HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 897 Controlled Substances
SPONSOR(S): Full Appropriations Council on General Government & Health Care; Llorente, Kelly, Skidmore and others
TIED BILLS: CS/HB 937 **IDEN./SIM. BILLS:** CS/CS/CS/CS/SB 462

	REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1)	Health Care Regulation Policy Committee	7 Y, 0 N	Calamas	Calamas
2)	Public Safety & Domestic Security Policy Committee	7 Y, 0 N	Kramer	Kramer
3)	Health & Family Services Policy Council	24 Y, 0 N	Lowell	Gormley
4)	Full Appropriations Council on General Government & Health Care	32 Y, 0 N, As CS	Massengale	Leznoff
5)				

SUMMARY ANALYSIS

The bill requires the Department of Health (DOH), by December 1, 2010, to design and establish a comprehensive electronic system to monitor the prescribing and dispensing of certain controlled substances. The bill requires prescribers and dispensers of certain controlled substances to report specified information to the DOH for inclusion in the system.

The bill provides exemptions from the data reporting requirements for controlled substances that are administered, dispensed, or ordered in specified settings or for specified categories of patients. Data regarding the dispensing of each controlled substance must be submitted to DOH, by a procedure and in a format established by DOH, and must include minimum information specified in the bill. Any person who knowingly fails to report the dispensing of a controlled substance commits a first-degree misdemeanor.

The Office of Drug Control, in coordination with DOH, is authorized to establish a direct-support organization to provide assistance, funding, and promotional support for activities authorized for the prescription drug monitoring program. The bill creates a 12-member Program Implementation and Oversight Task Force within the Executive Office of the Governor to monitor the implementation and safeguarding of the electronic system established for the prescription drug monitoring program.

The bill provides immunity from liability for prescribers and dispensers who in good faith receive and use information from the prescription drug monitoring program. A person may not recover damages against a prescriber or dispenser authorized to access information under the drug monitoring program for accessing or failing to access such information.

The bill requires each physician who practices in a privately owned pain-management facility that primarily engages in the treatment of pain by prescribing narcotic medications to register the facility with the DOH, unless it is a Florida-licensed hospital, ambulatory surgical center, or mobile surgical facility.

The Office of Drug Control has provided cost estimates ranging from $100,000 to $4,000,000 for the prescription drug monitoring program. DOH estimates costs for an in-house design and implementation of an electronic data base for the prescription drug monitoring program to be $4.3 million in Fiscal Year 2009-10, $2.2 million in Fiscal Year 2010-11 and $1.9 million in Fiscal Year 2011-12. However, the bill requires all costs incurred by DOH for the prescription drug monitoring program to be reimbursed through federal grants or private funding applied for or received by the State of Florida.

The effective date of the bill is July 1, 2009.

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 Substances Dispensing

Chapter 893, F.S., sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act. Controlled substances are classified into five schedules in order 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.

Section 893.05, F.S., allows a practitioner, in good faith and in the course of his or her professional practice only, to prescribe, administer, dispense, mix, or otherwise prepare a controlled substance. Section 893.02, F.S., defines practitioner to mean 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.

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 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;
- 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 proprietor of 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, 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, when such controlled substance may be dispensed upon oral prescription. No prescription for a Schedule II controlled substance may be refilled.[1] 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.[2] A pharmacist may dispense a one-time emergency refill of up to a 72-hour supply of the prescribed medication for any medicinal drug other than a medicinal drug listed in Schedule II.[3]

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.[4] The National Institute on Drug Abuse seeks to reverse this trend by increasing awareness and promoting additional research on the topic. 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.

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. A study in Australia indicated that most doctor shoppers switch only sporadically. However, the top 25 percent shop very actively, travel widely, and see many different practitioners, often on the same day. Doctor shoppers generally take the medicine themselves. Compared to the number of doctors consulted, in a recent survey most doctor shoppers have their prescriptions dispensed at few pharmacies.[5]

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[1] s. 893.04(1)(f), F.S.
[2] s. 893.04(1)(g), F.S.
[3] *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.
[4] Overview of Findings from the 2003 National Survey on Drug Use and Health, *see* http://oas.samhsa.gov/nhsda/2k3nsduh/2k3Overview.htm (last viewed March 16, 2007).

[5] *See*, www.hic.gov.au (last viewed March 24, 2009).

Use of prescription pain relievers without a doctor's prescription or only for the experience or feeling they caused ("nonmedical" use) is, after marijuana use, the second most common form of illicit drug use in the United States.[6] 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).[7]

The Substance Abuse and Mental Health Services Administration (SAMHSA) sponsors an annual national survey on drug use and health. The most recent survey[8] 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 the past 12 months, 55.7 percent reported they received the drug from a friend or relative for free. Another 9.3 percent bought the drugs from 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.[9]

According to recent U.S. DEA statistics, the top 25 pain management clinics for dispensing of time release opiods and other pain relievers are all located in Florida.[10]

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.[11]

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[6] 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 March 21, 2009); *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 March 21, 2009).

[7] 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 March 24, 2009), *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 March 21, 2009).

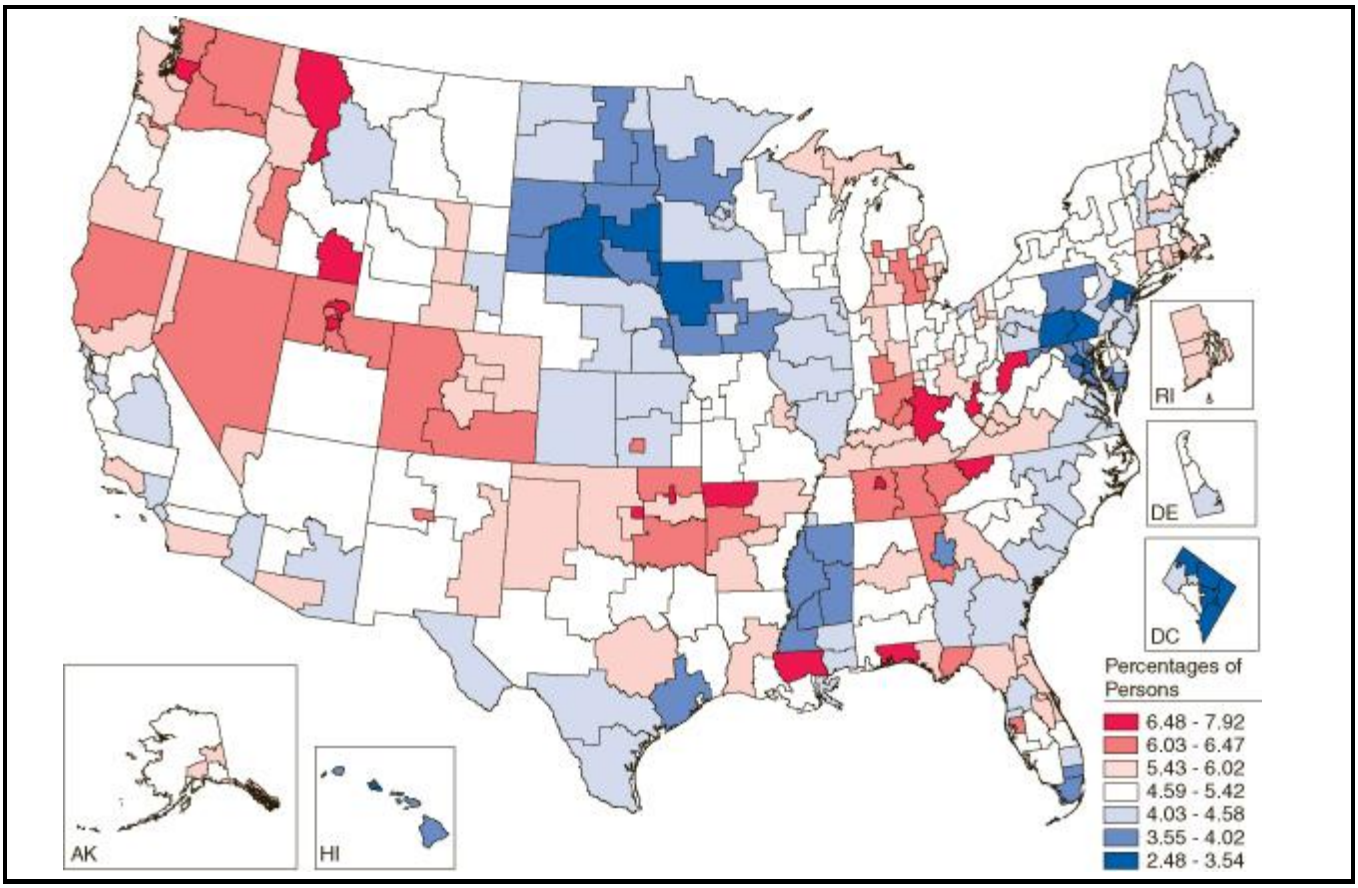
[8] 2006 National Survey on Drug Use and Health, U.S. Substance Abuse and Mental Health Services Administration, *see* http://www.oas.samhsa.gov/nsduh/2k6nsduh/2k6Results.cfm#High (last viewed March 21, 2009).

[9] *Id.*

[10] 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 March 24, 2009).

[11] 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 March 21, 2009).

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[12]. According to the Commission, prescription drugs are found in deceased persons in lethal amounts more often than illicit drugs.[13] According to the Commission's data, 1581 deaths in Florida from January 2008 through June 2008 were caused by prescription drugs.[14] That averages to 8.6 deaths per day.

Prescription Drug Monitoring Programs

Currenty, 38 states have enacted legislation establishing prescription-drug-monitoring programs, and 32 states have operational programs.[15] Prescription-drug-monitoring programs collect prescription data from pharmacies in either paper or electronic format. The data may be reviewed and analyzed for educational, public health, and investigational purposes. The goals of prescription monitoring systems are dependent on the mission of the state agency that operates the program or uses the data. Each state that has implemented a prescription-drug-monitoring program has its own set of goals for its program. Prescription monitoring systems may cover a specified number of controlled substances. Several states cover only controlled substances listed in Schedule II; while others cover a range of controlled substances

[12] Florida Department of Law Enforcement, Medical Examiners Commission, Drugs Identified in Deceased Persons Interim Report, November 2008, *see* http://www.fdle.state.fl.us/content/getdoc/036671bc-4148-4749-a891-7e3932e0a483/Publications.aspx (last viewed March 21, 2009). The prescription drugs tracked by the Commission are prescription benzodiazepines, Barisoprodol/Meprobamate, and all opioids, excluding heroin.
[13] *Id.*
[14] Florida Department of Law Enforcement, *supra* note 11 at Table 1, Summary of Drug-Related Deaths January – June 2008.
[15] National Alliance for Model State Drug Laws, Status of State Prescription Drug Monitoring Programs, *see* http://www.namsdl.org/presdrug.htm (last viewed March 21, 2009).

listed in Schedules II through V.[16] Prescription-drug-monitoring programs may also combine the use of serialized prescription forms by prescribing practitioners that are tracked by state officials and an electronic data system that tracks the prescriptions.

Advocates claim the potential advantages of an electronic prescription data collection system include the following:

- Identifies "doctor shoppers" by tracking all their prescribing physicians and purchases from pharmacies. Doctor shopping is when a person continually switches physicians so that they can obtain enough of a drug to feed their addiction;
- Provides complete and reliable information on prescribing and dispensing activities so that investigators can identify, rank, and set priorities for cases;
- Maximizes investigators' effectiveness by providing prescription data in a convenient, comprehensive, and timely method;
- Reduces intrusion into professional practices because investigators no longer need to make office visits to gather information on practitioner prescribing patterns; and
- Reduces the need for investigators to make pharmacy visits in order to gather data on pharmacy or pharmacists' dispensing patterns.

Privacy and Security
The 1996 Health Insurance Portability and Accountability Act (HIPAA) required the federal government to issue regulations protecting the privacy of health information. The U.S. Department of Health and Human Services (HHS) issued Standards for Privacy of Individually Identifiable Health Information on December 28, 2000, which took effect on April 14, 2003. The regulations establish a set of national standards for the protection of health information, and apply to health plans, health care clearinghouses and certain health care providers. The regulations permit states to afford greater privacy protections to health information. Exceptions for state law are provided for public health and state regulatory reporting.[17]

Some opponents of prescription monitoring systems dislike the concept of mandatory disclosure of protected health information and point to federal and state privacy laws as barriers to these monitoring systems. There is a possibility that the tracking system could violate the Florida Constitution's Right to Privacy. In 1980, the citizens of Florida approved an amendment to Florida's Constitution, which grants Florida citizens an explicit right of privacy. Contained in Article I, Section 23, the Constitution provides:

> Right of privacy--Every natural person has the right to be let alone and free from governmental intrusion into the person's private life except as otherwise provided herein. This section shall not be construed to limit the public's right of access to public records and meetings as provided by law.

This right to privacy protects Florida's citizens from the government's uninvited observation of or interference in those areas that fall within the range of the zone of privacy afforded under this provision.

Unlike the implicit privacy right of the Federal Constitution, Florida's express privacy provision is of itself a fundamental right that, once implicated, demands evaluation under a compelling state interest standard. The federal right of privacy is more limited than the state provision, and extends only to such fundamental interests as marriage, procreation, contraception, family relationships, and the rearing and education of children. Since the people of this state have exercised their prerogative and enacted an amendment to the Florida Constitution that expressly and succinctly provides for a strong right of privacy not found in the United States Constitution, it is much broader in scope than that of the Federal Constitution. Subsequently, the court has consistently held that Article I, section 23 was adopted in an effort to grant Floridians greater privacy protection than that available under the Federal Constitution.[18]

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[16] Some states, like Ohio, include non-controlled pain medications with high risk of abuse.
[17] U.S. Department of Health & Human Services, Health Information Privacy, *see* http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/index.html (last viewed March 21, 2009).
[18] In re T.W., 551 So.2d 1186 (Fla. 1989).

Funding
Beginning in 2002, Congress appropriated funding to the U.S. Department of Justice to support a Prescription Drug Monitoring Program.[19] The Program awards funds in the form of Harold Rogers grants to state regulatory and law enforcement agencies for the purposes of:

- Building a data collection and analysis system at the state level.
- Enhancing existing programs' ability to analyze and use collected data.
- Facilitating the exchange of collected prescription data among states.
- Assessing the efficiency and effectiveness of the programs funded by the grant program.[20]

In 2008, 17 grant awards were made to various state agencies and an educational institution, between $50,000 and $670,000, including an award to the Florida Department of Children and Family Services of $50,000.[21] Grants were awarded for planning, implementation and enhancement of prescription drug monitoring programs, and for training and technical assistance. Funding for Fiscal Year 2009 has not yet been determined.

American Society for Automation in Pharmacy
The American Society for Automation in Pharmacy (ASAP) is an organization whose mission is to "assist its member in advancing the application of computer technology in the pharmacist's role as caregiver and in the efficient operation and management of a pharmacy."[22] Its members include independent pharmacies and hospital pharmacies as well as individuals from colleges of pharmacy, state boards of pharmacy, state and national associations, and government agencies. The ASAP publishes standards for the implementation of prescribed drug monitoring programs.[23]

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. 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 electronic prescribing products. While the cost of the product varies, some products are available at no cost to the healthcare practitioner.[24]

In 2007, the Legislature passed and the Governor signed into law SB 1155. That bill required 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. As required by the bill, 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.[25] AHCA also reports annually to the Governor and Legislature on the implementation of electronic prescribing by health care practitioners, facilities and pharmacies.

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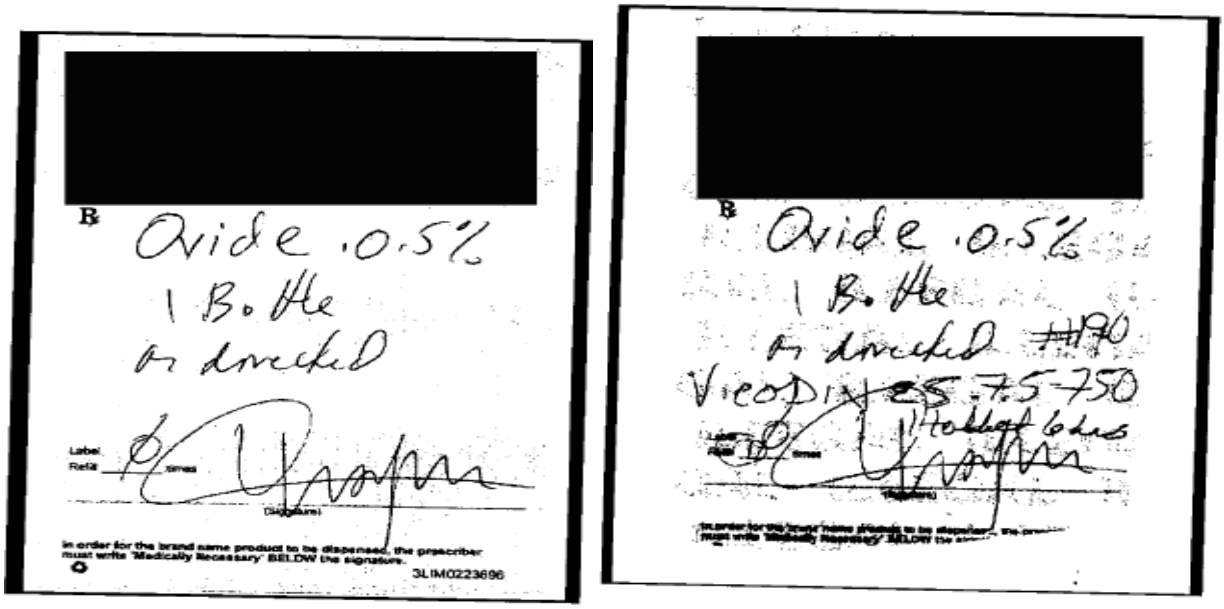
[19] U.S. Department of Justice Appropriations Act (Public Law 107-77).
[20] U.S. Department of Justice, Bureau of Justice Assistance, Harold Rogers Prescription Drug Monitoring Program, *see* http://www.ojp.usdoj.gov/BJA/grant/prescripdrugs.html (last viewed March 21, 2009).
[21] U.S. Department of Justice, Bureau of Justice Assistance, Harold Rogers Prescription Drug Monitoring Program FY 2008 Grantees, *see* http://www.ojp.usdoj.gov/BJA/grant/prescripdrugs.html (last viewed March 21, 2009).
[22] *See* http://www.asapnet.org/index.html.
[23] The Standards are available for purchase at http://www.asapnet.org/bookstore.html (last viewed March 24, 2009).
[24] *See e.g.,* http://www.nationalerx.com/ and http://www.iscribe.com/ (offering free web-based electronic prescribing software) (last viewed March 21, 2009); Florida ePrescribe Clearinghouse, Products and Services, *see* http://www.fhin.net/eprescribe/Technology/products.shtml (last viewed March 21, 2009).
[25] Florida E-Prescribe Clearinghouse, *see* http://www.fhin.net/eprescribe/Index.shtml (last viewed March 24, 2009); Agency for Health Care Administration, *see* http://ahca.myflorida.com/dhit/ElectronicPrescribing/ePrescribeIndex.shtml (last viewed March 24, 2009).

According to AHCA and the Institute of Medicine, electronic prescribing offers numerous benefits, including:[26]

- 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.[27,28] 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.[29]

According to AHCA, eliminating paper and handwritten prescriptions can reduce fraud and abuse related to alterations of the paper prescription. For example, this paper prescription for head lice written to a Medicaid recipient was altered to include 190 tablets of Vicodin, a controlled substance. According to AHCA, this alteration was discovered when the pharmacist returned the prescription to the prescribing doctor with a note about his illegible handwriting.[30]



[26] Agency for Health Care Administration, Advantages of ePrescribing, *see* http://www.fhin.net/eprescribe/Benefits/Benefits.shtml (last viewed March 24, 2009), *citing* Institute of Medicine, Committee on Identifying and Preventing Medication Errors, "Preventing Medication Errors: Quality Chasm Series" (2006).

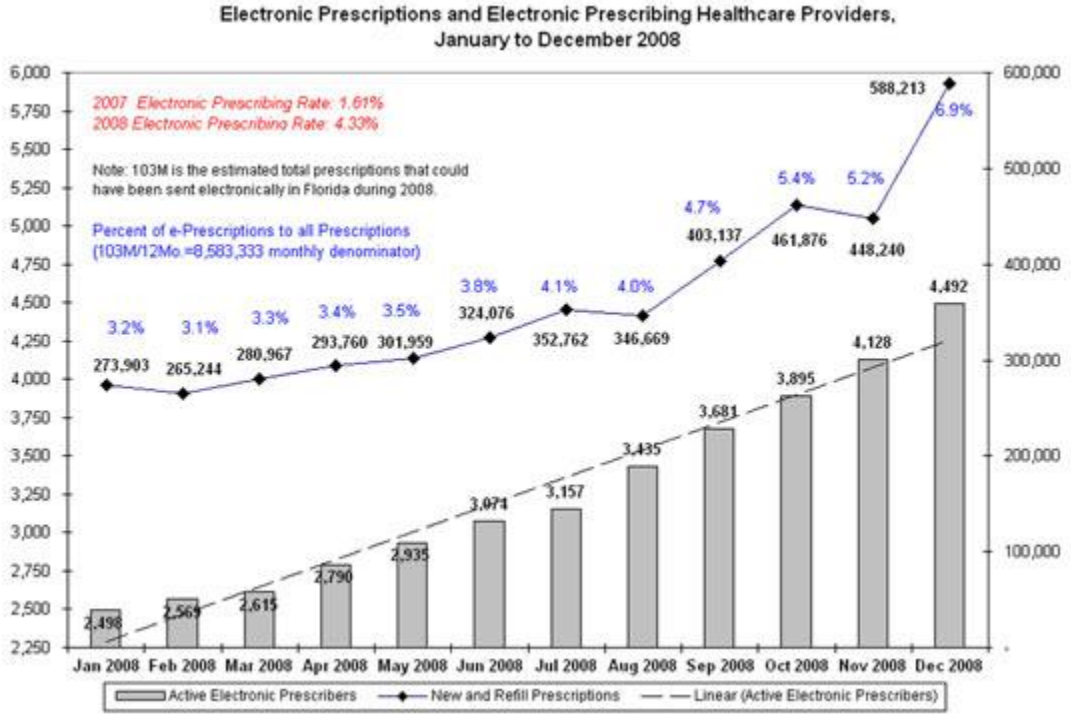
[27] Agency for Health Care Administration, Florida Center for Health Information and Policy Analysis, Second Annual Florida Electronic Prescribing Report, January 2009, *see* http://www.fhin.net/eprescribe/Index.shtml (last viewed March 21, 2009). "Secure access is possible using a virtual private network (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."

[28] *Id.* at 7.

[29] *Id.*

[30] *Id.* at 6.

The use of e-prescribing is rising. Of the 6,157 licensed pharmacies in Florida, 71.33 percent were activated to receive electronic prescriptions in 2008, an increase from 63 percent in 2007.[31] 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.[32] Among e-prescribers, the number of e-prescriptions issued per month rose 72 percent between 2007 and 2008.[33]



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

Some opponents of e-prescribing believe it imposes a significant financial burden on prescribing practitioners, and is a precursor to interoperable electronic medical records, the value of which is currently debated by medical community.[34]

Funding

Medicare has a new program to encourage physicians to adopt e-prescribing systems.[35] Beginning in 2009, and during the next four years, Medicare will provide incentive payments to eligible health care practitioners who use 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 one half percent incentive payment in 2013. Beginning in 2012, Medicare health care practitioners not using electronic prescribing will receive reduced payments for Medicare-covered services.[36] Exemptions may be awarded on a case-by-case basis if it is determined that compliance would result in significant hardship for the practitioner.[37]

The recently enacted American Recovery and Investment Act (ARRA)[38] authorized approximately $19 billion for Medicare and Medicaid incentives to assist providers in adopting health information technology as well as state loan programs. The incentives will be available for five years, starting in 2011.

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[31] Agency for Health Care Administration, ePrescribing Clearinghouse, ePrescribing Dashboard 2008 Metrics, *see* http://www.fhin.net/eprescribe/Dashboard/FLmetrics.shtml (last viewed March 21, 2009).
[32] *Id*.
[33] *Id*.
[34] *See, e.g.,* Stephen R. West, "Congress Shouldn't Practice Medicine", *Tallahassee Democrat*, February 8, 2009, available at http://tallahassee.com/article/20090208/OPINION05/902080311/1006/opinion (last viewed March 21, 2009); "Obama's $80 Billion Exaggeration", *Wall Street Journal*, *see* http://online.wsj.com/article/SB123681586452302125.html (last viewed March 21, 2009).
[35] Pursuant to the Medicare Improvements for Patients and Providers Act of 2008.
[36] *Id.* Reimbursement will be reduced by 1 percent in 2012, 1.5 percent in 2013 and 2 percent in 2014.
[37] Agency for Health Care Administration, ePrescribing Clearinghouse, ePrescribing Initiatives and Incentive Programs, *see* http://www.fhin.net/eprescribe/ePrescribingInitiatives/NationalIncentivePrograms.shtml (last viewed March 21, 2009).
[38] Public Law 111-05 (2009).

Effect of Proposed Changes

Prescription Drug Monitoring Program

The bill requires the Department of Health (DOH), by December 1, 2010, to design and establish a comprehensive electronic system for controlled substance prescriptions. The system must be designed to provide information regarding dispensed prescriptions of controlled substances in order to prevent the inadvertent, improper, or illegal use of controlled substances and may not infringe upon the legitimate prescribing of a controlled substance by a prescribing practitioner, dispensing pharmacist, or dispensing practitioner acting in good faith and in the course of professional practice.

The system must be consistent with standards of the American Society for Automation in Pharmacy for the monitoring of prescribing and dispensing controlled substances to an individual. The electronic system must also comply with the Health Insurance Portability and Accountability Act (HIPAA) and all other relevant state and federal privacy and security laws and regulations. The reporting of prescribed controlled substances must include a dispensing transaction with a dispenser who is not located in Florida but who is otherwise subject to the jurisdiction of Florida regarding that dispensing transaction.

The system will provide prescription information to a patient's health care practitioner and, as determined by DOH rule, advisory reports to pharmacies, prescribing practitioners, and dispensing health care practitioners. Advisory reports are written information concerning the dispensing of controlled substances provided by the department to a prescriber, dispenser, pharmacy, or patient. The advisory reports are not subject to discovery or introduction into evidence in any civil or administrative action against a prescriber, dispenser, pharmacy, or patient arising out of matters that are the subject of the report. A person who participates in the preparation of an advisory report is not permitted or may not be required to testify in any civil action regarding any findings, recommendations, evaluations, opinions, or other actions taken in connection with preparing the report.

The department, upon receipt of funding for the prescription drug monitoring program and in consultation with the Office of Drug Control, must adopt rules concerning the reporting, accessing the database, evaluation, management, development, implementation, and storage of information within the system, including rules for when advisory reports are provided to pharmacies, prescribers, and health care practitioners. The patients advisory reports must be provided in accordance with section 893.13(7)(a)8., Florida Statutes, which makes it unlawful for a person to withhold information from a practitioner from whom the person seeks to obtain a controlled substance or a prescription for a controlled substance that the person making the request has received a controlled substance or a prescription for a controlled substance of like therapeutic use from another practitioner within the previous 30 days.[39] The department must work with professional licensure boards and other appropriate organizations, including the Attorney General, the Florida Department of Law Enforcement, and the Agency for Health Care Administration, to develop rules appropriate for the prescription drug monitoring program.

DOH must notify all dispensers and prescribers subject to the reporting requirements of the implementation date for the reporting requirements. DOH must adopt rules to implement the prescription drug monitoring program by October 1, 2010. The pharmacy dispensing the controlled substance and each prescriber who directly dispenses a controlled substance must submit to the electronic system, by a procedure and in a format established by the DOH, the following minimum information for inclusion in the database:

- The name of the prescribing practitioner and the practitioner's federal Drug Enforcement Administration registration number, the practitioner's National Provider Identification or other appropriate identifier, and the date of the prescription.
- The date the prescription was filled and the method of payment.
- The name, address, and date of birth of the person for whom the prescription was written.
- The name, national drug code, quantity, and strength of the controlled substance dispensed.
- The full name, federal Drug Enforcement Administration registration (DEA) number and address of the pharmacy or other location from which the controlled substance was dispensed. If dispensed by

[39] A violation of s. 893.13 (7) (a) 8., F.S., is a third degree felony punishable by imprisonment up to five years and the imposition of a fine up to $5,000.

a practitioner other than a pharmacist, the dispensing practitioner's full name, DEA number and address.
- The name of the pharmacy or practitioner other than a pharmacist dispensing the controlled substance and the practitioner's National Provider Identification.
- Other appropriate identifying information as determined by DOH rule.

A dispensing practitioner or pharmacy must report to the DOH data regarding controlled substances subject to the requirements of the validation system as soon as possible, but not more than 15 days after the date the controlled substance is dispensed, each time that such controlled substance is dispensed. The bill provides that a pharmacy or dispensing practitioner must meet the reporting requirements by providing the information to DOH concerning each controlled substance in a DOH-approved, secure methodology and format. The formats may include, but are not limited to, submission via the Internet, on a disc, or by use of regular mail. The bill provides that the cost to the dispenser in submitting the required information may not be material or extraordinary as specified in the bill.

The bill creates exceptions to the reporting requirements for controlled substances that are:
- Administered by a health care practitioner directly to a patient if the amount of the controlled substance is adequate to treat the patient during that particular session;
- Administered by a pharmacist or a health care practitioner to a patient or resident receiving care as an admitted patient or resident at a hospital, nursing home, hospice, or intermediate care facility for the developmentally disabled which is licensed in Florida;
- Administered or dispensed to a person in the health care system of the Department of Corrections;
- Administered in the emergency room of a licensed hospital;
- Administered or dispensed by a health care practitioner to a person under the age of 16; or
- Dispensed by a pharmacist or a dispensing practitioner as a one-time, 72-hour emergency resupply of a controlled substance to a patient.

DOH may establish when to suspend and when to resume reporting information during a state-declared or nationally declared disaster.

A pharmacy, prescriber, or dispenser may access information in the prescription drug monitoring program's electronic system which relates to a patient of that pharmacy, prescriber, or dispenser for the purpose of reviewing the patient's controlled drug prescription history. Other access to the program's electronic system shall be limited to the program's manager and designated program staff, who may act only in the absence of the program manager. Access by the program manager or such designated staff is only for prescription drug program management and for management of the database. The information submitted to DOH under the prescription drug monitoring program may be transmitted to any person or agency authorized to receive it, and that person or agency may maintain the information received for up to 24 months before purging the information from its records. All required transmissions must comply with relevant federal and state privacy and security laws. However, any authorized agency receiving such information may maintain the information for a period longer than 24 months if the information is pertinent to an ongoing investigation or prosecution.

Any person who knowingly fails to report the dispensing of a controlled substance listed in Schedule II, Schedule III, or Schedule IV commits a first degree misdemeanor, punishable by jail up to 1 year, and a fine up to $1,000 may be imposed.

DOH must report performance measures as specified in the bill by each December 1, beginning in 2011. DOH staff may request data without identifying information so that the DOH may undertake public health care and safety initiatives that take advantage of observed trends. The Program Implementation and Oversight Task Force may request data without identifying information for its reporting to the Governor, the President of the Senate, and the Speaker of the House of Representatives.

All costs incurred by DOH for the prescription drug monitoring program, shall be reimbursed through federal, private, or grant funding applied for by the State of Florida. The establishment and implementation of the prescription drug monitoring program are contingent upon receipt of the non-state funding, and specific legislative appropriation may not be used to fund the program. DOH and state government must

cooperate in seeking grant funds and other funding for DOH so long as the costs of doing so are not considered material. DOH must comply with the competitive-solicitation requirements for the procurement of any goods or services required to implement the prescription drug monitoring program.

Direct-Support Organization

The Office of Drug Control, in coordination with DOH, may establish a direct-support organization to provide assistance, funding, and promotional support for activities authorized for the prescription drug monitoring program. The director of the Office of Drug Control must appoint a board of directors for the direct-support organization. Members of the board serve at the pleasure of the director. The direct-support organization may operate under written contract with the Office of Drug Control.

The bill specifies the requirements of the contract executed between the Office of Drug Control and the direct-support organization, which include:

- Approval of the articles of incorporation and bylaws of the direct-support organization by the Office of Drug Control.
- Submission of an annual budget for the approval of the Office of Drug Control.
- Annual certification by the Office of Drug Control in consultation with DOH that the direct-support organization is complying with the terms of the contract in a manner consistent with and in furtherance of the goals and purposes of the prescription drug monitoring program and in the best interest of the state. Such certification must be made annually and reported in the official minutes of a meeting of the direct-support organization.
- Reversion, without penalty, to the Office of Drug Control, or to the state if the Office of Drug Control ceases to exist, of all moneys and property held in trust by the direct-support organization for the benefit of the prescription drug monitoring program if the direct-support organization ceases to exist or if the contract is terminated.
- The fiscal year of the direct-support organization, which must begin July 1 of each year and end June 30 of the following year.
- The disclosure of the material provisions of the contract to donors of gifts, contributions, or bequests, including such disclosure on all promotional and fundraising publications, and an explanation to such donors of the distinction between the Office of Drug Control and the direct-support organization.

The direct-support organization is specifically authorized to collect and expend funds to be used for the functions of the organization's board of directors; establishing and administering the prescription drug monitoring program's electronic database; conducting studies on the efficiency and effectiveness of the program; providing funds for future enhancements of the program; providing health care practitioner education; providing funds for travel expenses and administrative costs; and fulfilling all other requirements needed to establish the program.

The activities of the direct-support organization must be consistent with the goals and mission of the Office of Drug Control, as determined by the office in consultation with DOH, and in the best interests of Florida. The direct-support organization must obtain a written approval from the director of the Office of Drug Control for any activities in support of the prescription drug monitoring program before undertaking those activities. The Office of Drug Control, in consultation with DOH, may permit, without charge, appropriate use of administrative services, property, and facilities of the Office of Drug Control and the department by the direct-support organization, as specified in the bill.

The direct-support organization must have an independent annual audit that must be provided to the Office of Drug Control and the Office of Policy and Budget in the Executive Office of the Governor.

Prescriber or Dispenser Immunity from Liability

A prescriber or dispenser is authorized access to the information under the prescription drug monitoring program for his or her patient for his or her review of the patient's controlled drug prescription history to ensure a proper standard of care. A prescriber or dispenser acting in good faith is immune from any civil, criminal, or administrative liability that might otherwise be incurred or imposed for receiving or using information from the prescription drug monitoring program. The bill does not create a private cause of

action, and a person may not recover damages against a prescriber or dispenser authorized to access information under the drug monitoring program for accessing or failing to access such information.

Feasibility Study and Training
To the extent that funding is provided, the Office of Drug Control may study the feasibility of enhancing the prescription drug monitoring program for the purposes of public health initiatives and statistical reporting The direct-support organization must provide funding for the DOH, in collaboration with the Office of Drug Control, to conduct training for health care practitioners and other appropriate persons in using the program to support the program enhancements.

Identification of Persons Acquiring Controlled Substances
The bill requires a pharmacist, pharmacy, or dispensing health care practitioner or his or her agent, before releasing a controlled substance to any person who is not known to the dispenser, to require the person to present valid photographic identification or other verification of his or her identity to the dispenser. If the person does not have proper identification, the bill allows the dispenser to verify the identity and the validity of the prescription for controlled substances through alternate means. Verification of health plan eligibility through a real-time inquiry or adjudication system is considered proper identification. The bill requires pharmacies and dispensers to maintain a record for two years of the person acquiring the controlled substance, which includes the person's name and signature using proper identification. "Proper identification" means a government-issued identification containing the person's picture, printed name, and signature. Institutional settings, long-term care facilities, and hospitals are exempt from the requirement to obtain proper identification.

Electronic Prescribing
The bill requires the Agency for Health Care Administration (AHCA) to continue implementing electronic prescribing by health care practitioners, health care facilities, and pharmacies, and the electronic prescribing clearinghouse.

Program Implementation and Oversight Task Force
The bill creates a 12-member Program Implementation and Oversight Task Force within the Executive Office of the Governor to monitor the implementation and safeguarding of the electronic system established for the prescription drug monitoring program. The task force must also ensure privacy, protection of individual medication history, and the electronic system's appropriate use by physicians, dispensers, pharmacies, law enforcement agencies, and those authorized to request information from the electronic system. The Office of Drug Control must submit a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives by December 1 of each year which contains a summary of the work and recommendations of the task force during that year. On July 1, 2012, a final report must be provided to the Governor, the President of the Senate, and the Speaker of the House of Representatives. The workgroup expires on July 1, 2012.

Registration of Pain-Management Facilities
The bill requires each privately owned pain-management facility that employs a Florida-licensed medical physician or osteopathic physician, who is primarily engaged in the treatment of pain by prescribing controlled substance medications to register the facility with DOH by January 4, 2010, unless it is a Florida-licensed hospital, ambulatory surgical center, or mobile surgical facility. A physician is primarily engaged in the treatment of pain by prescribing narcotic medications when the majority of the patients seen on any day the facility is open are issued narcotic prescriptions for the treatment of nonmalignant pain.

The bill requires DOH to inspect each pain-management facility annually to ensure that it complies with Board of Medicine or Board of Osteopathic Medicine rules as proposed in the bill, unless the facility is accredited by a nationally recognized accrediting agency approved by the Board of Medicine or the Board of Osteopathic Medicine, as applicable.

The bill requires the Board of Medicine or the Board of Osteopathic Medicine, as applicable, to adopt rules setting forth standards of practice for physicians practicing in privately owned pain-management facilities that primarily engage in the treatment of pain by prescribing controlled substance medications. The bill specifies criteria that the Board of Medicine or the Board of Osteopathic Medicine 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; and inspections.

The actual costs for registration and inspection or accreditation of a pain-management facility shall be paid by the physician seeking to register the facility.

The effective date of the bill is July 1, 2009.

B. SECTION DIRECTORY:

Section 1. Creates s. 893.055, F.S., relating to prescription drug monitoring program.
Section 2. Creates an unnumbered section of law relating to the Program Implementation and Oversight Task Force.
Section 3. Amends s. 458.309, F.S., relating to rulemaking authority for the practice of medicine.
Section 4. Amends s. 459.005, F.S., relating to rulemaking authority for the practice of osteopathic medicine.
Section 5. Provides an effective date of July 1, 2009.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   See Fiscal Comments.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill requires the physician who registers a pain-management facility to pay for the actual costs for registration and inspection of the facility. The bill does not establish the amount of the fee or authorize the DOH to set the fee within a specified range.

Pharmacies and other dispensers will incur costs to comply with the reporting requirements under the prescription drug monitoring program. The bill provides that such costs may not be material or extraordinary. Costs not considered to be material or extraordinary under the bill include, but are not limited to, regular postage, electronic media, regular electronic mail, and facsimile charges.

D. FISCAL COMMENTS:

The Office of Drug Control has provided cost estimates ranging from $100,000 to $4,000,000 for the prescription drug monitoring program. DOH estimates costs for an in-house design and implementation of an electronic data base for the prescription drug monitoring program to be $4.3 million in FY 2009-10, $2.2 million in FY 2010-11 and $1.9 million in FY 2011-12. However, the bill requires all costs incurred by DOH for the prescription drug monitoring program to be reimbursed through federal grants or private funding applied for or received by the State of Florida.

In addition, the bill provides for a direct-support organization that is specifically authorized to collect and expend funds to be used for the functions of the organization's board of directors; establishing and administering the prescription drug monitoring program's electronic database; conducting studies on the efficiency and effectiveness of the program; providing funds for future enhancements of the program; providing health care practitioner education; providing funds for travel expenses and administrative costs; and fulfilling all other requirements needed to establish the program.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or take an action requiring the expenditure of funds. The bill does not reduce the percentage of a state tax shared with counties or municipalities. The bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

The bill grants immunity from civil, criminal or administrative liability to a prescriber or dispenser acting in good faith for liability that might otherwise be incurred or imposed for receiving or using information from the prescription drug monitoring program. To the extent that this immunity imposes a possible barrier to a litigant's right to seek redress, it raises questions about infringements on the right to access to courts contained in Article I, Section 21, of the Florida Constitution.

State collection of patient-specific information on the use of controlled substances by law-abiding individuals may implicate the express right of privacy contained in Article I, Section 23, of the Florida Constitution.

B. RULE-MAKING AUTHORITY:

The bill appears to provide sufficient rulemaking authority to the Department of Health to establish a prescription drug monitoring program.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill amends chapter 893, Florida Statutes, the Florida Comprehensive Drug Abuse Prevention and Control Act, which already provides definitions for the chapter for various terms, including, "dispense," "practitioner," and "prescription." These terms as used in the chapter are comparable to those in the bill and appear to be redundant and confusing. For instance, the term "health care practitioner" as defined in the bill includes medical physicians, osteopathic physicians, naturopathic physicians, podiatric physicians, and dentists, but excludes veterinarians who also prescribe and may also dispense controlled substances under chapter 893, Florida Statutes.

IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES

On April 20, 2009, the Full Appropriations Council on General Government & Health Care adopted a strike-all amendment that changed or added the following:

- Replaces the Agency for Health Care Administration with the Department of Health as the responsible entity for establishing the prescription drug monitoring program.
- Changes the implementation date from June 30, 2010 to December 1, 2010.
- Specifies that a prescriber or dispenser is not liable for good faith use of the department-provided controlled substance prescription information of a patient.
- Authorizes the Office of Drug Control, in coordination with the department, to establish a direct-support organization.
- Requires the department, in collaboration with the Office of Drug Control, to study the feasibility of enhancing the prescription drug monitoring program for the purposes of public health initiatives and statistical reporting that respects the privacy of the patient, the prescriber and the dispenser.
- Specifies criteria for access to the information in the database.

- Establishes a 12-member Program Implementation and Oversight Task Force whose purpose is to monitor the implementation and safeguarding of the electronic system established for the prescription drug monitoring program; requires a report each December 1 that contains a summary of the task force's work and recommendations with a final report is due July 1, 2012, when the task force expires.
- Requires certain physicians who engage in pain management to register their clinics with the department, and requires the physician seeking to register the clinic to pay the costs of registration; requires the department to inspect each facility; and the requires the Boards of Medicine and Osteopathic Medicine to adopt rules setting standards of practice for certain physicians who engage in pain management.

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