

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.)

BILL: CS/SB 1824

SPONSOR: Health, Aging, and Long-Term Care Committee and Senator Fasano

SUBJECT: Veterinary Prescription Drugs

DATE: March 9, 2004 REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HC	Favorable/CS
2.	_____	_____	AHS	_____
3.	_____	_____	AP	_____
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____

I. Summary:

The bill defines “veterinary prescription drug wholesaler” to mean any person engaged in wholesale distribution of veterinary prescription drugs in or into Florida. The bill creates a new permit and annual permit fee for veterinary prescription drug wholesalers.

Veterinary prescription drug wholesalers that also distribute prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act 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, and the due diligence requirements for suppliers, which under the bill are limited to wholesale drug distributors, prescription drug wholesalers, out-of-state prescription drug wholesalers, and prescription drug repackagers.

The Department of Health’s authority to inspect specified establishments under its jurisdiction is revised to include veterinary prescription drug wholesale establishments as establishments subject to inspection by the department. Such wholesalers are subject to immediate closure and their products may be immediately seized, if the department determines that an imminent danger to the public health exists.

This bill amends sections 499.003, 499.01, 499.012, 499.0121, 499.041, and 499.065, Florida Statutes.

II. Present Situation:

The Bureau of Statewide Pharmaceutical Services of the Department of Health (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 chapter 499, Florida Statutes.

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.

Specified activities that are conducted in accordance with rules established by DOH are also exempt from the definition of wholesale distribution, which include:

- The sale, purchase, or trade of a prescription drug among federal, state, or local government health care entities that are under common control and authorized to purchase such drugs;
- The sale, purchase or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug for emergency medical reasons;
- The transfer of a prescription drug acquired by the medical director on behalf of a licensed emergency medical services provider and its transport vehicles for use in accordance with the provider’s license;
- The revocation of a sale or the return of a prescription drug to the person’s prescription drug wholesale supplier;
- The donation of a prescription drug by a health care entity to a not-for-profit charitable organization that is authorized to possess prescription drugs;
- The transfer of a prescription drug by a person authorized to purchase or receive prescription drugs to a person licensed or permitted to handle reverse distributions or destruction;
- The transfer of a prescription drug by a hospital or other health care entity to a person licensed under chapter 499, F.S., to repackage prescription drugs for the purpose of repackaging the prescription drug for use by that hospital or other health care entity and other health care entities that are under common control;
- The distribution of prescription drug samples by manufacturers’ representatives or distributors’ representatives conducted in accordance with s. 499.028, F.S.;
- The sale, purchase, or trade of blood and blood components intended for transfusion; and
- The lawful dispensing of a prescription drug in accordance with chapter 465, F.S., the Florida Pharmacy Act.

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 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 wholesaler drug distributor, a wholesale drug distributor must meet due diligence requirements which include:

- Entering an agreement by which the selling wholesale drug distributor will indemnify the purchasing wholesale drug distributor for any loss caused by drugs found to be counterfeit or distributed in violation of applicable federal or state drug distribution laws;
- Determining that the selling wholesale drug distributor has insurance coverage of no less than the greater of 1 percent of the total dollar volume of prescription drug sales or \$500,000; however the coverage need not exceed \$2 million;
- Obtaining specified information from the selling wholesale drug distributor;
- Verifying that the selling wholesale drug distributor’s Florida permit is valid; and
- Inspecting the selling wholesaler drug distributor’s licensed establishment to document that it has specified policies and procedures relating to the distribution of drugs and other specified procedures before purchasing any drug from a wholesaler to ensure that records related to the wholesale distribution of prescription drugs are maintained as required by law.

Under s. 499.065, F.S., DOH, notwithstanding s. 499.051, F.S.,⁴ relating to inspections and investigations, must inspect each prescription drug wholesale establishment, prescription drug repackager establishment, and retail pharmacy drug wholesaler establishment permitted under chapter 499, F.S., as often as necessary to ensure compliance with applicable laws and rules. The department must have the right of entry and access to these facilities at any reasonable time. The department may examine, sample, seize, and stop the sale or use of prescription drugs to determine the condition of those drugs. The department may immediately seize and remove any prescription drugs if the Secretary of Health or his or her designee determines that such prescription drugs represent a threat to the public health. The owner of any property seized under this section may, within 10 days after the seizure, apply to a court of competent jurisdiction for

¹ See s. 499.012, F.S.

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

³ See s. 499.012(9) and (11), F.S.

⁴ See s. 499.051, F.S., relating to inspections, which provides that any application for a permit under the Florida Drug and Cosmetic Act and rules adopted under that Act constitutes permission for agents of the Department of Health and the Florida Department of Law Enforcement, after presenting proper identification, to inspect, review, and copy financial documents or records related to the distribution of a drug in order to determine compliance with the Florida Drug and Cosmetic Act, and rules adopted by the Department of Health to administer that Act. The authority to inspect under s. 499.051, F.S., includes the authority to access, review, and copy any and all financial documents related to the activity of manufacturing, repackaging, or distributing prescription drugs.

whatever relief is appropriate. At any time after 10 days, the department may destroy the drugs as contraband.

The department may determine that a prescription drug wholesale establishment, prescription drug repackager establishment, or retail pharmacy drug wholesaler establishment permitted under chapter 499, F.S., is an imminent danger to the public health and require its immediate closure if such establishment fails to comply with applicable laws and rules and, due to such failure, presents an imminent threat to the public health, safety or welfare.⁵ Any establishment so deemed and closed must remain closed until allowed by the department or by judicial order to reopen.⁶ A refusal to allow entry to DOH for inspection at reasonable times, or a failure or refusal to provide the department with required documentation for purposes of inspection, constitutes an imminent danger to the public health.⁷

III. Effect of Proposed Changes:

Section 1. Amends s. 499.003, F.S., to define “veterinary prescription drug wholesaler” to mean any person engaged in wholesale distribution of veterinary prescription drugs in or into Florida.

Section 2. Amends s. 499.01, F.S., relating to permits issued under part I of chapter 499, F.S., the Florida Drug and Cosmetic Act, to require each person and establishment that intends to operate as a veterinary prescription drug wholesaler to obtain a permit.

Section 3. Amends s. 499.012, F.S., to require 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 s. 503(b) of the Federal Food, Drug, and Cosmetic Act (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 subsection (6)(d), (e), or (f) of s. 499.0121, F.S.

Section 4. Amends s. 499.0121, F.S., relating to due diligence requirements for suppliers, to provide that such requirements are limited to the following: a wholesale distributor, a prescription drug wholesaler, an out-of-state prescription drug wholesaler, or a prescription drug repackager.

Section 5. Amends s. 499.041, F.S., relating to fees, to authorize DOH to assess an annual fee for a veterinary prescription drug wholesaler’s permit that is not less than \$300 or more than \$500.

Section 6. Amends s. 499.065, F.S., relating to DOH’s authority to inspect specified establishments under its jurisdiction, to include veterinary prescription drug wholesale establishments as establishments subject to inspection by the department. Such wholesalers are

⁵ See s. 499.065(3), F.S.

⁶ See s. 499.065(3), F.S.

⁷ See s. 499.065(3), F.S.

subject to immediate closure and their products may be immediately seized, if the department determines that an imminent danger to the public health exists.

Section 7. Provides an effective date of July 1, 2004.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, s. 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Article I, s. 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

Establishments that are currently permitted as prescription drug wholesalers or out-of-state prescription drug wholesalers that qualify for the veterinary prescription drug permit created under the bill will save the costs associated with providing a \$100,000 refundable bond each year, the costs of fingerprinting key individuals affiliated or associated with the veterinary prescription drug wholesale operations (\$47 per person), and will have a reduced annual permit fee that may be not less than \$300 and no more than \$500 (the application fee for prescription drug wholesalers is \$800, and for out-of-state prescription drug wholesalers is \$700).

B. Private Sector Impact:

See comments in the Tax/Fee section.

C. Government Sector Impact:

The Department of Health reports that it will have a reduction in revenues because the annual fee range for the veterinary prescription drug wholesaler permit is lower than the current fee for prescription drug wholesalers. The department estimates that about 10 companies would convert their existing permits to the veterinary prescription drug wholesaler permit and that the reduction in revenue would be minimal. The department estimates a reduction of \$2,400 in revenue annually due to the conversion to the new permit.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Amendments:

None.

This Senate staff analysis does not reflect the intent or official position of the bill's sponsor or the Florida Senate.
