HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/CS/HB 225 Controlled Substances
SPONSOR(S): Health Care Appropriations Committee; Health Care Regulation Policy Committee
TIED BILLS: HB 7239 **IDEN./SIM. BILLS:**

	REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
Orig. Comm.:	Health Care Regulation Policy Committee	12 Y, 1 N, As CS	Calamas	Calamas
1)	Health Care Appropriations Committee	7 Y, 5 N, As CS	Clark	Massengale
2)				
3)				
4)				
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SUMMARY ANALYSIS

The Committee Substitute for House Bill 225 increases regulation and provides for public-private partnerships to address prescription drug abuse.

The bill requires pharmacies to participate in a multistate electronic prescribing network, and requires pharmacies to transmit dispensing information for controlled substances through the network. The bill makes these provisions effective July 1, 2012, and January 1, 2013, for new and existing pharmacies, respectively. Similarly, the bill requires physicians who dispense controlled substances to transmit dispensing information for controlled substances through the multistate network, effective January 1, 2013. The bill requires the Agency for Health Care Administration to negotiate access for law enforcement and state regulatory entities to controlled substance information through a multi-state electronic prescribing network.

The bill adds new requirements for pain clinic registration by prohibiting the Department of Health from registering pain clinics owned by anyone other than physicians or licensed health care clinics, pain clinics employing or contracting with a physician against whom regulatory action has been taken related to drug or alcohol abuse, and pain clinics with owners who have certain felony drug convictions. The bill also amends the definition of "clinics" to make it applicable to entities that are primarily engaged in the treatment pain by prescribing or dispensing controlled substances, as opposed to other methods of pain treatment.

The bill creates a registration requirement for health care practitioners to dispense controlled substances, which depends on medical community recommendations. The registration requirement is effective September 1, 2010, for practitioners in Broward, Palm Beach and Miami-Dade Counties, and is effective upon license renewal for other practitioners.

The bill adds practitioner regulations and penalties. It makes physician advertising of controlled substances and practicing medicine in an unregistered clinic, which is required to be registered, grounds for licensure action. The bill also makes it a licensure violation to dispense controlled substances without being registered, and to fail to transmit controlled substance information through the network.

The Agency for Health Care Administration is authorized to seek private grants and donations to establish state access to the private multistate electronic prescribing network data, and the Department of Health is authorized to charge a fee to support the registration of practitioners who dispense controlled substances.

The bill provides an effective date of July 1, 2010.

HOUSE PRINCIPLES

Members are encouraged to evaluate proposed legislation in light of the following guiding principles of the House of Representatives

- Balance the state budget.
- Create a legal and regulatory environment that fosters economic growth and job creation.
- Lower the tax burden on families and businesses.
- Reverse or restrain the growth of government.
- Promote public safety.
- Promote educational accountability, excellence, and choice.
- Foster respect for the family and for innocent human life.
- Protect Florida's natural beauty.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Controlled Substance Dispensing

Chapter 893, Florida Statutes, sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act.[1] Controlled substances are classified into five schedules 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. 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.

Pharmacists and Pharmacies

Section 893.04, Florida Statutes, authorizes a pharmacist, in good faith and in the course of professional practice to dispense controlled substances upon a written or oral prescription under specified conditions:

- 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; and
- The face of the prescription or written record for the controlled substance must include:
  - The full name and address of the person for whom, or the owner of the animal for which, the controlled substance is dispensed;
  - The full name and address of the prescribing practitioner and the prescriber's federal controlled substance registry number;
  - If the prescription is for an animal, the species of animal for which the controlled substance is prescribed;
  - The name of the controlled substance prescribed and the strength, quantity, and directions for the use thereof;

[1] *See, also,* the federal Controlled Substances Act, 21 U.S.C. 812.

- 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), Florida Statutes, 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.

Chapter 893, Florida Statutes, 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.[2] 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.[3] 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.[4]

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."[5] Department of Health rules apply this standard to controlled substances:[6]

> The following criteria shall cause a pharmacist to question whether a prescription was issued for a legitimate medical purpose:
> (a) Frequent loss of controlled substance medications;
> (b) Only controlled substance medications are prescribed for a patient;
> (c) One person presents controlled substance prescriptions with different patient names;
> (d) Same or similar controlled substance medication is prescribed by two or more prescribers at same time; and
> (e) 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. The Department of Health inspects pharmacies at least once a year to ensure compliance with statutory and regulatory requirements.[7]

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[2] s. 893.04(1)(f), F.S.
[3] s. 893.04(1)(g), F.S.
[4] *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.
[5] S. 465.023(1)(h), F.S.
[6] Rule 64B16-27.831, F.A.C.
[7] Rule 64B16-28.101, F.A.C.

Physicians

Section 893.05, Florida Statutes, 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.[8] Physician dispensing is regulated by the relevant medical boards within the Department of Health.

To dispense medications, rather than just prescribe them, physicians must register with the department and pay a fee of $100.[9] Physicians who only dispense complimentary medications, and who receive no direct or indirect payment or remuneration for the medications, are not required to register.[10] There are 7,108 registered dispensing practitioners in Florida.[11]

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 (see above).[12] Dispensing physicians are required to comply with all state and federal laws and regulations applicable to pharmacists and pharmacies (see above).[13] 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 also applies to dispensing physicians.

Dispensing Prohibitions

Currently, Florida law allows registered physicians to dispense any prescribed drug. Other states have varying degrees of regulation. Twenty states allow dispensing and require some form of dispensing license.[14] Twenty-three states allow dispensing, but do not require any license. One state allows dispensing, but requires a license to dispense controlled substances.

Some states prohibit physician dispensing entirely.[15] Montana, Texas and Utah prohibit all physician dispensing; Massachusetts allows physicians to dispense only a 72-hour supply for emergencies. These states do not distinguish between controlled substances and other medications; all are included in the prohibition.

Electronic Prescribing

Electronic prescribing is the electronic generation and transmission of a patient's prescription by a health care practitioner at the point of care. It includes two major functions: two-way electronic communication between physicians and pharmacies regarding new prescriptions, refills, change requests, prescription cancellations, and patient compliance; and communication with other health care partners, like payers, related to eligibility, formularies and medication history.[16]

Electronic prescribing involves a secure, electronic connection between the physician and the pharmacy. In addition, electronic prescribing software generally allows a healthcare practitioner to not only securely access the patient's health plan formulary, but also the patient's medication history, all at the point of care. Medication history is generally available in an 11- to 24-month rolling window, and it generally includes both written and electronically transmitted prescriptions. Numerous software companies offer stand-alone

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[8] S. 893.02, F.S.
[9] S. 465.0276(2)(a), F.S.; Rule 64B8-3.006, F.A.C.
[10] S. 465.0276(5), F.S.
[11] Provided by the Department of Health via email to committee staff, dated February 1, 2010, on file with the committee. This number includes 935 advanced registered nurse practitioners, 230 dentists, 4,925 medical doctors, 855 osteopathic physicians, 119 podiatric physicians, and 44 optometrists,
[12] S. 465.0276(3), F.S.
[13] S. 465.0276(2)(a), F.S.
[14] Dispensing Regulations by State, American Academy of Urgent Care Medicine, *see* http://aaucm.org/Professionals/MedicalClinicalNews/DispensingRegulations/default.aspx (last viewed January 30, 2010).
[15] *Id.*
[16] Agency for Health Care Administration, Florida Center for Health Information and Policy Analysis, Second Annual Florida Electronic Prescribing Report, January 2009, 2, *see* http://www.fhin.net/eprescribe/Index.shtml (last viewed February 23, 2010).

electronic prescribing products. While the cost of the product varies, some products are available at no cost to the healthcare practitioner.[17]

Section 408.0611, Florida Statutes, created in 2007, requires AHCA to work with private-sector initiatives and relevant stakeholders to create a "clearinghouse" of information on electronic prescribing for healthcare practitioners, facilities, and pharmacies. AHCA developed a website that provides information on the process and advantages of electronic prescribing, the availability of electronic prescribing software, including no-cost and low-cost software, and state and federal electronic prescribing incentive programs.[18] AHCA also reports annually to the Governor and Legislature on the implementation of electronic prescribing by health care practitioners, facilities and pharmacies.

According to AHCA and the Institute of Medicine, electronic prescribing offers numerous benefits, including:[19]

- Reduced health care and legal costs by preventing medication prescription errors caused by events such as illegible hand writing, look-alike or sound-alike drugs, drug-to-drug interactions, incorrect dosing, drug allergy reactions, duplication of drugs, etc.;
- Real-time communications between doctors, pharmacies and patients;
- Provision of drug pricing, payer coverage and preferred drug information;
- Improved clinical outcomes by creating complete patient medication history and providing critical drug alerts and patient specific information at the health care professionals' fingertips; and
- Reduction of fraud and crime by increasing the security of prescriptions.

According to AHCA's most recent report, E-prescribing improved prescription security by providing a complete audit trail of each transaction, from the prescribing physician's office to the dispensing pharmacy, to the patient picking up the prescription. E-prescribing requires a secure log-in process for prescribing practitioners and pharmacies, which must be credentialed and approved before they can participate.[20,21] E-prescribing provides an additional back-up for prescription records, which makes it useful in situations of natural disaster when paper records may be destroyed.[22]

The use of e-prescribing is rising. Of the 6,157 pharmacies in Florida in 2008, 71.33 percent were activated to receive electronic prescriptions, an increase from 63 percent in 2007.[23] Similarly, in 2007 the highest monthly total of e-prescribing healthcare professionals was 2,331. The highest monthly total of e-prescribing physicians in 2008 was 4,492, an increase of 92.75 percent.[24] Among e-prescribers, the number of e-prescriptions issued per month rose 72 percent between 2007 and 2008.[25]

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[17] *See e.g.,* http://www.nationalerx.com/ and http://www.iscribe.com/ (offering free web-based electronic prescribing software) (last viewed February 23, 2010); Florida ePrescribe Clearinghouse, Products and Services, *see* http://www.fhin.net/eprescribe/Technology/products.shtml (last viewed February 23, 2010).

[18] Florida E-Prescribe Clearinghouse, *see* http://www.fhin.net/eprescribe/Index.shtml (last viewed February 23, 2010); Agency for Health Care Administration, *see* http://ahca.myflorida.com/dhit/ElectronicPrescribing/ePrescribeIndex.shtml (last viewed February 23, 2010).

[19] Agency for Health Care Administration, Advantages of ePrescribing, *see* http://www.fhin.net/eprescribe/Benefits/Benefits.shtml (last viewed February 23, 2010), *citing* Institute of Medicine, Committee on Identifying and Preventing Medication Errors, "Preventing Medication Errors: Quality Chasm Series" (2006).

[20] Agency for Health Care Administration, Florida Center for Health Information and Policy Analysis, Second Annual Florida Electronic Prescribing Report, January 2009, *see* http://www.fhin.net/eprescribe/Index.shtml (last viewed February 23, 2010): "Secure access is possible using a virtual private network (VPN) connection over the Internet, which creates a protected electronic channel for the safe transmission of encrypted medication information. Infrastructure technology partners, vendors and others are bound through strong contracts to ensure the authentication of users, the integrity of prescriptions, and the privacy and security of personal health information that passes through the secure networks. Unwarranted prescription activity can be identified much more readily in the electronic system through the use of embedded auditing features."

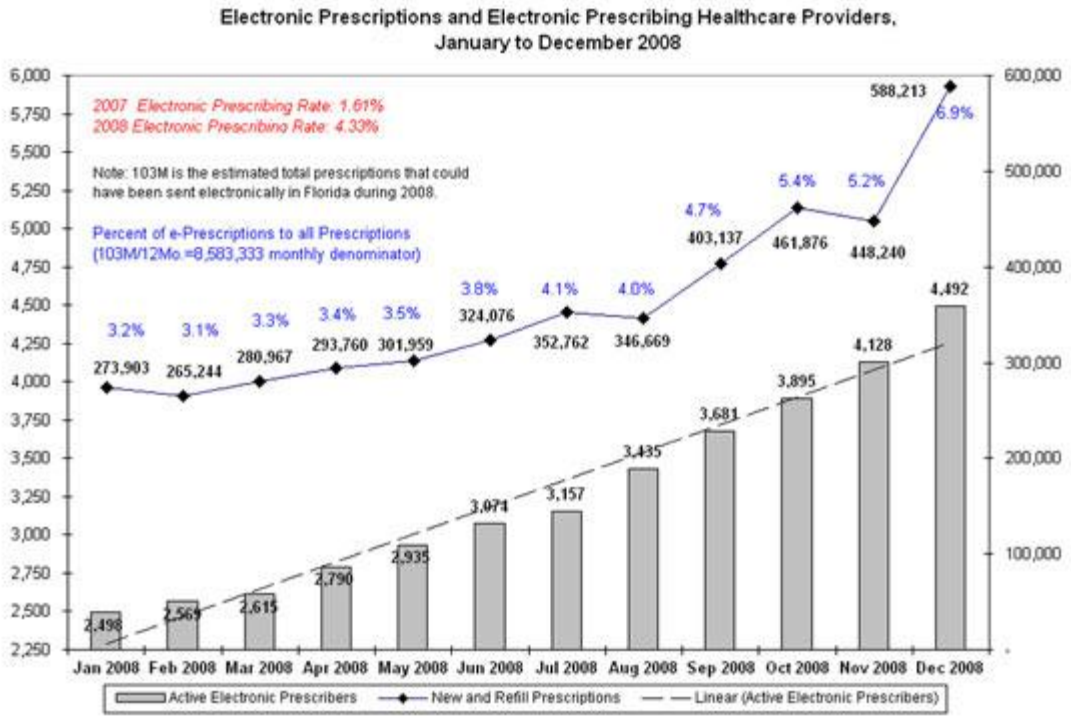
[21] *Id.* at 7.

[22] *Id.*

[23] Agency for Health Care Administration, ePrescribing Clearinghouse, ePrescribing Dashboard 2008 Metrics, *see* http://www.fhin.net/eprescribe/Dashboard/FLmetrics.shtml (last viewed February 23, 2010).

[24] *Id*.

[25] *Id*.



Source: SureScripts-RxHub, *cited in*, Agency for Health Care Administration, ePrescribing Clearinghouse, ePrescribing Dashboard 2008 Metrics.

Controlled Substance E-Prescribing

The Drug Enforcement Administration (DEA) requires every person who dispenses controlled substances to register with the DEA and obtain a unique registration number.[26] All prescriptions for controlled substances must include the DEA registration number of the prescribing practitioner.[27] The DEA prohibits the use of electronic prescribing for controlled substances.[28] On June 27, 2008, the DEA proposed rules that would allow practitioners to issue electronic prescriptions for controlled substances.[29] The proposed rules delineate system requirements for prescribing practitioners e-prescribing vendors, pharmacies, pharmacists, and others. Public comments on the proposed rules were due September 25, 2008, and the DEA received more than 500 comments.[30]

Federal Incentives and Penalties

The 2008 Medicare Improvements for Patients and Providers Act created a Medicare program to encourage physicians to adopt e-prescribing systems.[31] From 2009 through 2014, Medicare will provide incentive payments to eligible health care practitioners who demonstrate "meaningful use" of electronic prescribing. Practitioners will receive a 2 percent incentive payment in 2009 and 2010; a 1 percent incentive payment in 2011 and 2012; and a .5 percent incentive payment in 2013.

Beginning in 2012, Medicare health care practitioners not using electronic prescribing will receive reduced payments for Medicare-covered services: Reimbursements will be reduced 1 percent in 2012, 1.5 percent in 2013, and 2 percent in 2014 and ongoing.[32] Exemptions may be awarded on a case-by-case basis if it is determined that compliance would result in significant hardship for the practitioner.[33]

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[26] 21 C.F.R. 1301.11 (2010).
[27] 21 C.F.R. 1306.05 (2010).
[28] 21 C.F.R. 1306.05 (2010).
[29] Electronic Prescriptions for Controlled Substances, 73 Fed. Reg. 125 (June 27, 2008), (to be codified at 21 C.F.R. pts. 1300, 1304, 1306, 1311), *see* http://www.gpoaccess.gov/fr/index.html, last viewed February 23, 2010.
[30] Agency for Health Care Administration, Florida Center for Health Information and Policy Analysis, Second Annual Florida Electronic Prescribing Report, January 2009, *see* http://www.fhin.net/eprescribe/Index.shtml (last viewed February 23, 2010).
[31] Pub. L. No. 110-275 (2008).
[32] *Id.*
[33] Agency for Health Care Administration, ePrescribing Clearinghouse, ePrescribing Initiatives and Incentive Programs, *see* http://www.fhin.net/eprescribe/ePrescribingInitiatives/NationalIncentivePrograms.shtml (last viewed February 23, 2010).

The 2009 American Recovery and Investment Act (ARRA)[34] authorized approximately $19 billion for additional Medicare and Medicaid incentives to assist providers in adopting health information technology, and for state loan programs. The incentives will be available for five years, starting in 2011.

Electronic Prescribing Networks

To manage health care costs, private sector health care entities established secure internet-based networks for electronically connecting prescribers, dispensers, payers, and pharmacy benefits managers across the country. These e-prescribing networks use private contracting mechanisms to ensure that their technology partners and other affiliates properly authenticate users, maintain prescription integrity, and protect the privacy and security of the health information transmitted through the network. E-prescribing networks use national standards to certify e-prescribing software for use by physicians and pharmacies to participate in the networks.[35]

Until 2008, the two largest e-prescribing networks were RxHub and Surescripts. Both companies were established in 2001. RxHub was founded by three pharmacy benefits management companies, CVS Caremark Corporation, Express Scripts, Inc., and Medco Health Solutions.[36] RxHub focused on providing services related to the delivery of medication information to e-prescribing physicians.[37] Surescripts was created by the National Association of Chain Drug Stores and the National Community Pharmacists Association.[38] Surescripts focused on the provision of services related to electronic communication of prescription information between physicians and pharmacies.[39] In 2008, the two companies merged under the name Surescripts-RxHub, later Surescripts, and became the single largest e-prescribing network, nationally.

According to AHCA, Surescripts does not develop or endorse specific e-prescribing software. Rather, it works with vendors that supply electronic health record and e-prescribing applications to connect their applications to the network.[40] Both stand-alone e-prescribing systems and full electronic medical records systems can be used to connect to the network. There are more than 30 Surescripts-certified technology partners available in Florida.[41]

According to 2009 Surescripts' data, the network has access to 27 payer sources, 49 states have patient accessibility rates of 50 percent or more, and the network accesses more than 220 million patient records annually.[42] Nationally, the network includes major chain pharmacies like Walgreens, CVS, and Wal-Mart, and over 10,000 independent pharmacies.[43] In Florida, more than 8,000 physicians have access to the network, as do the majority of pharmacies. By agreement with AHCA, Florida Medicaid prescription drug data will be added this year.[44] According to Surescripts, the network now includes cash and paper transactions, rather than just electronic and third-party-paid transactions, if the prescribing or dispensing entity uses the network for that purpose.

Prescription Drug Diversion and Abuse

According to the Substance Abuse and Mental Health Services Administration, more than 6.3 million Americans reported using prescription drugs for nonmedical reasons in 2003.[45] 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

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[34] Public Law 111-05 (2009).
[35] Agency for Health Care Administration, Florida Center for Health Information and Policy Analysis, Second Annual Florida Electronic Prescribing Report, January 2009, 7, *see* http://www.fhin.net/eprescribe/Index.shtml (last viewed February 23, 2010).
[36] *See*, http://www.surescripts.com/the-company.html.
[37] Agency for Health Care Administration, Florida Center for Health Information and Policy Analysis, Second Annual Florida Electronic Prescribing Report, January 2009, 24 *see* http://www.fhin.net/eprescribe/Index.shtml (last viewed February 23, 2010).
[38] *See,* http://www.surescripts.com/the-company.html.
[39] Agency for Health Care Administration, Florida Center for Health Information and Policy Analysis, Second Annual Florida Electronic Prescribing Report, January 2009, 24 *see* http://www.fhin.net/eprescribe/Index.shtml (last viewed February 23, 2010).
[40] *Id* at 2.
[41] Presentation by Tom Groom, Senior Vice President, Surescripts, to the Health Regulation Policy Committee, March 25, 2009.
[42] Presentation by Tom Groom, Senior Vice President, Surescripts, to the Health Regulation Policy Committee, March 25, 2009.
[43] See, http://www.surescripts.com/the-company.html; http://www.surescripts.com/connected-pharmacies.html.
[44] Presentation by Tom Groom, Senior Vice President, Surescripts, to the Health Regulation Policy Committee, March 25, 2009.
[45] Overview of Findings from the 2003 National Survey on Drug Use and Health, *see* http://oas.samhsa.gov/nhsda/2k3nsduh/2k3Overview.htm (last viewed January 30, 2010).

substances, central nervous system depressants, and stimulants—when abused can alter the brain's activity and lead to dependence and possible addiction.

Prescription drug abuse also occurs when a person illegally obtains a legal prescription drug for nonmedical use. People obtain these drugs in a variety of ways, including "doctor shopping," in which the person continually switches physicians so that they can obtain enough of the drug to feed their addiction. By frequently switching physicians, the doctors are unaware that the patient has already been prescribed the same drug and may be abusing it. Some physicians prescribe and dispense medically unjustifiable amounts of controlled substances, and are aware of their patients' abuse.[46]

Use of prescription pain relievers without a doctor's prescription or only for the experience or feeling they cause ("nonmedical" use) is, after marijuana use, the second most common form of illicit drug use in the United States.[47] According to the Drug Abuse Warning Network (DAWN), approximately 324,000 emergency department visits in 2006 involved the nonmedical use of pain relievers (including both prescription and over-the-counter pain medications).[48]

According to research by the National Institute on Drug Abuse,[49] 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 controlled substance schedules.[50]

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
Coca Leaves	

[46] *See*, Press Release, U.S. Att'y No. Dist. Fla., Destin Physician Sentenced to Life Imprisonment for Illegal Distribution of Controlled Substances, *see* http://www.justice.gov/usao/fln/press%20releases/2010/jan/webb.html (last viewed January 30, 2010); The Oxycontin Express (Vanguard, 2009) *see* http://www.hulu.com/watch/100279/vanguard-the-oxycontin-express (last viewed January 30, 2010).
[47] Substance Abuse and Mental Health Services Administration, Office of Applied Studies, Results from the 2007 National Survey on Drug Use and Health: National findings (DHHS Publication No. SMA 08-4343, NSDUH Series H-34) (2008), *see* http://oas.samhsa.gov/p0000016.htm (last viewed January 30, 2010); *cited in*, The NSDUH Report, Trends in Nonmedical Use of Prescription Pain Relievers: 2002 to 2007, Feb. 5, 2009, *see* http://www.oas.samhsa.gov/2k9/painRelievers/nonmedicalTrends.cfm (last viewed January 30, 2010).
[48] Substance Abuse and Mental Health Services Administration, Office of Applied Studies, Drug Abuse Warning Network, 2006: National Estimates of Drug-Related Emergency Department Visits, (August 2008), *see* http://dawninfo.samhsa.gov/files/ED2006/DAWN2K6ED.pdf (last viewed January 30, 2010), *cited in*, The NSDUH Report, Trends in Nonmedical Use of Prescription Pain Relievers: 2002 to 2007, Feb. 5, 2009, *see* http://www.oas.samhsa.gov/2k9/painRelievers/nonmedicalTrends.cfm (last viewed January 30, 2010).
[49] National Institutes of Health, National Institute on Drug Abuse, *see*, http://www.drugabuse.gov/Researchreports/Prescription/prescription2.html.
[50] National Institutes of Health, National Institute on Drug Abuse, *see*, http://www.drugabuse.gov/DrugPages/DrugsofAbuse.html (last viewed January 30, 2010); U.S. Drug Enforcement Administration, *see*, http://www.justice.gov/dea/pubs/scheduling.html (last viewed January 30, 2010). This is a very basic list which describes the parent chemicals, not the salts, isomers and salts of isomers, esters, ethers and derivatives which may also be controlled substances.

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
Secobarbital	Seconal, Tuinal

Sufentanil	Sufenta
Thebaine	Precursor of many narcotics
Schedule III - (less potential for abuse than Schedules I or II substances; 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
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 substances; 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
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 substances; 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[51] indicates there are 7.0 million (2.8 percent) persons aged 12 or older who used prescription-type psychotherapeutic drugs nonmedically in the past month. Of these, 5.2 million used pain relievers, an increase from 4.7 million in 2005.

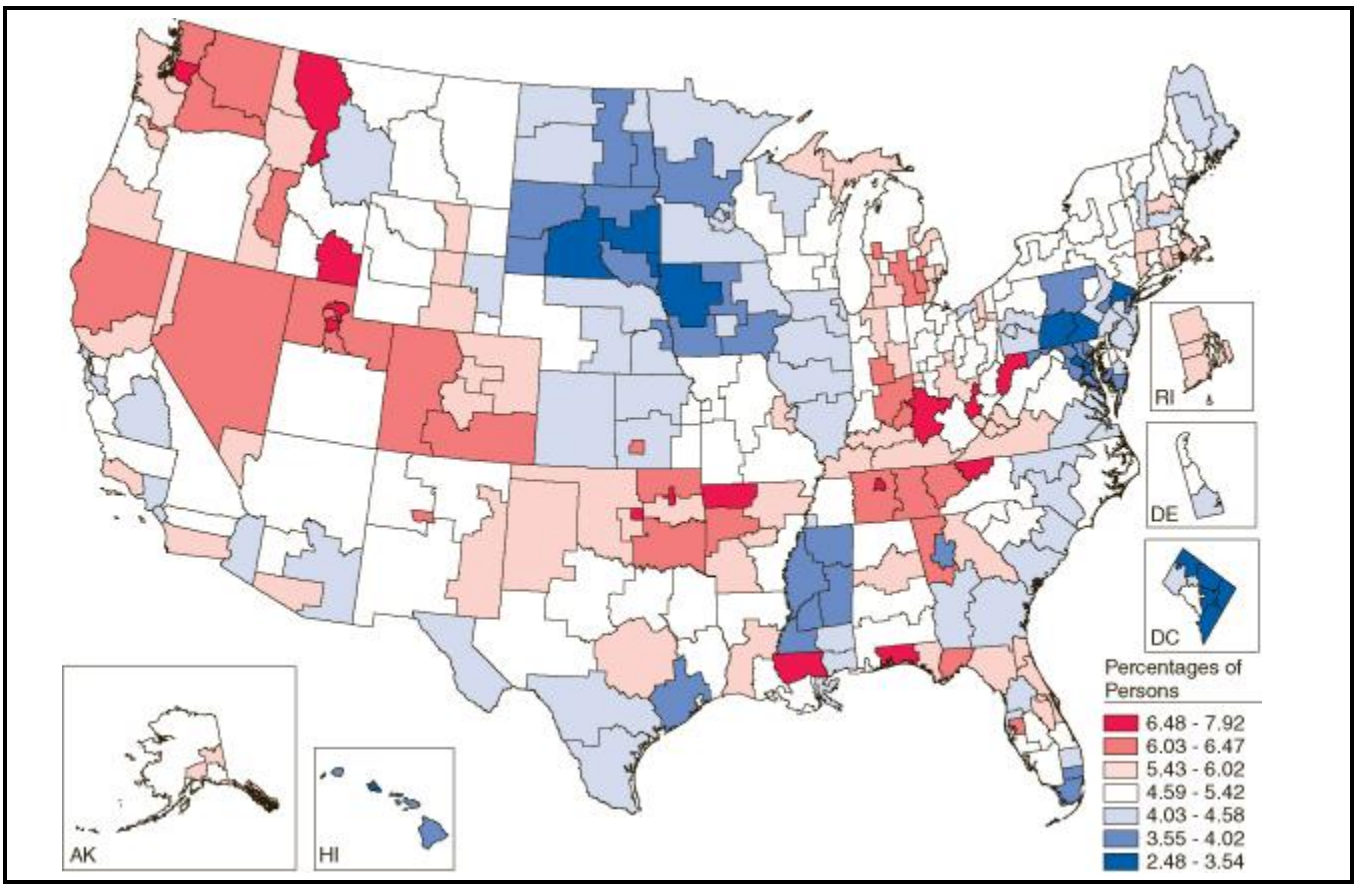
Of those 7 million people who used pain relievers nonmedically in a 12-month period, 55.7 percent reported they received the drug from a friend or relative for free. Another 9.3 percent bought the drugs from

[51] 2006 National Survey on Drug Use and Health, U.S. Substance Abuse and Mental Health Services Administration, *see* http://www.oas.samhsa.gov/nsduh/2k6nsduh/2k6Results.cfm#High (last viewed January 30, 2010).

a friend or family member. Another 19.1 percent reported they obtained the drug through just one doctor. Only 3.9 percent got the pain relievers from a drug dealer or other stranger, and only 0.1 percent reported buying the drug on the Internet. Among those who reported getting the pain reliever from a friend or relative for free, 80.7 percent reported in a follow-up question that the friend or relative had obtained the drugs from just one doctor, while only 1.6 percent reported that the friend or relative had bought the drug from a drug dealer or other stranger.[52]

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 2.48 percent in area of the District of Columbia to a high of 7.92 percent in northwest Florida. In Florida, for example, Palm Beach County measured 4.53 percent; Broward County measured 3.82 percent; Miami-Dade and Monroe Counties measured 3.59 percent; and Escambia, Okaloosa, Santa Rosa and Walton Counties combined measured 7.92 percent.[53]

Figure 1. Nonmedical Use of Pain Relievers in the Past Year among Persons Aged 12 or Older, by Substate Region*: Percentages, Annual Averages Based on 2004, 2005, and 2006 NSDUHs



Source: Substance Abuse and Mental Health Services Administration, Office of Applied Studies. (June 19, 2008). The NSDUH Report: Nonmedical Use of Pain Relievers in Substate Regions: 2004 to 2006.

The Florida Medical Examiners Commission reports on drug-related deaths in Florida, and specifically tracks deaths caused by abuse of prescriptions drugs[54]. According to the commission, prescription drugs are found in deceased persons in lethal amounts more often than illicit drugs.[55] According to the commission's data, 1,157 deaths in Florida from January 2009 through June 2009 were caused by prescription drugs, or about 6.3 deaths per day.[56]

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[52] *Id.*
[53] Substance Abuse and Mental Health Services Administration, Office of Applied Studies, The NSDUH Report: Nonmedical Use of Pain Relievers in Substate Regions: 2004 to 2006, June 19, 2008, *see* http://www.oas.samhsa.gov/2k8/pain/substate.cfm (last viewed January 30, 2010).
[54] Florida Department of Law Enforcement, Medical Examiners Commission, Drugs Identified in Deceased Persons Interim Report, November 2009, *see* http://www.fdle.state.fl.us/content/getdoc/036671bc-4148-4749-a891-7e3932e0a483/Publications.aspx (last viewed January 30, 2010).
[55] *Id.*
[56] *Id.*

According to recent U.S. DEA statistics, the top 25 pain management clinics for dispensing of time release opioids and other pain relievers are all located in Florida.[57] The U.S. Drug Enforcement Administration identified the 50 practitioners who dispense the most Oxycodone in the country. All 50 top-dispensing practitioners are in Florida, and 33 are in Broward County.[58]

Physician Dispensing of Oxycodone, by County[59]

County	Units Oxycodone
Broward	6,584,200
Palm Beach	1,809,400
Miami-Dade	450,000
Pinellas	308,400
Hillsborough	277,300
Lake	220,400
Orange	111,200
Seminole	109,760

Physician Dispensing of Oxycodone in Palm Beach, Broward, Miami-Dade Counties, by Zip Code[60]

Zip Code	Units Oxycodone
33311	1,235,700
33309	775,400
33334	727,600
33407	575,100
33313	442,800
33324	436,600
33009	396,000
33312	340,900
33020	329,000
33162	314,800
33301	285,900
33463	277,500
33417	241,700
33431	227,600
33325	198,800
33483	193,600
33323	186,800
33021	153,600
33487	151,200
33321	143,200
33445	142,700
33016	135,200
33024	130,200
33069	126,600
33023	122,800
33063	118,000
33073	111,900
33317	109,100
33308	107,000
33064	106,300

In 2009, the State Attorney for the Seventeenth 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

[57] Data drawn from the Automation of Reports and Consolidated Orders System, U.S. Department of Justice Drug Enforcement Administration, provided by the Florida Office of Drug Control via email March 22, 2009, on file with the Health Regulation Policy Committee, *see* http://www.deadiversion.usdoj.gov/arcos/index.html (last viewed January 30, 2010).
[58] Data drawn from the Automation of Reports and Consolidated Orders System, July-December 2008, U.S. Department of Justice Drug Enforcement Administration, provided by the Florida Office of Drug Control via email March 22, 2009, on file with the Health Regulation Policy Committee, *see* http://www.deadiversion.usdoj.gov/arcos/index.html (last viewed January 30, 2010)
[59] *Id.*
[60] *Id.*

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.[61]

Prescription Drug Monitoring Program and Pain Clinic Regulation

In the 2009 Regular Session, the Legislature passed Senate bill 462 (chapter 2009-198, Laws of Florida) to address the problem of prescription drug abuse. The bill:

- required the Department of Health to establish a database of controlled substances dispensed to all patients in Florida;
- required all pharmacies and all dispensing physicians to report all controlled substance dispensing to the department within 15 days of dispensing;
- required the department to load the reported dispensing information into the database, and make it available to practitioners, regulators, and criminal justice entities upon their request;
- required all pain clinics, defined as entities that advertise for pain management services or employ a physician who is primarily engaged in the treatment of pain by prescribing or dispensing controlled substances, to register with the department;
- required the medical boards to adopt rules for the standards of medical practice in pain clinics;
- created a task force within the Executive Office of the Governor, chaired by the Office of Drug Control, to monitor and report on the implementation of the database; and
- authorized the Office of Drug Control within the Executive Office of the Governor to establish a direct support organization to solicit public and private funding for the database.

As of January 2010, the department has implemented the clinic registration requirement, and the boards have begun rulemaking on the standards of practice.[62] The Office of Drug Control has established the direct support organization. To date, the department has received a $20,000 grant from the National Association of State Controlled Substance Authorities (NASCSA). In addition, $400,000 has been generated to fund the database, via a grant from the U.S. Department of Justice awarded to the Department of Children and Families prior to the passage of the bill. However, the Department of Health has not received the award.[63]

According to the Department of Health, it requires, but has not yet received, $608,187 to fund planned expenditures in Fiscal Year 2010-2011. Of this amount, the department has applied for and been awarded, but not yet received $5,810 (NASCSA Grant 2). The department also has applied for, but has not been awarded or received an additional $373,423 grant from the U.S. Department of Justice. The department plans to receive the balance of the required funding ($228,954) from the direct support organization.

The department's planned procurement date for the database vendor was May 14, 2010; however, the department must receive grant funds prior to initiating procurement. According to the department, if it receives the funds the week of April 12, it can begin procurement June 4, 2010. Further delay in funds access will further delay procurement and implementation.

Effect of Proposed Changes

The Committee Substitute for House Bill 225 makes several regulatory changes to address the problem of prescription drug abuse, related to pharmacies, physicians, pain clinics, and access to controlled substance dispensing information.

The bill amends sections 458.309 and 459.005, Florida Statutes, to add requirements for pain clinic registration. It prohibits DOH from registering pain clinics owned by anyone other than physicians or health

[61] 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.
[62] *See,* Rules 64B8-9.0131, 64B8-9.0132, 64B8-9.0133, F.A.C., under development.
[63] PL2009-198 Implementation of the Prescription Drug Monitoring Program & Pain Clinic Registration Florida Department of Health, Florida Department of Health, presentation to the House Health Regulation Policy Committee, January 12, 2010; Prescription Drug Monitoring Program PL2009 – 198 Implementation Status Plan, Florida Office of Drug Control, Executive Office of the Governor, presentation to the House Health Regulation Policy Committee, January 12, 2010.

care clinics licensed under part X of chapter 400, Florida Statutes,[64] pain clinics employing or contracting with a physician against whom regulatory action has been taken related to drug or alcohol abuse, and pain clinics with owners who have certain felony drug convictions. The bill also amends the definition of "clinics" to make it applicable only to entities that are primarily engaged in the treatment of pain by prescribing or dispensing controlled substances, as opposed to other methods of pain treatment.

The bill amends sections 458.331, 459.015 and 465.0276, Florida Statutes, to add practitioner regulations and penalties. It makes advertising controlled substances and practicing medicine in an unregistered clinic which is required to be registered grounds for physician licensure action.

The bill amends sections 465.0276, Florida Statutes, to create a new registration process for practitioners who dispense controlled substances. Such practitioners must register with the Board of Pharmacy and pay a fee of up to $100. The registration requirement takes effect September 1, 2010, in Broward, Palm Beach, and Miami-Dade Counties, which are the counties with the most significant controlled substance access. It takes effect elsewhere as each physician renews his or her (biennial) license.

For the registration process, the bill requires the Board of Pharmacy to request notarized references from specified medical practitioners:

- The presidents of the Florida Medical Association and the Osteopathic Medical Association;
- The dean of any Florida medical school;
- The hospital medical chiefs of hospitals within 50 miles of the practitioner's practice location;
- The president of the practitioner's state specialty society, if any; and
- The president of every county medical association in the practitioner's practice area.

The bill requires that reference request will inquire whether the referring entity:

- Has personal knowledge of the practitioner;
- Has had an opportunity to form an opinion of the practitioner's medical skills and ethics;
- Is aware of any incidents in the practitioner's medical practice which reflect insufficient skill or medical ethics to properly dispense controlled substances;
- Is aware of any facts or circumstances which indicate the practitioner is likely dispense controlled substances without clinical justification; and
- Recommends the practitioner for controlled substance dispensing registration.

These practitioners may provide a reference or may decline to provide a reference. For those who choose to provide a reference, the bill provides immunity from civil liability for the information conveyed in the reference, if provided in good faith.

Practitioners must have at least one positive reference and no negative references to register: the bill prohibits the Board of Pharmacy from registering any practitioner with a negative reference or with no positive reference.
The bill creates section 408.0513, Florida Statutes, which requires AHCA to negotiate access to controlled substance information through a multi-state electronic prescribing network for law enforcement and state regulatory entities. Access to the information available in the network is limited to criminal justice agencies, as defined in s. 119.011, F.S., engaged in an active investigation involving a specific violation of law, and the department or relevant regulatory board involved in a specific investigation involving a regulated person. Section 119.011 defines "criminal justice agency" as:

[64] Part X of ch. 400, F.S., contains the Health Care Clinic Act. This act was passed in 2003 to reduce fraud and abuse in the personal injury protection (PIP) insurance system. Under the act, clinics are licensed by AHCA. Licensure applications must identify the owners, medical director, and medical providers employed by the clinic. Applicants must provide proof of compliance with applicable rules and financial ability to operate. A level 2 background screening is required of each applicant for clinic licensure, and certain criminal offenses bar licensure. Each clinic must have a medical director or clinic director who agrees in writing to accept legal responsibility for: Ensuring that all practitioners providing health care services or supplies to patients maintain a current, active, and unencumbered Florida license; reviewing patient referral contracts or agreements made by the clinic; ensuring that all health care practitioners at the clinic have active appropriate certification or licensure for the level of care being provided; serving as the clinic records owner; ensuring compliance with recordkeeping, office surgery, and adverse incident laws and rules; conducting systematic reviews of clinic billings to ensure billings are not fraudulent or unlawful. AHCA may deny, revoke, or suspend a health care clinic license and impose administrative fines of up to $5,000 per violation.

- Any law enforcement agency, court, or prosecutor;
- Any other agency charged by law with criminal law enforcement duties;
- Any agency having custody of criminal intelligence information or criminal investigative information for the purpose of assisting law enforcement agencies in the conduct of certain investigations; and
- The Department of Corrections.

The bill amends ss. 465.018 and 465.023, F.S., to drive controlled substance dispensing information into the existing multi-state prescription drug information network by requiring pharmacies to participate in a multi-state electronic prescribing network, and to transmit dispensing information for controlled substances through the network. The bill also makes failure to so transmit controlled substance dispensing information grounds for pharmacy permit disciplinary action. The bill makes these provisions effective July 1, 2012, for new pharmacies and January 1, 2013, for existing pharmacies.

The bill amends ss. 465.0276, and 465.023, F.S., to drive controlled substance dispensing information into the existing multi-state prescription drug information network by requiring practitioners who demonstrate ability to participate in a multi-state electronic prescribing network, and to transmit dispensing information for controlled substances through the network. The bill also makes failure to so transmit controlled substance dispensing information grounds for licensure disciplinary action. The bill makes these provisions effective July 1, 2012, for new controlled substance dispensing practitioners, and January 1, 2013, for existing controlled substance dispensing practitioners.

The bill authorizes AHCA to adopt rules to implement section 408.0513, Florida Statutes. The bill authorizes the department to adopt rules establishing procedures for quadrennial renewal of controlled substance dispensing practitioner registration.

The bill provides an effective date of July 1, 2010.

B. SECTION DIRECTORY:

Section 1. Creates s. 408.0513 related to access to prescription drug medication history.
Section 2. Amends s. 458.309, F.S., related to rulemaking authority.
Section 2. Amends s. 458.331, F.S., related to grounds for disciplinary action and action by the board and department.
Section 3. Amends s. 459.005, F.S., related to rulemaking authority.
Section 4. Amends s. 459.015, F.S., related to grounds for disciplinary action and action by the board and department.
Section 5. Amends s. 465.018, F.S., related to community pharmacies and permits.
Section 6. Amends s. 465.023, F.S., related to pharmacy permittees and disciplinary action.
Section 7. Amends s. 465.0276, F.S., related to dispensing practitioners.
Section 8. Provides an effective date of July 1, 2010.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

The bill requires the Board of Pharmacy, within the Department of Health, to create an additional, quadrennial registration process for controlled substance dispensing with a fee of up to $100. Practitioners in Broward, Palm Beach and Miami-Dade Counties must register by September 1, 2010, and all other practitioners must register upon their next biennial license renewal. There are currently 7,108 registered dispensing practitioners in Florida; 6,129 of which are authorized by their

practice acts to (prescribe and) dispense controlled substances.[65] It is not known how many practitioners will register to dispense controlled substances. Assuming 100 percent of these practitioners request registration as a controlled substance dispensing practitioner and the department adopts the full $100 fee, the bill will generate $612,900 in fee revenues over the next two fiscal years.

2. Expenditures:

   See Fiscal Comments.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill requires pharmacies to participate in, and transmit controlled substance dispensing information through, a multistate electronic prescribing network as a condition of permitting. According to the Agency for Health Care Administration, more than 70 percent of pharmacies in Florida are activated to receive electronic prescriptions. Such pharmacies may incur transmission transaction costs if they do not currently use these systems for controlled substance prescriptions. The approximately 30 percent of pharmacies in Florida that are not activated to participate in a multistate e-prescribing network will incur activation costs, which may include computer upgrades, software purchases, licensing agreements, and the above-mentioned transaction costs. These costs will vary with each pharmacy.

D. FISCAL COMMENTS:

The costs of access to information contained in an existing multistate network are unknown, and are subject to negotiation by the Agency for Health Care Administration. The agency is authorized to seek private grants and donations to implement this provision.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   This bill does not appear to require counties or municipalities to take an action requiring the expenditure of funds, reduce the authority that counties or municipalities have to raise revenue in the aggregate, nor reduce the percentage of state tax shared with counties or municipalities.

2. Other:

   None.

B. RULEMAKING AUTHORITY:

No additional rulemaking authority is required to implement the provisions of the bill. The bill's provisions related to controlled substance dispensing registration are sufficient for implementation and require no regulatory interpretation or definition.

C. DRAFTING ISSUES OR OTHER COMMENTS:

[65] This includes 230 dentists, 4,925 medical doctors, 855 osteopathic physicians, 119 podiatric physicians. Provided by the Department of Health via telephone to committee staff,

None.

IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES

On March 1, 2010, the Health Care Regulation Policy Committee adopted a proposed committee substitute for House Bill 225. The proposed committee substitute made the following changes to HB 225:

- Amended current law to clarify that the pain management clinic registration requirement only applies to clinics that primarily treat pain by prescribing or dispensing controlled substances;
- Deleted the requirement that medical directors of pain management clinics be board-certified in pain management in order to register the clinic with the Department of Health;
- Deleted Schedule IV controlled substances from the list of controlled substances banned from physician dispensing by the bill;
- Made it a felony of the third degree for physicians to dispense Schedule II or III controlled substances beyond the 72-hour limit;
- Excepted unremunerated medication samples from the dispensing prohibition;
- Deleted the requirement for pharmacies not using the multi-state electronic prescribing network for controlled substance dispensing to report that dispensing to the Agency for Health Care Administration;
- Required pharmacies to use the multi-state electronic prescribing network to transmit information on all controlled substance dispensing as a condition of licensure;
- Delayed the effective date for new pharmacies to demonstrate the ability to participate in and transmit information through a multi-state electronic prescribing network to July 1, 2012; and
- Delayed the effective date for existing pharmacies to transmit dispensing information on Schedule II and III controlled substances to January 1, 2013.

The bill was reported favorably as a committee substitute.

On April 9, 2010, the Health Care Appropriations Committee adopted a strike-all amendment and an amendment to the strike-all amendment that differ from committee substitute in the following ways:

- Prohibits registration of a pain management clinic not fully owned by a physician or group of physicians, or a health care clinic licensed under part X of chapter 400, Florida Statutes;
- Modifies the description of “clinic” to exclude entities that provide non-prescription pain management;
- Removes the 72-hour supply limit on practitioner dispensing of controlled substances, and the third degree felony for violations of the limit;
- Creates a registration requirement for health care practitioners to dispense controlled substances;
- Makes it a licensure violation to dispense controlled substances without being registered; and
- Requires physicians who dispense Schedule II and III controlled substances to transmit certain information through a multistate electronic prescribing network.

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