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 Appropriations Subcommittee on General Government

BILL:	PCS/CS/SB 1604 (141410)
INTRODUCER:	Appropriations Subcommittee on General Government; Health Policy Committee; and Senator Grimsley
SUBJECT:	Drugs, Devices, and Cosmetics
DATE:	February 15, 2016
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Stovall	HP	**Fav/CS**
2.	Davis	DeLoach	AGG	**Recommend: Fav/CS**
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

PCS/CS/SB 1604 updates the Florida Drug and Cosmetic Act (Act) to bring it into conformity with the federal Food, Drug and Cosmetic Act (federal act). Recent amendments to the federal act preempted Florida's regulatory structure. The bill replaces provisions relating to pedigree papers with federal requirements for a transaction history, transaction information, or transaction statement for certain recordkeeping for the manufacture and distribution of prescription drugs. Certain activities are exempted from the definition of wholesale distribution in order to conform regulatory oversight in Florida to the federal regulatory scheme.

The bill provides for administrative efficiencies and cost savings for:

- Initial and renewal permitting for prescription drug wholesale distributors and out-of-state prescription drug wholesale distributors by eliminating the distinction between primary and secondary wholesalers and the supplemental information required of a secondary wholesaler for permitting;
- Allowing certain key personnel to submit an affidavit that information submitted on a previous personal statement remains unchanged;
- Modifying the requirement for a surety bond; and
- Authorizing the Department of Business and Professional Regulation (DBPR) to contract with a vendor or enter into interagency agreements for electronic fingerprinting.

The bill establishes a nonresident prescription drug repackager permit, along with the requirement to obtain such a permit if a repackager located outside the state distributes its repackaged prescription drugs into the state. This repackager is also required to comply with provisions applicable to prescription drug manufacturers. The DBPR must establish a virtual prescription drug manufacturer permit and a virtual out-of-state prescription drug manufacturer permit for manufacturers that do not physically manufacture and possess their prescription drugs.

The DBPR is also authorized to issue non-disciplinary citations for violations of the Act for which there is no substantial threat to the public health, safety, or welfare.

The bill has an indeterminate, but most likely insignificant, fiscal impact on state funds.

This bill is effective July 1, 2016.

II. Present Situation:

The Florida Drug and Cosmetic Act (Act) is found in ch. 499, F.S. The 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. The DBPR is responsible for regulating and enforcing the Act and is specifically charged with administering and enforcing the Act to prevent fraud, adulteration, misbranding, or false advertising in the preparation, manufacture, repackaging, or distribution of drugs, devices, and cosmetics.[1]

In 2003, the Legislature enacted the Prescription Drug Protection Act,[2] which put in place strong safeguards for the distribution of prescription drugs in, into, and from this state. 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.[3] 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.

The Prescription Drug Protection Act required prescription drug wholesalers to provide pedigree papers (a transaction history for tracing a prescription drug through the market) for the wholesale distribution of prescription drugs, strengthened permitting requirements for prescription drug wholesale distributors, especially for wholesale distributors that did not purchase directly from drug manufacturers (referred to as secondary wholesalers), and established significant criminal penalties for prescription drug violations related to counterfeiting and diversion.

In 2013, the Drug Quality and Security Act (DQSA) amended the federal act. The DQSA established a uniform national policy for product tracing and other requirements relating to the prescription drug supply chain. The DQSA expressly preempted states from establishing or continuing in effect any requirements for tracing products through the distribution system which are inconsistent with, more stringent than, or in addition to, any requirement applicable under DQSA. The preemption also included prohibiting states from establishing or continuing any standards, requirements, or regulations with respect to wholesale prescription drug distributor or

[1] *See* s 499.002, F.S.
[2] *See* ch. 2003-155, L.O.F.
[3] The report is available at: http://myfloridalegal.com/grandjury17.pdf (last visited Jan. 24, 2016).

third-party logistics provider licensure that are inconsistent with, less stringent than, directly related to, or covered by the standards and requirements of the DQSA.[4]

III. Effect of Proposed Changes:

Section 1 amends s. 499.003, F.S., to revise definitions to conform to the changes made to the Florida Drug and Cosmetic Act in this bill. New definitions are provided for: "active pharmaceutical ingredient"[5] and "affiliate." The following definitions are repealed: "affiliated group," "authenticate," "drop shipment," "normal distribution chain," "pedigree paper," "primary wholesale distributor," and "secondary wholesale distributor." The following definitions are substantially revised:

- "Distribute" means to sell, purchase, trade, deliver, handle, store, or receive. The term does not mean to administer or dispense. Deleted from the definition is the concept of offering to perform any of these activities and the method of distribution, i.e., by passage of title, physical movement, or both. The exemption for billing and invoicing activities is also deleted from the definition, but is addressed as an exception to the definition of wholesale distribution.
- "Manufacturer" is reworded to more accurately describe co-licensed partners and private label distributors. Third party logistics (TPL) providers are deleted from the definition.
- "Wholesale distribution" is clarified that the term includes both the distribution to a person and the receipt by a person, of a prescription drug, other than the consumer or patient. The exceptions to wholesale distribution are expanded and revised. Drug shortages not caused by a public health emergency are not deemed an emergency medical reason for the distribution of a prescription drug by a retail pharmacy. This provision is found in rule, but is now specifically addressed in statute. New exclusions from the definition of wholesale distribution include:
  - Intracompany distribution between members of an affiliate or within a manufacturer;
  - Distribution of a prescription drug by the manufacturer of that prescription drug;
  - Distribution of a prescription drug by a TPL provider in accordance with state and federal law if the TPL provider does not own the drug;
  - Distribution of, or offer to distribute, a prescription drug by an repackager that is registered under the federal act that owned or possessed the drug and which repackaged it;
  - The purchase or other acquisition by a dispenser, hospital, or other health care entity for use by that dispenser, hospital, or other health care entity;
  - Distribution of a prescription drug for the purpose of repacking the drug owned by a hospital for the hospital's use or other health care entity that is under common control with the hospital;
  - Distribution of minimal quantities of prescription drugs by a retail pharmacy to a licensed practitioner for office use in compliance with the Florida Pharmacy Act and its rules;
  - Distribution of an intravenous prescription drug that is intended for replenishment of fluids and electrolytes, or to maintain the equilibrium of water and minerals in the body;
  - Distribution of a prescription drug that is intended for irrigation or sterile water;
  - Distribution of exempt medical convenience kits;

[4] *See* sec. 585 of the Food, Drug, and Cosmetic Act.
[5] The definition of "active pharmaceutical ingredient" is moved from within the definition of "drug."

  - Transport by a common carrier if it does not own the prescription drug;
  - Saleable returns when conducted by a dispenser;
  - Facilitating the distribution of a prescription drug by providing solely administrative services;
  - Distribution of a specially-priced or donated prescription drug by a charitable organization to a licensed health care practitioner, health care clinic permitted pursuant to the Act, or to the Department of Health (DOH) or other governmental health care entity for providing emergency medical services, if the distributor and recipient receive no direct or indirect financial benefit other than tax benefits for charitable contributions; and
  - Distribution of a medical gas in compliance with part III of the Act.
- "Wholesale distributor" means a person other than a manufacturer, a manufacturer's co-licensed partner, a TPL provider, or a repackager, who is engaged in wholesale distribution.

Sections 2, 3, 4, and 20 amend s. 499.005, F.S., relating to prohibited acts; s. 499.0051, F.S., relating to criminal acts; s. 499.006, F.S., relating to adulterated drug or device; and s. 921.0022, F.S., relating to the criminal punishment code. The bill removes references to Florida's pedigree requirements throughout chapter 499, F.S. In addition, the bill replaces the references to "pedigree papers" with references to "transaction history", "transaction information", or "transaction statement" to conform to federal requirements, the federal pre-emption of individual state regulation pertaining to certain recordkeeping for the manufacture and distribution of prescription drugs, and changes made by this bill.

Section 5 amends s. 499.01, F.S., relating to permits to:
- Add a nonresident prescription drug repackager permit. This permit is required for any person located outside Florida but within the United States or its territories that repackages prescription drugs and distributes them into Florida. This permittee is required to comply with all provisions and rules that are applicable to prescription drug manufacturers and must be registered as a drug establishment with the federal Food and Drug Administration (FDA).
- Require the DBPR to adopt rules for issuing a virtual prescription drug manufacturer permit and virtual nonresident prescription drug manufacturer permit to a person that manufactures prescription drugs but does not make or take physical possession of any prescription drugs, for example when a contract manufacturer is used. Because these manufacturers do not possess prescription drugs, the DBPR is authorized to exempt them by rule from certain establishment, security, and storage requirements.
- Delete the $100,000 security bond requirement for prescription drug wholesalers and out-of-state prescription drug wholesaler; however a similar, less costly requirement is added to s. 499.012, F.S.
- Require an out-of-state prescription drug wholesaler, a TPL provider, or a nonresident prescription drug manufacturer distributing prescription drug active pharmaceutical ingredients into the state for the manufacture of an approved drug or biologic, which is not licensed by its resident state, to be licensed or registered under the federal act and for the recipient in Florida to maintain documentation of the supplier's compliance.
- Conform requirements of various permits to the repeal of the pedigree paper requirements.
- Remove the restriction that the exemption from permitting for a nonresident prescription drug manufacturer to distribute prescription drug active pharmaceutical ingredients for research is applicable only if the distributions are in limited quantities, require that the label

of a prescription drug active pharmaceutical ingredient bear specific caution statement terminology, and require that a prescription drug manufacturer that obtains an active pharmaceutical ingredient from an exempt manufacturer maintain certain records detailing the specific clinical trials or biostudies for which the ingredient was obtained.

- Exempt a restricted prescription drug distributor that repackages and distributes a prescription drug to a not-for-profit rural hospital from compliance with current state and federal current good manufacturing practices relating to repackaging. Alternate provisions are made for the labeling of those prescription drugs.

Section 6 amends s. 499.012, F.S., relating to permit application requirements to:

- Clarify that a prescription drug manufacturer permit may be issued to the same address as a licensed nuclear pharmacy, even if the nuclear pharmacy holds a special sterile compounding permit under the Florida Pharmacy Act.
- Authorize the Department of Business and Professional Regulation (DBPR) to issue a retail pharmacy drug wholesale distributor permit to the address of a community pharmacy, even if the community pharmacy holds a special sterile compounding permit, as long as the community pharmacy is not a closed pharmacy.
- Provide that applications pending resolution of a deficiency after two years from the time the DBPR notified the applicant of the deficiency automatically expire.
- Require the DBPR to maintain trade secret information submitted in an application as trade secret.
- Authorize the issuance of four-year permits on selected permit types identified in rule.
- Authorize the DBPR to send a permit renewal notification at least 90 days before the expiration date of all permits which conspicuously notes the expiration date of the permit and that the establishment may not operate unless the permit is renewed timely. The renewal notification will eliminate the costs associated with sending the renewal application.
- For a prescription drug wholesale distributor or out-of-state prescription drug wholesale distributor permit:
    - Require a $100 delinquent fee for a renewal application that is submitted later than 45 days prior to the permit's expiration date.
    - Substitute submission of the applicant's gross annual receipts attributable to prescription drug wholesale distribution activities for the previous tax year in lieu of more extensive information pertaining to prescription drug sales during certain intermediate timeframes and annually, purchases directly from manufacturers for renewal permits, and estimated information for new applicants.
    - Allow a surety bond issued in this state or any other state or other equivalent security such as an irrevocable letter of credit, or a deposit in a trust account or financial institution, which includes the state as a beneficiary, to satisfy the bond requirement. The amount of the surety bond is tiered based on the applicant's annual gross receipts. A bond of $100,000 is applicable if the annual gross receipts of the applicant's previous tax year is over $10 million, or $25,000 if the annual gross receipts is $10 million or less.
    - Repeal the additional information required to be submitted by secondary wholesalers (wholesalers that did not purchase directly from manufacturers) since the concept of primary wholesale distributor and secondary wholesale distributor is eliminated in this bill.

- Require proof of establishment inspection by the DBPR, the FDA, or another governmental entity. The DBPR may recognize the inspection conducted by another state if that state's laws are substantially equivalent to the laws in Florida.
- Authorize the DBPR to contract with a vendor or enter into interagency agreements to handle electronic fingerprinting.
- Streamline the renewal requirements for the submission of a personal information statement for certain key individuals by allowing submission of a certification under oath that the most recently submitted statement submitted to the DBPR remains unchanged.

Section 7 amends s. 499.01201, F.S., to make conforming changes by removing obsolete references to the pedigree statutes in ch. 499, F.S.

Section 8 amends s. 499.0121, F.S., relating to the storage and handling of prescription drugs to conform changes associated with the repeal of the pedigree paper requirements and to include standards for active pharmaceutical ingredients that apply to other prescription drugs. This section is also amended to increase the number of unit doses, from 5,000 to 7,500 unit doses, of any one controlled substance that may be ordered during a one-month period before triggering an assessment by the wholesaler as to whether the purchase of that controlled substance is reasonable.

Section 9 amends s. 499.015, F.S., relating to registration of drugs, devices, and cosmetics to synchronize the expiration date of product registrations with the expiration date of the applicable manufacturing or repacking permit.

Section 13 amends s. 499.066, F.S., relating to penalties, to authorize the DBPR to adopt rules identifying low-risk violations of the act and applicable penalties, including monetary assessments and other remedial measures, for which a non-disciplinary citation may be issued. The person to whom a citation is issued may choose, in lieu of accepting the citation, to have the matter investigated more fully and processed according to the full procedures for violations of the Act in which discipline may be imposed. The low-risk violation are ones for which there is no substantial threat to the public health, safety, or welfare.

Section 14 amends s. 499.82, F.S., relating to definitions under ch. 499, Part III, F.S., (medical gas). Specifically, s. 499.82, F.S., amends the definition of "wholesale distribution" to clarify that the exceptions to wholesale distribution listed in the federal act – including the distribution of medical gases – are not included in the exemptions to wholesale distribution in Florida as that term relates to medical gases.

Sections 10, 11, 12, 15, 17, 18 and 19 amend s. 499.03, F.S., relating to possession of prescription drugs, s. 499.05, F.S., relating to rules, s. 499.051, F.S., relating to inspections and investigations, s. 499.89, F.S., relating to recordkeeping, s. 409.9201, F.S., relating to Medicaid fraud, s. 499.067, F.S., relating to denial, suspension or revocation of permit, certification, or registration, and s. 794.075, F.S., relating to sexual predators, respectively, to conform these sections of law to changes made in the bill.

Section 16 repeals s. 499.01212, relating to pedigree papers.

Section 21 provides that the effective date of the act is July 1, 2016.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

PCS/CS/SB 1604 updates and conforms the regulations for the distribution of prescription drugs in or into this state and eliminates potential ambiguity between Florida's requirements and a uniform national approach. This uniformity should generate savings by regulated persons. Other changes to permit application submission requirements may streamline initial and renewal administrative paperwork, resulting in efficiencies in time and costs. Anecdotal information received from multiple wholesale distributors suggests that the annual submission of the renewal application consumes approximately 40 hours.

Cost savings associated with the reduction of information that is required to be provided in distributor permit applications and renewals could result in an estimated annual savings of $225,379 to the industry each year and an estimated saving of $1,105 per year per permittee.[6]

Allowing a surety bond that was obtained for licensure in another state to satisfy Florida's requirement for a surety bond for prescription drug wholesale distributors and out-of-state wholesale distributors will generate a cost saving of $100,000 per qualifying permit. The tiered surety bond requirement may also help small businesses.

C. Government Sector Impact:

The bill provides for administrative efficiencies for the Department of Business and Professional Regulations (DBPR) in the regulation and enforcement of the Act which will

[6] *See* DBPR, *Senate Bill 1604 Analysis*, p. 13, (on file with the Senate Committee on Health Policy).

generate cost savings. The DBPR will annually save $579 in postage from changes to the process for renewal of permits.[7] The DBPR will incur costs for technology changes in order to implement this Act; however, these costs can be absorbed within existing resources.

The bill amends ch. 499, F.S., to bring the statutes into conformity with the federal act, which has three permits not in current Florida law: nonresident repackager, virtual prescription drug manufacturer, and nonresident virtual prescription drug manufacturer. The entities that fall into these three new permits are already issued another type of permit by the DBPR. Under the bill, these permittees will be reclassified into the new permits and will not be charged a second time for the current permits. There will be no increased costs to the industry or increase in revenue to the DBPR.[8] These three new permits will impose an initial registration fee of $1,500 and a biennial registration fee of $1,500.[9] The current biennial fees for the virtual prescription drug manufacturer and the nonresident prescription drug manufacturer are $1,500; therefore, the cost will remain the same for these entities. The current biennial fee for the nonresident repackager is $1,600, as these entities are currently permitted as an out-of-state prescription drug wholesale distributor. The $100 difference in this fee is negligible, as the DBPR does not believe that there is a significant number of entities to whom this would apply.[10]

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill exempts the distribution of minimal quantities of prescription drugs by a retail pharmacy for office use in compliance with the Florida Pharmacy Act and its rules from the definition of wholesale distribution. However, the requirement for a retail pharmacy drug wholesale distributor permit is still required in s. 499.01(2)(g), F.S., for a retail pharmacy that engages in the wholesale distribution of prescription drugs to practitioners of up to 30 percent of the pharmacy's total annual prescription drug purchases. It is not apparent how these two sections of law are intended to co-exist and additional legislative direction may be warranted.

Lines 1580-1589 exempt a restricted prescription drug distributor that repackages and distributes a prescription drug to a not-for-profit rural hospital from compliance with *all* current state and federal current good manufacturing practices relating to repackaging. This may be overly broad and might create unreasonable risks for persons receiving those drugs in the rural hospital. Also, this provision may be read as exempting compliance with current good manufacturing practices for all repacked and distributed prescription drugs to all health care entities if at least one of the recipients is a rural hospital.

[7] *Id*.
[8] *Id.*
[9] *Id*.
[10] *Id*.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 499.003, 499.005, 499.0051, 499.006, 499.01, 499.012, 499.01201, 499.0121, 499.015, 499.03, 499.05, 499.051, 499.066, 499.82, 499.89, 409.9201, 499.067, 794.075, and 921.0022.

This bill repeals section 499.01212 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

Recommended CS/CS by Appropriations Subcommittee on General Government on February 11, 2016:
The CS:

- Increases the number of unit doses, from 5,000 to 7,500 unit doses, of any one controlled substance that may be ordered during a one-month period before triggering an assessment by the wholesaler as to whether the purchase of that controlled substance is reasonable; and
- Specifies the equivalent security provided in lieu of a surety bond must include the State of Florida as a beneficiary, payable to the Professional Regulation Trust Fund within the DBPR.

CS by Health Policy on January 26, 2016:.
The CS corrects a reference to a prescription drug manufacturer distributing their prescription drugs as opposed to engaging in the wholesale distribution of those drugs to comport with the federal act. The CS also reinstates the mandatory registration of cosmetic products manufactured in this state.

B. Amendments:

None.