HOUSE OF REPRESENTATIVES STAFF ANALYSIS

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

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		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 also 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.

The FDA prohibits adulterated or misbranded cosmetic products from being sold to consumers and enforces cosmetic product labeling requirements. Unlike drugs, cosmetic products are not subject to safety inspections and premarket approval. However, the FDA encourages cosmetic manufacturers to voluntarily submit information on facilities, products, and ingredients, which provides the FDA with post-market product information and assists in the assessment of product safety. DBPR's Division of Drugs, Devices, and Cosmetics (Division) regulates cosmetics that are manufactured and repackaged in Florida. Cosmetic manufacturers must hold an active cosmetic manufacturer permit issued by the Division. In addition, each product produced or repackaged by such manufacturers is required to be registered with the Division. A certificate of free sale (COFS) is a document issued by a regulatory agency containing information about a product's regulatory or marketing status. The Division offers these for cosmetic products.

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 renewal requirements for wholesale distributor permits by reducing the information required to be provided in 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. 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 removes the requirement that Florida cosmetic manufacturers register cosmetic products with the Division. As such, cosmetic manufacturers located in Florida will no longer be required to register cosmetic products with the Division. In lieu of mandatory registration, the bill provides for a voluntary product registration which is limited to those entities that are legally authorized to manufacture, package, repackage or relabel the products in Florida. Additionally, the bill limits DBPR's ability to issue COFSs to issuance of certificates to those cosmetic products that voluntarily register with the Division.

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.

The bill has a significant negative 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 acquire drug products from a wholesale distributor, not directly from the manufacturer.[7]

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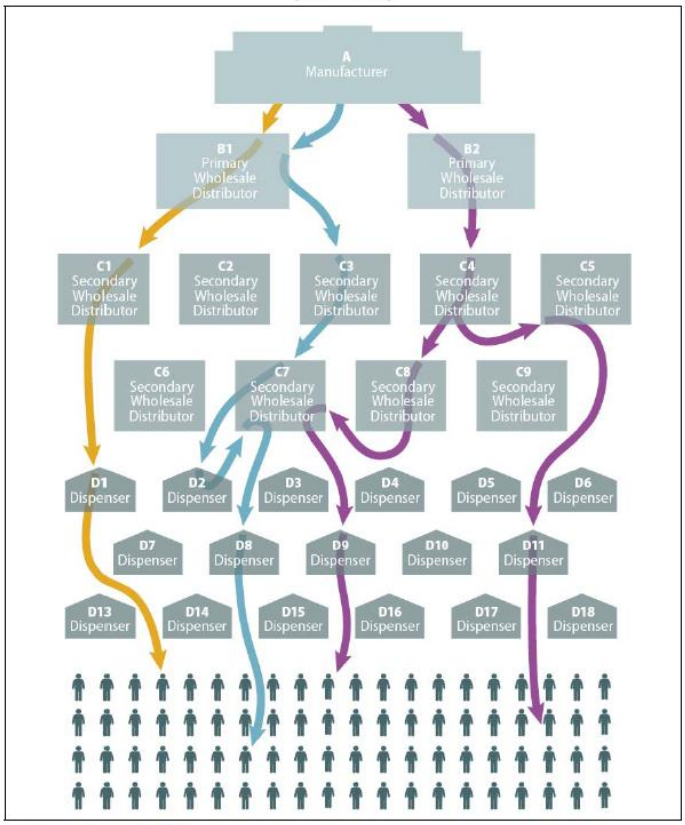
[1] Susan Thaul, *Pharmaceutical Supply Chain Security*, Congressional Research Service (October 31, 2013) p. 1, *available at* http://www.ncsl.org/documents/statefed/health/CRS-PharmSupChSec2013.pdf (last visited January 22, 2016)
[2] Id.
[3] Statement of Janet Woodcock, Director, Center for Drug Evaluation 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 also 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 the use of 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 of drugs at the package level as they are distributed in the United States.

The 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.[19] 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
- Facilitates more efficient recalls of drug products.[20]

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.

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[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] 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).
[20] Id.

- *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.[21]

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.[22]

Regulation of Drugs, Devices, and Cosmetics in Florida

Part I of ch. 499, F.S., requires the Department of Business and Professional Regulation (DBPR) to regulate drugs, devices, and cosmetics.[23] 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.[24]

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 of a bond and extensive background information for various employees of the wholesale distributor;[25] more thorough documentation requirements for the distribution of prescription drugs, including broader application of the pedigree paper[26] to most wholesale distributions;[27] enhanced criminal penalties for, among other things, distribution of contraband prescription drugs;[28] and stronger departmental enforcement authority to protect the prescription drug supply chain.[29]

Permitting

[21] Id.
[22] States will continue to license wholesale distributors, but they will be required to do so utilizing the federal standards established.
[23] 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.
[24] 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.
[25] 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).
[26] 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.
[27] 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.")
[28] 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").
[29] S. 499.0051(12) and (13), F.S.

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.[30]

Pedigree Papers

Florida law required, until preempted by the DQSA, that 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] 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.[32]

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.

[30] S. 499.012(8)(g), F.S.
[31] S. 499.01212(1), F.S.
[32] S. 499.01212(2)(a), F.S.

- 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.[33]

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).

Federal Regulation of Cosmetics

In the United States more than 8 billion cosmetics are sold annually which results in over $60 billion in annual sales.[34] FDA's definition of cosmetics covers a broad range of products. For regulatory purposes, the term includes products for the eyes, face, nails, hair, skin, and mouth, which may be in the form of products such as makeup, polish, hair dyes, fragrances, deodorants, shave gel, oral care, lotions, bath products, and products for infants and children.[35]

The FDA regulates cosmetics under the authority of the FDCA and the Fair Packaging and Labeling Act (FPLA). The FDCA prohibits the adulteration and misbranding of cosmetics and the introduction, receipt, and delivery of adulterated or misbranded cosmetics into interstate commerce.[36] A cosmetic is considered to be adulterated if it contains a substance that may cause injury to users under the conditions of use prescribed on the product's labeling or if it contains a soiled or decomposed substance.[37] A cosmetic is considered to be misbranded if its labeling is false or misleading, if it does not bear the required labeling information, if the container is made or filled in a deceptive manner, or if it does not comply with child resistant packaging requirements.[38] The FDA is authorized to take action against a cosmetic on the market if a product is found to be adulterated or misbranded, as well as companies and individuals who market such products.[39] However, the FDA does not have the authority to require a manufacturer to recall a cosmetic product from the marketplace, although the agency has general regulations on voluntary recalls.[40]

Voluntary Regulations

[33] S. 499.01212(2)(b), F.S.
[34] Statement of Michael Landa, Director, Center for Food Safety and Applied Nutrition, 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 "Examining the Current State of Cosmetics," March 27, 2012, http://www.fda.gov/NewsEvents/Testimony/ucm297215.htm (last visited January 22, 2016).
[35] 21 C.F.R. §720.4(c)(12) (1992).
[36] Amalia Corby-Edwards, *FDA Regulation of Cosmetics and Personal Care Products*, Congressional Research Service, July 9, 2012, available at http://asbcouncil.org/sites/default/files/library/docs/crs_report_fda_regulation_of_cosmetics_and_personal_care_products.pdf (last visited January 22, 2016).
[37] Id.
[38] Id.
[39] U.S. FOOD AND DRUG ADMINISTRATION, *FDA Authority over Cosmetics*, March 20, 2014, http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074162.htm (last visited December 10, 2015).
[40] *Supra*, note 36.

The FDA's legal authority over cosmetics is less comprehensive than other products it regulates, such as drugs and medical devices, with respect to mandatory product approval, regulation, and registration. The FDA does not impose registration requirements on cosmetic manufacturers, but it allows cosmetic manufactures to follow voluntary registration regulations. These voluntary regulations include facility registration, reporting of product's ingredients, and reporting of adverse reactions to products.

Voluntary cosmetic regulation compliance is managed electronically through the FDA's Voluntary Cosmetic Registration Program (VCRP). The VCRP is an electronic reporting system for manufacturers, packers, and distributors of cosmetic products that are distributed commercially in the United States.[41] Voluntary submission to the VCRP provides the FDA with information on cosmetic businesses and products, which helps support product safety review processes.[42] As of December 2015, there are 2,970 active online accounts, 1,473 registered establishments, and 45,103 product formulations on file with the VCRP.[43]

Labeling

The FPLA requires that packages and their labels provide consumers with accurate information about the quantity of contents to prevent consumer deception.[44] FPLA regulations require cosmetic product labels to disclose:[45]

- Identification of the product;
- Net quantity of contents in terms of weight, measure, or numerical count;
- Material facts about product and its use, such as directions for safe use;
- Name and place of business of the product's manufacturer, packer, or distributor;
- Warning and caution statements for products that are required to bear such statements by the FDCA and FDA regulations; and
- A list of ingredients in descending order of predominance.

Product Ingredients

The FDA is not statutorily authorized to approve a premarket cosmetic product. Therefore, manufactures are responsible for verifying the safety of their products before they are sold to consumers. FDA regulations prohibit or restrict the use of 10 types of ingredients in cosmetic products including chloroform, bithioniol, methylene chloride, and mercury-containing compounds[46] and require warning statements on the labels of certain types of cosmetics. Manufacturers must remove dangerous products from the market once a safety concern emerges. The FDA can pursue enforcement actions against such products or against firms or individuals who violate the law.[47] In general, except for color additives and those ingredients that are prohibited or restricted by regulation, a manufacturer may use any ingredient in the formulation of a cosmetic, provided that the:[48]

- Ingredient and the finished cosmetic are safe under labeled or customary conditions of use;
- Product is properly labeled; and
- Use of the ingredient does not otherwise cause the cosmetic to be adulterated or misbranded under the laws that FDA enforces.

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[41] U.S. FOOD AND DRUG ADMINISTRATION, *Voluntary Cosmetic Registration Program*, http://www.fda.gov/Cosmetics/RegistrationProgram/default.htm (last visited December 10, 2015).
[42] Information from the VCRP is used by the Cosmetic Ingredient Review, an industry funded organization, to assess ingredient safety and determine priorities for ingredient safety review. *Id.*
[43] U.S. FOOD AND DRUG ADMINISTRATION, *Registration Reports*, http://www.fda.gov/Cosmetics/RegistrationProgram/RegistrationReports/default.htm (last visited December 9, 2015).
[44] 15 U.S.C. § 1451-1460 (2009).
[45] *Supra*, note 34.
[46] U.S. FOOD AND DRUG ADMINISTRATION, *Prohibited and Restricted Ingredients*, http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm127406.htm (last visited December 10, 2015).
[47] *Supra*, note 34.
[48] *Supra*, note 39.

Florida Cosmetic Regulation

DBPR's Division of Drugs, Devices, and Cosmetics (Division) regulates Florida cosmetic manufacturers and registers cosmetic products manufactured or repackaged in Florida.

Manufacturer Permit

Cosmetic manufacturers physically located in Florida must obtain a cosmetic manufacturer permit through the Division.[49] Manufacture in this context means the preparation, deriving, compounding, propagation, processing, producing, or fabrication of any cosmetic.[50] Cosmetic manufacturers also repackage products by changing the container, wrapper, or label of a product, which may include altering the quantity of a product into different containers.[51] A person that only labels or changes the label of a cosmetic, but does not open the container sealed by the manufacturer of the product, is exempt from obtaining a permit.[52]

Applicants for a cosmetic manufacturer permit must complete and submit an application, pass an onsite inspection,[53] and pay a fee. Applicants must pay a fee of $800 for a biennial permit and a one-time pre-permit inspection fee of $150.[54] As of November 2014, there were 125 establishments with Division issued cosmetic manufacturer permits.[55]

Division regulations provide guidelines for cosmetic manufacturers to ensure cosmetic product safety and quality and compliance with FDA laws and regulations. The regulations provide that: [56]

- Manufacturers must assure that personnel do not contribute to contamination or adulteration of the product;
- Any facility used for the manufacture, processing, packaging, or labeling of a cosmetic shall be of suitable size and construction to produce a product that is not adulterated or misbranded;
- Any facility and equipment used in the manufacture, processing, packaging, or labeling of a cosmetic shall be maintained in a clean and sanitary condition;
- Components, containers, and closures shall not be reactive, additive, or absorptive so as to alter the safety or purity of the cosmetic;
- Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the cosmetic product; and
- An appropriate identification or tracking system should be in place to facilitate a rapid and effective recall or market withdrawal.

Registration of Products

Cosmetics manufactured, packaged, repackaged, labeled or relabeled in Florida must be registered with the Division.[57] Products that are both a cosmetic and a drug must be registered as a drug.[58] Registration of cosmetic products requires a manufacturer to submit a detailed Division application, a copy of the product labels, and a fee for each product.[59] The application includes the following information:

[49] S. 499.01(2)(o), F.S.
[50] FLORIDA DEP'T OF BUSINESS AND PROFESSIONAL REGULATION, *Cosmetic Manufacturer,* http://www.myfloridalicense.com/dbpr/ddc/CosmeticManufacturer.html (last visited December 11, 2015).
[51] Id.
[52] *Supra*, note 49.
[53] If the applicant also holds an Over-the-Counter Drug Manufacturer or Prescription Drug Manufacturer permit at the same time an inspection is not required. *Supra*, note 50
[54] *Supra*, note 50.
[55] Letter from the Director of the Division of Drugs, Devices, and Cosmetics to a representative of the Florida Cosmetic Manufacturers Coalition on November 26, 2014. (on file with Health Quality Subcommittee staff).
[56] Rule 61N-1.010, F.A.C.
[57] S. 499.015(1)(a), F.S.
[58] Rule 61N-1.016(1)(a), F.A.C.
[59] S. 499.015, F.S.

- Manufacturer's contact and address information, type of ownership, and operating hours;
- Name of product as shown on label;
- Identification of the product, if it is for professional use only;
- Manufacturer of the product, including its name, city, and state;
- Identical cosmetic products information; and
- Signed affidavit section.[60]

New cosmetic products must be registered prior to sale. If a manufacturer has existing registered products, its registered product list must be updated through the formal application process to include any new products.[61] The registration and biennial renewal fee for each cosmetic product is $30.

Manufacturers often produce similar products or slightly alter products from an outside manufacturer; for example, they may use a different brand name, container, or scent for an almost identical product. In these instances, for registration purposes, the product is not considered separate and distinct. The process for "identical products" requires submission of an application and a $15 fee and biennial renewal fee for each additional size, quantity, color, flavor, and scent of a registered cosmetic product.[62]

The Division reviews applicants' product labels to determine compliance with the requirements of the FDCA.[63] The Division reviews the ingredients of the cosmetic to determine if the ingredients are approved for use in cosmetics or otherwise safe for cosmetic products.[64] Division pharmacists or drug inspectors review products that may contain ingredients that are prohibited or may change the classification of the product to a drug.[65] Currently, there are 13,024 active cosmetic product registrations with the Division.[66]

Inspection and Investigation of Cosmetic Manufacturers

Passing an onsite inspection is a prerequisite to issuance of a Cosmetic Manufacturer permit, unless the applicant also holds an Over-the-Counter Drug Manufacturer or Prescription Drug Manufacturer permit at the same address.[67] Additionally, once a permit has been issued to a cosmetic manufacturer, it is subject to inspection and investigation, whether announced or unannounced, by the Division and the Department of Law Enforcement.[68]

Certificates of Free Sale

Manufacturers exporting products from the United States are often asked by foreign customers or foreign governments to supply a certificate of free sale (COFS) to ensure that products are in compliance with FDA laws and regulations. A COFS is a document issued by a regulatory agency containing information about a product's regulatory or marketing status.[69] A COFS verifies that products being exported are freely marketed without restriction and are approved for sale in the United States and Florida.[70]

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[60] FLORIDA DEP'T OF BUSINESS AND PROFESSIONAL REGULATION, *Application for Product Registration-Cosmetics Form No.: DBPR-DDC-228*, available at http://www.myfloridalicense.com/DBPR/ddc/documents/Product_Registration_Cosmetic_App-228.pdf (last visited December 14, 2015).
[61] Rule 61N-1.016(4)(b), F.A.C.
[62] Rule 61N-1.016(1)(b), F.A.C.
[63] Rule 61N-1.009, F.A.C.
[64] Florida Department of Business and Professional Regulation, 2016 Legislative Bill Analysis SB 176, September 29, 2015. (SB 176 is identical to HB 261, analysis is on file with Health Quality Subcommittee staff).
[65] *Supra*, note 55.
[66] *Supra*, note 64.
[67] *Supra*, note 50.
[68] S. 499.051(1), F.S.; Rule 61N-1.019(1)-(3), F.A.C.
[69] U.S. FOOD AND DRUG ADMINISTRATION, *FDA Export Certificate,* December 18, 2014, http://www.fda.gov/RegulatoryInformation/Guidances/ucm125789.htm, (last visited December 15, 2015).
[70] Enterprise Florida, *Certificate of Free Sale*, available at https://www.enterpriseflorida.com/wp-content/uploads/certificate-of-free-sale-flyer.pdf (last visited December 14, 2015).

A COFS can be issued by a federal, state, city office or a non-governmental association such as a Chamber of Commerce. The Division, when requested by a cosmetic manufacturer, issues a COFS for a registered cosmetic product that is to be exported to another country.[71] Enterprise Florida will prepare a COFS for firms involved in the exporting of products manufactured in, or distributed from Florida for a fee of $20.00.[72]

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.

Preemption of Pedigree law

The bill remove 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 requires nonresident prescription drug manufacturers to comply with the Florida requirements for prescription drug manufacturers and allows DBPR to issue a virtual nonresident prescription drug manufacturing permit to entities outside of Florida that manufacture prescription drugs but do not

[71] Rule 61N-1.017, F.A.C.
[72] *Supra*, note 70.

actually make or take physical possession of the prescription drugs. DBPR may adopt rules exempting the nonresident virtual manufacturers from certain establishment, security and storage requirements.

Cosmetic Product Registration

The bill removes the requirement that Florida cosmetic manufacturers register cosmetic products with the Division. As such, cosmetic manufacturers located in Florida will no longer be required to register cosmetic products with the Division. In lieu of mandatory registration, the bill provides for a voluntary product registration which is limited to those entities that are legally authorized to manufacture, package, repackage or relabel the products in Florida.

The bill requires product registrations issued after July 1, 2016, to expire on the same date as the manufacturing permit of the manufacturer that manufactures the product. This will ensure that both the product registration and permit renewals will be on the same schedule.

Certificate of Free Sale

The bill limits DBPR's ability to issue COFSs to issuance of certificates to those cosmetic products that voluntarily register with the Division. While COFSs would not be available from the Division for unregistered cosmetic products, they would continue to be available from other entities for exported cosmetic products, including Enterprise Florida.

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. 794.075, F.S., relating to sexual predators; erectile dysfunction drugs.
Section 19: Amends s. 921.0022, F.S., relating to criminal punishment code; offense severity ranking chart.

Section 20: Provides an effective date.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   The Division will experience a decrease in revenues, of approximately $208,180, annually, associated with no longer receiving payment of fees for cosmetic product registration and product registration renewal by creating a voluntary registration scheme.[73]

   There are 13,024 current, active registered cosmetic products. Product registrations are renewed biennially. The Division's biennial renewal fees from the 13,024 products are approximately $330,465 (or $165,232.50 annually). The bill would reduce the Division's revenue from these fees and the revenue reductions would increase the Division fund's anticipated deficit.[74]

2. Expenditures:

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

[73] Department of Business and Professional Regulation, Agency Analysis for 2016 HB 1211
[74] Department of Business and Professional Regulation, Agency Analysis for 2016 HB 261

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Cost savings associated with renewal of permits could results in an estimated annual savings of $225,379 to the industry each year and an estimated saving of $1,105 per year per permittee.[75]

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

None.

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.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

[75] *Supra*, note 73.