499.01, F. S., requiring 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 chapter 465, F. S., except as provided in section 499.01(2)(d), Florida Statutes.

**Section 5.** - Amends s. 499.012, F. S., establishing 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 6.** – Amends s. 499.0121, F.S., to allow for direct shipments of prescription drugs.

**Section 7.** - Amends s. 499.01221(1)(d) F. S., deleting 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 8.** - Amends s. 499.041, F. S., requiring 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 9.** - Amends s. 499.065, F. S., requiring DOH to inspect each limited prescription drug veterinary wholesaler; permitting 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 10.** – Amends s. 499.0661, F.S., to provide for an emergency suspension of a permittee if charged with specified violations.

**Section 11.** – Amends s. 499.067, F.S., to prohibit issuance of permits under certain circumstances.

**Section 12.** – Provides an effective date of July 1, 2006.

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<sup>13</sup> According to Department of Health records from 2003.



## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

### A. FISCAL IMPACT ON STATE GOVERNMENT:

#### 1. Revenues:

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

#### 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:

None

**IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES**

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

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

On April 20, 2006, the Health & Families Council adopted one amendment and voted the bill favorably. The amendment made a number of changes to the current prescription drug pedigree paper provisions. The amendment:

- Expands the options available to meet the prescription drug pedigree paper tracking requirements;
- Provides alternative pedigree paper requirements for prescription drugs purchased directly from the manufacturer and prescription drugs shipped directly from the manufacturer to an end user;
- Authorizes DOH to revoke a permittee's permit in an emergency situation.
- Directs DOH to publish a list of current revoked permits on their website.

The analysis is drafted to the council substitute.