HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 751 Prescription Drug Wholesale Regulations
SPONSOR(S): Health & Human Services Quality Subcommittee; Brandes
TIED BILLS: **IDEN./SIM. BILLS:** SB 1006

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health & Human Services Quality Subcommittee	14 Y, 0 N, As CS	Poche	Calamas
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Part I of Chapter 499 requires the Department of Business and Professional Regulation (DBPR) to regulate drugs, devices, and cosmetics. A significant majority of the regulations relate to the distribution of prescription drugs into and within Florida. In particular, the regulations require licensure of various entities in the distribution chain, such as prescription drug manufacturers and prescription drug wholesale distributors. In total, Florida has 20 distinct permits for these entities.

Out-of-state prescription drug wholesale distributors who wish to operate in Florida must obtain an out-of-state prescription drug wholesale distribution permit. In order to obtain the permit, a prospective permittee must comply with and meet many requirements set out in statute and administrative rule.

CS/HB 751 establishes two new exemptions from the permitting process for distribution of prescription drugs and active pharmaceutical ingredients within the state. First, an establishment located in the U.S. may distribute an active pharmaceutical ingredient (API), without a permit, to a Florida-licensed manufacturer for the purpose of manufacturing a prescription drug product approved by the federal Food and Drug Administration. Second, an establishment located within the U.S. may distribute limited quantities of non-repackaged prescription drugs to a Florida-licensed manufacturer for research and development. The bill allows the holder of a letter of exemption from DBPR to receive limited quantities of prescription drugs from an establishment in the U.S. for research and development, teaching, or testing.

The bill makes other regulatory changes, such as:

- Amending the definition of “establishment” to account for permittees that have multiple buildings on a compound or campus;
- Amending the definition of “distribute” or “distribution” to exclude billing and invoicing activities involved in wholesale distribution transactions;
- Amending the definition of “drug” and “prescription drug” to include API; and
- Strengthening recordkeeping and reporting requirements for entities claiming an exemption or receiving prescription drugs from an entity claiming an exemption.

The bill does not appear to have a fiscal impact on state or local government.

The bill provides an effective date of July 1, 2012.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Regulation of Drugs, Devices, and Cosmetics

Part I of Chapter 499 requires the Department of Business and Professional Regulation (DBPR) to regulate drugs, devices, and cosmetics.[1] A significant majority of the regulations relate to the distribution of prescription drugs into and within Florida. In particular, the regulations require licensure of various entities in the distribution chain, such as prescription drug manufacturers and prescription drug wholesale distributors. In total, Florida has 20 distinct permits for these entities. Among many other provisions, the chapter provides for:

- Criminal prohibitions against the 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, which includes 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:

- A significantly stronger wholesale distributor permit, requiring, among other items, a posting of a bond and extensive background information for various employees of the wholesale distributor;[2]
- More thorough documentation of the distribution of prescription drugs, including broader application of the pedigree paper to most wholesale distributions;[3]
- Enhanced criminal penalties for, among other things, distribution of contraband prescription drugs;[4] and
- Stronger departmental enforcement authority to protect the prescription drug supply chain.[5]

These stricter regulations were prompted by the report of a Grand Jury convened by the Florida Supreme Court in 2002 at the request of Governor Jeb Bush.[6] The Grand Jury noted that "first tier" wholesale distributors (AmerisourceBergen, Cardinal Health, and McKesson) controlled approximately 90 percent of wholesale prescription drug distribution market. This is the "primary market." The

[1] S. 27, ch. 2010-161, Law of Fla., shifted responsibility for operation and enforcement of the Florida Drugs, Device s, and Cosmetics Act from the Department of Health to the Department of Business and Professional Regulation. Proposed legislation has been filed for the 2012 Regular Session to make necessary changes to chapter 499 to reflect the change of departmental oversight; *see* Florida House of Representatives, Bills for Regular Session 2012, *HB 5511 Department of Business and Professional Regulation*, available at http://myfloridahouse.gov/Sections/Bills/billsdetail.aspx?BillId=48947.

[2] 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).

[3] 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.")

[4] 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").

[5] S. 499.0051(12) and (13), F.S.

[6] *See* First Interim Report of the Seventeenth Statewide Grand Jury, Case No. SC02-2645 (2003).

remaining stock was purchased from "second tier" wholesale distributors, a "secondary market" of hundreds of smaller wholesale distributors. In this secondary market, prescription drugs may move "up, down, and sideways through the distribution system, [creating] opportunities for adulterated drugs that have been diverted from other sources to enter the distribution system." It is this secondary tier that the Grand Jury, much like Congress in the 1980s,[7] identified as one of the primary points of introduction of counterfeit or adulterated drugs. Neither the Grand Jury nor Congress attributed fault to the prescription drug manufacturers in knowingly participating in the introduction of contraband drugs in the secondary market.[8]

The act identifies authorized and proscribed activities for each permitted entity, as well as particular storage, handling, and recordkeeping requirements for each. Administrative and criminal penalties may result for the failure to comply with requirements in the act or administrative rules.[9]

The table below lists all permit types for entities involved in the manufacture, distribution and dispensing of controlled substances in the state of Florida, as regulated by chapter 499, F.S., and the number of licenses or permits issued by DOH and DBPR for each permit type.[10]

Ch. 499, F.S., Permit Types	Licenses/ Permitees/ Registrants	Complaints
Prescription Drug Manufacturer	111	29
Non-resident Prescription Drug Manufacturer	845	40
Prescription Drug Repackager	26	13
Prescription Drug Wholesale Distributor	129	90
Out-of-State Prescription Drug Wholesale Distributor	257	70
Retail Pharmacy Drug Wholesale Distributor	59	70
Prescription Drug Wholesale Distributor - Broker Only	8	7

Active Pharmaceutical Ingredient

Active pharmaceutical ingredients (API) are chemicals used in the manufacturing of pharmaceutical drugs. APIs include substances manufactured by processes such as:

- Chemical synthesis;
- Fermentation process;
- Recombinant DNA or other biotechnology methods;
- Isolation/recovery from natural sources; or
- Any combination of these processes.[11]

[7] *See* Pub. L. No. 100-293 (1988) (finding that "the existence and operation of a wholesale submarket, commonly known as the 'diversion submarket', prevents effective control over or even routine knowledge of the true sources of prescription drugs in a significant number of cases.").

[8] *See* H.R. Rep. No. 100-76 (1987) and S. Rep. No. 100-303 (1988). The report did note that two practices—providing drug samples and discount sales to health care institutions (e.g., hospitals)—provided potential opportunity for abuse. In particular, "the existing system of providing [drug] samples of pharmaceutical products to physicians through manufacturers' sales representatives invites abuse" (*emphasis added*). In addition, "the resale of prescription drugs by health care entities to persons outside the corporate umbrella of the [entity] helps fuel the diversion market. Such sales . . . are economical only because many manufacturers sell much more cheaply to certain institutions than to wholesale customers" (*emphasis added*).

[9] Chapter 64F-12, Florida Administrative Code, contains the rules adopted under the Act's authority.

[10] Email correspondence from the DBPR staff to Health and Human Services Quality Subcommittee staff on January 30, 2012; the last column of the chart includes the number of complaints received by DOH and DBPR for each license or permit type from FY 2009-2010 through FY 2010-2011.

[11] LGM Pharma, *Active Pharmaceutical Ingredients*, available at http://www.lgmpharma.com/resources/active-pharmaceutical-ingredients/ (last viewed on February 1, 2012).

An active ingredient is the substance or mixture of substances in a pharmaceutical drug that is biologically active. The active ingredient is the product component responsible for an effect the product was designed to have. In the biomedical industry, the active ingredient performs the intended chemistry or biochemistry in the body inducing the therapeutic or cleaning response. The purpose of API is to cause pharmacological activity or other direct effect in the diagnosis, mitigation, treatment, cure, or prevention of disease or to affect the structure and function of the human body or other animals.[12]

In- State and Out-of-State Prescription Drug Wholesale Distributor Regulation

A "wholesale distributor" is defined in chapter 499, F.S., as any person engaged in wholesale distribution (the distribution of prescription drugs to persons other that a consumer or patient)[13] of prescription drugs in or into this state, including, but not limited to, manufacturers, repackagers, warehouses, retail pharmacies, and their respective agents that conduct wholesale distributions.[14]

A prescription drug wholesale distributor located in Florida may engage in the distribution of prescription drugs within the state upon receiving a prescription drug wholesale distributor permit.[15] A prospective permittee must complete and submit the proper application to DBPR, along with the applicable fee.[16] A prospective permittee must designate in writing at least one natural person to serve as the certified designated representative (CDR). Certification and operating requirements for CDRs include:

- Submission of a CDR application to DBPR;
- Payment of the appropriate fees;
- The CDR must be at least 18 years of age
- The CDR must have not less than two years of verifiable full-time work experience in a pharmacy licensed in this state or another state, where the person's responsibilities included, but were not limited to, recordkeeping for prescription drugs, or have not less than two years of verifiable full-time managerial experience with a prescription drug wholesale distributor licensed in this state or in another state;
- Receipt of a passing score of at least 75 percent on an examination given by the department regarding federal laws governing distribution of prescription drugs and this part and the rules adopted by the department governing the wholesale distribution of prescription drugs;
- The CDR must be employed in a managerial position by the wholesale distributor, actively involved in and aware of actual daily operations and be physically present at the establishment during normal business hours, except for time periods when absent due to illness, family illness or death, scheduled vacation, or other authorized absence; and
- May serve as a designated representative for only one wholesale distributor at any one time.[17]

A prospective permittee must post a surety bond of $100,000, which will be used to pay penalties imposed by DBPR and reimburse the department for fees and costs incurred in investigating and assessing the penalties. Certain individuals associated with the prospective permittee must provide a personal information statement, including a set of fingerprints for a criminal background check, to the DBPR as part of the application process. These individuals include the CDR or CDR candidate, the manager of the establishment and the next four highest ranking employees responsible for prescription

[12] *Id.*
[13] S. 499.003(54), F.S.; *see also* Rule 64F-12.001, F.A.C.
[14] S. 499.003(55), F.S.
[1515] S. 499.01(2)(d), F.S.; *see also* s. 499.012(8) and (9)(a), F.S.
[16] Rule 64F-12.015(7), F.A.C., contains the complete permitting requirements for a Prescription Drug Wholesale Distributor permit; *see also* Rule 64F-12.018(2)(b), F.A.C., for fee schedule.
[17] Florida Department of Business and Professional Regulation, *DRUGS, DEVICES AND COSMETICS PROGRAM-PRESCRIPTION DRUG WHOLESALE DISTRIBUTOR-REQUIREMENTS*; available at http://www.myfloridalicense.com/dbpr/ddc/PrescriptionDrugWholesalerDistributor.html (last viewed January 30, 2012); *see also* Rule 64F-12.015(9), F.A.C.

drug wholesale operations at the establishment, and all affiliated parties[18] of the establishment. Lastly, the distribution facility must submit to pre-application inspection before the permit can be issued.[19]

Out-of-state prescription drug wholesale distributors are required to obtain a specific permit in order to distribute drugs in the state.[20] They are defined within statute as wholesale distributors located outside of the state that engage in the wholesale distribution of prescription drugs into the state, which must be permitted by DBPR, and which must comply with all provisions required of a wholesale distributor under part I of chapter 499, F.S. They must obtain an out-of-state prescription drug wholesale distributor permit to distribute prescription drugs in the state.[21]

Upon application for a permit, an out-of-state prescription drug wholesale distributor is required to post a bond of $100,000.[22] The bond will be used to pay any administrative penalties imposed by DBPR against the distributor and to pay any fees and costs incurred by DBPR in investigating and assessing the penalties.[23] Also, statute requires the wholesale distributor to, at all times, maintain a valid license or permit to operate as a wholesale distributor in the state where it is a resident in order to operate as a wholesale distributor in Florida.[24]

Specific requirements for obtaining an initial out-of-state prescription drug wholesale distributor permit are found in administrative rule.[25] The prospective permittee must obtain an application form and fingerprint cards from DBPR.[26] The completed application form must be completed and submitted to DBPR.[27] Next, a Personal Information Statement must be completed by the prospective permittee's manager, the next four highest ranking employees of the prospective permittee who are responsible for prescription drug operations, and all affiliated parties.[28] Each required party must submit a completed fingerprint card and $47.00 to DBPR.[29] The prospective permittee must submit a copy of the resident state's license or permit which allows the prospective permittee to conduct wholesale distribution of prescription drugs in that state.[30] However, if the resident state does not require a license or permit to engage in wholesale distribution of prescription drugs, then the prospective permittee must submit to DBPR the following:

- Written confirmation on the letterhead of the resident state agency responsible for regulating prescription drugs that a license or permit to engage in wholesale distribution of prescription drugs within the resident state is not required[31]; and
- A signed statement from the prospective permittee that it will comply with all storage, handling, and recordkeeping requirements of the resident state with regard to the sale and distribution of prescription drugs into Florida[32]; or

[18] S. 499.003(3), F.S., defines "affiliated party" as (i) directors, officers, trustees, partners, or committee member of a permittee or applicant or a subsidiary or service corporation of the permittee or applicant; (ii) any person who, directly or indirectly, manages, controls or oversees the operation of a permittee or applicant, regardless of whether such person is a partner, shareholder, manager, member, officer, director, independent contractor, or employee of the permittee or applicant; and (iii) up to five natural individual owners, to the extent that any owns at least five percent of the permittee or applicant.
[19] *See supra* at FN 15.
[20] S. 499.01(1)(e), F.S.
[21] S. 499.01(2)(e), F.S.
[22] *Id.*; *see also* Rule 64F-12.015(7)(e)5., F.A.C.
[23] *Id.*
[24] S. 499.01(2)(e)1., F.S.
[25] Rule 64F-12.015(7)(e), F.A.C.; *see also* s. 499.012, F.S., for additional specific requirements for permitting.
[26] Rule 64F-12.015(7)(e)1., F.A.C.
[27] Rule 64F-12.015(7)(e)2., F.A.C., requires Form DH 2124 to be completed by the prospective permittee. It is likely that the form designation has changed since program administration has been moved to DBPR; however, the Rules have not been updated to reflect the shift in program oversight.
[28] Rule 64F-12.015(7)(e)3., F.A.C., requires Form DH 2125, the "Personal Information Statement", to be filed with DBPR.
[29] Rule 64F-12.015(7)(e)4., F.A.C.
[30] Rule 64F-12.015(7)(e)6., F.A.C.
[31] Rule 64F-12.015(7)(e)6.a., F.A.C.
[32] Rule 64F-12.015(7)(e)6.b., F.A.C.

- If the resident state does not have storage, handling and recordkeeping requirements, a signed statement that the prospective permittee with comply with all storage, handling, and recordkeeping requirements found in the applicable federal statute.[33]

The prospective permittee must identify a person within the company who is certified, pursuant to s. 499.012(16), F.S.,[34] to serve as the designated representative for the prospective permittee.[35] Any change of the certified designated representative must be reported to DBPR.[36] Lastly, the prospective permittee must pay all applicable fees, which include an annual fee of $800, a Certification as Designated Representative fee of $150, and non-refundable Initial Application/On-Site Inspection fee of $150.[37]

Effect of Proposed Changes

CS/HB 751 creates new subsection (3) of s. 499.01, F.S., containing the exemptions to the permitting process that currently exist in law and the exemptions that are established by the bill. The bill allows for distribution of prescription drugs within the state for purposes of manufacturing, teaching, testing, and research and development, while providing oversight and regulation by DBPR.

The bill creates two new exemptions from the permitting process under s. 499.01, F.S.

Finished Product Exemption

The first new exemption allows an establishment located in the U.S. to distribute API, as defined in the bill, to a Florida-licensed prescription drug manufacturer for the manufacturing of finished prescription drug products. The bill requires that the finished prescription drug product be approved pursuant to one of four FDA applications:

- New Drug Application;
- Abbreviated New Drug Application, which is used for generic drugs;
- New Animal Drug Application; or
- Biologics License Application, which is used to seek approval of a protein based drug or vaccine.

As a result, to claim this exemption from the Florida permitting process, the API must be used to produce a prescription drug which is approved by the federal Food and Drug Administration. The out-of-state establishment must maintain a valid license or permit in its resident state in order to distribute API within the state. Also, both the distributor and the Florida-licensed manufacturer must comply with all recordkeeping requirements, but are exempt from compliance with the pedigree paper requirements under s. 499.01212, F.S.

The bill amends two definitions contained in s. 499.003, F.S., for purpose of the new exemptions. The definition of "drug" is amended to include "active pharmaceutical ingredient" and a definition of the term. The term "prescription drug" is amended to specify the circumstance in which an active pharmaceutical ingredient will be considered a prescription drug.

Research and Development Exemption

The second new exemption allows an establishment located within the U.S. to distribute limited quantities of non-repackaged prescription drugs to a Florida-licensed prescription drug manufacturer for research and development. Also, the exemption permits the holder of a letter of exemption, issued by

[33] *Id.*; *see also* 21 C.F.R. 205.50 (2003) for storage, handling, and recordkeeping requirements.
[34] S. 499.012(16), F.S., contains application requirements and qualifying requirements that must be met before a person can be certified as the prospective permittee's designated representative.
[35] Rule 64F-12.015(7)(e)7., F.A.C.
[36] *Id.*; a prospective permittee must use Form DH 2130 to communicate any change in certified designated representative to DBPR.
[37] Rule 64F-12.015(7)(e)8., F.A.C.; *see also* Rule 64F-12.018(3), (4)(a), and (4)(b), F.A.C., outlining applicable fee amounts.

DBPR pursuant to s. 499.03(4), F.S., to receive limited quantities of prescription drugs for the purpose of research, teaching, or testing.

The bill requires DBPR to define, by rule, what constitutes "limited quantities". The definition may include a limit on the total amount of prescription drugs distributed within the state for purposes of teaching, testing, research and development. It may also include a limit on the amount of allowable transactions within a given time period.

To claim this exemption to the permitting process, the out-of-state establishment must maintain a license or permit in its resident state to engage in the distribution of prescription drugs. All purchasers and recipients of prescription drugs under this exemption must ensure that the products are not resold to persons or used on humans, except in lawful and federally authorized and regulated clinical studies and biostudies. Also, the distributor and recipient or purchaser under this provision of the bill must comply with all recordkeeping requirements and pedigree paper requirements. Finally, any package or container of any API distributed within the state for the purpose of teaching, testing, or research and development must have a label on it with the following statement: "Caution: Research, Teaching, or Testing Only – Not for Manufacturing, Compounding, or Resale".

Other Requirements

The bill requires all recipients of prescription drugs from distributors claiming an exemption to the permitting process, as established by the bill, to maintain the following records for all distributors and establishments from whom they purchase or receive prescription drugs:

- FDA establishment registration number;
- Resident state prescription drug wholesale distribution license, permit, or registration number; and
- A copy of the most recent establishment inspection report completed by the resident state or FDA.

The bill confirms that all persons claiming an exemption under the provisions of the bill are subject to s. 499.005, F.S., which lists prohibited and unlawful acts under part I of chapter 499, F.S., and s. 499.0051, F.S., which lists criminal acts. Also, persons claiming an exemption must make available to DBPR, within 48 hours of a request, all records related to prescription drugs distributed within the state, including financial records that must be maintained pursuant to s. 499.051(4), F.S. Lastly, the bill requires a recipient of misbranded or adulterated prescription drugs distributed under the provisions of the bill to report such drugs to DBPR within 14 days of receipt.

Finally, the bill makes changes to certain definitions. The definition of "establishment" is amended to include reference to one or more suites, units, floors, or buildings operated and controlled by entities under common control. The bill also requires that each individual suite, unit, floor, or building be specified in the most recent permit application. The change acknowledges the fact that a permittee may have more than one location in a campus or compound setting. In such a case, additional permits are not required for each location. Also, the definition of "distribute" or "distribution" is amended to exclude billing and invoicing activities that typically follow a wholesale distribution transaction.

The bill grants express rulemaking authority to DBPR to implement the provisions of the bill.

The bill expressly states that nothing in the bill relieves any person of the responsibility to comply with all federal and state laws regarding controlled substances.

B. SECTION DIRECTORY:

Section 1: Amends s. 499.003, F.S., relating to definitions of terms used in this part.
Section 2: Amends s. 499.01, F.S., relating to permits.
Section 3: Provides an effective date of July 1, 2012.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill may entice out-of-state prescription drug wholesale distributors which had refrained from applying for a permit to distribute in Florida due the permitting process to enter the Florida market by taking advantage of the permitting exemptions proposed by the bill. Additional distributors in the market may make it easier for in-state manufacturers to obtain API.

D. FISCAL COMMENTS:

DBPR does not anticipate an increase or decrease in the number of out-of-state prescription drug wholesale distributors licensed by the department.[38] DBPR will be required to modify its online license and information databases as a result of the provisions of this bill, but expects to complete the modifications within current budgetary resources.[39]

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.

[38] Florida Department of Business and Professional Regulation, Office of Legislative Affairs, *2012 Legislative Analysis Form for SB1006/HB 751*, page 3 (on file with the Health and Human Services Quality Subcommittee).
[39] *Id.*

B. RULE-MAKING AUTHORITY:

The bill grants DBPR appropriate rulemaking authority sufficient to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

Line 55 contains the phrase “substantially all” within the definition of “prescription drug”, with regard to when API can be considered a prescription drug. The term “substantially all” is not defined in the bill or the applicable statute.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On January 31, 2012, the Health and Humans Services Quality Subcommittee adopted a strike-all amendment for House Bill 751. The strike-all amendment made the following changes to the bill:

- Amended the definitions of “distribute” or “distribution”, “drug”, “establishment”, and “prescription drug”;
- Created an exception to permitting requirements to allow an establishment located in the U.S. to distribute active pharmaceutical ingredients to a Florida-licensed manufacturer for the purpose of manufacturing finished prescription drug products under certain conditions;
- Created an exception to permitting requirements to allow an establishment located in the U.S. to distribute limited amounts of non-repackaged prescription drugs to a Florida-licensed manufacturer, or holder of an exemption letter issued DBPR, for research and development under certain conditions;
- Preserved the current exemption from licensure as a non-resident manufacturer of active pharmaceutical ingredients to distribute to Florida manufacturers for research and development, and use in federally authorized and regulated biostudies and clinical studies;
- Preserved the current exemption from licensure as an out-of-state prescription drug distributor for intracompany transfers from an out-of-state distributor licensed in another state to a distributor in Florida under the same name;
- Created a new subsection in s. 499.01, F.S., containing all exemptions from the permitting process detailed above;
- Required in-state recipients of prescription drugs to ensure that the product is not resold to persons or used on humans, except in lawful clinical trials and biostudies;
- Required a label to be placed on all prescription drugs distributed in Florida for the purpose of research and development, teaching, or testing clearly stating that the drug is for research, teaching, or testing only and not to be used for manufacturing, compounding, or resale;
- Required in-state recipients of prescription drugs from exempted sources to maintain certain records on the source of the prescription drugs, including a copy of the most recent inspection report from the exempted source’s resident state or the FDA from all distributors and establishments from whom prescription drugs are purchased or received;
- Required entities engaging in the distribution of prescription drugs to provide all records related to distribution to DBPR within 48 hours of a request from the department;
- Required entities that receive misbranded or adulterated drugs to report the receipt of these drugs to DBPR within 14 days of receipt;
- Made a failure to comply with the provisions of the bill unlawful pursuant to s. 499.005(14), F.S.;
- Made a knowing failure to comply with the provisions of the bill a second degree felony pursuant to s. 499.0051(4), F.S.; and
- Reaffirmed that the exemptions provided by the bill do not relieve any person of the responsibility to comply with federal and state laws related to controlled substances.

The bill was reported favorably as a committee substitute. The analysis reflects the committee substitute.