

The Florida Senate
PROFESSIONAL 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: Health Regulation Committee

BILL: SB 2122

INTRODUCER: Senator Baker

SUBJECT: Veterinary Drugs/Distribution

DATE: March 25, 2007

REVISED: 03/27/07

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Munroe</u>	<u>Wilson</u>	<u>HR</u>	<u>Fav/1 amendment</u>
2.	<u></u>	<u></u>	<u>AG</u>	<u></u>
3.	<u></u>	<u></u>	<u>RI</u>	<u></u>
4.	<u></u>	<u></u>	<u></u>	<u></u>
5.	<u></u>	<u></u>	<u></u>	<u></u>
6.	<u></u>	<u></u>	<u></u>	<u></u>

Please see last section for Summary of Amendments

- Technical amendments were recommended
- Amendments were recommended
- Significant amendments were recommended

I. Summary:

The bill revises the restrictions on limited prescription drug veterinary wholesaler permit holders to allow them to sell *prescription and veterinary drugs* to a larger class of entities, which include:

- A veterinary prescription drug wholesaler,
- Another limited prescription drug veterinary wholesaler,
- Any wholesaler whose permit is substantially equivalent to a veterinary prescription drug wholesaler or limited prescription drug veterinary wholesaler, and
- A wholesaler who is authorized to engage in the wholesale distribution of prescription drugs issued by another state that does not issue a substantially equivalent permit.

The bill repeals a provision, which prohibits a limited prescription drug veterinary wholesaler permit holder from distributing human drugs for use on humans.

This bill amends section 499.012, Florida Statutes.

II. Present Situation:

The Department of Health 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 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

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.

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(1)(d), F.S., defines a “veterinary legend 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 act⁶ (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 for the pedigree paper requirements in paragraph (6)(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.

Section 499.012(2), F.S., was amended last year to create a permit for a limited prescription drug veterinary wholesaler. The limited prescription drug veterinary wholesaler 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.

Paragraph 499.012(2)(h), F.S., provides that the limited prescription drug wholesaler permit is

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.

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, 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 limited prescription drug veterinary permit holder must be engaged in the business of wholesaling prescription and veterinary legend drugs under the following conditions:

- The person is engaged in wholesaling prescription and veterinary legend drugs to persons:
 - Licensed as veterinarians practicing on a 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 permit holder 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 permit holder cannot distribute human drugs for use on humans.
- The permit holder must submit a \$20,000 bond or equivalent surety.
- The permit holder 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 permit holder must comply with s. 499.0121, F.S., storage, labeling, and recordkeeping requirements, 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 permit holder 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.

A glitch or potential conflict exists in the law establishing the requirements for limited prescription drug veterinary wholesale permits. Subparagraph 499.012(2)(h)3., F.S., prohibits a limited prescription drug veterinary wholesaler permit holder from distributing human drugs for use on humans. Subparagraph 499.012(h)5.F.S., requires a limited prescription drug veterinary wholesaler permit holder to maintain at all times a license or permit to engage in the wholesale distribution of prescription drugs in compliance with the laws of the state in which it is a resident. Only the State of Florida issues a limited prescription drug veterinary wholesaler permit, so in order for an applicant to comply with the requirements of subparagraph 499.012(h)5.F.S., the applicant must hold permit to engage in wholesale distribution of human drugs in all states in which the permit holder operates.

Under current law, a limited prescription drug veterinary wholesale permit holder may make a limited distribution of human prescription drugs to veterinarians, research and teaching facilities, and law enforcement. The current law restricts such permit holders to companies that do not sell human drugs to pharmacies, hospitals, or other persons in order to keep the human distribution supply chain separate. The Department of Health does not issue the limited prescription drug wholesaler permit to any company that is located outside of Florida. The Department of Health does not issue wholesale drug distribution permits to companies in Florida that have facilities, which are licensed as prescription drug wholesalers in other states.

III. Effect of Proposed Changes:

The bill amends paragraph 499.012(2)(h), F.S., to revise the restrictions on limited prescription drug veterinary wholesaler permit holders to allow them to sell *prescription and veterinary drugs* to a larger class of entities, which include:

- A veterinary prescription drug wholesaler,
- Another limited prescription drug veterinary wholesaler,
- Any wholesaler whose permit is substantially equivalent to a veterinary prescription drug wholesaler or limited prescription drug veterinary wholesaler, and
- A wholesaler who is authorized to engage in the wholesale distribution of prescription drugs issued by another state that does not issue a substantially equivalent permit.

The bill repeals subparagraph 499.012(2)(h)3., F.S., which prohibits a limited prescription drug veterinary wholesaler permit holder from distributing human drugs for use on humans.

The bill provides an effective date upon becoming a law.

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, Section 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, Section 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.

D. Other Constitutional Issues:

To implement the bill, the Department of Health would be required to determine what constitutes a “substantially equivalent authorization, permit, or license issued by another state” for a limited prescription drug veterinary wholesaler permit.

It is unclear what standards and procedures the Department of Health will establish for determining what constitutes a “substantially equivalent authorization, permit, or license issued by another state” for a limited prescription drug veterinary wholesaler permit. To the extent that the bill does not provide sufficient guidelines to the Department of Health, it raises the question of whether the bill provides adequate limitations and safeguards so that the Legislature’s delegation to DOH is not a violation of Section 3, Article II of the Florida Constitution. The department would be authorized to substitute its judgment for that of the Legislature.

Under the nondelegation doctrine, the Florida Supreme Court struck down a former section of law respecting the power of the Board of Psychological Examiners to grant certificates with the title “psychologist” and to determine the qualifications of applicants as unconstitutional in that it failed sufficiently to fix the standards to be applied and in effect delegated the application of the statute without sufficient limitations on the board’s discretion.⁷

Section 3, Article II of the Florida Constitution provides that the powers of the state government shall be divided into legislative, executive, and judicial branches. No person belonging to one branch shall exercise any powers appertaining to either of the other branches unless expressly provided herein. The Florida Supreme Court recently reiterated the requirements of the nondelegation doctrine:

“[U]nder article II, section 3 of the constitution the Legislature ‘may not delegate the power to enact a law or the right to exercise unrestricted discretion in applying the law.’⁸ This prohibition, known as the nondelegation doctrine, requires that ‘fundamental and primary policy decisions . . . be made by members of the [L]egislature who are elected to perform those tasks, and [that the] administration of legislative programs must be pursuant to some minimal standards and guidelines ascertainable by reference to the enactment establishing the program.’⁹

The Florida Supreme Court has acknowledged that “[w]here the Legislature makes the fundamental policy decision and delegates to some other body the task of implementing that policy under adequate safeguards, there is no violation of the [Delegation of Powers] doctrine.”¹⁰ “In other words, statutes granting power to the executive branch ‘must clearly announce adequate standards to guide . . . in the execution of the powers delegated. The statute must so clearly define the power delegated that the [executive branch] is precluded from acting from whim, showing favoritism, or exercising unbridled discretion.’¹¹

⁷ See *Husband v. Cassel*, 130 So.2d 69 (1961).

⁸ See *Bush v. Schiavo*, 885 So.2d 321 at 331 citing *Sims v. State*, 754 So.2d 657, 668 (Fla.2000).

⁹ See *Bush v. Schiavo*, 885 So.2d 321 at 331 citing *Askew v. Cross Key Waterways*, 372 So.2d 913, 925 (Fla.1978).

¹⁰ See *Askew v. Cross Key Waterways*, 372 So.2d 913 at 921. (Fla.1978).

¹¹ See *Bush v. Schiavo*, 885 So.2d 321 at 331 citing *Lewis v. Bank of Pasco County*, 346 So.2d 53, 55-56 (Fla.1976).

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:

Florida regulates the distribution of human prescription drugs to prevent the introduction of adulterated or counterfeit drugs into the prescription drug supply chain. The Department of Health has indicated that the bill would revise the existing restrictions on limited prescription veterinary wholesale permit holders, which prevent their ability to sell drugs for human use. The department asserts that the lifting of existing restrictions would permit the drugs for human use, which are distributed by limited prescription veterinary wholesale permit holders to be integrated back into the human distribution supply chain.

VIII. Summary of Amendments:

Barcode 834570 by Health Regulation:

Narrows the class of entities to which a limited prescription drug veterinary wholesaler may sell prescription and veterinary drugs. Provides that a more stringent authorization, permit, or license is an authorization, permit, or license to distribute prescription drugs as defined by federal law to any person who is authorized to sell, distribute, purchase, trade, or use those drugs on or for humans.

This Senate Professional Staff Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.
