HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/CS/HB 751 Prescription Drugs
SPONSOR(S): Health & Human Services Committee; Health & Human Services Quality Subcommittee, Brandes
TIED BILLS: **IDEN./SIM. BILLS:**

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 & Human Services Committee	16 Y, 0 N, As CS	Poche	Gormley

SUMMARY ANALYSIS

CS/CS/HB 751 addresses several aspects of prescription drug regulation in Florida.

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.

The bill establishes three 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. Third, the bill allows the holder of a restricted prescription drug distributor permit to repackage prescription drugs for distribution to a hospital or other health care entity under common control without obtaining a prescription drug repackager permit.

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 amends several definitions in conjunction with the regulation of controlled substance prescribing and pain-management clinics. The bill requires a physician to register as a controlled substance prescribing practitioner only if he or she is prescribing Schedule II through IV controlled substances. Rheumatologists, psychiatrists, and certain board-eligible physicians are exempted from the registration requirements and standards of practices for controlled substance prescribers in s. 456.44, F.S. Physiatrists are no longer exempted from the same provisions.

The bill exempts pain management clinics owned and operated by rheumatologists and certain board-eligible physicians from pain management clinic registration requirements in chapter 458, F.S., and chapter 459, F.S. Pain management clinics owned and operated by a physician multi-specialty practice are also exempted from registration requirements, provided one or more physicians in the practice is board-eligible or meets certain certification requirements.

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

Controlled Substances

Controlled substances are drugs with potential for abuse. Chapter 893, F.S., sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act and classifies controlled substances into five categories, known as schedules. The distinguishing factors between the different drug schedules are the "potential for abuse"[1] of the substance contained therein and whether there is a currently accepted medical use for the substance. These schedules are used to regulate the manufacture, distribution, preparation and dispensing of the substances. Substances in Schedule I have a high potential for abuse and have no currently accepted medical use in the United States.[2] Heroin, peyote, and cannabis are examples of Schedule I drugs. Schedule II drugs have a high potential for abuse and a severely restricted medical use. Cocaine and morphine are examples of Schedule II drugs. Schedule III controlled substances have less potential for abuse than Schedule I or Schedule II substances and have some accepted medical use. Substances listed in Schedule III include anabolic steroids, codeine, and derivatives of barbituric acid. Schedule IV and Schedule V substances have a low potential for abuse, compared to substances in Schedules I, II, and III, and currently have accepted medical use. Substances in Schedule IV include phenobarbital, librium, and valium. Substances in Schedule V include certain stimulants and narcotic compounds.

Any health care professional wishing to prescribe controlled substances must apply for a prescribing number from the federal Drug Enforcement Administration (DEA). Prescribing numbers are linked to state licenses and may be suspended or revoked upon any disciplinary action taken against a licensee. The DEA will grant prescribing numbers to a wide range of health care professionals, including physicians, nurse practitioners, physician assistants, optometrists, dentists, and veterinarians, but such professionals may only prescribe controlled substances which have been authorized to them under state law. Prescribing numbers must be renewed every 3 years.

Controlled Substance Prescribing

As of January 1, 2012, every physician, podiatrist, or dentist who prescribes controlled substances in the state for the treatment of chronic nonmalignant pain must register as a controlled substance prescribing practitioner and comply with certain practice standards specified in statute and rule.

Before prescribing any controlled substances for the treatment of chronic nonmalignant pain, a practitioner must document certain characteristics about the nature of the pain, success of past treatments, any underlying health problems, and history of alcohol and substance abuse. The practitioner must develop a written plan for assessing the patient's risk for aberrant drug-related behavior and monitor such behavior throughout the course of controlled substance treatment. Each practitioner must also enter into a controlled substance agreement with their patients; such agreements must include the risks and benefits of controlled substance use, including the risk for addiction or dependence; the number and frequency of permitted prescriptions and refills; a statement of reasons for discontinuation of therapy, including violation of the agreement; and the requirement that patients' chronic nonmalignant pain only be treated by one practitioner at a time unless otherwise authorized and documented. This agreement must be signed by the patient or his or her legal representative and by the prescribing practitioner.

[1] *See* s. 893.02(19), F.S.
[2] *See* s. 893.03, F.S.

Patients treated with controlled substances must been seen by their prescribing practitioners at least once every 3 months to monitor progress and compliance, and detailed medical records relating to such treatment must be maintained. Patients at special risk for drug abuse or diversion may require co-monitoring by an addiction medicine physician or a psychiatrist. Anyone with signs or symptoms of substance abuse must be immediately referred to a pain management physician, an addiction medicine specialist, or an addiction medicine facility.

Anesthesiologists, physiatrists, neurologists, and surgeons are exempt from these provisions. Physicians who hold certain credentials relating to pain medicine are also exempt.

Pain Management Clinics

A pain management clinic is any facility that advertises pain management services or where a majority of patients are prescribed opioids, benzodiazepines, barbiturates, or carisoprodol for the treatment of chronic nonmalignant pain. Pain-management clinics are regulated by the practice acts for medical doctors and osteopathic physicians in s. 458.3265, F.S., and s. 459.0137, F.S. Until January 1, 2016, all pain management clinics must register with the Department of Health (DOH) and meet certain provisions concerning staffing, sanitation, recordkeeping, and quality assurance. Clinics are exempt from these provisions if they are:

- Licensed under ch. 395, F.S., as a hospital, ambulatory surgical center, or mobile surgical facility;
- Staffed primarily by surgeons;
- Owned by a publicly held corporation whose shares are traded on a national exchange or on the over-the-counter market and whose total assets at the end of the corporation's most recent fiscal quarter exceeded $50 million;
- Affiliated with an accredited medical school at which training is provided for medical student, residents, or fellows;
- Not involved in prescribing controlled substances for the treatment of pain;
- Owned by a corporate entity exempt from federal taxation under 26 U.S.C. s. 501(c)(3); or
- Wholly owned and operated by anesthesiologists, physiatrists, or neurologists, or physicians holding certain credentials in pain medicine.

All clinics must be owned by at least one licensed physician or be licensed as a health care clinic under part X of ch. 400, F.S., to be eligible for registration. DOH is prohibited from registering an entity:

- Not owned by a physician;
- Whose DEA number has ever been revoked;
- Whose application for a license to prescribe, dispense, or administer a controlled substance has been denied by any jurisdiction; or
- Who have been convicted of certain drug-related crimes in any jurisdiction.

Pain management clinics are inspected annually by DOH unless they hold current certification from a DOH-approved national accrediting agency. DOH may suspend or revoke clinic registration or impose administrative fines of up to $5,000 per violation for any offenses against state pain management clinic provisions or related federal laws and rules.

If the registration for a pain management clinic is revoked for any reason, the clinic must cease to operate immediately, remove all signs or symbols identifying the facility as a pain management clinic, and dispose of any medication on the premises. No owner or operator of the clinic may own or operate another pain clinic for five years after revocation of registration.

Board Certification Organizations

The American Board of Medical Specialties (ABMS) certifies physicians in medical subspecialties. Established in 1933, ABMS assists 24 member specialty boards in developing and implementing

standards in the ongoing evaluation and certification of physicians.[3] ABMS member boards certify physicians in more than 150 different specialties and subspecialties. ABMS board certification is available to both allopathic and osteopathic physicians. Another standard of certification for osteopathic physicians is receiving a certificate of added qualification through the American Osteopathic Association (AOA).[4]

The American Board of Pain Medicine (ABPM) administers a psychometrically developed and practice-related examination in the field of pain medicine to qualified candidates.[5] Physicians who have successfully completed the ABPM credentialing process and examination are issued certificates as specialists in the field of pain medicine and designated as Diplomates of the ABPM.[6]

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.[7] 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;[8]
- More thorough documentation of the distribution of prescription drugs, including broader application of the pedigree paper to most wholesale distributions;[9]
- Enhanced criminal penalties for, among other things, distribution of contraband prescription drugs;[10] and

[3] *See* American Board of Medical Specialties website at http://www.abms.org. (last viewed on February 20, 2012).
[4] American Osteopathic Association, *Certification of Osteopathic Physicians,* available at http://www.osteopathic.org/osteopathic-health/about-dos/do-certification/Pages/default.aspx (last viewed February 20, 2012).
[5] *See* American Board of Pain Medicine website available at http://www.abpm.org/about (last viewed on February 23, 2012).
[6] *Id.*
[7] 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.
[8] 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).
[9] 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.")
[10] 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").

- Stronger departmental enforcement authority to protect the prescription drug supply chain.[11]

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.[12] 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 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,[13] 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.[14]

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.[15]

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.[16]

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:

[11] S. 499.0051(12) and (13), F.S.
[12] *See* First Interim Report of the Seventeenth Statewide Grand Jury, Case No. SC02-2645 (2003).
[13] *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.").
[14] *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*).
[15] Chapter 61N-1, Florida Administrative Code, contains the rules adopted under the Act's authority (formerly housed in Chapter 64F-12, Florida Administrative Code).
[16] 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.

- Chemical synthesis;
- Fermentation process;
- Recombinant DNA or other biotechnology methods;
- Isolation/recovery from natural sources; or
- Any combination of these processes.[17]

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.[18]

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)[19] 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.[20]

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.[21] A prospective permittee must complete and submit the proper application to DBPR, along with the applicable fee.[22] 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.[23]

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[17] LGM Pharma, *Active Pharmaceutical Ingredients*, available at http://www.lgmpharma.com/resources/active-pharmaceutical-ingredients/ (last viewed on February 1, 2012).
[18] *Id.*
[19] S. 499.003(54), F.S.; *see also* Rule 61N-1.001, F.A.C.
[20] S. 499.003(55), F.S.
[2121] S. 499.01(2)(d), F.S.; *see also* s. 499.012(8) and (9)(a), F.S.
[22] Rule 61N-1.015(7), F.A.C., contains the complete permitting requirements for a Prescription Drug Wholesale Distributor permit; *see also* Rule 61N-1.018(2)(b), F.A.C., for fee schedule.
[23] Florida Department of Business and Professional Regulation, *DRUGS, DEVICES AND COSMETICS PROGRAM-*

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 drug wholesale operations at the establishment, and all affiliated parties[24] of the establishment. Lastly, the distribution facility must submit to pre-application inspection before the permit can be issued.[25]

Out-of-state prescription drug wholesale distributors are required to obtain a specific permit in order to distribute drugs in the state.[26] 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.[27]

Upon application for a permit, an out-of-state prescription drug wholesale distributor is required to post a bond of $100,000.[28] 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.[29] 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.[30]

Specific requirements for obtaining an initial out-of-state prescription drug wholesale distributor permit are found in administrative rule.[31] The prospective permittee must obtain an application form and fingerprint cards from DBPR.[32] The completed application form must be completed and submitted to DBPR.[33] 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.[34] Each required party must submit a completed fingerprint card and $47.00 to DBPR.[35] 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.[36] 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:

PRESCRIPTION DRUG WHOLESALE DISTRIBUTOR-REQUIREMENTS; available at http://www.myfloridalicense.com/dbpr/ddc/PrescriptionDrugWholesalerDistributor.html (last viewed January 30, 2012); *see also* Rule 61N-1.015(9), F.A.C.

[24] 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.

[25] *See supra* at FN 15.

[26] S. 499.01(1)(e), F.S.

[27] S. 499.01(2)(e), F.S.

[28] *Id.*; *see also* Rule 61N-1.015(7)(e)5., F.A.C.

[29] *Id.*

[30] S. 499.01(2)(e)1., F.S.

[31] Rule 61N-1.015(7)(e), F.A.C.; *see also* s. 499.012, F.S., for additional specific requirements for permitting.

[32] Rule 61N-1.015(7)(e)1., F.A.C.

[33] Rule 61N-1.015(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.

[34] Rule 61N-1.015(7)(e)3., F.A.C., requires Form DH 2125, the "Personal Information Statement", to be filed with DBPR.

[35] Rule 61N-1.015(7)(e)4., F.A.C.

[36] Rule 61N-1.015(7)(e)6., F.A.C.

- 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[37]; 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[38]; or
- 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.[39]

The prospective permittee must identify a person within the company who is certified, pursuant to s. 499.012(16), F.S.,[40] to serve as the designated representative for the prospective permittee.[41] Any change of the certified designated representative must be reported to DBPR.[42] 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.[43]

Restricted Prescription Drug Distributor Permit- Health Care Entity

The Restricted Prescription Drug Distributor permit is required for a hospital or health care entity[44] to transfer prescription drugs among hospitals or other health care entities that are under common control[45] or are members of a group purchasing organization.[46]. Transfers are limited to a facility under common control or member of the group purchasing organizations, either of which must be licensed with a pharmacy permit that allows for obtaining and possessing prescription drugs.[47]

To obtain a Restricted Prescription Drug Distributor permit, an entity must obtain, complete, and file the appropriate application.[48] The applying entity must submit a listing of all locations under common control that will be receiving distributions of prescription drugs under the permit, including the name and address of the facility and the pharmacy or other applicable permit number that allows the location to possess prescription drugs.[49] If the applying entity is a group purchasing organization, or a member of such an organization, the entity must provide a copy of the contract establishing the members of the group purchasing organization and include a listing of all of the locations that will be receiving

[37] Rule 61N-1.015(7)(e)6.a., F.A.C.
[38] Rule 61N-1.015(7)(e)6.b., F.A.C.
[39] *Id.*; *see also* 21 C.F.R. 205.50 (2003) for storage, handling, and recordkeeping requirements.
[40] 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.
[41] Rule 61N-1.015(7)(e)7., F.A.C.
[42] *Id.*; a prospective permittee must use Form DH 2130 to communicate any change in certified designated representative to DBPR.
[43] Rule 61N-1.015(7)(e)8., F.A.C.; *see also* Rule 61N-1.018(3), (4)(a), and (4)(b), F.A.C., outlining applicable fee amounts.
[44] S. 499.003(23), F.S., defines a "health care entity" as "…a closed pharmacy or any person, organization, or business entity that provides diagnostic, medical, surgical, or dental treatment or care, or chronic or rehabilitative care, but does not include any wholesale distributor or retail pharmacy licensed under state law to deal in prescription drugs."
[45] This language can be found in Rule 61N-1.023(2), F.A.C. The text of the rule references s. 499.012(1)(a)3., F.S., for the definition of "common control". However, no such statutory provision exists. A definition of "common control" is found in s. 499.003(54)(a)3., but is limited for the purposes of the definition of "wholesale distribution". The definition of "common control" is "…the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, by voting rights, by contract, or otherwise."
[46] *Id.* The text of the rule references s. 499.012(1)(a)1., F.S., for the definition of "group purchasing organization". However, no such statutory provision exists. A reference to a "group purchasing organization", but no definition of the term, can be found in s. 499.003(54)(a)1., F.S., in relation to the definition of "wholesale distribution". The statutory section reads, "The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a prescription drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of that organization."
[47] Rule 61N-1.023(2), F.A.C.
[48] Rule 61N-1.015(8)(b)2., F.A.C., requires Form DH 1033, "Application for Permit Under Chapter 499, F.S.", to be used for this purpose.
[49] Rule 61N-1.015(8)(b)3., F.A.C.

distributions of prescription drugs under the permit through membership in the organization.[50] The fee for the permit is $600, renewable on a biennial basis.[51]

Prescription Drug Repackaging in Florida

A prescription drug repackager permit is required for any person that repackages a prescription drug in Florida.[52] The permit authorizes the wholesale distribution of prescription drugs repackaged at the establishment. The term "repackage" is defined in Florida statutes to include "…repacking or otherwise changing the container, wrapper, or labeling to further the distribution of the drug, device, or cosmetic."[53] Examples of repackaging include:

- Altering a packaging component that is, or may be, in direct contact with the drug, device, or cosmetic;
- Altering a manufacturer's package for sale under a label different from the manufacturer; and
- Altering a package of multiple-units, which the manufacturer intended to be distributed as one unit, for sale or transfer to a person engaged in the further distribution of the product.[54]

To obtain a prescription drug repackager permit, a person located in Florida must have an FDA establishment registration number or provide documentation to DBPR showing an exemption from registration with the FDA.[55] An entity must obtain, complete, and submit the appropriate application to DBPR.[56] The fee for the permit is $1,500, which is renewable on a biennial basis.[57] In addition, an entity must pay an initial application on-site inspection fee of $150.[58]

Effect of Proposed Changes

Controlled Substance Regulation

CS/CS/HB 751 amends definitions found in s. 456.44, F.S. The definition of "addiction medicine specialist" is revised to include a board-certified psychiatrist and delete reference to a board-certified physiatrist. The definition of "board-certified pain management physician" is amended to include a physician certified in pain management by the ABMS.

Instead of requiring certain physicians to register as controlled substance prescribing practitioners if any controlled substances are prescribed for the treatment of chronic nonmalignant pain, the bill requires registration only if the physician prescribes controlled substances in schedules II-IV. The bill requires that patients who are especially at risk for substance abuse and are prescribed controlled substances for treatment be co-managed by the prescribing physician and an addictionologist or a psychiatrist, rather than a physiatrist. The bill adds a board-certified rheumatologist and certain board-eligible practitioners to the list of physicians exempt from the standards of practice for prescribing controlled substances contained in s. 456.44, F.S., and excludes pain related to rheumatoid arthritis from the definition of "chronic nonmalignant pain".

The bill amends s. 458.3265, F.S., and s. 459.0137, F.S., to revise the definition of "chronic nonmalignant pain" to exclude pain related to rheumatoid arthritis. The PCS adds the following exemptions from registration as pain-management clinics:

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[50] *Id.*
[51] Rule 61N-1.018(3), F.A.C.
[52] Florida Department of Business and Professional Regulation, Drugs, Devices, and Cosmetics Program, *Prescription Drug Repackager*, available at http://www.myfloridalicense.com/dbpr/ddc/PrescriptionDrugRepackager.html. (last viewed on February 18, 2012).; *see also* s. 499.01(2)(b), F.S.
[53] S. 499.003(49), F.S.
[54] *See supra* at FN 46.
[55] Rule 61N-1.015(6)(c)5., F.A.C.
[56] Rule 61N-1.015(6)(c)2., F.A.C., requires Form DH 1033, "Application for Permit Under Chapter 499, F.S.", to be submitted; *see also* s. 499.012, F.S., for additional permit application requirements.
[57] Rule 61N-1.018(1), F.A.C.
[58] Rule 61N-1.018(4)(b), F.A.C.

- Clinics wholly owned by one or more board-certified rheumatologists;
- Clinics wholly owned by one or more board-eligible anesthesiologists, physiatrists, rheumatologists, or neurologists; and
- Clinics wholly owned by board-eligible or board-certified medical specialists in a multi-specialty practice in which one or more of the specialists has completed a fellowship in pain medicine approved by certain accrediting organizations or is also board-certified in pain medicine, recognized by certain accrediting organizations, and performs interventional pain procedures.

Prescription Drug Distribution and Repackaging Regulation

CS/CS/HB 751 creates new subsections (3) and (4) of s. 499.01, F.S., containing the exemptions to the permitting process that currently exists 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 three 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 five FDA applications:

- New Drug Application;
- Abbreviated New Drug Application, which is used for generic drugs;
- New Animal Drug Application;
- Therapeutic Biologic 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 and has not been withdrawn or removed from the U.S. market for public health reasons.

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 DBPR pursuant to s. 499.03(4), F.S., to receive limited quantities of prescription drugs for the purpose of research, teaching, or testing.[59]

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.

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. 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

[59] Section 499.03(4), F.S., allows the DBPR to adopt rules relating to persons engaged in lawful teaching, research, or testing who possess prescription drugs and allows the department to issue letters of exemption to permit the lawful possession of prescriptions drugs by those persons.

following statement: “Caution: Research, Teaching, or Testing Only – Not for Commercial Use, Distribution, or Resale”.

Establishments claiming the Finished Product Exemption or the Research and Development Exemption must also comply with the following provisions under the bill:

- Maintain a license or permit as a manufacturer or wholesale distributor in the state from which the prescription drugs are distributed;
- For the recipients or purchasers of prescription drugs from establishments claiming an exemption, maintain the FDA establishment number of the establishment where the prescription drugs are manufactured, the distributing establishment’s resident state license, permit or certificate number, and the most recent resident state or FDA inspection report for the distributing establishment; and
- Comply with all recordkeeping requirements under s. 499.0121(6), F.S., but are exempt from the pedigree paper requirements of s. 499.01212, F.S.

Hospital Repackaging Exemption

The bill provides that a prescription drug repackager permit is not required for the holder of a restricted prescription drug distributor permit that is a health care entity to repackage prescription drugs in Florida for its own use or distribution to a hospital or other health care entity for their own use. To qualify for the exemption, the health care entity intending to repackage prescription drugs must:

- Notify DBPR, in writing, of its intent to repackage and distribute prescription drugs consistent with this provision at least thirty days prior to repackaging the prescription drugs;
- Be under common control with the hospital or other health care entity to which it intends to distribute the repackaged prescription drugs;
- Repackage the prescription drugs in a manner consistent with state and federal good manufacturing practices; and
- Label the repackaged prescription drugs pursuant to state and federal laws and statutes.

A distributor of repackaged prescription drugs pursuant to these provisions is exempt from the product registration requirements of s. 499.015, F.S., which would otherwise be applicable to the prescription drugs that are repackaged and distributed.

This exemption would allow hospital systems and other health care entity systems to repackage and distribute prescription drugs to other entities within the system, such as an urgent care clinic, an ambulatory surgical center, or a diagnostic imaging center, without the need for an additional permit and without the need to register each repackaged drug and pay the associated fees.

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 definition specifically excludes the non-drug components of a device regulated by chapter 499, F.S. The term “prescription drug” is amended to specify the circumstance in which an active pharmaceutical ingredient will be considered a prescription drug.

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 two additional definitions. First, the definition of "establishment" is amended to include one or more contiguous buildings or building subdivisions, including suites, units, and floors, or to one or more buildings located on a single controlled-access property owned or by entities under common control. To be considered contiguous, buildings or building subdivisions must adjoin or share a sufficient common boundary to allow full access to the whole establishment without crossing a public roadway, waterway, or similar boundary.

The bill also requires that each individual suite, unit, floor, or building be specified in the most recent permit application. An establishment cannot expand to include other buildings or building subdivisions under its' current permit without an approved change of address application required by s. 499.012(6)(a), F.S. 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, so long as each location is listed in the current permit.

Second, the definition of "distribute" or "distribution" is amended to exclude billing, invoicing, and payment collection and processing activities that are normally involved in 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. 456.44, F.S., relating to controlled substance prescribing.
Section 2: Amends s. 458.3265, F.S., relating to pain-management clinics.
Section 3: Amends s. 459.0137, F.S., relating to pain-management clinics.
Section 4: Amends s. 499.003, F.S., relating to definitions.
Section 5: Amends s. 499.01, F.S., relating to permits.
Section 6: 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:

Psychiatrists, rheumatologists, and practitioners who work under their supervision will be exempt from certain controlled substance prescribing and pain management clinic registration provisions. Certain board-eligible practitioners will also be exempt from controlled substance prescribing and pain management clinic registration provisions.

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.[60] 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.[61]

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:

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

C. DRAFTING ISSUES OR OTHER COMMENTS:

Line 63 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.

[60] 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).
[61] *Id.*

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On February 23, 2012, the Health and Human Services Committee adopted four amendments to the PCS for CS/HB 751. The amendments:

- Corrected a drafting error by removing the duplicate term, “that has not been repackaged”;
- Exempted certain physicians who are board-eligible in certain specialties from the controlled substance prescribing provisions of s. 465.44, F.S.;
- Exempted certain physician specialists who are board-certified by the American Board of Pain Medicine from the controlled substance prescribing provisions of s. 465.44, F.S.;
- Exempted pain management clinics owned and operated by certain board-eligible physician specialists from pain management clinic registration requirements in s. 458.3265, F.S., and s. 459.0137, F.S.;
- Exempted pain management clinics owned and operated by a physician multi-specialty practice from pain management clinic registration requirements in s. 458.3265, F.S., and s. 459.0137, F.S., provided at least one member of the practice is board-eligible; and
- Added board-certification in pain medicine recognized by the American Board of Pain Medicine and board-approval recognized by the American Association of Physician Specialists to the list of certifications or eligibilities required of at least one member of a physician multi-specialty practice which owns and operates a pain management clinic in order to be exempt from the clinic registration requirements of s. 458.3265, F.S., and s. 459.0137, F.S.

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