

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Health Regulation Committee

BILL: SB 1006

INTRODUCER: Senator Latvala

SUBJECT: Prescription Drug Wholesale Regulations

DATE: February 3, 2012

REVISED: 02/17/12

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Wilson	Stovall	HR	Pre-meeting
2.			CM	
3.			BC	
4.				
5.				
6.				

I. Summary:

The bill establishes a permit by endorsement for out-of-state prescription drug wholesale distributors that satisfy the requirements of chapter 499, Florida Statutes, and hold a valid drug wholesale distributor license or permit from another state.

This bill substantially amends section 499.01 of the Florida Statutes.

II. Present Situation:

Part I of ch. 499, F.S., is the Florida Drug and Cosmetic Act (the Act). One purpose of the Act is to safeguard the public health and promote the public welfare by protecting the public from injury by product use and by merchandising deceit involving drugs, devices, and cosmetics. Another purpose of the Act is to promote uniformity between state and federal laws and their administration and enforcement, throughout the United States.

Section 499.01, F.S., requires a variety of manufacturers, distributors, and other business entities involved in the preparation, manufacture, repackaging, or distribution of drugs, devices, and cosmetics to obtain a permit prior to operating. One of the permits is for out-of-state prescription drug wholesale distributors which engage in the wholesale distribution of prescription drugs into Florida. An out-of-state prescription drug wholesale distributor must be permitted by the Department of Business and Professional Regulation (department or DBPR) and comply with all the provisions required of a wholesale distributor by the Act. An out-of-state prescription drug wholesale distributor must submit a bond of \$100,000 or other equivalent means of security.

Section 499.012(8), F.S., sets forth the application requirements for an out-of-state prescription drug wholesale distributor. Generally, the applicant must identify the business (name and trade names, address, and telephone number); and provide information about the ownership, operations and affiliated groups,¹ including the name and address of each shareholder of a corporation that owns 5 percent or more of the corporation; a background statement and fingerprint card for affiliated persons;² the estimated or actual annual dollar volume of certain activities pertaining to prescription drugs by the applicant; a copy of the deed or lease for the business property; a list of all licenses and permits issued to the applicant by any other state which authorize the applicant to purchase or possess prescription drugs; and documentation of the credentialing policies and procedures for customers if the applicant intends to sell Schedule II or Schedule III controlled substances to physicians in Florida.³

In 2003, the Legislature enacted the Prescription Drug Protection Act.⁴ This legislation was predicated on the findings and recommendations of the report of the Seventeenth Statewide Grand Jury in its First Interim Report to the Legislature.⁵ That grand jury was called to examine, among other matters, the safety of prescription drugs in Florida. In particular, they examined the situation concerning the sale and re-sale of prescription drugs in the wholesale market. Prior to enactment of this legislation, the Act included a provision for licensure by reciprocity. However, the following language was removed in the Prescription Drug Protection Act:⁶

The department may adopt rules that allow out-of-state drug wholesalers to obtain a drug wholesale permit on the basis of reciprocity to the extent that an out-of-state drug wholesaler:

- a. Possesses a valid permit granted by another state that has requirements comparable to those that a drug wholesaler in this state must meet as prerequisites to obtaining a permit under the laws of this state.
- b. Can show that the other state from which the wholesaler holds a permit would extend reciprocal treatment under its own laws to a drug wholesaler of this state.

Effective October 1, 2011, all of the statutory powers, duties, and functions, records, personnel, property, and unexpended balances of appropriations, allocations, or other funds for the administration of ch. 499, F.S., relating to drugs, devices, cosmetics, and household products were transferred from the Department of Health to the DBPR.⁷

¹ “Affiliated group” is defined in s. 499.003(2), F.S., to mean an affiliated group as defined by s. 1504 of the Internal Revenue Code of 1986, as amended, which is composed of chain drug entities, including at least 50 retail pharmacies, warehouses, or repackagers, which are members of the same affiliated group. The affiliated group must disclose the names of all its members to the department.

² “Affiliated party” is defined in s. 499.003(3), F.S. In summary, it means a director, officer, trustee, partner, or committee member or a subsidiary or service corporation of the permittee or applicant; a person who, directly or indirectly, manages, controls, or oversees the operation of a permittee or applicant; and the five largest natural shareholders that own at least 5 percent of the permittee or applicant.

³ The specific application requirement is for documentation of the credentialing policies and procedures requirements by s. 499.0121(14), F.S., however, that subsection addresses reporting requirements. Subsection (15) addresses credentialing requirements for physician-customers for certain controlled substances.

⁴ See ch. 2003-155, L.O.F.

⁵ The report is available at: <<http://myfloridalegal.com/pages.nsf/Main/09558F82389E020785256CDA006DB01A>> (Last visited on February 6, 2012).

⁶ See s. 13, ch. 2003-155, L.O.F.

⁷ See s. 27, ch. 2010-161, L.O.F.

Licensure by Endorsement

Licensure by endorsement is usually a streamlined application process that is available to individuals or organizations that are licensed in another state that has significantly comparable licensing requirements to the state in which the licensure applicant wishes to be licensed. Typically, licensure by endorsement means that a licensure applicant is eligible for a license without any additional schooling or examination.

III. Effect of Proposed Changes:

The bill amends s. 499.01, F.S., to require the DBPR to issue an out-of-state permit by endorsement to an applicant who, upon applying to the department and remitting a filing fee, set by the board, demonstrates to the board that the applicant satisfies the requirements of the Act and holds a valid drug wholesale distributor license or permit from another state. The bill authorizes an out-of-state prescription drug wholesale distributor that holds a valid permit under the Act on July 1, 2012, to continue to operate under that permit until its expiration, at which time the distributor may apply for a permit by endorsement.

Currently, prescription drug wholesaler distributors that are located outside of the State of Florida, but that are distributing prescription drugs into Florida, have to be permitted as an out-of-state prescription drug wholesale distributor. In order to be permitted, the applicant must demonstrate that the applicant:

- Has a license or permit to engage in wholesale distribution in the applicant's state of residence; and
- Complies with all the provisions required of a wholesale distributor under the Act.

The bill does not change any of the current permitting requirements for an out-of-state prescription drug wholesale distributor.

The effective date of the bill is July 1, 2012.

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 the 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.

V. Fiscal Impact Statement:**A. Tax/Fee Issues:**

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

The DBPR indicates that some modifications to information systems will be required, but the modifications can be made with existing resources.

VI. Technical Deficiencies:

On line 4, the bill refers to the Department of Health. Responsibility for ch. 499, F.S., has been transferred from the Department of Health to the DBPR.

On line 47, the bill refers to “the board” as the entity responsible for setting the filing fee and ultimately approving the application for a permit. There is no board with any authority over ch. 499, F.S. The DBPR, not a board, has the regulatory authority over these permits.

VII. Related Issues:

The bill does not address whether the DBPR is to inspect out-of-state prescription drug wholesale distributor permittees by endorsement.

VIII. Additional Information:**A. Committee Substitute – Statement of Substantial Changes:**

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.