

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/CS/HB 7095 PCB HHSC 11-03 Controlled Substances

SPONSOR(S): Appropriations Committee; Judiciary Committee and Health & Human Services Committee, Schenck

TIED BILLS: IDEN./SIM. BILLS:

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Health & Human Services Committee	13 Y, 5 N	Calamas	Gormley
1) Judiciary Committee	12 Y, 6 N, As CS	Thomas	Havlicak
2) Appropriations Committee	24 Y, 0 N, As CS	Jones Darity	Leznoff

SUMMARY ANALYSIS

The bill addresses the problem of prescription drug abuse in Florida by amending regulation of each entity in the supply chain: wholesale distributors, pain-management clinics, pharmacies, pharmacists, and physicians. The bill creates criminal violations, amends the prescription drug monitoring program, and requires immediate action by law enforcement and regulators.

The bill requires distributors to report distribution data to the Department of Health (DOH), credential purchasers of controlled substances, including criminal background screening, and places limits on distribution certain controlled substances to retail pharmacies. The bill makes improper distribution and false reporting third degree felonies.

The bill amends the definition of "pain-management clinic" and exempts clinics owned by certain physicians from regulatory requirements. The bill also sets standards for the operation of pain-management clinics and requires physicians practicing in the clinics to ensure they are met.

The bill bans dispensing of Schedule II and Schedule III controlled substances by a physician and makes such dispensing both a third degree felony and grounds for licensure discipline. Dispensing physicians must return existing inventories of these controlled substances to the wholesale distributors from which they were purchased within 10 days of enactment of the bill, or turn in all inventories to law enforcement to be destroyed. Wholesale distributors are required to buy back the controlled substances at the practitioner's purchase price.

The bill requires practitioners treating chronic, non-cancer pain with controlled substances to register with their boards, maintain a prescription log and make it available to DOH and the Department of Law Enforcement (FDLE). The bill creates a standard of care for all physicians prescribing controlled substances for treatment of chronic non-cancer pain, regardless of setting, and provides an exemption for physicians meeting certain requirements. The bill requires that prescriptions for controlled substances must be written on a counterfeit-proof prescription pad from a DOH-approved vendor or electronically prescribed.

The bill creates additional standards for obtaining and maintaining a pharmacy permit, including onsite inspections, financial disclosures, and exclusions based on criminal or permitting discipline history. The bill limits the community pharmacies allowed to dispense Schedule II and Schedule III controlled substances to pharmacies that meet specific criteria, including permitting under the new standards. In addition, the bill creates additional grounds for denial or discipline of a pharmacist license, based on errors or omissions in processing prescription drugs.

The bill adds criminal provisions related to theft of, and burglary of a structure or conveyance with the intent to steal, controlled substances and requires a pharmacist to report the obtaining or attempting to obtain controlled substances by improper means and the discovery of a theft or loss of a controlled substance to law enforcement. Failure to report is a second degree misdemeanor.

The bill prohibits donations from pharmaceutical manufacturers to support the prescription drug monitoring program, modifies data submission requirement to 7 days from 15 days, and removes references to the Office of Drug Control.

The bill directs DOH to declare a public health emergency on the third day after enactment of the law. Upon the declaration, FDLE and local law enforcement are authorized to secure, on-site, all unreturned inventories of Schedule II and Schedule III controlled substances 24 hours per day until the dispensing physician is returns the controlled substances to the wholesale distributor. Any remaining inventory becomes contraband on the tenth day following enactment, and law enforcement is required to seize the inventory and destroy it pursuant to applicable law. The bill sunsets these provisions on January 1, 2013.

The bill appropriates \$3 million in non-recurring General Revenue funds to defray the cost to law enforcement for the quarantine period, investigative activities, and prosecution of crimes related to prescribed controlled substances. The bill may have a negative fiscal impact on local government. (See Fiscal Comments).

The bill is effective on July 1, 2011, and specified provisions are effective January 1, 2012.

This document does not reflect the intent or official position of the bill sponsor or House of Representatives.

STORAGE NAME: h7095c.APC

DATE: 4/14/2011

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.

Prescription Drug Abuse

Most people who take prescription medications take them responsibly; however, the nonmedical use or abuse of prescription drugs remains a serious public health concern in the United States. Certain prescription drugs – opioid substances, central nervous system depressants, and stimulants – when abused can alter the brain’s activity and lead to dependence and possible addiction. According to research by the National Institute on Drug Abuse³, the three most abused classes of prescription drugs are:

- Opioids, used to treat pain. Examples include codeine (Schedules II, III, V), oxycodone (OxyContin, Percocet – Schedule II), and morphine (Kadian, Avinza -Schedule II);
- Central nervous system depressants, used to treat anxiety and sleep disorders. Examples include barbiturates (Mebaral, Nembutal) and benzodiazepines (Valium, Xanax) (all in Schedule IV); and
- Stimulants, used to treat ADHD, narcolepsy, and obesity. Examples include dextroamphetamine (Dexedrine, Adderall) and methylphenidate (Ritalin, Concerta) (all in Schedule II).

The Substance Abuse and Mental Health Services Administration (SAMHSA) sponsors an annual national survey on drug use and health. The most recent survey⁴ indicates there are 6.9 million (2.8 percent) persons aged 12 or older who used prescription-type psychotherapeutic drugs non-medically in 2007. Of these, 5.2 million persons used pain relievers, a number similar to the number of persons aged 12 or older reported to be using pain relievers non-medically in 2006.⁵

Of those 6.9 million people who used prescription-type psychotherapeutic drugs non-medically in the 12-month period, 56.5 percent reported they received the drug from a friend or relative for free, 8.9 percent bought the drugs from a friend or family member, 18.1 percent reported they obtained the drug through just one doctor, only 4.1 percent got the pain relievers from a drug dealer or other stranger, and only 0.5

¹ See s. 893.02(19), F.S.

² See s. 893.03, F.S.

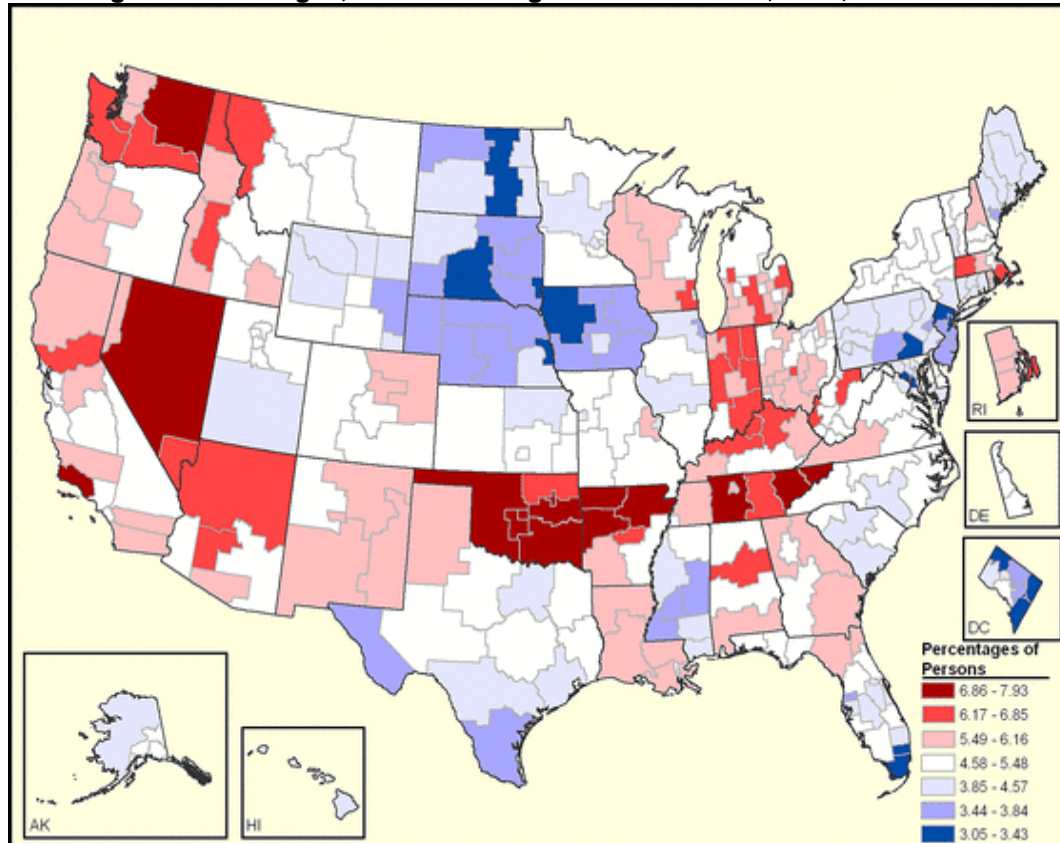
³ See <http://www.nida.nih.gov/drugpages/prescription.html> (last visited March 28, 2011).

⁴ 2007 National Survey on Drug Use and Health, U.S. Substance Abuse and Mental Health Services Administration, *see* <http://oas.samhsa.gov/NSDUH/2k9NSDUH/2k9ResultsP.pdf> (last visited March 28, 2011).

⁵ *Id.*

percent reported buying the drug on the Internet. Among those who reported getting the pain reliever from a friend or relative for free, 81.0 percent reported in a follow-up question that the friend or relative had obtained the drugs from just one doctor, while only 1.8 percent reported that the friend or relative had bought the drug from a drug dealer or other stranger.⁶ According to the Drug Abuse Warning Network (DAWN), approximately 516,000 emergency department visits in 2009 involved analgesics, including both prescription and over-the-counter pain medications; 416,450 involved opiates and opioids.⁷

Figure C3.3 Nonmedical Use of Pain Relievers in Past Year among Persons Aged 12 or Older, by Substate Region: Percentages, Annual Averages Based on 2006, 2007, and 2008 NSDUHs.



Source: Substance Abuse and Mental Health Services Administration, Office of Applied Studies (August 2010), National Survey on Drug Use and Health, 2006-2008 (last viewed February 23, 2011), see <http://oas.samsha.gov/substate2k10/SecC.htm#FigC3.3>

As the preceding map shows, national data indicate that the percent of the population using prescription pain relievers for nonmedical purposes in the past year ranged from a low of 3.1 percent in the areas of the District of Columbia and parts of Maryland and New Jersey to a high of 7.9 percent in parts of Oklahoma. In Florida, for example, Palm Beach County measured between 3.85 and 4.57 percent; Broward, Miami-Dade and Monroe Counties measured between 3.05 and 3.43 percent; and Escambia, Okaloosa, Santa Rosa and Walton Counties combined measured between 4.58 and 5.48 percent.⁸

The abuse of prescription drugs is becoming more prevalent and more deadly than the abuse of illicit drugs, such as heroin, cocaine, and methamphetamine. The Florida Medical Examiners Commission reports on drug-related deaths in Florida, and specifically tracks deaths caused by the abuse of prescription drugs. According to the Commission, prescription drugs are found in deceased persons in lethal amounts more often than illicit drugs. The most recent report, examining drug-related deaths for the

⁶ *Id.*

⁷ National Estimates of Drug-Related Emergency Department Visits 2004-2009, see <https://dawninfo.samsha.gov/data/default.asp?met=All> (last visited March 28, 2011).

⁸ Substance Abuse and Mental Health Services Administration, Office of Applied Studies, National Survey on Drug Use and Health, 2006, 2007, and 2008. See <http://oas.samsha.gov/substate2k10/statefiles/FL.htm> (last visited March 28, 2011).

first six months of 2010, found 1,268 deaths caused by prescription drugs.⁹ The rate of deaths caused by prescription drugs during the first six months of 2010 averaged 7 fatalities per day.¹⁰

In 2009, the State Attorney for the 17th Judicial Circuit (Broward County) empanelled a grand jury to consider the proliferation of pain clinics in Broward County and their effect on the community, and to make recommendations on what can be done to protect the public from the dangers of pain clinics. The grand jury interim report found that physicians in pain clinics dispense controlled substances directly to patients, rather than the patient going to a pharmacy to fill the prescription. Among other things, the grand jury recommended the state prohibit dispensing prescription drugs in pain clinics.¹¹ The grand jury noted that the typical 30 day “cocktail” of controlled substances prescribed by a physician at a pill mill consists of:

- 150 to 240 30-milligram Roxicodone pills;
- 90 to 100 10-milligram Percocet pills;
- 300 50 milligram tablets of Soma, a muscle relaxer; and
- 2 milligram pills of Xanax, an anti-anxiety medication.¹²

Florida is widely viewed as a major source of prescription drugs for people from other states. According to the Drug Enforcement Administration (DEA), of the top 50 practitioners dispensing oxycodone in the United States during the period of October 2008 to March 2009, all but 1 physician were located in Florida.¹³ The top 49 practitioners dispensing oxycodone in the United States were concentrated in nine counties.¹⁴ Broward County contains half of the top dispensing practitioners, who were responsible for 55.4 percent of total units of oxycodone dispensed in the country during this time period.¹⁵ In Florida, 9,201,731 dose units of oxycodone were dispensed during one six month time period.¹⁶ The following tables illustrate the amount of oxycodone being dispensed by physicians in central and south Florida during a recent six month time period, by county and zip code.¹⁷

County	Units Oxycodone
Broward	5,233,785
Palm Beach	2,368,430
Miami-Dade	646,500
Pinellas	192,400
Hillsborough	184,330
Lake	169,200
Seminole	164,686
Orange	133,600

Zip Code	Units Oxycodone
33309	1,014,800
33334	666,700
33311	660,900
33009	526,100
33313	500,900
33445	500,700
33407	469,400
33162	420,200
33324	384,385
33421	380,400
33312	347,700
33417	308,230

Zip Code	Units Oxycodone
33020	281,500
33444	239,500
33179	226,300
33463	187,700
33308	176,600
33021	176,000
33487	166,700
33023	141,700
33301	120,400
33323	118,400
33432	117,800
33325	114,700

⁹ *Drugs Identified in Deceased Persons by Florida Medical Examiners*, 2010 Interim Report, Medical Examiners Commission, FDLE, December 2010, at <http://www.fdle.state.fl.us/Content/getdoc/8a59bd00-c38d-4be1-ac06-715a273b552e/MEC-2010-Interim-Report.aspx> (last visited March 28, 2011).

¹⁰ *Id.*

¹¹ *The Proliferation of Pain Clinics in South Florida*, Interim Report of the Broward County Grand Jury, Circuit Court of the Seventeenth Judicial Circuit, November 19, 2009.

¹² *Id.*

¹³ Automation of Reports and Consolidated Orders System (ARCOS) data for Oct. 2008 to March 2009 provided by the U.S. DEA through the Broward County Sheriff’s Office, September 2009.

¹⁴ *Id.*

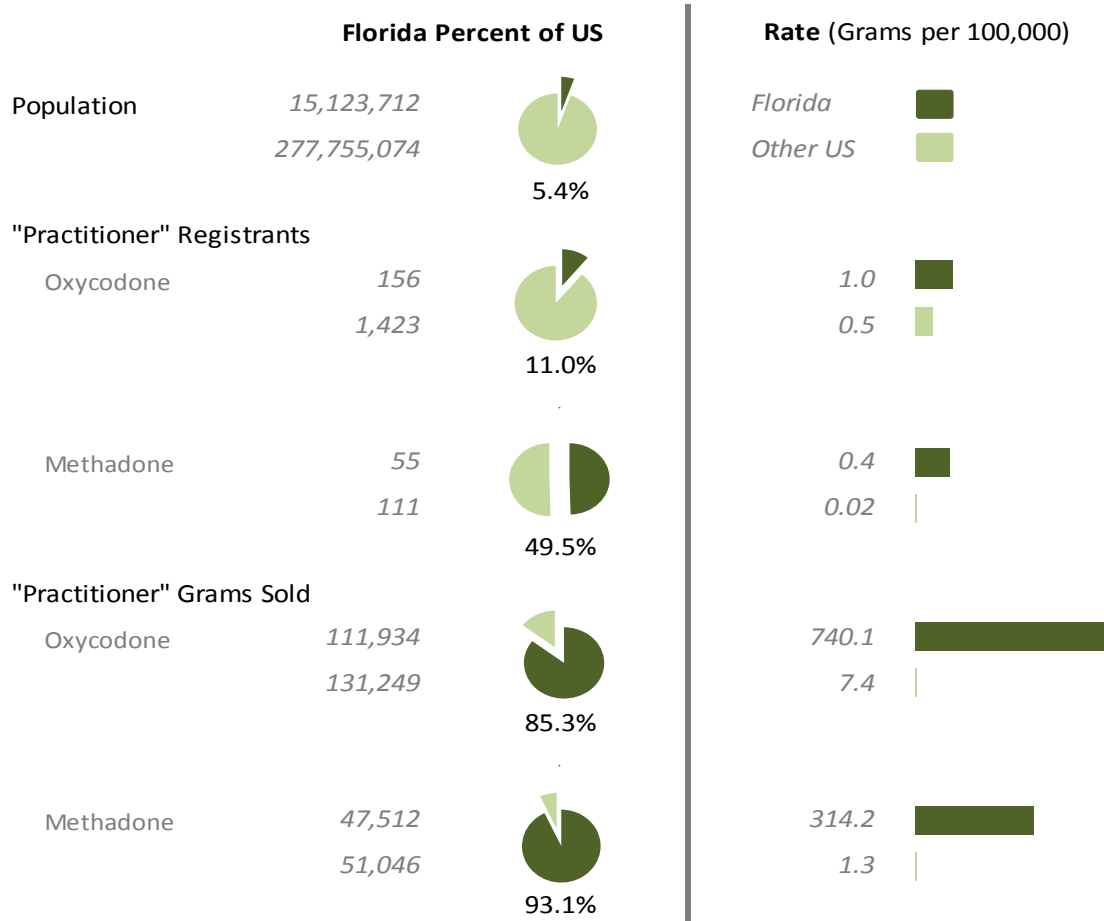
¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *Id.*

The following chart reports the dispensing of oxycodone and methadone by physicians in Florida compared to physicians in the rest of the country. The population of Florida accounts for less than 6 percent of the total population of the United States, but Florida has 11 percent of the physicians who dispense oxycodone, and almost 50 percent of the physicians who dispense methadone in the U.S. Physicians in Florida dispense more than 85 percent of the oxycodone dispensed by physicians in the U.S., and over 93 percent of the methadone dispensed by physicians in the U.S.¹⁸

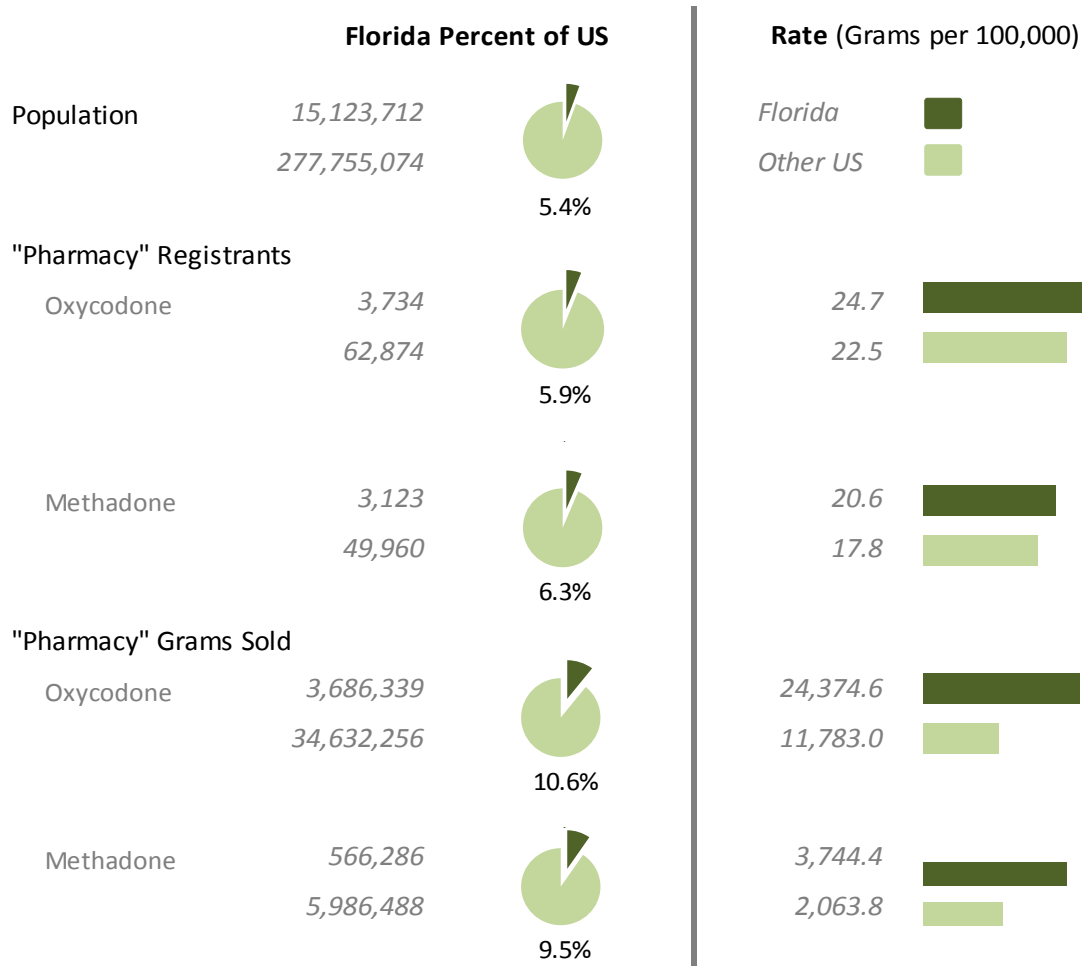
Controlled Drug Dispensing by Practitioners



¹⁸ U.S. Department of Justice, Drug Enforcement Agency, Automation of Reports and Consolidated Orders System, 2006.

The chart below illustrates how much oxycodone and methadone is dispensed by pharmacies in Florida compared to pharmacies in the rest of the country. The population of Florida accounts for less than 6 percent of the total population of the United States. Florida pharmacies dispense more than 10 percent of the oxycodone and nearly 10 percent of the methadone dispensed in the U.S. by pharmacies.¹⁹

Controlled Drug Dispensing by Pharmacies



Controlled Substance Distribution and Dispensing Regulation

Manufacturers and Distributors

The manufacture and distribution of controlled substance prescription drugs in Florida are regulated under ch. 893, F.S., the Florida Comprehensive Drug Abuse Prevention and Control Act, and ch. 499, F.S. The federal government also regulates controlled substance prescription drugs through the U.S Controlled Substance Act.

Part I of chapter 499, F.S., requires DOH 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.

¹⁹ *Id.*

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.
- Establishment of 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.
- Establishment of the Cancer Drug Donation Program.
- Establishment of numerous enforcement avenues for DOH of Health, 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.²⁰
- More thorough documentation of the distribution of prescription drugs, including broader application of the pedigree paper to most wholesale distributions.²¹
- Enhanced criminal penalties for, among other things, distribution of contraband prescription drugs.²²
- Stronger departmental enforcement authority to protect the prescription drug supply chain.²³

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 for each permit type. The last column includes the number of complaints received by DOH for each license or permit type since July 1, 2009.

Ch. 499, F.S., Permit Types	Licenses/ Permitees/ Registrants	Complaints
Prescription Drug Manufacturer	106	15
Non-resident Prescription Drug Manufacturer	800	20
Prescription Drug Repackager	29	6
Prescription Drug Wholesale Distributor	131	31
Out-of-State Prescription Drug Wholesale Distributor	254	28
Retail Pharmacy Drug Wholesale Distributor	73	15
Prescription Drug Wholesale Distributor - Broker Only	4	1

Pharmacies

Chapter 465, F.S., requires DOH and the Board of Pharmacy to regulate the practice of pharmacy. Community pharmacies²⁴ are required to obtain a permit from the Board of Pharmacy. Pharmacy applicants are required to submit to a national criminal background check for each person having an ownership interest of 5 percent or more in the pharmacy, and for each person who manages or oversees the operation of the pharmacy, including officers and members of the board of directors. The board is

²⁰ See s. 499.01(2)(d), F.S. (requiring \$100,000 bond or other means of equivalent security) and s. 499.012(8) and (9), F.S. (requiring, e.g., place of residence for 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).

²¹ See 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.").

²² See 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").

²³ See s. 499.065, F.S. (authorizing DOH to immediately close a wholesale facility if it constitutes an imminent danger to public health).

²⁴ Chapter 465, F.S., distinguishes community pharmacies from institutional pharmacies, or pharmacies located in nursing homes or hospitals that dispense medications to patients for use within the institutions. Section 465.019, F.S.

required to deny the application if any person affiliated with the pharmacy has ever been convicted of a pharmacy-related crime, or of health care fraud, or has been terminated for cause by any state Medicaid program or the federal Medicare program. The board is also required to deny the application if the applicant or affiliated person has ever dispensed a drug when the pharmacist knew or had reason to believe the prescription was not based on a valid physician-patient relationship.²⁵

The board is required to adopt rules for the operation of pharmacies, and DOH inspects pharmacies annually to ensure compliance. Permittees are subject to disciplinary action, including fines and permit revocation or suspension, for violations of law and rule. Grounds include violation of federal and state controlled substance laws, various criminal convictions, and dispensing drugs when the pharmacist knew or had reason to believe the prescription was not based on a valid physician-patient relationship.²⁶

Pharmacists

Pharmacists are required to obtain a license from the Board of Pharmacy. Section 465.007, F.S., provides that pharmacist applicants must receive a degree from an accredited school of pharmacy, complete an internship program, and pass an examination. The board is required to adopt rules for the standard of pharmacy practice, and pharmacists are subject to disciplinary action, including fines and license revocation or suspension, for violations of law and rule. Grounds include violation of federal and state controlled substance laws, failing to report to DOH a physician who the pharmacist knows has violated his or her practice act, and dispensing drugs when the pharmacist knew or had reason to believe the prescription was not based on a valid physician-patient relationship.²⁷

Section 893.04, F.S., authorizes a pharmacist, in good faith and in the course of professional practice to dispense controlled substances upon a written or oral prescription. An oral prescription must be promptly reduced to writing by the pharmacist. The written prescription must be dated and signed by the prescribing practitioner on the date issued. The face of the prescription or written record for the controlled substance must include:

- The full name and address of the person for whom the controlled substance is dispensed;
- The full name and address of the prescribing practitioner and the prescriber's federal controlled substance registry number;
- The name of the controlled substance prescribed and the strength, quantity, and directions for the use thereof;
- The number of the prescription, as recorded in the prescription files of the pharmacy in which it is filed; and
- The initials of the pharmacist filling the prescription and the date filled.

Section 893.04(1)(d), F.S., requires the pharmacy in which a prescription for controlled substances is filled to retain the prescription on file for a period of 2 years. The original container in which a controlled substance is dispensed must bear a label with the following information:

- The name and address of the pharmacy from which the controlled substance was dispensed;
- The date on which the prescription for the controlled substance was filled;
- The number of the prescription, as recorded in the prescription files of the pharmacy in which it is filled;
- The name of the prescribing practitioner;
- The name of the patient for whom, or of the owner and species of the animal for which, the controlled substance is prescribed;
- The directions for the use of the controlled substance prescribed in the prescription; and
- A clear, concise warning that it is a crime to transfer the controlled substance to any person other than the patient for whom prescribed.

²⁵ Section 465.022, F.S. A valid practitioner-patient relationship includes a documented patient evaluation, medical history, physical examination, and any other requirement established by the practitioner's practice act or rule.

²⁶ Section 465.023, F.S.

²⁷ Section 465.016, F.S.

Chapter 893, F.S., imposes other limitations on controlled substance prescriptions. A prescription for a Schedule II controlled substance may be dispensed only upon a written prescription of a practitioner, except in an emergency situation, as defined by rule of DOH. No prescription for a Schedule II controlled substance may be refilled.²⁸ No prescription for a controlled substance listed in Schedules III, IV, or V may be filled or refilled more than five times within a period of 6 months after the date on which the prescription was written unless the prescription is renewed by a practitioner.²⁹ A pharmacist may dispense a one-time emergency refill of up to a 72-hour supply of a prescribed medication, except for those listed in Schedule II.³⁰

In addition to these requirements for dispensing controlled substances, pharmacies must comply with regulations that apply to all dispensing. A pharmacy cannot dispense a medication if the prescription is not based on a "valid practitioner-patient relationship." Such a relationship includes "a documented patient evaluation, including history and a physical examination adequate to establish the diagnosis for which any drug is prescribed".³¹ DOH rules apply this standard to controlled substances.³² The following criteria shall cause a pharmacist to question whether a prescription was issued for a legitimate medical purpose:

- Frequent loss of controlled substance medications,
- Only controlled substance medications are prescribed for a patient,
- One person presents controlled substance prescriptions with different patient names,
- Same or similar controlled substance medication is prescribed by two or more prescribers at same time,
- Patient always pays cash and always insists on brand name product.

If any of those criteria are met, the pharmacy must copy the patient's photo identification for its records, and confirm the prescription with the physician. DOH inspects pharmacies at least once a year to ensure compliance with statutory and regulatory requirements.³³

Physicians

Section 893.05, F.S., allows a practitioner, in good faith and in the course of professional practice only, to prescribe, administer, dispense, mix, or otherwise prepare a controlled substance. "Practitioner" means a licensed medical physician, a licensed dentist, a licensed veterinarian, a licensed osteopathic physician, a licensed naturopathic physician, or a licensed podiatrist, if such practitioner holds a valid federal controlled substance registry number.³⁴

Physician dispensing is regulated by the Board of Medicine and the Board of Osteopathic Medicine within the DOH. In order to dispense medications, rather than just prescribe them, physicians must register with the relevant board and pay a fee of \$100.³⁵ Physicians who only dispense complimentary medications, and who receive no direct or indirect payment or remuneration for the medications, are not required to register.³⁶

DOH must inspect any facility in which a physician dispenses medication, such as a physician office or medical clinic, with the same frequency as it inspects pharmacies, that is, at least once a year.³⁷ Dispensing physicians are required to comply with all state and federal laws and regulations applicable to pharmacists and pharmacies.³⁸ For example, a pharmacy is not permitted to dispense a drug if the

²⁸ Section 893.04(1)(f), F.S.

²⁹ Section 893.04(1)(g), F.S.

³⁰ See 21 C.F.R. 1306.11(d)(1), which provides that, in an emergency situation, a pharmacist may dispense a Schedule II controlled substance upon receiving oral authorization of a prescribing practitioner if the quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period.

³¹ Section 465.023(1)(h), F.S.

³² Rule 64B16-27.831, F.A.C.

³³ Rule 64B16-28.101, F.A.C.

³⁴ Section 893.02, F.S.

³⁵ Section 465.0276(2)(a), F.S. and rule 64B8-3.006, F.A.C.

³⁶ Section 465.0276(5), F.S.

³⁷ Section 465.0276(3), F.S.

³⁸ Section 465.0276(20)(a), F.S.

prescription is not based on a valid practitioner-patient relationship, which requires a patient history and a physical examination adequate to establish the diagnosis. This requirement applies to dispensing physicians as well.

There are 6,335 registered dispensing physicians in Florida, broken down by practitioner type in the table below.³⁹

Dispensing Physicians	Total
Podiatric Physician	132
Dentist	199
Medical Doctor	5116
Osteopathic Physician	888
Total	6335

The table below summarizes the number of complaints received by DOH about dispensing practitioners since 2006. The table also includes the number of disciplinary actions taken against dispensing practitioners during the same time period.⁴⁰

Dispensing Practitioners	2006-07	2007-08	2008-09	2009-10	2010-3/11	Avg./ Yr.
Complaints Received	59	37	59	117	71	68.6
Disciplinary Action Taken	5	12	2	9	20	9.6
Citations Issued (Minor Violations)	65	57	85	33	33	54.6
Complaints, s. 465.016(1)(s), F.S. ⁴¹	100	34	24	33	16	41.4
Disciplinary Action, s. 465.016(1)(s), F.S.	22	11	5	5	2	9

Currently, Florida law allows registered physicians to dispense any prescribed drug. Other states have varying degrees of regulation.⁴² Twenty-six states allow dispensing of controlled substances and require some form of dispensing license. Nineteen states allow dispensing but do not require any license. One state allows dispensing but requires a license to dispense controlled substances. Montana and Utah prohibit physician dispensing entirely, for all drugs. Massachusetts and Texas limit controlled substance dispensing to a 72-hour supply in emergency situations, and impose other restrictions.⁴³

Currently, Florida law allows physicians to prescribe controlled substances, and does not require any additional licensure or registration for the privilege, other than the physician's license. Other states have varying degrees of regulation. Twelve states require an additional license or registration to prescribe controlled substances.⁴⁴

Pain-Management Clinics

In 2009 and 2010, the Legislature enacted laws to regulate pain-management clinics and physicians who practice in them.⁴⁵ 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. Pain clinics are defined as facilities or offices which advertise in any medium for any type of pain-management services or employ a physician

³⁹ Florida Department of Health, Presentation to the House Health and Human Services Committee, February 24, 2011, on file with the Committee.

⁴⁰ *Id.*

⁴¹ Section 465.016(1)(s), F.S., prohibits dispensing when a pharmacist has reason to believe a valid relationship does not exist between the patient and the physician. Dispensing practitioners are also subject to this requirement. The last two rows of the chart reflect complaints against physicians under this section.

⁴² Survey of Rules Governing Physician Dispensing Controlled Substances (CS) in All 50 States and the District of Columbia, created by Health and Human Services Committee staff, on file with the Committee.

⁴³ *Id.*

⁴⁴ *Id.* Maryland, Massachusetts, Michigan, Missouri, Nevada, New Jersey, New Mexico, Oklahoma, Rhode Island, South Dakota, Texas and Utah.

⁴⁵ Chapter 2009-198, L.O.F.; ch. 2010-211, L.O.F.

who is primarily engaged in the treatment of pain by prescribing or dispensing controlled substance medications. A physician is primarily engaged in the treatment of pain by prescribing controlled substances if the majority of the patients seen on any day the facility is open are issued controlled substance prescriptions for the treatment of nonmalignant pain.⁴⁶

Pain clinics are required to register with DOH; however, the following entities are exempt from registration:

- Hospitals
- Clinics primarily providing surgical services
- Certain publicly held corporations
- Clinics affiliated with medical schools
- Clinics that do not use controlled substances
- Not-for-profit clinics

DOH is prohibited from registering an entity:

- Not owned by a physician;
- Whose Drug Enforcement Administration 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.

Registered pain management clinics must have a designated physician who meets certain criteria to take responsibility for the clinic's activities. According to the Boards of Medicine and Osteopathic Medicine, as of the end of February 2011, 382 medical doctors and 64 doctors of osteopathic medicine registered as dispensing physicians for pain clinics in Florida.⁴⁷

All physicians practicing in pain clinics are prohibited from dispensing more than a 72-hour supply to a patient paying with cash, check or credit card. A violation is a third degree felony.⁴⁸ DOH and the relevant boards are required to adopt rules setting forth standards of practice for physicians practicing in pain clinics. Specifically, the rules must address:

- Facility operations;
- Physical operations;
- Infection control requirements;
- Health and safety requirements;
- Quality assurance requirements;
- Patient records;
- Training requirements for all facility health care practitioners;
- Inspections;
- Data collection and reporting requirements; and
- The maximum number of controlled substance prescriptions that can be written by a physician in a clinic in one day.

Pain-management clinics are subject to annual inspection and are subject to registration revocation and fines of up to \$5,000 per day for violations. If a clinic's registration is revoked, its owners and operators may not apply for a new registration for 5 years. There are currently 860 pain-management clinics registered with DOH.⁴⁹

Pain-management clinics that did not meet the ownership requirements of either s. 458.3265, F.S., or s. 459.0137, F.S., which became effective on October 1, 2010, began receiving Notices of Intent to Administratively Revoke (ITAR) the Certificate of Registration, required for operation of a clinic, from DOH. The ITAR notified each non-compliant clinic of the intent of DOH to revoke the certificate due to the clinic's

⁴⁶ Section 458.3265(1)(a), F.S.

⁴⁷ Florida Department of Health, Presentation to the House Health and Human Services Committee, February 24, 2011, on file with the Health & Human Services Committee.

⁴⁸ A third degree felony is punishable by a term of imprisonment not exceeding 5 years (s. 775.082 (3)(d), F.S.) and a fine not exceeding \$5,000 (s. 775.083(1)(c), F.S.).

⁴⁹ *Id.*

failure to meet the ownership requirements. As of the end of February 2011, DOH issued 236 ITARs. The following table illustrates the status of the ITARs:

Status of Pain Clinics Considered for Revocation	Total
Pain clinics closed through Notice of Intent to Administratively Revoke (ITAR)	54
Pain clinics pending action after ITAR	72
Pain clinics in compliance after ITAR	110
Total ITARs	236

Of the 72 pain clinics that are awaiting further action after the ITAR was issued, 30 clinics requested a formal hearing regarding DOH's intent to revoke the certificate, 19 clinics defaulted, or otherwise did not answer the ITAR, and 23 cases are awaiting additional documentation from the clinic or a decision from DOH regarding revocation.

The next table specifies the number of complaints filed against pain clinics from January 2010 to the end of February 2011 for practicing without a license:

Complaint Source	Complaints Jan 2010 – February 2011
Consumer	2
Other Registrant	3
Other State Agency	2
Internally Generated	119
Anonymous	3
TOTAL	129

According to DOH, the overwhelming majority of complaints came from within DOH. These complaints were generated during the initial inspection process.

Current law imposes several requirements on physician practice in pain clinics, and provides licensure and criminal penalties for violations. Physicians are prohibited from practicing medicine in an unregistered pain clinic, which is a third degree felony.⁵⁰ A physician must perform a physical examination of a patient on the same day that a controlled substance prescription drug is dispensed to a patient. If a physician prescribes or dispenses a controlled substance in an amount greater than a 72-hour supply, the physician must document in the patient's medical record the reason for prescribing or dispensing that amount.

A physician practicing in a pain-management clinic is responsible for maintaining control and security over his or her prescription pad blanks. The physician is also required to comply with the counterfeit-resistant prescription pad requirement pursuant to statute and rule. Lastly, a designated physician for a pain-management clinic must notify the applicable board within ten days of terminating his or her employment with the pain-management clinic for which he or she is designated as required by statute and rule.

During the Special Legislative Session held in November 2010, the Legislature overrode the gubernatorial veto of HB 1565, which passed in the 2010 Regular Legislative Session.⁵¹ The changes to the Administrative Procedures Act (ch. 120, F.S.) made by HB 1565 affect the implementation of proposed

⁵⁰ Sections 458.327 and 459.013, F.S. On September 23, 2010, a lawsuit was filed challenging the constitutionality of these section of law. Among other arguments, the plaintiffs (physicians, a pain clinic and a patient) argued the definition of "pain-management clinic" in the law is unconstitutionally vague such that it violates the right to due process and that the definition's reference to advertising violates the right to free speech. No dispositive rulings have issued in the case. *P.R.A. v. Fla. Dept. Health*, N.D. Fla. (2010)

⁵¹ Chapter 2010-279, L.O.F. The law requires state agencies to determine the impact of proposed agency rules on small businesses. If the rules will have an adverse impact on small businesses or increase regulatory costs in the aggregate in the amount of \$200,000 in the first year of enactment, an agency must prepare a statement of estimated regulatory cost (SERC). The SERC must determine whether the rules will financially impact small businesses by \$1,000,000.00 or more over the first five years of enactment. If the economic analysis concludes that the rules meet or exceed the threshold, the rules must be presented to the Speaker of the House of Representatives and the President of the Senate and cannot be finalized until ratified by the Legislature.

rules by the Board of Medicine on standards of practice for medical doctors practicing in pain management clinics.⁵² The Board of Osteopathic Medicine Standards of Practice for osteopathic physicians practicing in pain management clinics are in effect now and are not impacted by the new legislation.⁵³

The last table combines the number of licenses, permits or registrations issued by DOH to dispensing practitioners, community pharmacies and pain clinics to dispense controlled substances in Florida with complaint and disciplinary information:

Dispensing of Controlled Substances by Location					
Locations	Licenses/ Permitees/ Registrants	Complaints	Probable Cause Found	Discipline	Appeals July 2009 to Date
Dispensing Practitioners	6335	188	40	29	1
Community Pharmacies	4632	460	61	56	0
Pain Clinics	860	173	11	2	0

Access to Records without Subpoena or Consent

In Florida, patients have a constitutional right to privacy under Article I, Section 23 of the State Constitution and judicial decisions. Although Florida courts have recognized patients' right to secure the confidentiality of their health information, including medical records, as a right to privacy, that right must be balanced with and yields to any compelling state interest. Several statutes authorize the release of patient records without consent of the person to whom they pertain.

Section 893.07, F.S., requires any person who dispenses controlled substances to make and maintain records, including prescription records, relating to the receipt and disposition of the controlled substances. The record of all controlled substances sold, administered, dispensed, or otherwise disposed of shall show the date of selling, administering, or dispensing; the correct name and address of the person to whom or for whose use, or the owner and species of animal for which, sold, administered, or dispensed; and kind and quantity of controlled substances sold, administered, or dispensed.⁵⁴ This statute further provides that the records are to be kept and made available for a period of at least 2 years for inspection and copying by law enforcement officers whose duty it is to enforce the laws of this state relating to controlled substances.⁵⁵

Effect of Proposed Changes

The bill makes various regulatory changes to licensure and permitting requirements for entities in the controlled substance distribution chain, creates or modifies disciplinary penalties, creates or modifies criminal penalties. The bill modifies the requirements of the prescription drug monitoring program, and provides for certain immediate actions to address abuse prescription drug practices.

Physicians

The bill prohibits physician dispensing of controlled substances in Schedules II and III, making such dispensing a third degree felony and grounds for disciplinary action against a physician or osteopathic

⁵² Proposed Rule 64B8-9.0131, F.A.C., related to standards of practice for medical doctors practicing in pain clinics, is pending legislative ratification. Proposed Rule 64B8-9.0134, F.A.C., related to the maximum number of prescriptions for medical doctors practicing in registered pain management clinics, may require ratification when rulemaking is complete and the rule is filed for adoption. Rulemaking & Regulation Subcommittee, Legislative Ratification Request Log, February 28, 2011.

⁵³ Rule 64B15-14.0051, F.A.C. and Rule 64B15-14.0052, F.A.C.

⁵⁴ Section 893.07(3), F.S.

⁵⁵ Section 893.07(4), F.S.

physician. Such disciplinary action includes license restriction, suspension, revocation and probation, or fines, letters of reprimand, remedial education, or corrective action.

The bill creates new regulatory requirements for physicians who prescribe controlled substances to treat chronic, non-cancer pain, regardless of the setting in which the physician practices. This provision codifies some provisions of rules adopted by the Board of Osteopathic Medicine, and some provisions of rules proposed by the Board of Medicine, to regulate physicians practicing in pain management clinics, but applies them to all physicians who treat chronic non-cancer pain with controlled substances.

Effective January 1, 2012, such physicians must register with their respective boards and comply with the standards of practice in the bill. Physicians must maintain a log of all prescriptions which distinguishes unduplicated patients but which does not disclose patient identifying information, and make the logs available to DOH and FDLE upon demand. Physicians must comply with standards of care for prescribing controlled substances, including:

- A complete medical history and physical examination of the patient;
- A medical record which documents the medical indications for use of a controlled substance;
- An assessment of the patients' risk for aberrant drug-related behavior, such as abuse, and ongoing monitoring of the patient's risk;
- A written treatment plan for the patient;
- An informed consent agreement;
- Periodic review of the treatment and regular patient visits; and
- Referral to specialists as necessary to achieve treatment objectives, with particular attention to certain high-risk patients, and mandatory referral for patients with symptoms of substance abuse.

The bill expressly provides that these standards do not supersede the standards of practice recognized in general law for health care licensure. Thus the bill provisions establish a minimum standard. Physicians who are board-certified in pain management, and other board-certified physicians who have completed a fellowship in pain medicine, are exempt from the registration requirements and these statutory standards of care if they provide interventional pain procedures routinely billed using surgical codes.

The bill requires physicians prescribing a controlled substance to use a counterfeit-proof prescription pad purchased from an approved vendor. DOH is required to approve the prescription pad vendors, and vendors must report practitioner purchases of prescription pads to DOH.

Pharmacists

The bill provides new grounds for denial of a pharmacist license or disciplinary action on the license. Pharmacists who commit an error or omission in processing prescription drugs are subject to fine, probation, corrective action, refund of patient fees, a letter of reprimand, remedial education, or suspension, revocation, or restriction of their licenses. The bill delineates the errors or omissions subject to such actions including, for example, an error in interpreting or validating a prescription, performing pharmaceutical calculations, or providing patient counseling.

Pharmacies

The bill adds new permitting requirements for community pharmacies. All applicants and all affiliated persons must be over the age of 18. Business entity applicants must register with the Department of State and have a federal employer tax identification number. The bill requires pharmacy applicants to:

- Pass an onsite inspection, which DOH must make within 90 days prior to issuing the permit;
- Pay or make arrangements to pay amounts owed to DOH;
- Submit a signed affidavit disclosing financial interests in other pharmacies in the last 5 years which have closed or which permit has been relinquished, suspended or revoked and explaining the reasons for those actions;
- Submit written policies and procedures for dispensing controlled substances to minimize dispensing based on fraud or invalid practitioner-patient relationships.

The bill requires the Board of Pharmacy to deny a community pharmacy permit application if: any affiliated person:

- Has been convicted of, or entered a guilty or no contest plea to a felony under chapters 409, 817, or 893 or a similar offense in any other jurisdiction since July 1, 2009;
- Has been convicted of, or entered a guilty or no contest plea to a felony under certain federal Medicare and Medicaid laws since July 1, 2009;
- Has been terminated for cause from the Florida Medicaid program, unless in good standing for the last 5 years;
- Has been terminated for cause from any state other Medicaid program, unless in good standing for the last 5 years and the termination occurred at least 20 years prior;
- Is listed on the federal HHS list of excluded individuals and entities; or
- Has violated any provision of ch. 465, 499, or certain federal drug laws

The bill authorizes the Board of Pharmacy to deny a community permit application, or revoke or suspend a permit, if the applicant pharmacy or certain persons affiliated with the applicant or pharmacy under certain circumstances:

- If the applicant or permit-holder, or certain interested persons, had a prior permit which was disciplined, abandoned or became null and void after notice that disciplinary action would be taken;
- If the applicant or certain interested persons or anyone with an ownership interest over 5 percent, has failed to pay any outstanding fines, liens or Medicaid overpayments, unless there is an approved repayment plan.

The bill prohibits the Board of Pharmacy from taking action on the application if any affiliated entity has entered a pretrial intervention or drug diversion program until final resolution of the case.

The bill requires Board of Pharmacy to adopt rules for procedures for dispensing controlled substances to minimize dispensing based on fraud or invalid practitioner-patient relationships. The Board must also adopt rules for recordkeeping necessary to ensure public protection, and the bill requires such records to be maintained at least 4 years and to be readily available for inspection by DOH.

The bill creates new requirements to maintain a community pharmacy permit. Current law requires permittees to have a designated prescription department manager. The bill provides that the designated prescription department manager is responsible for maintaining all pharmacy drug records required by state or federal law, and for ensuring compliance with laws and rules for the practice of pharmacy. In addition, the designated prescription department manager is responsible for ensuring the security of the prescription department, and must notify the Board of any theft or significant loss of a controlled substance within one business day. The permittee must notify DOH within 10 days of employing a designated prescription department manager, and must notify DOH within 10 days of any change in the designated pharmacy manager or consultant pharmacist.⁵⁶ The bill provides that a designated prescription department manager may not manage more than one pharmacy location unless approved by the Board.

The bill requires pharmacies dispensing controlled substances to maintain a log of all prescriptions filled, and to make the controlled substances log available to DOH or FDLE upon request.

The bill provides that, effective January 1, 2012, a community pharmacy may not dispense a controlled substance listed in Schedule II or Schedule III unless the pharmacy:

- Is wholly owned by a corporation whose shares are publicly traded on a recognized stock exchange; or
- Is wholly owned by a corporation having more than \$100 million of business taxable assets in this state; or
- Has been continuously permitted for at least 10 years; or
- Is wholly owned or operated by a licensed hospice, hospital or nursing home or exclusively serves hospice, hospital or nursing home patients; or

⁵⁶ A consultant pharmacist is responsible for maintaining all drug records required by law and for establishing drug handling procedures for the safe handling and storage of drugs, and is licensed separately under s. 465.0125, F.S.

- Received or renewed a permit after January 1, 2012, such that it is subject to the new permitting requirements.

Wholesale Distributors

The bill requires wholesale distributors of controlled substances to electronically submit to DOH a monthly report of its distributions of controlled substances listed in Schedules II, III, IV, and V within the state of Florida. The bill specifies the information to be included in the reports. DOH must share the reported data with FDLE and local law enforcement agencies upon request. DOH must monitor purchasing from wholesalers to identify patterns that are inconsistent with the purchasing entity's clinical needs. FDLE must investigate purchases that are inconsistent with the entity's clinical needs to determine whether any violations of ch. 893, F.S., have occurred.

The bill requires wholesale distributors to maintain policies to review and determine the credentials of physicians and pharmacies that purchase Schedule II or Schedule III controlled substances from the wholesale distributor. Documentation of these policies must be submitted to DOH as part of an application for a permit or to renew a permit for a prescription drug wholesale distributor, and a distributor must maintain records of credentialing and make them available to DOH upon request. The credentials must include:

- Determination of the clinical nature of the entity, including any specialty practice area;
- Review of the receiving entity's history of Schedule II and Schedule III controlled substance purchasing from the wholesale distributor;
- Determination that the receiving entity's Schedule II and Schedule III controlled substance purchasing history, if any, is consistent with and reasonable for that entity's clinical business needs; and
- A level 2 background screening pursuant to chapter 435 through DOH of any person who owns a controlling interest in or, directly or indirectly, manages, oversees or controls the operation of the entity, including officers and members of the board of directors of an entity that is a corporation.

The bill requires distributors to take reasonable measures to know their customers, and establish policies and procedures for identifying and preventing suspicious transactions. Distributors must assess orders for more than 5,000 unit doses of a controlled substance in one month and determine whether the purchase is reasonable. The bill also requires distributors to report certain transaction which may indicate the drugs will be used in violation of the law.

The bill requires that each wholesale distributor may not distribute:

- More than 5,000 unit doses of oxycodone, hydromorphone, hydrocodone, or methadone a benzodiazepine (or their derivatives, components or precursors) to a retail pharmacy⁵⁷ in any given month.
- Controlled substances to an entity if any criminal history record check for any person associated with that entity shows the person has been convicted of a crime related to controlled substances, the practice of pharmacy, or dispensing of medicinal drugs.

Pain-Management Clinics

The bill amends pain-management clinic regulation laws in ss. 458.3265 and 459.0137. Specifically, the bill modifies the definition of "pain-management clinic" to limit it to treatment with certain drugs, rather than any controlled substance: opioids, barbiturates, benzodiazepines or carisoprodol. The new definition removes the reference to advertising for pain treatment in the current definition, and amends the activity and proportion of the activity included in the definition. The bill also amends the definition of "chronic nonmalignant pain" to exclude pain related to rheumatoid arthritis.

The bill provides an exemption from pain-management clinic registration if the clinic is wholly owned by one or a group of certain medical specialists who are board-certified in pain management, or have completed a

⁵⁷ "Retail pharmacy" is a community pharmacy licensed under chapter 465 that purchases prescription drugs at fair market prices and provides prescription services to the public.

fellowship in pain medicine, and perform interventional pain procedures routinely billed using surgical codes.

The bill requires physicians practicing in pain-management clinics to notify the relevant board in writing within 10 days of starting or ending practice there.

The bill imposes certain requirements for physicians practicing in pain-management clinics. This codifies some provisions of rules adopted by the Board of Osteopathic Medicine, and some provisions of rules proposed by the Board of Medicine, to regulate physicians practicing in pain management clinics. Physicians are responsible for ensuring the clinic's compliance with requirements for facility and physical operations, infection control, health and safety, quality assurance, and data collection and reporting. The bill amends DOH rulemaking authority to delete authority to promulgate rules on these matters.

The bill sunsets ss. 458.3265 and 459.0137, effective January 1, 2016.

Criminal Penalties

The bill adds new criminal penalties, and clarifies existing violations.

- The bill makes it a first degree misdemeanor for a pharmacist, pharmacy intern, or other employee working for or at a pharmacy to fail to report to the county sheriff, within 24 hours, an individual obtaining or attempting to obtain a controlled substance through fraudulent methods or representations. The bill defines what constitutes a sufficient report to include a copy of the prescription and information identifying the prescriber and patient.
- The bill amends the burglary statute, adding burglary of a structure or conveyance with the intent to steal controlled substances, making that a second degree felony.⁵⁸ The bill allows for separate judgments and sentences for applicable possession of a controlled substance offense or trafficking in a controlled substance offense when all offenses include the same amount of a controlled substance.
- The bill makes theft of any amount of a controlled substance grand theft in the third degree, punishable as a third degree felony.⁵⁹ The bill allows for separate judgments, as well as, separate sentences for possession of a controlled substance or trafficking in a controlled substance if all offenses include the same amount of controlled substance.
- The bill requires all thefts or loss of controlled substances to be reported to the sheriff of the county where the theft or loss occurred within 24 hours of discovery of the theft or loss. Failure to report the theft or loss of a controlled substance listed in Schedule III, IV, or V within 48 hours of discovery of the theft or loss is a second degree misdemeanor.⁶⁰ Failure to report the theft or loss of a controlled substance listed in Schedule II within 48 hours of discovery of the theft or loss is a first degree misdemeanor.
- The bill makes knowingly submitting a false drug distribution report a 3rd degree felony.
- The bill makes distributing controlled substances improperly a 3rd degree felony.

Prescription Drug Monitoring Program

⁵⁸ A second degree felony is punishable by a term of imprisonment not exceeding 15 years (s. 775.082(3)(c), F.S.) and a fine not exceeding \$10,000 (s. 775.083(1)(b), F.S.).

⁵⁹ A third degree felony is punishable by a term of imprisonment not exceeding 5 years (s. 775.082(3)(d), F.S.) and a fine not exceeding \$5,000 (s. 775.083(1)(c), F.S.).

⁶⁰ A second degree misdemeanor is punishable by a term of imprisonment not exceeding 60 days (s. 775.082(4)(b), F.S.) and a fine not exceeding \$500 (s. 775.083(1)(e), F.S.).

The bill modifies current law related to the prescription drug monitoring program. Currently, pharmacies and dispensing practitioners are required to submit dispensing information to the state database within 15 days. The bill reduces the reporting time to 7 days. The bill prohibits donations of pharmaceutical manufacturers from being used to support the monitoring program through the direct support organization. The bill removes references to the Office of Drug Control and its director and replaces them with references to DOH and the state surgeon general. In particular, the bill revises direct support organization provisions to establish DOH as responsible agency in place of the Office of Drug Control and requiring the state surgeon general to appoint the board of the direct support organization.

Immediate Actions

The bill requires all physicians, within ten days of the effective date of the bill, to return all undispensed Schedule II and Schedule III controlled substances purchased under each physician's Drug Enforcement Administration (DEA) number to the wholesale distributor from which the controlled substances were purchased or turn in all such undispensed controlled substances to law enforcement and abandon the medication. The bill establishes a buy-back program which requires wholesale distributors to purchase the remaining Schedule II and Schedule III controlled substance inventory of each physician at the original purchase price. Each wholesale distributor must report to DOH, by August 1, 2011, regarding each inventory buy-back processed by the wholesale distributor. The report must include information on the returning entity, the returned drugs, the practitioner, and the date.

The bill directs DOH, immediately on the enactment date of the bill, to declare a public health emergency regarding controlled substance prescription drugs in the state of Florida pursuant to s. 381.00315, F.S. Section 381.00315, F.S., authorizes the State Health Officer (the State Surgeon General) to declare a public health emergency, which is the "occurrence, or threat thereof, whether natural or manmade, that results or may result in substantial injury or harm to the public health from infectious disease, chemical agents, nuclear agents, biological toxins, or situations involving mass casualties or natural disasters." In the event of a declared emergency, the State Health Officer may take actions that are necessary to protect the public health, and any order she issues is immediately enforceable by law enforcement officers under s. 381.0012, F.S. The bill requires DOH, the Attorney General, FDLE, and local law enforcement to take the following actions upon the declaration of the public health emergency:

- DOH must identify, within 2 days of the declaration, the dispensing practitioners who purchased more than an average of 2,000 unit doses of Schedule II and Schedule III controlled substances per month in the six months preceding the declaration of the public health emergency.
- DOH must identify the dispensing practitioners within the group originally identified who pose the greatest public health risk based on the following factors:
 - the risk of non-compliance with the buy-back program or forfeiture to law enforcement;
 - the amount of Schedule II and Schedule III controlled substances purchased;
 - the type of medical practice; and
 - any other factor determined by the State Health Officer.
- The Attorney General shall coordinate with federal law enforcement agencies to accomplish the provisions of the act.
- FDLE shall coordinate all efforts of local law enforcement to accomplish the provisions of the act.
- FDLE shall, on the third day following enactment of the act, enter the business premises of the dispensing practitioners determined to be the greatest risk to public health by DOH and quarantine the inventory of Schedule II and Schedule III controlled substances on site.
- FDLE or local law enforcement shall provide 24 hour a day security of the quarantined inventory through the tenth day following enactment of the law to ensure compliance with the buy-back program.

The bill deems any remaining Schedule II and Schedule III controlled substance inventory contraband under s. 893.12, F.S., on the 11th day after enactment, and requires law enforcement to seize and destroy it pursuant to the procedures of that section. An appropriation of \$3 million in non-recurring funds is appropriated to defray the cost to FDLE and local law enforcement agencies of securing Schedule II and

Schedule III controlled substance inventories during the quarantine period, investigative activities, and prosecution of crimes related to prescribed controlled substances.

The bill repeals the public health emergency section of the act on January 1, 2013.

The bill eliminates the Program Implementation and Oversight Task Force, created by chapter 2009-198, Laws of Florida. The purpose of the Task Force is to monitor the implementation of the electronic prescription drug monitoring program, to ensure the privacy of the information submitted to the drug monitoring database, and to ensure the appropriate use of the database by the medical professionals and members of law enforcement with access to it. The Task Force is headed by the Office of Drug control. Database security and access will be governed by the requirements of s. 893.055, F.S., and through the DOH contract with the database vendor.

The bill provides for an effective date of July 1, 2011, except as otherwise provided in the bill.

B. SECTION DIRECTORY:

- Section 1:** Amends s. 456.072, F.S., relating to grounds for discipline; penalties and enforcement.
- Section 2:** Amends s. 456.42, F.S., relating to written prescriptions for medicinal drugs.
- Section 3:** Creates s. 456.44, F.S., relating to controlled substance prescribing.
- Section 4:** Amends s. 458.3265, F.S., relating to Pain-management clinics.
- Section 5:** Amends s. 458.327, F.S., relating to penalties for violations.
- Section 6:** Amends s. 458.331, F.S., relating to grounds for disciplinary action; action by the board and department.
- Section 7:** Amends s. 459.0137, F.S., relating to pain-management clinics.
- Section 8:** Amends s. 459.013, F.S., relating to penalties for violations.
- Section 9:** Amends s. 459.015, F.S., relating to grounds for disciplinary action; action by the board and department.
- Section 10:** Amends s. 465.015, F.S., relating to violations and penalties.
- Section 11:** Amends s. 465.016, F.S., relating to disciplinary actions.
- Section 12:** Amends s. 465.018, F.S., relating to community pharmacies; permits.
- Section 13:** Amends s. 465.022, F.S., relating to pharmacies; general requirements; fees.
- Section 14:** Amends s. 465.0276, F.S., relating to dispensing practitioners.
- Section 15:** Amends s. 400.0051, F.S., relating to criminal acts.
- Section 16:** Amends s. 499.012, F.S., relating to permit application requirements.
- Section 17:** Amends s. 499.0121, F.S., relating to storage and handling of prescription drugs; recordkeeping.
- Section 18:** Amends s. 499.05, F.S., relating to rules.
- Section 19:** Amends s. 499.067, F.S., relating to denial, suspension, or revocation of permit, certification or registration.
- Section 20:** Amends s. 810.02, F.S., relating to burglary.
- Section 21:** Amends s. 812.014, F.S., relating to theft.
- Section 22:** Amends s. 893.055, F.S., relating to prescription drug monitoring program.
- Section 23:** Amends s. 893.065, F.S., relating to counterfeit-resistant prescription blanks for controlled substances listed in Schedule II, Schedule III, or Schedule IV.
- Section 24:** Amends s. 893.07, F.S., relating to records.
- Section 25:** Repeals s. 2 of chapter 2009-198, Laws of Florida, relating to the Program Implementation and Oversight Task Force.
- Section 26:** Creates an unnumbered section of law, relating to a buyback program, public health emergency and provision for repeal.
- Section 27:** Provides for an effective date of July 1, 2011, except as otherwise specified in the bill.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

See "Fiscal Comments".

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

See "Fiscal Comments".

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill prohibits physicians from dispensing Schedule II and Schedule III controlled substances. This will negatively impact the income of those physicians who previously dispensed these controlled substances and the clinics that employ them. Future dispensing of these controlled substances formerly done by physicians will shift to pharmacies.

The bill requires wholesale distributors of controlled substances to purchase undispensed physician inventories of Schedule II and Schedule III controlled substances within ten days of enactment. If the controlled substances bought back by the distributors are eligible for resale, the distributors may resell the drugs, which may mitigate losses. If inventory is tainted or expired, or is not sellable for another reason, the distributor will realize a negative economic impact. The bill also requires wholesale distributors to credential purchasing physicians and pharmacies, including background screening, and to report distribution data to DOH. Distributors may incur additional expenses to comply with these requirements.

The bill limits distribution of certain drugs to 5,000 unit doses per pharmacy per month per wholesale distributor. This could negatively impact the income of pharmacies which previously purchased and dispensed more of those drugs.

The bill institutes new regulatory requirements for pharmacies. The bill limits the community pharmacies which may dispense a controlled substance listed in Schedule II or Schedule III, effective January 1, 2012, and provides exemptions from that limitation. The exemptions create a prioritization process for implementation of the new permitting requirements, which would apply to all community pharmacies and compliance with which provides and exemption to the dispensing prohibition for those pharmacies which do not meet a listed exemption. If the permitting process is delayed past January 1, 2012, pharmacies which are not re-permitted under the new standards and which do not meet one of the other exemptions not able to sell a full range of controlled substances until the permit process is complete.

D. FISCAL COMMENTS:

The bill requires DOH to register certain physicians which prescribe controlled substances for certain purposes, and to increase regulation of pharmacies. In addition, DOH must receive data from wholesale distributors, use it for regulatory purposes, and coordinate use of the data for public safety purposes with FDLE. These activities may result in an indeterminate negative fiscal impact on DOH.

However, DOH may be able to perform these functions within existing resources, similar to its ability to absorb the new regulatory system for pain-management clinics over the last two years.

The bill requires FDLE and local law enforcement to secure quarantined inventory on-site from the third day after enactment through the 10th day after enactment, and thereafter seize the inventory. The bill makes an appropriation of \$3 million in non-recurring funds from the General Revenue Fund to FDLE to reimburse local law enforcement agencies for these activities, and provides for proration if the requests for reimbursement exceed the appropriation amount.

The Criminal Justice Impact Conference has not met to determine the prison bed impact of the bill. The bill may have a prison bed impact on the Department of Corrections in that it creates new third degree felony offenses. However, since the felony is unranked the impact will likely be insignificant.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Section 18(d) of Article VII of the Florida Constitution prohibits the Legislature from binding any county or municipality by any general law requiring it to spend funds or take actions requiring expenditures, with certain exceptions. While the bill requires counties or municipalities to take specific short-term law enforcement actions that may result in the expenditure of funds, the bill appears to be exempt from the requirements of Article VII, Section 18 of the Florida Constitution because it is a criminal law.

In addition, the bill makes an appropriation of \$3 million in non-recurring funds from the General Revenue Fund to FDLE to reimburse local law enforcement agencies for these activities. These funds would place the local mandate analysis in one of the mandate exceptions under Sec. 18(a), Art. VII - providing an exception for instances in which the Legislature appropriates funds sufficient to fund the expenditure.

2. Other:

The bill may implicate Section 12 of Article I of the Florida Constitution and the Fourth Amendment to the U.S. Constitution. These sections protect citizens from unreasonable searches and seizures by government. It may be argued that the seizure of inventories of controlled substances that remain with physicians after the ten-day buyback period violate these provisions. However, the bill does provide for the buy back of the inventories from the wholesaler.

B. RULE-MAKING AUTHORITY:

The bill grants rule-making authority to DOH to implement and enforce the wholesale distributor reporting requirements created by s. 499.0121(14), F.S., and the wholesale distributor credentialing requirements of s. 499.0121(15). The bill provides specific guidance to DOH for drafting the rules necessary to implement the reporting requirements.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 30, 2011, the Judiciary Committee adopted a strike-all amendment that changed the bill as follows:

- Requires use of tamper-proof prescription pads or electronic prescribing for any prescription for controlled substances.
- Limits the dispensing ban for practitioners to controlled substances listed in Schedule II or III.
- Limits the community pharmacies permitted to dispense controlled substances to pharmacies that meet specific criteria – that the pharmacy:
 - is wholly owned by a publicly traded corporation; or
 - is wholly owned by a corporation having more than \$100 million of business taxable assets in Florida; or
 - has been continuously permitted for at least 10 years.
- Establishes new requirements for distributors of controlled substances that:
 - Require reporting of receipts and distributions of all controlled substances and provide specific requirements regarding the content and timing of these reports.
 - Require policies and procedures for credentialing purchasers of controlled substances.
 - Establish specific requirements for credentialing procedures.
 - Limit the amount of any one controlled substance that may be distributed to each pharmacy to no more than 5,000 unit doses in any given month.
 - Direct the Department of Health to deny, suspend, or revoke a distributor's permit for failure to credential its purchasers.
- Increases resources available for law enforcement activities related to controlled substances to \$3 million in non-recurring funds to be used for coordinated efforts with local law enforcement.
- Directs the Department of Health and the Florida Department of Law Enforcement to continuously monitor distribution of controlled substances and to act on distributions that appear suspicious or excessive.

This analysis is drafted to the Committee Substitute.

On April 12, 2011, the Appropriations Committee adopted a strike-all amendment and an amendment to the amendment that changed the Committee Substitute for the bill as follows:

Physicians

- Requires registration for practitioners prescribing controlled substances to treat chronic, non-cancer pain.
- Requires prescribers of controlled substances to maintain a log of all prescriptions.
- Requires prescribers to make logs available to the Department of Health (DOH) and the Florida Department of Law Enforcement (FDLE) upon demand.
- Requires vendors of approved prescription pads to report practitioner purchases of prescription pads to DOH.
- Enacts standards of care for all physicians prescribing controlled substances for treatment of chronic non-cancer pain, regardless of setting, including a drug abuse risk assessment and ongoing monitoring.
- Provides for exceptions for credentialed interventional pain physicians.

Wholesale Distributors

- Requires wholesale distributors to credential physicians and pharmacies that purchase Schedule II or Schedule III controlled substances. Credentialing policies must be submitted to DOH as part of an application for a permit or to renew a permit for a prescription drug wholesale distributor. Credentialing must include:
 - Determination of the clinical nature of the entity;
 - Review of the receiving entity's history of purchasing Schedule II and Schedule III controlled substances;

- Determination that purchasing history, if any, is consistent with and reasonable for that entity's clinical business needs; and
- Level 2 background screening of any person who owns, manages, oversees or controls the operation of the purchasing entity, including officers and members of the board of directors of an entity that is a corporation (with exceptions for large corporations).
- Prohibits distribution of more than 5,000 unit doses of specific drugs (oxycodone, hydromorphone, hydrocodone, or methadone or their derivatives) to a retail pharmacy (a pharmacy serving the public, as opposed to a closed pharmacy) in any given month.
- Requires distributors to investigate suspicious transactions, including those involving more than 5,000 unit doses of controlled substances in any given month.
- Makes knowingly submitting a false drug distribution report a 3rd degree felony.
- Makes distributing controlled substances improperly a 3rd degree felony.

Community Pharmacies

- Creates new requirements to receive a community pharmacy permit:
 - Mandatory on-site inspections
 - Disclosure of financial interests
 - Designated pharmacy manager is responsible for compliance
 - Specific grounds for permit denial, including criminal history and prior non-compliance with specific regulations.
- Prohibits community pharmacies from dispensing a controlled substance listed in Schedule II or Schedule III unless the pharmacy:
 - Is wholly owned by a corporation whose shares are publicly traded on a recognized stock exchange; or
 - Is wholly owned by a corporation having more than \$100 million of annual business revenues in this state; or
 - Has been continuously permitted for at least 10 years; or,
 - Is wholly owned or operated by a licensed hospice, hospital or nursing home or exclusively serves hospice, hospital or nursing home patients; or
 - Received or renewed a permit after January 1, 2012, such that it is subject to the new permitting requirements.
- Requires pharmacies dispensing controlled substances to maintain a log of all prescriptions filled.
- Requires pharmacies to make the controlled substances log available to DOH or FDLE upon request.

Pharmacists

- Provides new grounds for denial of a pharmacist license and disciplinary action on the license based on errors or omissions in processing prescription drugs.

Pain Management Clinics

- Maintains requirement for registration of pain clinics; removes provisions repealing this requirement.
- Enacts specific provisions in Board of Medicine proposed rules for pain clinic practice into law.
- Sunsets the pain clinic regulations in 2016.

Prescription Drug Monitoring Program

- Prohibits donations of pharmaceutical manufacturers from being used to support the monitoring program.
- Modifies data submission requirement to 7 days from 15 days.
- Revises direct support organization provisions to establish DOH as responsible agency in place of the Office of Drug Control.

The analysis reflects the Committee Substitute for the Committee Substitute.