# HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** CS/HB 1211 Drugs, Devices, and Cosmetics
**SPONSOR(S):** Health Quality Subcommittee; Plakon
**TIED BILLS:** **IDEN./SIM. BILLS:** SB 1604

| REFERENCE | ACTION | ANALYST | STAFF DIRECTOR or BUDGET/POLICY CHIEF |
|---|---|---|---|
| 1) Health Quality Subcommittee | 13 Y, 0 N, As CS | Langston | O'Callaghan |
| 2) Government Operations Appropriations Subcommittee | | | |
| 3) Health & Human Services Committee | | | |

## SUMMARY ANALYSIS


The U.S. Food and Drug Administration (FDA) regulates the manufacture of prescription drugs, which typically includes making drugs (preparation, deriving, compounding, propagation, processing, producing, or fabrication) on a large scale for marketing and distribution of the product for unidentified patients. Generally, state boards of pharmacy continue to have primary responsibility for oversight and regulation of the practice of pharmacy, however, the FDA regulates, and in some cases preempts state action, through the Drug Quality and Security Act (DQSA) and federal Food, Drug, and Cosmetic Act (FDCA). The DQSA created a national uniform standard with preemption of state pedigree laws that previously existed in 29 states, including Florida. In lieu of conflicting pedigree requirements from state to state, the DQSA creates an interoperable, electronic system for the tracing of drugs at the package level as they are distributed in the United States.

Part I of ch. 499, F.S., requires the Department of Business and Professional Regulation (DBPR) to regulate drugs, devices, and cosmetics. These regulations oversee various entities in the distribution chain, such as prescription drug manufacturers and prescription drug wholesale distributors, and relate to the distribution of prescription drugs into and within Florida. Additionally, from 2003 until preempted by the DQSA in 2013, Florida law required each person who was engaged in the wholesale distribution of prescription drugs to provide a pedigree paper that detailed the transaction history for tracing each prescription drug through the market.

A wholesale distributor must take reasonable measures to identify its customers, understand the normal and expected transactions conducted by those customers, and identify those transactions that are suspicious in nature. Current law requires a wholesale distributor to assess orders for greater than 5,000 unit doses of any one controlled substance in any one month to determine whether the purchase is reasonable or suspicious.

CS/HB 1211 amends several provisions of ch. 499, F.S., to bring it into conformity with the DQSA. The bill substantially revises the definition section of s. 499.003, F.S., to incorporate definitions of terms from the DQSA, delete terms made obsolete by the DQSA, and address the removal of federally preempted portions of ch. 499, F.S.

The bill eases the initial application and renewal requirements for wholesale distributor permits by reducing the information required to be provided those documents. Additionally, the bill clarifies which entities are required to be permitted as wholesale distributors and revises the current bond requirement for wholesale distributors. The bill establishes a nonresident prescription drug repackager permit for those entities that repackage prescription drugs outside of Florida and distribute those prescription drugs into Florida. The bill also establishes a virtual prescription drug repackager permit and a virtual nonresident prescription drug manufacturer permit. With respect to cosmetic product registration and cosmetic manufacturer permits, the bill aligns the expiration date of the registration of products with the expiration date of the manufacturer's permit.

The bill increases the number of unit doses, from 5,000 to 7,500 unit doses, of a 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.

The bill authorizes DBPR to adopt rules to issue remedial, non-disciplinary citations to entities for certain alleged violations of the provisions of ch. 499, F.S.

The bill has an indeterminate, possibly positive, fiscal impact on the Department of Business and Professional Regulation and no fiscal impact on local governments.

The bill provides an effective date of July 1, 2016.

## FULL ANALYSIS

## I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

**Present Situation**

The Pharmaceutical Supply Chain

The drug that a patient gets from the pharmacy changes hands many times between when it was manufactured and when the pharmacist dispenses it to the patient; during that time, there are potential opportunities for the drug to be mishandled, diverted, or substituted with a counterfeit.[1] The pharmaceutical supply chain begins with the ingredients a manufacturer uses to make a drug, carries through the manufacturing process, and continues through the distribution system of wholesalers, warehouses, and transportation to the dispensing retail and institutional pharmacies, to the patient receiving the drug.[2]

In April 2013, the Director of the U.S. Food and Drug Administration's (FDA) Center for Drug Evaluation and Research described the pharmaceutical supply chain as follows:

> [T]he increasingly complex drug supply chain, from raw source materials to finished products for consumers, presents multiple opportunities for the product to be contaminated, diverted, or otherwise adulterated. Our efforts to secure the supply chain include minimizing risks that arise anywhere along the supply chain continuum, from sourcing a product's ingredients through the overseeing of a product's manufacture, storage, transit, sale, and distribution. A breach at any point in this continuum could lead to dangerous and even deadly outcomes for patients.[3]

*Participants in the Pharmaceutical Supply Chain*

A manufacturer produces the drug product and is usually the entity that submits the application to the FDA for approval to market the product or that holds the approval. A wholesale distributor receives the drug from the manufacturer and sells the drug to "persons other than a consumer or patient."[4] Generally, there are three types of wholesale distributors:

- A primary wholesale distributor obtains the drug products directly from the manufacturer and sells them to other wholesalers or dispensers.[5]
- An authorized distributor of record (ADR) is a wholesale distributor that has a relationship with a manufacturer that is ongoing, defined in regulations as including a written agreement specifying which products it will distribute and for which time period.[6]
- A secondary wholesale distributor is a wholesale distributor that acquires drug products from a wholesale distributor, not directly from the manufacturer.[7]

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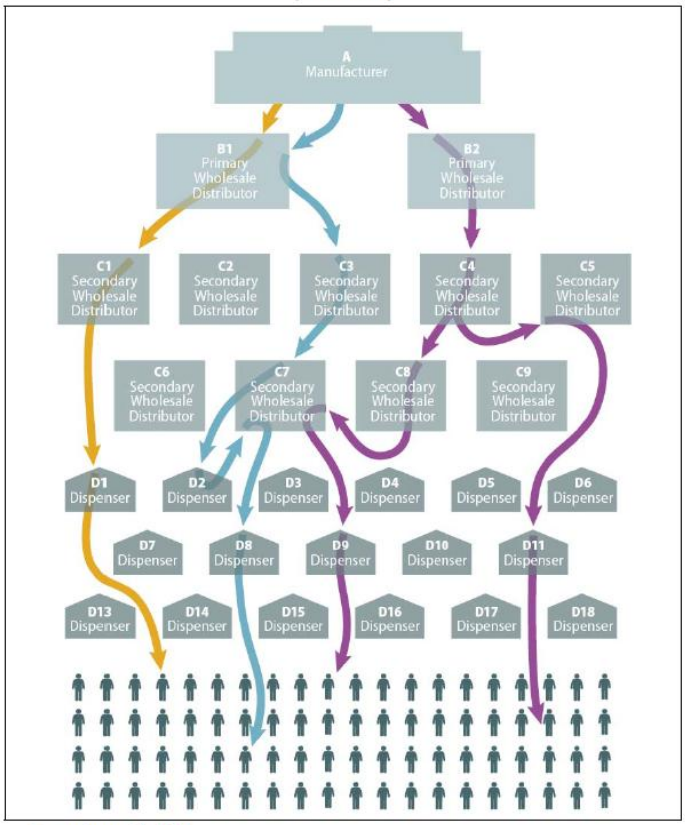
[1] Susan Thaul, *Pharmaceutical Supply Chain Security*, Congressional Research Service (October 31, 2013) p. 1, *available at* http://www.ncsl.org/documents/statefed/health/CRS-PharmSupChSec2013.pdf (last visited January 22, 2016)
[2] Id.
[3] Statement of Janet Woodcock, Director, Center for Drug Evaluation and Research, Food and Drug Administration, Department of Health and Human Services, before the Subcommittee on Health, Committee on Energy and Commerce, U.S. House of Representatives, hearing on "Securing Our Nation's Prescription Drug Supply Chain," April 25, 2013, http://www.fda.gov/NewsEvents/Testimony/ucm349186.htm (last visited January 22, 2016)
[4] 21 C.F.R. § 203.3.
[5] . The three largest primary wholesale distributors accounted for 85% of U.S. pharmaceutical wholesaling revenue. *After Heparin: Protecting Consumers from the Risks of Substandard and Counterfeit Drugs*, Pew Health Group, (July 12, 2011), http://www.pewtrusts.org/en/research-and-analysis/reports/2011/07/12/after-heparin-protecting-consumers-from-the-risks-of-substandard-and-counterfeit-drugs (last visited January 22, 2016); see also, Adam Fein, *Trends and top distributors in the pharmaceuticals sector*," in MDM Market Leaders 2012: Top Pharmaceuticals Distributors, (2013), http://www.mdm.com/2012-mdm-market-leaders-top-pharmaceuticals-distributors (last visited January 22, 2016)
[6] 21 C.F.R. § 203.3.
[7] *Supra*, note 1 at 4.

Also within the supply chain, a repackager removes a drug from its container and places it in another, usually smaller, container for sale to a distributor or dispenser.[8] Additionally, a third-party logistics provider takes temporary physical possession of the drug, but does not assume ownership of the drug.[9]

At the end of the supply chain, a dispenser provides the drug to the patient. A dispenser can be an independent, community pharmacy; a retail chain pharmacy; a hospital or health care facility; or doctor's office.[10]

A manufacturer may sell directly to a dispenser, however, typically it sells to a primary wholesale distributor, who in turn sells directly to a dispenser or may sell to a secondary wholesale distributor, who then sells the drug to the dispenser.[11] A dispenser may return certain drugs to the wholesaler who has the option to sell it to a dispenser, a wholesaler, or return it to the manufacturer.[12] Interspersed throughout the chain may be third-party logistics providers who transport or warehouse the drug under contract to the manufacturer, distributor, or dispenser.[13]

**Figure 1. Downstream Pharmaceutical Supply Chain**
(for illustration)




Source: Prepared by CRS.

[14]

Since its passage in 1938, the federal Food, Drug, and Cosmetic Act (FDCA), has addressed and indirectly influences the pharmaceutical supply chain; Congress has made focused attempts at improving supply chain security by amending the FDCA.

Federal Regulation of the Pharmaceutical Supply Chain

[8] U.S. Pharmacopeia, *Packaging Practice—Repackaging a Single Solid Oral Drug Product into a Unit-Dose Container*, http://www.pharmacopeia.cn/v29240/usp29nf24s0_c1146.html (last visited January 22, 2016); and Florida Department of Business and Professional Regulation, *Prescription Drug Repackager*, http://www.myfloridalicense.com/dbpr/ddc/PrescriptionDrugRepackager.html (last visited January 22, 2016).
[9] *Supra*, note 1 at 4.
[10] Id.
[11] Id. at 5.
[12] Id.
[13] Id.
[14] Id. at 6.

The FDA regulates the manufacture of prescription drugs, which typically includes making drugs (preparation, deriving, compounding, propagation, processing, producing, or fabrication) on a large scale for marketing and distribution of the product for unidentified patients. Generally, state boards of pharmacy continue to have primary responsibility for oversight and regulation of the practice of pharmacy, however, the FDA regulates, and in some cases preempts state action, through the Drug Quality and Security Act (DQSA) and the FDCA.

*Drug Quality and Security Act (DQSA)*

Previously, under the Prescription Drug Marketing Act,[15] the wholesale distribution of prescription drugs was monitored through a pedigree to prevent the introduction and retail sale of substandard, ineffective, and counterfeit drugs in the pharmaceutical supply chain.[16] The DQSA amended the FDCA to create a national track-and-trace system to monitor the movement of drugs through the pharmaceutical supply chain. The DQSA created a national uniform standard with preemption of state pedigree laws[17] that previously existed in 29 states, including Florida.[18] In lieu of conflicting pedigree requirements from state to state, the DQSA creates an interoperable, electronic system for the tracing all drugs transactions at the package level as they are distributed in the United States. The three key components for the DQSA tracing requirements are the transaction history, the transaction information, and the transaction statement.

- *Transaction history:* the statement that includes the transaction information for each prior transaction going back to the manufacturer of the product.[19]
- *Transaction information:* the proprietary or established name or names of the product; the strength and dosage form of the product; the National Drug Code number of the product; the container size; the number of containers; the lot number of the product; the date of the transaction; the date of the shipment, if more than 24 hours after the date of the transaction; the business name and address of the person from whom ownership is being transferred; and the business name and address of the person to whom ownership is being transferred.[20]
- *Transaction statement:* the statement that the entity transferring ownership in a transaction is authorized as required under the DQSA; received the product from a person that is authorized as required under the DQSA; received transaction information and a transaction statement from the prior owner of the product; did not knowingly ship a suspect or illegitimate product; had systems and processes in place to comply with verification requirements; did not knowingly provide false transaction information; and did not knowingly alter the transaction history.[21]

The electronic tracing system, which will be implemented over a ten-year span, will facilitate the exchange of information at the individual package level about where a drug has been in the supply chain.[22] The new system created by the DQSA:

- Enables verification of the legitimacy of the drug product identifier down to the package level;
- Enhances detection and notification of illegitimate products in the drug supply chain; and

[15] 21 U.S.C. § 353(e)(1)(A) and 21 C.F.R. part 203.
[16] U.S. Food and Druga Administration, *CPG Sec. 160.900 Prescription Drug Marketing Act -- Pedigree Requirements under 21 CFR Part 203*, http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm073857.htm (last visited January 22, 2016).
[17] A drug pedigree is a statement of origin that identifies each prior sale, purchase, or trade of a drug, including the date of those transactions and the names and addresses of all parties to them. Under the pedigree requirement, each person who is engaged in the wholesale distribution of a prescription drug in interstate commerce, who is not the manufacturer or an authorized distributor of record for that drug, must provide to the person who receives the drug a pedigree for that drug.
[18] In 2011, the National Alliance for Model State Drug Laws (NAMSDL) identified 20 states with pedigree-related statutes; NAMSDL, Drug Pedigree Requirements for Pharmacies and Wholesalers: State Statutes, July 2011, and 16 states with pedigree-related regulations, NAMSDL, *Drug Pedigree Requirements for Pharmacies and Wholesalers: State Regulations*, (July 2011). 29 states have laws or regulations that go "beyond the federal PDMA standards." Testimony of Elizabeth A. Gallenagh, Vice President, Government Affairs and General Counsel, Healthcare Distribution Management Association, before the U.S. House Energy and Commerce Committee, Subcommittee on Health, April 25, 2013.
[19] 21 U.S.C. § 360eee(25).
[20] 21 U.S.C. § 360eee(26).
[21] 21 U.S.C. § 360eee(27).
[22] U.S. Food and Druga Administration, *Drug Supply Chain Security Act (DSCSA)*, http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ (last visited January 21, 2016).

- Facilitates more efficient recalls of drug products.[23]

Among key provisions implemented over the next 10 years are requirements for:

- *Product identification*: Manufacturers and repackagers must put a unique product identifier on certain prescription drug packages, for example, using a bar code that can be easily read electronically.
- *Product tracing*: Manufacturers, wholesaler drug distributors, repackagers, and many dispensers in the drug supply chain must provide information about a drug and who handled it each time it is sold in the U.S. market.
- *Product verification*: Manufacturers, wholesaler drug distributors, repackagers, and many dispensers must establish systems and processes to be able to verify the product identifier on certain prescription drug packages.
- *Detection and response*: Manufacturers, wholesaler drug distributors, repackagers, and many dispensers must quarantine and promptly investigate a drug that has been identified as suspect, meaning that it may be counterfeit, unapproved, or potentially dangerous.
- *Notification*: Manufacturers, wholesaler drug distributors, repackagers, and many dispensers must establish systems and processes to notify FDA and other stakeholders if an illegitimate drug is found.[24]

Additionally, the DQSA established uniform national licensing standards for pharmaceutical wholesale distributors and preempts state laws, regulations, and requirements regarding wholesale distributor licensure that are inconsistent with, less stringent than, directly related to, or covered by the standards established by the DQSA. States will continue to license wholesale distributors, but they will be required to do so utilizing the federal standards established.[25]

Regulation of Drugs, Devices, and Cosmetics in Florida

Part I of ch. 499, F.S., the Florida Drug and Cosmetic Act, requires the Department of Business and Professional Regulation (DBPR) to regulate drugs, devices, and cosmetics.[26] Most of the regulations relate to the distribution of prescription drugs into and within Florida. In particular, the regulations require various entities in the distribution chain, such as prescription drug manufacturers and prescription drug wholesale distributors, to obtain permits. In total, Florida has 17 distinct permits for these entities.[27] Among many other provisions, the chapter provides for:

- Criminal prohibitions against distribution of contraband and misbranded prescription drugs;
- Regulation of the advertising and labeling of drugs, devices, and cosmetics;
- Permits for manufacturing and distributing drugs, devices, and cosmetics;
- Regulation of the wholesale distribution of prescription drugs with pedigree papers;
- Regulation of the provision of drug samples;
- The Cancer Drug Donation Program; and
- Numerous enforcement avenues for DBPR, including seizure and condemnation of drugs, devices, and cosmetics.

Many of these regulations have been significantly strengthened in recent years, including more stringent requirements to obtain a wholesale distributor permit, requiring, among other items, a posting

[23] Id.
[24] Id.
[25] States will continue to license wholesale distributors, but they will be required to do so utilizing the federal standards established.
[26] S. 27, ch. 2010-161, Law of Fla., shifted responsibility for operation and enforcement of the Florida Drugs, Devices, and Cosmetics Act from the Department of Health to the Department of Business and Professional Regulation.
[27] A permit is required for a prescription drug manufacturer; a prescription drug repackager; a nonresident prescription drug manufacturer; a prescription drug wholesale distributor; an out-of-state prescription drug wholesale distributor; a retail pharmacy drug wholesale distributor; a restricted prescription drug distributor; a complimentary drug distributor; a freight forwarder; a veterinary prescription drug retail establishment; a veterinary prescription drug wholesale distributor; a limited prescription drug veterinary wholesale distributor; an over-the-counter drug manufacturer; a device manufacturer; a cosmetic manufacturer; a third party logistics provider; or a health care clinic establishment. S. 499.01(1), F.S.

of a bond and extensive background information for various employees of the wholesale distributor;[28] more thorough documentation requirements for the distribution of prescription drugs, including broader application of the pedigree paper[29] to most wholesale distributions;[30] enhanced criminal penalties for, among other things, distribution of contraband prescription drugs;[31] and stronger departmental enforcement authority to protect the prescription drug supply chain.[32]

*Permitting*

An application for a permit or to renew a permit for a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor must include:

- Certain personal identification and contact information;
- Estimates, in total dollar volume of prescription drug sales and purchases;
- Financial information;
- Information about the property on which the business is located;
- Information related to out-of-state licenses;
- Employee information, including fingerprints;
- Any other relevant information that DBPR requires, including, but not limited to, any information related to whether the applicant satisfies the definition of a primary wholesale distributor or a secondary wholesale distributor; and
- Documentation of the credentialing policies and procedures.

For an applicant that is a secondary wholesale distributor, the permit application must contain each of the following:

- A personal background information statement containing the background information and fingerprints each person named as the manager of the establishment, each designated representative, and each affiliated party of the applicant;
- If any of the five largest shareholders of the corporation seeking the permit is a corporation, the name, address, and title of each corporate officer and director of each such corporation; the name and address of such corporation; the name of such corporation's resident agent, such corporation's resident agent's address, and such corporation's state of its incorporation; and the name and address of each shareholder of such corporation that owns 5 percent or more of the stock of such corporation;
- The name and address of all financial institutions in which the applicant has an account which is used to pay for the operation of the establishment or to pay for drugs purchased for the establishment, together with the names of all persons that are authorized signatories on such accounts;
- The sources of all funds and the amounts of such funds used to purchase or finance purchases of prescription drugs or to finance the premises on which the establishment is to be located; and
- If any of the funds identified were borrowed, copies of all promissory notes or loans used to obtain such funds.[33]

*Pedigree Papers*

[28] S. 499.01(2)(d), F.S. (requiring a bond of $100,000 or other means of equivalent security) and s. 499.012(8) and (9), F.S. (requiring, in addition to other information, place of residence for the past 7 years, fingerprints, photograph taken within 30 days, and name, address, occupation, and date and place of birth of each member of the person's immediate family who is 18 years of age or older).
[29] A pedigree paper is a record that documents the movement of drugs, devices or cosmetics through the chain of commerce. A pedigree paper must provide a complete audit trail from a person's receipt or acquisition to sale or other disposition of the product or component. Rule 61N-1.012(1)(a), F.A.C.
[30] S. 499.01212, F.S. ("Each person who is engaged in the wholesale distribution of a prescription drug must, prior to or simultaneous with each wholesale distribution, provide a pedigree paper to the person who receives the drug.")
[31] S. 499.0051(6), F.S. (imposing a second degree felony for "a person who is knowingly in actual or constructive possession of any amount of contraband prescription drugs, who knowingly sells or delivers, or who possesses with intent to sell or deliver any amount of contraband prescription drugs").
[32] S. 499.0051(12) and (13), F.S.
[33] S. 499.012(8)(g), F.S.

Florida law required, from 2003 until preempted by the DQSA in 2013, each person who was engaged in the wholesale distribution of a prescription drug to provide a pedigree paper, which provided the transaction history for tracing a prescription drug through the market, under the Prescription Drug Protection Act.[34] The pedigree was required to be completed prior to or simultaneous with each wholesale distribution. The Prescription Drug and Protection Act not only required pedigree papers for the wholesale distribution of prescription drugs, but also increased permitting requirements for prescription drug wholesale distributors and established criminal penalties for prescription drug violations related to counterfeiting and diversion.[35]

For the wholesale distribution of a prescription drug within the normal distribution chain, a pedigree paper was required to contain:

- The statement: "This wholesale distributor purchased the specific unit of the prescription drug directly from the manufacturer."
- The manufacturer's national drug code identifier and the name and address of the wholesale distributor and the purchaser of the prescription drug.
- The name of the prescription drug as it appears on the label.
- The quantity, dosage form, and strength of the prescription drug.[36]

For all other wholesale distributions of prescription drugs, the pedigree paper was required to contain:

- The quantity, dosage form, and strength of the prescription drugs.
- The lot numbers of the prescription drugs.
- The name and address of each owner of the prescription drug and his or her signature.
- Shipping information, including the name and address of each person certifying delivery or receipt of the prescription drug.
- An invoice number, a shipping document number, or another number uniquely identifying the transaction.
- A certification that the recipient wholesale distributor has authenticated the pedigree papers.
- The unique serialization of the prescription drug, if the manufacturer or repackager has uniquely serialized the individual prescription drug unit.
- The name, address, telephone number, and, if available, e-mail contact information of each wholesale distributor involved in the chain of the prescription drug's custody.[37]

[34] Ch. 2003-155, Laws of Fla.; s. 499.01212(1), F.S.
[35] Id.
[36] S. 499.01212(2)(a), F.S.
[37] S. 499.01212(2)(b), F.S.

*Unit Doses*

While not required by the FDCA, the federal Drug Enforcement Agency (DEA) requires distributors to have a system to identify suspicious orders of controlled substances and to notify the DEA of such orders.[38] In Florida, DBPR requires wholesale distributors to take reasonable measures to identify their customers, understand the normal and expected transactions conducted by those customers, and identify those transactions that are suspicious in nature.[39] A wholesale distributor must report to DBPR suspicious transactions, such as those involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the wholesale distributor believes indicates that the listed chemical will be used in violation of the law.[40] The DEA does not establish a quantity of a controlled substance that makes an order "suspicious;" however, Florida law requires a wholesale distributor to assess orders for greater than 5,000 unit doses of any one controlled substance in any one month to determine whether the purchase is reasonable or suspicious.[41]

*Non-Disciplinary Citations*

DBPR may bring an enforcement action, including the issuance of Notices of Violations and Administrative Complaints, against entities that have violated the provisions of ch. 499, F.S., that are not harmful or unsafe to the public health, such as changing ownership and continuing to operate without notifying DBPR. However, DBPR does not currently have the authority to issue such citations under ch. 499, F.S. DBPR does have this authority for the other professions it regulates under ch. 455, F.S. (Business and Professional Regulation); similarly, the Department of Health has this authority under ch. 456, F.S. (Health Professions and Occupations).

**Effect of the Bill**

Alignment of Ch. 499, F.S., with the DQSA

HB 1211 amends several provisions of ch. 499, F.S., to bring it into conformity with the DQSA's amendments to the FDCA.

*Definitions*

The bill substantially revises the definition section of s. 499.003, F.S., to incorporate definitions of terms from the DQSA, delete terms made obsolete by the DQSA, and address the removal of federally preempted portions of ch. 499, F.S. Of note, the bill substantially revises the definition of wholesale distribution and removes the definitions for primary and secondary distribution as well as what it means to distribute in order to comply with the DQSA. The bill excludes the following activities from the definition of wholesale distribution:

- 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 third-party logistics provider in accordance with state and federal law if the third-party logistics 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 for office use in compliance with the Florida Pharmacy Act and its rules;

[38] 21 C.F.R. § 1301.74(b).
[39] S. 499.0121(15)(b), F.S.
[40] Id.
[41] Id.

- 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;
- 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 Florida Drug and Cosmetic Act, or to the 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 Florida Drug and Cosmetic Act.

*Preemption of Pedigree law*

The bill removes references to Florida's pedigree requirements throughout ch. 499, F.S. Additionally, where appropriate, the bill replaces the references to "pedigree papers" with references to "transaction history, transaction information, or transaction statement" to account for the DQSA's preemption of Florida's pedigree law and the requirements for the new tracking and tracing program under the DQSA.

*Permits and Permitting*

The bill eases the renewal requirements for wholesale distributor permits by reducing the information required to be provided in the initial application and renewals. Additionally, it clarifies the entities that are required to be permitted as wholesale distributors in Florida and removes current bond requirement for wholesale distributors. It conforms the wholesale distributor bond requirement of the DQSA, allowing wholesale distributors with annual sales of $10,000,000 or less to provide proof of $25,000 bond or other equivalent security.

The bill clarifies when the Division can issue a prescription drug manufacturer permit to a nuclear pharmacy and a retail pharmacy wholesale distributor permit to a community pharmacy.

The bill removes the requirement that repackagers comply with the same requirements as wholesale distributors and requires repackagers to comply with requirements applicable to prescription drug manufacturers to comport to the provisions of the DQSA.

The bill establishes a nonresident prescription drug repackager permit for those entities that repackage prescription drugs outside of Florida and distribute those prescription drugs into Florida. The nonresident prescription drug repackager must comply with manufacture requirements to be permitted, comply with all state and federal good manufacturing practices, and be registered with the federal government.

The bill also establishes a virtual prescription drug manufacturer permit and a virtual nonresident prescription drug manufacturing permit for entities that manufacture prescription drugs but do not actually make or take physical possession of the prescription drugs. Because these manufacturers neither make nor take possession of prescription drugs, the DBPR is authorized to adopt rules exempting the nonresident virtual manufacturers from certain establishment, security and storage requirements.

With respect to cosmetic product registration and cosmetic manufacturer permits, the bill aligns the expiration date of the registration of products with the expiration date of the manufacturer's permit.

*Unit Doses*

The bill increases the number of unit doses, from 5,000 to 7,500 unit doses, of a 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.

Non-Disciplinary Citations

The bill authorizes DBPR to adopt rules to issue remedial, non-disciplinary citations to entities for alleged violations of the provisions of ch. 499, F.S. These citations may be issued, within 12 months of the occurrence, for violations that do not pose a substantial threat to the public health, safety, and welfare. The subject of the citation must be given the option to refuse the citation and have the allegations investigated pursuant to the provisions of s. 499.051, F.S., relating to investigations. The citation becomes a non-disciplinary final order if not timely disputed. DBPR is authorized to recover investigatory costs as part of the citation and adopt rules to designate the monetary assessments and other remedial measures that must be taken as a result of a citation.

B. SECTION DIRECTORY:

**Section 1:** Amends s. 499.003, F.S., relating to definitions of terms used in this part.
**Section 2:** Amends s. 499.005, F.S., relating to prohibited acts.
**Section 3:** Amends s. 499.0051, F.S., relating to criminal acts.
**Section 4:** Amends s. 499.006, F.S., related to adulterated drug or device.
**Section 5:** Amends s. 499.01, F.S., relating to permits.
**Section 6:** Amends s. 499.012, F.S., relating to permit application requirements.
**Section 7:** Amends s. 499.01201, F.S., relating to Agency for Health Care Administration review and use of statute and rule violation or compliance data.
**Section 8:** Amends s. 499.0121, F.S., relating to storage and handling of prescription drugs.
**Section 9:** Amends s. 499.015, F.S., relating to registration of drugs, devices, and cosmetics; issuance of certificates of free sale.
**Section 10:** Amends s. 499.03, F.S., relating to possession of certain drugs without prescriptions unlawful; exemptions and exceptions.
**Section 11:** Amends s. 499.05, F.S., relating to rules.
**Section 12:** Amends s. 499.051, F.S., relating to inspections and investigations.
**Section 13:** Amends s. 499.066, F.S., relating to penalties; remedies.
**Section 14:** Amends s. 499.82, F.S., relating to definitions.
**Section 15:** Amends s. 499.89, F.S., relating to recordkeeping.
**Section 16:** Repeals s. 499.01212, F.S.
**Section 17:** Amends s. 409.9201, F.S., related to Medicaid fraud.
**Section 18:** Amends s. 499.067, F.S., relating to denial, suspension, or revocation of permit, certification, or registration.
**Section 19:** Amends s. 794.075, F.S., relating to sexual predators; erectile dysfunction drugs.
**Section 20:** Amends s. 921.0022, F.S., relating to criminal punishment code; offense severity ranking chart.
**Section 21:** Provides an effective date.

## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

The Division may see an indeterminate increase in revenues from fees collected from non-disciplinary citations.

2. Expenditures:

The Division will save $579 annually in postage from changes to the process for renewal of permits.[42]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

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.[43]

D. FISCAL COMMENTS:

Each of the three new permits created in the bill, nonresident repackager, virtual prescription drug manufacturer, and nonresident virtual prescription drug manufacturer, will impose an initial registration fee of $1,500 and a biennial registration fee of $1,500.[44] However, DBPR already issues another type of permit to these manufacturers, at the same cost; therefore, there will be no increased revenue for the Division from these permits, and any changes from the creation of the new permits will be absorbed within current resources.[45]

## III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

DBPR is authorized to adopt rules to:

- Set permitting renewal schedules;
- Determine violations of ch. 499, F.S., for which non-disciplinary citations may be issued;
- Determine the monetary assessment and other remedial measures that an entity issued a non-disciplinary citation must comply with to satisfy the citation; and
- Provide for the issuance of virtual prescription drug manufacturer (resident & nonresident) permits, including rules pertaining to establishment, security and storage.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

[42] Id.
[43] Department of Business and Professional Regulation, Agency Analysis of 2016 House Bill 1211, p. 11 (Jan. 16, 2016) (on file with Health Quality Subcommittee staff).
[44] Id.
[45] Email from Colton Madill, Department of Business and Professional Regulation, RE: 1211 (Jan. 26, 2016) (on file with Health Quality Subcommittee staff).

## IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On January 25, 2016, the Health Quality Subcommittee adopted three amendments to the bill that:

- Remove voluntary cosmetic product registration, restore mandatory cosmetic product registration, and align the expiration date of the registration of cosmetic products with the expiration date of the cosmetic manufacturer's permit.
- Increase the number of unit doses, from 5,000 to 7,500 unit doses, of a 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.
- Amends cross-references to conform statutes to changes made by the bill.

The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute.