HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: PCB HHSC 11-03 Controlled Substances
SPONSOR(S): 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

SUMMARY ANALYSIS

PCB HHSC 11-03 bans dispensing of controlled substances by medical practitioners in the state of Florida. Dispensing of controlled substances by a physician or osteopathic physician in Florida is a third degree felony and grounds for licensure disciplinary action.

The PCB requires all dispensing physicians in Florida to return all inventories of controlled substances to the wholesale distributors from which the controlled substances were purchased within 10 days of the 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 PCB directs the Department of Health (DOH) to declare a public health emergency on the third day after enactment of the law. Upon the declaration of a public health emergency, the Department of Law Enforcement (FDLE) and local law enforcement is authorized to secure, on-site, all unreturned inventories of controlled substances 24 hours per day until the dispensing physician is able to return the controlled substances to the wholesale distributor. The bill provides that remaining inventory becomes contraband on the tenth day following enactment of the law, and requires law enforcement to seize the inventory and destroy it pursuant to applicable law. The bill sunsets these provisions on January 1, 2013.

The PCB repeals current laws related to the establishment, management and operation of pain-management clinics, including the regulations that affect physicians and osteopathic physicians practicing medicine in pain-management clinics or serving as a designated physician for a pain-management clinic.

The PCB adds criminal provisions related to theft of controlled substances and burglary of a structure or conveyance with the intent to steal controlled substances. The PCB also requires a pharmacist, a pharmacy intern or an employee of a pharmacy to report the obtaining or attempt to obtain controlled substances by fraudulent methods or misrepresentations and the discovery of a theft or loss of controlled substance to law enforcement. Failure to report these activities is a second degree misdemeanor.

The PCB appropriates $1.5 million in non-recurring General Revenue funds to defray the cost to law enforcement to secure controlled substance inventories during the quarantine period.

The bill appears to have a significant negative fiscal impact on local government. (See Fiscal Comments).

The bill is effective upon becoming a law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Controlled Substances

Controlled substances are drugs with potential for abuse. They are classified into five schedules based on the range of abuse potential and medical value for patients. Substances in Schedule I have a high potential for abuse and have no currently accepted medical use in the United States. 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 Abuse[1], 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 most commonly abused drugs (highlighted below) are found in all four prescribable controlled substance Schedules.

Substance	Other Names
Schedule II - high potential for abuse; severely restricted medical use	
1-Phenylcyclohexylamine	Precursor of PCP
1-Piperidinocyclohexanecarbonitrile	PCC, precursor of PCP
Alfentanil	Alfenta
Alphaprodine	Nisentil
Amobarbital	Amytal, Tuinal
Amphetamine	Dexedrine, Biphetamine
Anileridine	Leritine
Benzoylecgonine	Cocaine metabolite
Bezitramide	Burgodin
Carfentanil	Wildnil

[1] *See* http://www.nida.nih.gov/drugpages/prescription.html

Substance	Other Names
Coca Leaves	
Cocaine	Methyl benzoylecgonine, Crack
Codeine	Morphine methyl ester, methyl morphine
Dextropropoxyphene, bulk (non-dosage forms)	Propoxyphene
Dihydrocodeine	Didrate, Parzone
Diphenoxylate	
Diprenorphine	M50-50
Ecgonine	Cocaine precursor, in Coca leaves
Ethylmorphine	Dionin
Etorphine HCl	M 99
Fentanyl	Innovar, Sublimaze, Duragesic
Glutethimide	Doriden, Dorimide
Hydrocodone	dihydrocodeinone
Hydromorphone	Dilaudid, dihydromorphinone
Isomethadone	Isoamidone
Levo-alphacetylmethadol	LAAM, long acting methadone, levomethadyl acetate
Levomethorphan	
Levorphanol	Levo-Dromoran
Meperidine	Demerol, Mepergan, pethidine
Meperidine intermediate-A	Meperidine precursor
Meperidine intermediate-B	Meperidine precursor
Meperidine intermediate-C	Meperidine precursor
Metazocine	
Methadone	Dolophine, Methadose, Amidone
Methadone intermediate	Methadone precursor
Methamphetamine	Desoxyn, D-desoxyephedrine, ICE, Crank, Speed
Methylphenidate	Ritalin
Metopon	
Moramide-intermediate	
Morphine	MS Contin, Roxanol, Duramorph, RMS, MSIR
Nabilone	Cesamet
Opium extracts	
Opium fluid extract	
Opium poppy	Papaver somniferum
Opium tincture	Laudanum
Opium, granulated	Granulated opium
Opium, powdered	Powdered Opium
Opium, raw	Raw opium, gum opium
Oxycodone	OxyContin, Percocet, Tylox, Roxicodone, Roxicet,
Oxymorphone	Numorphan
Pentobarbital	Nembutal
Phenazocine	Narphen, Prinadol
Phencyclidine	PCP, Sernylan
Phenmetrazine	Preludin
Phenylacetone	P2P, phenyl-2-propanone, benzyl methyl ketone
Piminodine	
Poppy Straw	Opium poppy capsules, poppy heads
Poppy Straw Concentrate	Concentrate of Poppy Straw, CPS
Racemethorphan	
Racemorphan	Dromoran
Remifentanil	Ultiva

Substance	Other Names
Secobarbital	Seconal, Tuinal
Sufentanil	Sufenta
Thebaine	Precursor of many narcotics
Schedule III - (less potential for abuse than Schedules I or II; some accepted medical use)	
Amobarbital & noncontrolled active ingred.	Amobarbital/ephedrine capsules
Amobarbital suppository dosage form	
Anabolic steroids	"Body Building" drugs
Aprobarbital	Alurate
Barbituric acid derivative	Barbiturates not specifically listed
Benzphetamine	Didrex, Inapetyl
Boldenone	Equipoise, Parenabol, Vebonol, dehydrotestosterone
Buprenorphine	Buprenex, Temgesic
Butabarbital	Butisol, Butibel
Butalbital	Fiorinal, Butalbital with aspirin
Chlorhexadol	Mechloral, Mecoral, Medodorm, Chloralodol
Chlorotestosterone (same as clostebol)	if 4-chlorotestosterone then clostebol
Chlorphentermine	Pre-Sate, Lucofen, Apsedon, Desopimon
Clortermine	Voranil
Clostebol	Alfa-Trofodermin, Clostene, 4-chlorotestosterone
Codeine & isoquinoline alkaloid 90 mg/du	Codeine with papaverine or noscapine
Codeine combination product 90 mg/du	Empirin, Fiorinal, Tylenol, ASA or APAP w/codeine
Dehydrochlormethyltestosterone	Oral-Turinabol
Dihydrocodeine combination product 90 mg/du	Synalgos-DC, Compal
Dihydrotestosterone (same as stanolone)	see stanolone
Dronabinol in sesame oil in soft gelatin capsule	Marinol, synthetic THC in sesame oil/soft gelatin
Drostanolone	Drolban, Masterid, Permastril
Ethylestrenol	Maxibolin, Orabolin, Durabolin-O, Duraboral
Ethylmorphine combination product 15 mg/du	
Fluoxymesterone	Anadroid-F, Halotestin, Ora-Testryl
Formebolone (incorrect spelling in law)	Esiclene, Hubernol
Hydrocodone & isoquinoline alkaloid 15 mg/du	Dihydrocodeinone+papaverine or noscapine
Hydrocodone combination product 15 mg/du	Tussionex, Tussend, Lortab, Vicodin, Hycodan, Anexsia ++
Ketamine	Ketaset, Ketalar, Special K, K
Lysergic acid	LSD precursor
Lysergic acid amide	LSD precursor
Mesterolone	Proviron
Methandienone (see Methandrostenolone)	
Methandranone	
Methandriol	Sinesex, Stenediol, Troformone
Methandrostenolone	Dianabol, Metabolina, Nerobol, Perbolin
Methenolone	Primobolan, Primobolan Depot, Primobolan S
Methyltestosterone	Android, Oreton, Testred, Virilon
Methyprylon	Noludar
Mibolerone	Cheque
Morphine combination product/50 mg/100 ml or gm	
Nalorphine	Nalline
Nandrolone	Deca-Durabolin, Durabolin, Durabolin-50
Norethandrolone	Nilevar, Solevar
Opium combination product 25 mg/du	Paregoric, other combination products
Oxandrolone	Anavar, Lonavar, Provitar, Vasorome
Oxymesterone	Anamidol, Balnimax, Oranabol, Oranabol 10

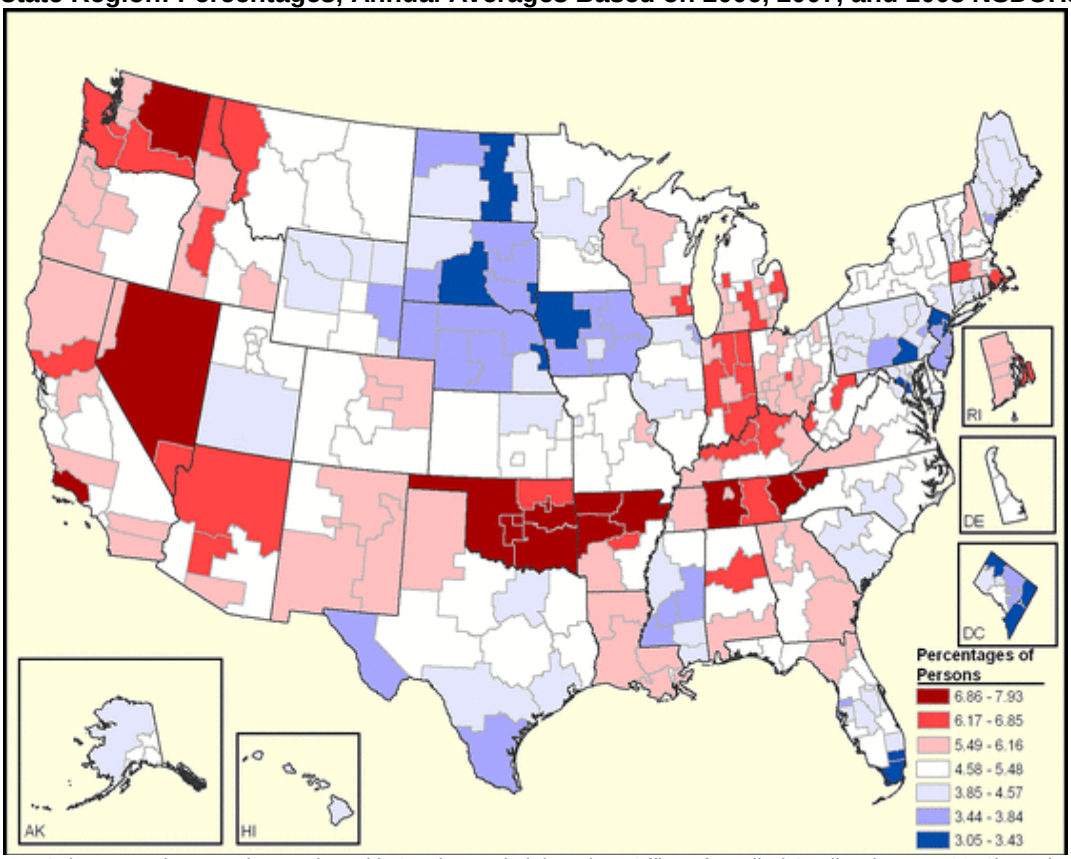
Substance	Other Names
Oxymetholone	Anadrol-50, Adroyd, Anapolon, Anasteron, Pardroyd
Pentobarbital & noncontrolled active ingred.	FP-3
Pentobarbital suppository dosage form	WANS
Phendimetrazine	Plegine, Prelu-2, Bontril, Melfiat, Statobex
Secobarbital & noncontrolled active ingred	various
Secobarbital suppository dosage form	various
Stanolone	Anabolex, Andractim, Pesomax, dihydrotestosterone
Stanozolol	Winstrol, Winstrol-V
Stimulant compounds previously excepted	Mediatric
Sulfondiethylmethane	
Sulfonethylmethane	
Sulfonmethane	
Talbutal	Lotusate
Testolactone	Teslac
Testosterone	Android-T, Androlan, Depotest, Delatestryl
Thiamylal	Surital
Thiopental	Pentothal
Tiletamine & Zolazepam Combination Product	Telazol
Trenbolone	Finaplix-S, Finajet, Parabolan
Vinbarbital	Delvinal, vinbarbitone
Schedule IV - (less potential for abuse than Schedules I, II, or III; some accepted medical use)	
Alprazolam	Xanax
Barbital	Veronal, Plexonal, barbitone
Bromazepam	Lexotan, Lexatin, Lexotanil
Butorphanol	Stadol, Stadol NS, Torbugesic, Torbutrol
Camazepam	Albego, Limpidon, Paxor
Cathine	Constituent of "Khat" plant
Chloral betaine	Beta Chlor
Chloral hydrate	Noctec
Chlordiazepoxide	Librium, Libritabs, Limbitrol, SK-Lygen
Clobazam	Urbadan, Urbanyl
Clonazepam	Klonopin, Clonopin
Clorazepate	Tranxene
Clotiazepam	Trecalmo, Rize
Cloxazolam	Enadel, Sepazon, Tolestan
Delorazepam	
Dexfenfluramine	Redux
Dextropropoxyphene dosage forms	Darvon, propoxyphene, Darvocet, Dolene, Propacet
Diazepam	Valium, Valrelease
Dichloralphenazone	Midrin, dichloralantipyrine
Diethylpropion	Tenuate, Tepanil
Difenoxin 1 mg/25 ug AtSO4/du	Motofen
Estazolam	ProSom, Domnamid, Eurodin, Nuctalon
Ethchlorvynol	Placidyl
Ethinamate	Valmid, Valamin
Ethyl loflazepate	
Fencamfamin	Reactivan
Fenfluramine	Pondimin, Ponderal
Fenproporex	Gacilin, Solvolip
Fludiazepam	
Flunitrazepam	Rohypnol, Narcozep, Darkene, Roipnol

Substance	Other Names
Flurazepam	Dalmane
Halazepam	Paxipam
Haloxazolam	
Ketazolam	Anxon, Loftran, Solatran, Contamex
Loprazolam	
Lorazepam	Ativan
Lormetazepam	Noctamid
Mazindol	Sanorex, Mazanor
Mebutamate	Capla
Medazepam	Nobrium
Mefenorex	Anorexic, Amexate, Doracil, Pondinil
Meprobamate	Miltown, Equanil, Deprol, Equagesic, Meprospan
Methohexital	Brevital
Methylphenobarbital (mephobarbital)	Mebaral, mephobarbital
Midazolam	Versed
Modafinil	Provigil
Nimetazepam	Erimin
Nitrazepam	Mogadon
Nordiazepam	Nordazepam, Demadar, Madar
Oxazepam	Serax, Serenid-D
Oxazolam	Serenal, Convertal
Paraldehyde	Paral
Pemoline	Cylert
Pentazocine	Talwin, Talwin NX, Talacen, Talwin Compound
Petrichloral	Pentaerythritol chloral, Periclor
Phenobarbital	Luminal, Donnatal, Bellergal-S
Phentermine	Ionamin, Fastin, Adipex-P, Obe-Nix, Zantryl
Pinazepam	Domar
Pipradrol	Detaril, Stimolag Fortis
Prazepam	Centrax
Quazepam	Doral, Dormalin
Sibutramine	Meridia
SPA	1-dimethylamino-1,2-diphenylethane, Lefetamine
Temazepam	Restoril
Tetrazepam	
Triazolam	Halcion
Zaleplon	Sonata
Zolpidem	Ambien, Stilnoct,Ivadal
Schedule V - (low potential for abuse compared to Schedule IV; some accepted medical use)	
Codeine preparations - 200 mg/100 ml or 100 gm	Cosanyl, Robitussin A-C, Cheracol, Cerose, Pediacof
Difenoxin preparations - 0.5 mg/25 ug AtSO4/du	Motofen
Dihydrocodeine preparations 10 mg/100 ml or 100 gm	Cophene-S, various others
Diphenoxylate preparations 2.5 mg/25 ug AtSO4	Lomotil, Logen
Ethylmorphine preparations 100 mg/100 ml or 100 gm	
Opium preparations - 100 mg/100 ml or gm	Parepectolin, Kapectolin PG, Kaolin Pectin P.G.
Pyrovalerone	Centroton, Thymergix

The Substance Abuse and Mental Health Services Administration (SAMHSA) sponsors an annual national survey on drug use and health. The most recent survey[2] indicates there are 6.9 million (2.8 percent) persons aged 12 or older who used prescription-type psychotherapeutic drugs non-medically in the past month. 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.[3]

Of those 6.9 million people who used pain relievers non-medically in the 12-month period, 56.5 percent reported they received the drug from a friend or relative for free. Another 8.9 percent bought the drugs from a friend or family member. Another 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 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.[4] 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.[5]

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-

[2] 2007 National Survey on Drug Use and Health, U.S. Substance Abuse and Mental Health Services Administration, *see* http://oas.samhsa.gov/2k7nsduh/2k7Results.cfm
[3] *Id.*
[4] *Id.*
[5] National Estimates of Drug-Related Emergency Department Visits 2004-2009, *see* https://dawninfo.samhsa.gov/data/default.asp?met=All

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.[6]

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 first six months of 2010, found 1,268 deaths caused by prescription drugs.[7] The rate of deaths caused by prescription drugs during the first six months of 2010 averaged 7 fatalities per day.[8]

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.[9] 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"[10]

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.[11] The top 49 practitioners dispensing oxycodone in the United States were concentrated in nine counties.[12] 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.[13] In Florida, 9,201,731 dose units of oxycodone were dispensed during one six month time period.[14] 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:[15]

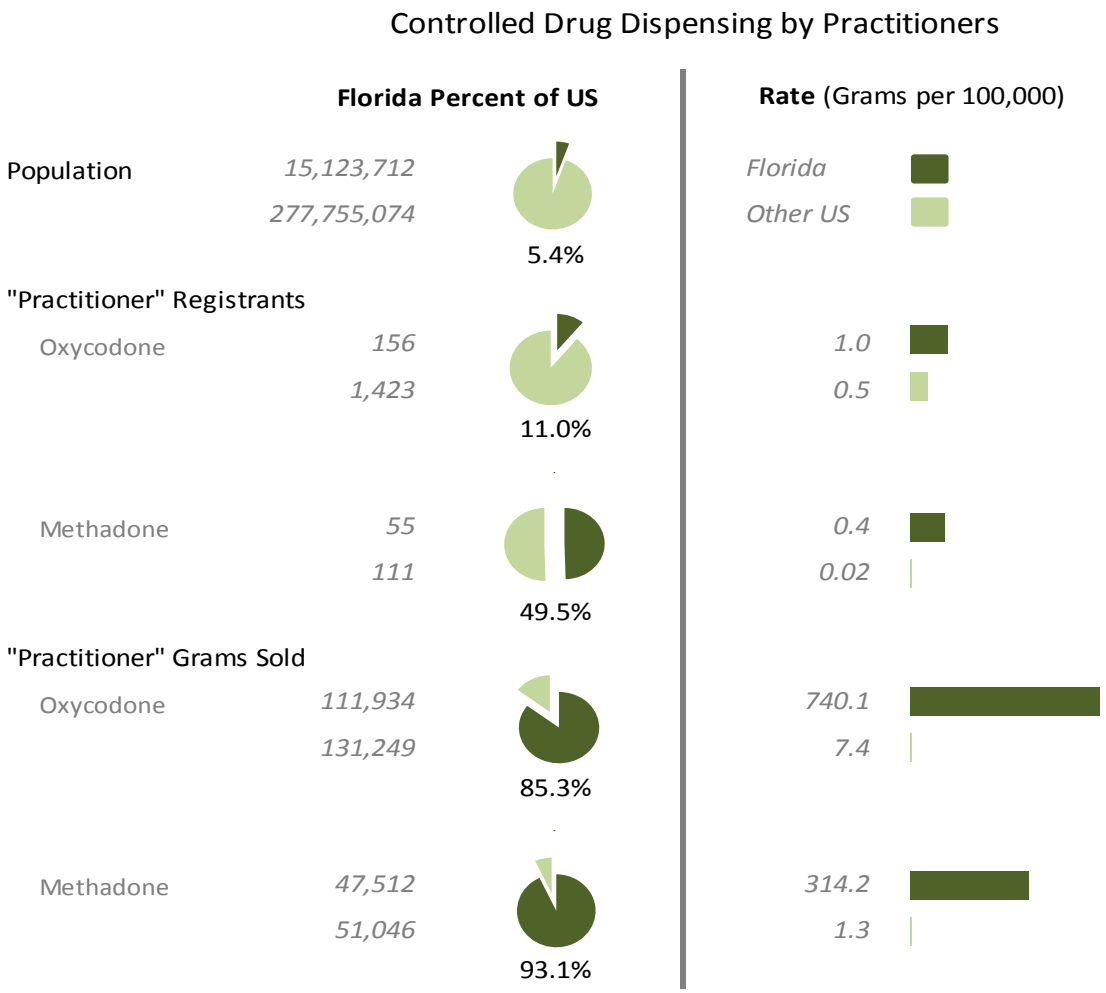
County	Units Oxycodone
Broward	5,233,785
Palm Beach	2,368,430
Miami-Dade	646,500
Pinellas	192,400
Hillsborough	184,330
Lake	169,200
Seminole	164,686
Orange	133,600

[6] 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.
[7] *Drugs Identified in Deceased Persons by Florida Medical Examiners*, 2010 Interim Report, Medical Examiners Commission, FDLEFDLE, December 2010, at http://www.fdle.state.fl.us/Content/getdoc/8a59bd00-c38d-4be1-ac06-715a273b552e/MEC-2010-Interim-Report.aspx
[8] *Id.*
[9] 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.
[10] *Id.*
[11] 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
[12] *Id.*
[13] *Id.*
[14] *Id.*
[15] *Id.*

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

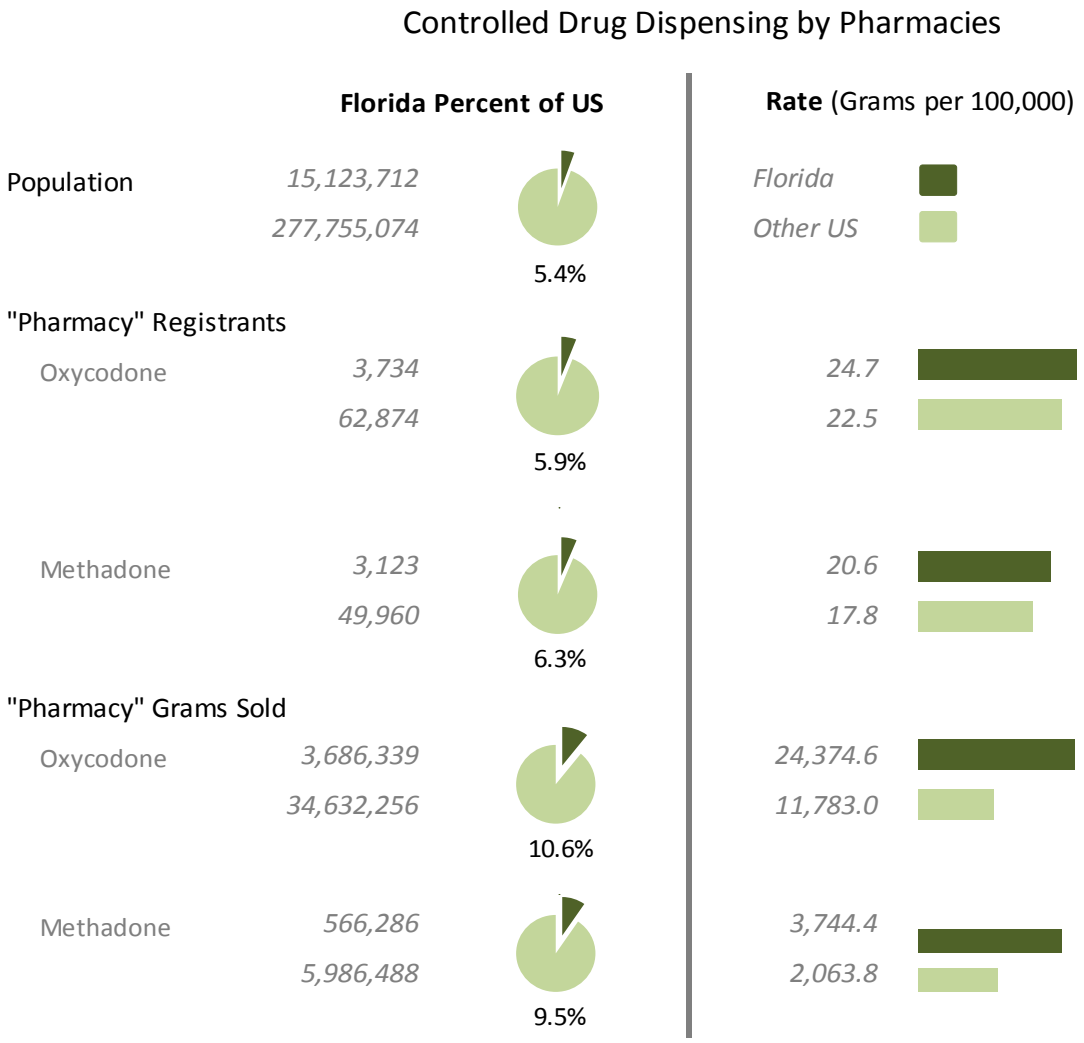
Zip Code	Units Oxycodone
33020	281,500
33444	239,500
33179	226,300
33463	187,700
33308	176,600
33021	176,000
33487	166,700
33023	141,700
33301	120,400
33323	118,400
33432	117,800
33325	114,700

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 U.S., and over 93 percent of the methadone dispensed by physicians in the U.S.[16]



[16] 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.[17]



Controlled Substance Distribution and Dispensing Regulation

Manufacturers and Distributors

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

Part I of Chapter 499 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.

Among many other provisions, the chapter provides for:

- Criminal prohibitions against the distribution of contraband and misbranded prescription drugs.

[17] *Id.*

- 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 the Department 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.[18]
- More thorough documentation of the distribution of prescription drugs, including broader application of the pedigree paper to most wholesale distributions.[19]
- Enhanced criminal penalties for, among other things, distribution of contraband prescription drugs.[20]
- Stronger departmental enforcement authority to protect the prescription drug supply chain.[21]

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 pharmacies[22] 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 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

[18] *See* s. 499.01(2)(d), F.S. (2008) (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).
[19] *See* s. 499.01212, F.S. (2008) ("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.")
[20] *See* s. 499.0051(6), F.S. (2008) (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").
[21] *See* s. 499.065, F.S. (2008) (authorizing the department to immediately close a wholesale facility if it constitutes an imminent danger to public health).
[22] Ch. 465, F.S., distinguishes community pharmacies from institutional pharmacies, or pharmacies located in nursing homes or hospitals which dispense medications to patients for use within the institutions. S. 465.019, F.S.

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.[23]

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. [24]

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.[25]

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.

[23] S. 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.
[24] S. 465.023, F.S.
[25] S. 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 the department. No prescription for a Schedule II controlled substance may be refilled.[26] 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.[27] 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.[28]

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".[29] DOH rules apply this standard to controlled substances.[30] 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.[31]

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.[32]

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.[33] Physicians who only dispense complimentary medications, and who receive no direct or indirect payment or remuneration for the medications, are not required to register.[34]

The Department 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.[35] Dispensing physicians are required to comply with all state and federal laws and regulations applicable to

[26] S. 893.04(1)(f), F.S.
[27] S. 893.04(1)(g), F.S.
[28] *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.
[29] S. 465.023(1)(h), F.S.
[30] Rule 64B16-27.831, F.A.C.
[31] Rule 64B16-28.101, F.A.C.
[32] S. 893.02, F.S.
[33] S. 465.0276(2)(a), F.S. and rule 64B8-3.006, F.A.C.
[34] S. 465.0276(5), F.S.
[35] S. 465.0276(3), F.S.

pharmacists and pharmacies.[36] For example, a pharmacy is not permitted to dispense a drug if the 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.[37]

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 the Department about dispensing practitioners since 2006. The table also includes the number of disciplinary actions taken against dispensing practitioners during the same time period.[38]

Dispensing Practitioners	2006-07	2007-08	2008-09	2009-10	2010-3/2011	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.[39]	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. Twenty-six states allow dispensing of controlled substances and require some form of dispensing license.[40] Nineteen states allow dispensing but do not require any license.[41] One state allows dispensing but requires a license to dispense controlled substances.[42] Montana and Utah prohibit physician dispensing entirely, for all drugs.[43] Massachusetts and Texas limit controlled substance dispensing to a 72-hour supply in emergency situations, and impose other restrictions.[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

[36] S. 465.0276(20)(a), F.S.
[37] Florida Department of Health, Presentation to the House Health and Human Services Committee, February 24, 2011, on file with the Committee.
[38] *Id.*
[39] S. 465.016(1)(s), F.S., prohibits dispensing when a pharmacist has reason to believe a valid relationship does not exists 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.
[40] 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
[41] *Id.*
[42] *Id.*
[43] *Id.*
[44] *Id.*
[45] Ch. 2009-198, Laws of Fla. (2009); ch. 2010-211, Laws of Florida (2010).

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. 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 the department.[48]

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 the

[46] S. 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 Committee.
[48] *Id*.

Department. The ITAR notified each non-compliant clinic of the intent of the Department to revoke the certificate due to the clinic's failure to meet the ownership requirements. As of the end of February 2011, the Department 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 the Department'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 the Department 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 the Department. 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.[49]. 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.[50] The changes to the

[49] SS. 458.327, 459.013, F.S.

[50] Ch. 2010-279, Laws of Florida. 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.

Administrative Procedures Act (ch. 120) made by HB 1565 will affect the implementation of proposed rules by the Board of Medicine on standards of practice for medical doctors practicing in pain management clinics.[51] 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.[52]

The last table combines the number of licenses, permits or registrations issued by the Department 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.[53] 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.[54]

Effect of Proposed Changes

The PCB prohibits physician dispensing of controlled substances in Schedules II, III, IV and V. The PCB makes dispensing a controlled substance included in Schedule II, III, IV, or V a third degree felony and grounds for disciplinary action against a physician or osteopathic physician. Such actions include license restriction, suspension, revocation and probation, or fines, letters of reprimand, remedial education, or corrective action.

[51] 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.
[52] Rule 64B15-14.0051, F.A.C. and Rule 64B15-14.0052, F.A.C.
[53] S. 893.07(3), F.S.
[54] S. 893.07(4), F.S.

The PCB requires wholesale distributors of controlled substances to submit a weekly electronic report of its distributions of controlled substances listed in Schedules II, III, IV, and V within the state of Florida. The PCB specifies the information to be included in the reports.

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

- The PCB 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 PCB defines what constitutes a sufficient report to include a copy of the prescription and information identifying the prescriber and patient.

- The PCB amends the burglary statute, adding burglary of a structure or conveyance with the intent to steal controlled substances, making that a second degree felony. The PCB 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 PCB makes theft of any amount of a controlled substance grand theft in the third degree, punishable as a third degree felony. The PCB allows for separate judgments and sentences are allowed for possession of a controlled substance or trafficking in a controlled substance if all offenses include the same amount of controlled substance.

- The PCB requires all thefts or loss of controlled substances to be reported to the sheriff of the county where the theft or loss occurred within 48 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.. 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 PCB requires all physicians, within ten days of the effective date of the bill, to return all undispensed 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 undispensed controlled substances to law enforcement and abandon the medication. The PCB establishes a buy-back program which requires wholesale distributors to purchase the remaining 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 PCB 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, which 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 PCB 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 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 those 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 controlled substance 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.
- The FDLE shall coordinate all efforts of local law enforcement to accomplish the provisions of the act.
- The 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 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 PCB deems any remaining 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 $1.5 million in non-recurring funds is appropriated to defray the cost to FDLE and local law enforcement agencies of securing controlled substance inventories during the quarantine period.

The PCB repeals the public health emergency section on January 1, 2013.

The PCB repeals controlled substance regulation laws enacted in 2009 and 2010. Specifically, the PCB eliminates:

- Regulation of pain-management clinics as business establishments under s. 456.037, F.S.; and
- Registration requirements for pain-management clinics under s. 458.3265, F.S. and s. 459.0137, F.S., including:
    - criminal penalties for operating an unregistered pain-management clinic;
    - criminal penalties for prescribing or dispensing in an unregistered pain-management clinic;
    - physician licensure penalties for failing to comply with various requirements for registration of or practice in pain-management clinics;
    - physician licensure penalties for violations by designated physicians;
    - physician ownership requirement for pain-management clinics; and
    - access to pain-management clinic patient records without patient consent
- 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 database is being repealed by PCB HHS 11-04, and the Task Force is no longer necessary.

The PCB provides for an effective date immediately upon becoming a law.

B. SECTION DIRECTORY:

Section 1: Amends s. 456.037, F.S., relating to business establishments; requirements for active status licenses; delinquency; discipline; applicability.
Section 2: Amends s. 456.057, F.S., relating to ownership and control of patient records; report or copies of records to be furnished.
Section 3: Repeals s. 458.3265, F.S., relating to pain-management clinics.
Section 4: Amends s. 458.327, F.S., relating to penalty for violations.
Section 5: Amends s. 458.331, F.S., relating to grounds for disciplinary action; action by the board and department.
Section 6: Repeals s. 459.0137, F.S., relating to pain-management clinics.
Section 7: Amends s. 459.013, F.S., relating to penalty for violations.

Section 8: Amends s. 459.015, F.S., relating to grounds for disciplinary action; action by the board and department.
Section 9: Amends s. 465.015, F.S., relating to violations and penalties.
Section 10: Amends s. 465.0276, F.S., relating to dispensing practitioner.
Section 11: Amends s. 499.005, F.S., relating to prohibited acts.
Section 12: Amends s. 499.0121, F.S., relating to storage and handling of prescription drugs; recordkeeping.
Section 13: Amends s. 499.05, F.S., relating to rules.
Section 14: Amends s. 810.02, F.S., relating to burglary.
Section 15: Amends s. 812.014, F.S., relating to theft.
Section 16: Amends s. 893.07, F.S., relating to records.
Section 17: Repeals s. 2 of Chapter 2009-198, 2009 Laws of Florida, relating to the Program Implementation and Oversight Task Force.
Section 18: Creates an unnumbered section of law, relating to a Buy-Back Program; public health emergency; repeal.
Section 19: Provides an effective date upon becoming law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   The elimination of all regulations governing the establishment and operation of pain-management clinics will eliminate pain clinic registration and inspection fees.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   The PCB 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 PCB makes an appropriation of $1.5 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.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The PCB prohibits physicians from dispensing controlled substances. This will negatively impact the revenue income of those physicians who previously dispensed controlled substances and the clinics which employ them. Controlled substance dispensing business formerly done by physicians will shift to pharmacies.

The PCB requires wholesale distributors of controlled substances to purchase undispensed physician inventories of 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.

D. FISCAL COMMENTS:

None.

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. The PCB appears to require counties or municipalities to take actions requiring the expenditure of funds: the PCB 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 PCB makes an appropriation of $1.5 million in non-recurring funds from the General Revenue Fund to FDLE to reimburse local law enforcement agencies for these activities, and so appears to fall under Sec. 18(a), Art. VII, providing an exception for instances in which the Legislature appropriates funds sufficient to fund the expenditure. This exception also requires a legislative determination that the law fulfills in important state interest. While the PCB does not explicitly make this finding, it is possible to infer it from the whereas clauses of section 18 and the declaration of a public health emergency.

In addition, the PCB may be exempt under the criminal law provision of Sec. 18(d) of Art. VII

2. Other:

The PCB may implicate Section I2 of Article I of the Florida Constitution and the Fourth Amendment to the U.S. Constitution.

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. 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