The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Health Regulation Committee

BILL:	CS/SB 818
INTRODUCER:	Health Regulation Committee and Senator Fasano
SUBJECT:	Controlled Substances
DATE:	March 16, 2011 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Stovall	HR	**Fav/CS**
2.			CJ	
3.			BC	
4.				
5.				
6.				

Please see Section VIII. for Additional Information:

A. COMMITTEE SUBSTITUTE.....	X	Statement of Substantial Changes
B. AMENDMENTS.....		Technical amendments were recommended
		Amendments were recommended
		Significant amendments were recommended

I. Summary:

This bill further refines the regulation of controlled substances by:

- Authorizing a 1-hour continuing education course relating to the Prescription Drug Monitoring Program (PDMP) to count toward requirements for the initial and renewal licensure of a practitioner whose lawful scope of practice authorizes the practitioner to prescribe, administer, or dispense controlled substances;
- Establishing criminal penalties for certain persons advertising that the individual or business is engaged in the dispensing of controlled substances;
- Revising the physician survey instrument to collect data concerning the use of the PDMP and requiring the aggregated reporting of this data;
- Adding an exception to the requirement to register as a pain-management clinic in the allopathic medicine and osteopathic medicine practice acts when a majority of the physicians who provide services in the clinic primarily provide interventional pain procedures of the type routinely billed using surgical codes;
- Removing the requirement that effective July 1, 2012, allopathic physicians working in a pain-management clinic must have completed a pain medicine fellowship or a pain-medicine residency;

- Requiring, under the two practice acts, a physician, an advanced registered nurse practitioner, or a physician assistant to perform an appropriate medical examination prior to and on the same day that the physician dispenses or prescribes controlled substances in a pain-management clinic;
- Establishing additional criminal penalties for fraudulently registering or attempting to register a pain-management clinic, failing to perform a physical examination of a patient at a pain-management clinic on the day in which a controlled substance is dispensed or prescribed to a patient, and prescribing or dispensing controlled substances in excess of a 72-hour dose without documenting that the dosage is within the standard of care as set forth in a specified rule;
- Requiring the Board of Medicine or the Board of Osteopathic Medicine to suspend a physician's license for at least 6 months and impose a fine of at least $10,000 per count when a physician in a pain-management clinic violates the standard of practice as set forth in law or rule;
- Requiring a pharmacist or any person working under the direction of a pharmacist to report to the local county sheriff's office identifying information concerning a person obtaining or attempting to obtain a controlled substance from the pharmacy through a fraudulent method or representation within 24 hours of learning of the fraud or attempted fraud, to avoid committing a misdemeanor of the first degree;
- Requiring a dispensing practitioner to register with the Board of Pharmacy as a dispensing practitioner who dispenses controlled substances, upon payment of a fee not to exceed $100, prior to dispensing controlled substances and to renew the registration every 4 years;
- Amending the elements of the crimes of burglary and grand theft to include certain activities related to controlled substances;
- Prohibiting a person from adulterating a controlled substance by altering its manufactured form or changing its integrity or composition without the prescribing physician's direction to do so based on the patient's medical need for such alteration. Requiring the prescription to specify this adulteration of the dispensed form and the medical necessity for it. If a person unlawfully adulterates a controlled substance in this manner, the issuance of the entire prescription for the controlled substance becomes invalid. A law enforcement officer is authorized to seize the controlled substance as evidence and the bill provides for the return of the controlled substance under certain circumstances. The bill also prohibits a prescribing practitioner from writing a prescription for a controlled substance for a patient, another person, or an animal and authorizing or directing the adulteration of the dispensed form when it is not medically necessary for the treatment of the patient;
- Enhancing provisions pertaining to the PDMP and the monitoring database to:
    - Require the database comply with the National All Schedules Prescription Electronic Reporting (NASPER) Act's minimum requirements for authentication of a practitioner who requests information in the database;
    - Allow corrections to the database when notified by a health care practitioner or pharmacist;
    - Collect additional information in the database concerning refills;
    - Reduce the timeframe for reporting to 7 days;
    - Modify who must report data;

  - Require a pharmacy, prescriber, practitioner, or dispenser to register with the Department of Health (Department) before being authorized to access information in the database;
  - Require persons supporting the PDMP who may have access to the information in the database to undergo fingerprinting for state and federal background screening;
  - Authorize the Attorney General to access the database under certain conditions for Medicaid investigations as well as the Agency for Health Care Administration (Agency) for Medicaid fraud cases or Medicaid investigation, involving prescribed controlled substances;
  - Require a government-issued photo identification to be provided in person by a person requesting access to verify the accuracy of the database information;
  - Delete the provision that all costs for administering the PDMP must be funded through federal grants or private funding; and
  - Authorize the State Surgeon General to enter into a reciprocal agreement for the sharing of PDMP information with another state that has a compatible PDMP, within certain parameters, and providing for the related exceptions for the public records exemption;
- Requiring certain persons who are required to maintain records and inventory controlled substances to report the theft or loss of a controlled substance to a local county sheriff's office within 48 hours after the discovery of the theft or loss, or face criminal penalties;
- Codifying into law certain judicial opinions that construe the Legislature's intent concerning inspection powers previously conferred upon law enforcement officers which allows them to access, review, examine, and copy pharmacy records concerning controlled substances without a subpoena or search warrant and without giving prior notice of the records' examination and copying to the person to whom the particular pharmacy records refer;
- Prohibiting and clarifying prohibited acts relating to a person obtaining or attempting to obtain from a practitioner, controlled substances or a prescription for controlled substances that are not medically necessary; or a health care practitioner providing such controlled substance by misrepresentation, fraud, forgery, deception, subterfuge, or concealment of a material fact. A material fact includes whether the person has an existing prescription for a controlled substance issued for the same time period by another practitioner or has received a controlled substance or a prescription for a controlled substance of like therapeutic use within the previous 30 days;
- Authorizing local administrative action to abate activity at a pain-management clinic upon the declaration of a public nuisance based on the occurrence of certain criminal activity; and
- Prohibiting a pharmacist from interchanging or substituting an opioid analgesic drug for an opioid analgesic drug incorporating a tamper-resistance technology in certain situations.

This bill substantially amends the following sections of the Florida Statutes: 400.9905; 456.013; 458.305; 458.3191; 458.3192; 458.3265; 458.327; 458.331; 459.003; 459.013; 459.0137; 459.015; 465.015; 465.0276; 766.101; 810.02; 812.014; 893.04; 893.055; 893.0551; 893.07; 893.13; and 893.138.

The bill creates s. 893.021 and two unnumbered sections of law.

The effective date of the bill is October 1, 2011.

II. Present Situation:

Prescription drug abuse is the most threatening substance abuse issue in the State of Florida.[1] The number of deaths caused by at least one prescription drug increased from 1,234 in 2003 to 2,488 in 2009 (a 102 percent increase). This translates to seven Floridians dying per day. The drugs that caused the most deaths were oxycodone; all benzodiazepines, including alprazolam; methadone; ethyl alcohol; cocaine; morphine; and hydrocodone.

Controlled Substances

Chapter 893, F.S., sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act. This chapter classifies controlled substances into five schedules in order to regulate the manufacture, distribution, preparation, and dispensing of the substances.

- A Schedule I substance has a high potential for abuse and no currently accepted medical use in treatment in the United States and its use under medical supervision does not meet accepted safety standards. Examples: heroin and methaqualone.
- A Schedule II substance has a high potential for abuse, a currently accepted but severely restricted medical use in treatment in the United States, and abuse may lead to severe psychological or physical dependence. Examples: cocaine and morphine.
- A Schedule III substance has a potential for abuse less than the substances contained in Schedules I and II, a currently accepted medical use in treatment in the United States, and abuse may lead to moderate or low physical dependence or high psychological dependence or, in the case of anabolic steroids, may lead to physical damage. Examples: lysergic acid; ketamine; and some anabolic steroids.
- A Schedule IV substance has a low potential for abuse relative to the substances in Schedule III, a currently accepted medical use in treatment in the United States, and abuse may lead to limited physical or psychological dependence relative to the substances in Schedule III. Examples: alprazolam; diazepam; and phenobarbital.
- A Schedule V substance has a low potential for abuse relative to the substances in Schedule IV, a currently accepted medical use in treatment in the United States, and abuse may lead to limited physical or psychological dependence relative to the substances in Schedule IV. Examples: low dosage levels of codeine; certain stimulants; and certain narcotic compounds.

A prescription for a controlled substance listed in Schedule II may be dispensed only upon a written prescription of a practitioner, except that in an emergency situation, as defined by Department rule, it may be dispensed upon oral prescription but is limited to a 72-hour supply. A prescription for a controlled substance listed in Schedule II may not be refilled.[2] A pharmacist may not dispense more than a 30-day supply of a controlled substance listed in Schedule III upon an oral prescription issued in this state.[3]

[1] *Florida Office of Drug Control 2010 Annual Report*, prepared by the Executive Office of the Governor.
[2] s. 893.04(1)(f), F.S.
[3] s. 893.04(2)(e), F.S.

Dispensing, Prescribing, and Administering

"Dispense" means the transfer of possession of one or more doses of a medicinal drug by a pharmacist or other licensed practitioner to the ultimate consumer thereof or to one who represents that it is his or her intention not to consume or use the same but to transfer the same to the ultimate consumer or user for consumption by the ultimate consumer or user.[4]

"Prescribing" is issuing a prescription. For purposes of the bill, a "prescription" includes an order for drugs that is written, signed, or transmitted by word of mouth, telephone, telegram, or other means of communication by a practitioner licensed by the laws of the state to prescribe such drugs, issued in good faith and in the course of professional practice, intended to be filled or dispensed by another person licensed to do so.[5]

"Administer," for purposes of the bill, means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a person.[6]

Dispensing Practitioner

Chapter 465, F.S., relating to the practice of pharmacy, contains the provisions for a dispensing practitioner.[7] Under this chapter, a practitioner authorized by law to prescribe drugs may dispense those drugs to his or her patients in the regular course of his or her practice. If a practitioner intends to dispense drugs for human consumption for a fee or remuneration of any kind, the practitioner must register with his or her professional licensing board as a dispensing practitioner, comply with and be subject to all laws and rules applicable to pharmacists and pharmacies, and give the patient a written prescription and advise the patient that the prescription may be filled in the practitioner's office or at any pharmacy.

A dispensing practitioner is prohibited from dispensing more than a 72-hour supply of a controlled substance for any patient in a pain-management clinic who pays for the medication by cash, check, or credit card, except if the controlled substance is dispensed:

- To a workers' compensation patient;
- To an insured patient who pays a copayment or deductible with cash, check, or credit card; or
- As a complimentary package to the practitioner's own patient without remuneration of any kind, whether direct or indirect.[8]

Practitioners in Florida who are authorized to prescribe prescription drugs include medical physicians, physician assistants, osteopathic physicians, advanced registered nurse practitioners, podiatrists, naturopathic physicians, dentists, and veterinarians.

However, s. 893.02, F.S., of the Florida controlled substances act defines which practitioners may prescribe a controlled substance under Florida law. A "practitioner" is defined to mean a licensed medical physician, dentist, veterinarian, osteopathic physician, naturopathic physician,

[4] s. 893.02(7), F.S.
[5] s. 893.02(20), F.S.
[6] s. 893.02(1), F.S.
[7] s. 465.0276, F.S.
[8] s. 465.0276(1)(b), F.S., enacted in 2010-211.

or podiatrist, if such practitioner holds a valid federal controlled substance registry number. Accordingly, the prescribing of controlled substances is a privilege that is separate from the regulation of the practice of the prescribing practitioner.

Regulation of Pain-Management Clinics

Chapter 2010-211, Laws of Florida, (the pill mill bill) was enacted to more aggressively regulate pain-management clinics. The requirement to register pain-management clinics and initial regulation was enacted by the 2009 Legislature.[9]

The pill mill bill requires businesses that meet the definition of a pain-management clinic to register with the Department, unless exempted from registration. Ownership of pain-management clinics is limited to allopathic physicians, osteopathic physicians, or groups of allopathic physicians and osteopathic physicians, and health care clinics that are licensed under part X of ch. 400, F.S.

Each pain-management clinic must designate a physician who is responsible for complying with all requirements related to registration and operation of the clinic in compliance with the law. Only a physician licensed under ch. 458, F.S., relating to the practice of medicine, (The Medical Practice Act), or ch. 459, F.S., relating to the practice of osteopathic medicine may dispense a controlled substance on the premises of a registered pain-management clinic.

The pill mill bill requires allopathic physicians and osteopathic physicians practicing in a pain-management clinic to comply with specific provisions, including but not limited to:

- Performing a physical examination of a patient on the same day that he or she dispenses or prescribes a controlled substance;
- Documenting in a patient's record the reason for prescribing or dispensing more than a 72-hour does of controlled substances for the treatment of chronic nonmalignant pain,[10] if he or she prescribes or dispenses in excess of that quantity; and
- Maintaining control and security of his or her prescription blanks and any other method used for prescribing controlled substances, and notifying the Department within 24 hours following a theft, loss, or breach of these instruments.

The pill mill bill provides for various forms of enforcement against a pain-management clinic or practitioner through administrative means including fines and suspension or revocation of a license and through the imposition of criminal penalties. The additional criminal violations created include: a third degree felony to knowingly operate, own, or manage a non-registered pain-management clinic that is required to be registered; a first degree misdemeanor to knowingly prescribe or dispense, or cause to be prescribed or dispensed, controlled substances in an unregistered pain-management clinic that is required to be registered; and a third degree felony to dispense more than a 72-hour supply of controlled substances to a patient in a pain-management clinic who pays for the medication by cash, check, or credit card.

[9] *See* sections 3 and 4 of ch. 2009-198, L.O.F.

[10] Chronic nonmalignant pain is defined as pain unrelated to cancer which persists beyond the usual course of the disease or the injury that is the cause of the pain or more than 90 days after surgery. *See* s. 458.3265(4), F.S., and s. 459.0137(4), F.S.

Prescription Drug Monitoring Program (PDMP)

Chapter 2009-197, L.O.F, established the PDMP in s. 893.005, F.S. This law requires the Department, by December 1, 2010, to design and establish a comprehensive electronic system to monitor the prescribing and dispensing of certain controlled substances. Prescribers and dispensers of certain controlled substances must report specified information to the Department for inclusion in the system. Vendor protests to the procurement process for a contractor to develop the PDMP have delayed implementation of the PDMP database.

Data regarding the dispensing of each controlled substance must be submitted to the Department no more than 15 days after the date the drug was dispensed, by a procedure and in a format established by the Department, and must include minimum information specified in s. 893.005, F.S. Any person who knowingly fails to report the dispensing of a controlled substance commits a first degree misdemeanor. This law provides exemptions from the data reporting requirements for controlled substances when specified acts of dispensing or administering occur.

Section 893.0551, F.S., enacted at the same time, provides for a public records exemption for certain personal information of a patient and certain information concerning health care professionals. This section sets forth enumerated exceptions for disclosure of this information after the Department ensures the legitimacy of the person's request for the information.

The National Alliance for Model State Drug Laws identifies the benefits of a PDMP: as a tool used by states to address prescription drug abuse, addiction, and diversion. It may serve several purposes such as:

- Support access to legitimate medical use of controlled substances,
- Identify and deter or prevent drug abuse and diversion,
- Facilitate and encourage the identification, intervention with and treatment of persons addicted to prescription drugs,
- [Provide data on use and abuse trends for public health initiatives], and
- Educate individuals about PDMPs and the use, abuse and diversion of and addiction to prescription drugs.[11]

As of July 2010, 34 states have operational PDMPs that have the capacity to receive and distribute controlled substance prescription information to authorized users. States with operational programs include: Alabama, Arizona, California, Colorado, Connecticut, Hawaii, Idaho, Illinois, Indiana, Iowa, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Nevada, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Vermont, Virginia, West Virginia, and Wyoming. Washington State's PDMP was operational but has been suspended due to fiscal constraints.[12]

[11] *See* The United State Department of Justice, Drug Enforcement Administration, Office of Diversion Control, Q & A, found at: < http://www.deadiversion.usdoj.gov/faq/rx_monitor.htm,>, (Last visited on March 11, 2011). The fourth purpose as reported in the Q & A reads: "inform public health initiatives through outlining of use and abuse trends."
[12] *Id.*

Seven states, Alaska, Florida, Kansas, New Jersey, Oregon, South Dakota and Wisconsin and one U.S. territory (Guam) have enacted legislation to establish a PDMP, but are not fully operational. Delaware has legislation pending to establish a PDMP.

Program Implementation and Oversight Task Force

The Program Implementation and Oversight Task Force[13] is created within the Executive Office of the Governor. The purpose of the Implementation and Oversight Task Force is to monitor the implementation and safeguarding of the PDMP monitoring database, and to 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.

National All Schedules Prescription Electronic Reporting (NASPER) Act

NASPER was signed into law on August 11, 2005, making it the only statutorily authorized program to assist states in combating prescription drug abuse of controlled substances through a prescription monitoring program (PDMP). NASPER fosters interstate communication by providing grants to set up or improve state systems that meet basic standards of information collection and privacy protections that will make it easier for states to share information. This will enable authorities to identify prescription drug abusers as well as the "problem doctors" who betray the high ethical standards of their profession by over or incorrectly prescribing prescription drugs.[14]

Health Care Clinics

Currently, cash-only health care clinics are not licensed by the Agency. A "clinic" as defined in s. 400.9905(4), F.S., means an entity at which health care services are provided to individuals and which tenders charges for reimbursement for such services.… This definition applies only to clinics that seek reimbursement from third-party payers, such as insurance, Medicaid, Medicare, etc. Cash-only or point-of-sale clinics are not covered by this definition.

The Agency indicates it has licensed approximately 200 health care clinics that are pain-management clinics which are not fully owned by medical or osteopathic physicians.[15]

Tamper-Resistant Technology

Due to the growing abuse associated with certain painkillers, in February 2009, the FDA announced that it plans to implement a Risk Evaluation and Mitigation Strategy (REMS) requirement for all extended-release opioid analgesics. The REMS plan is driving current research and development efforts and may ultimately drive prescribing of newer tamper-resistant extended-release opioids.

[13] *See* section 2, ch. 2009-198, L.O.F.
[14] *See:* <http://www.nasper.org/database.htm>, (Last visited on March 11, 2011).
[15] Agency 2011 Bill Analysis & Economic Impact Statement for SB 818, on file with the Senate Health Regulation Committee.

At least three versions have been through or are making their way through the FDA approval process. One, which was developed by Pain Therapeutics/King Pharmaceuticals, is called Remoxy. Another, developed by Alpharma which is now owned by King Pharmaceuticals, is called Embeda. The third is a product developed by Purdue Pharma. The principle is the same for each though the methods of deterring abuse/misuse of the medicine are different. The principle is that efforts to tamper with the medicine in order to get high will result in negating the properties of the medicine that cause the high. For example, Embeda uses a technology that sequester a substance called naltrexone which is only released when the pill is tampered with - crushed, chewed, or dissolved. Naltrexone basically prevents the morphine, the opioid analgesic, from producing any semblance of a high.[16]

The U.S. Food and Drug Administration has approved a new formulation of the controlled-release drug OxyContin. Rexista™ (oxycodone) is a unique dosage form, designed to be resistant to well-documented abuse that is experienced with current oxycodone products. This new formulation is designed to decrease the likelihood that this medication will be misused or abused, and result in overdose. The new formulation adds in new tamper-resistant features aimed at preserving the controlled release of the active ingredient, oxycodone. This includes abuse by injection when combined with solvents and by nasal inhalation when crushed or powdered. Rexista™ is also designed to resist release of the entire dose when consumed with alcohol, a significant problem with some opioid drugs, such as hydromorphone.[17]

III. Effect of Proposed Changes:

Section 1 amends s. 400.9905, F.S., to revise the definition of "clinic" and "portable equipment provider" for purposes of the licensure of health care clinics by the agency. "Clinic" is defined to mean an entity at which health care services are provided to individuals and which tenders charges for *payment* for such services, including a mobile clinic and a portable equipment provider. The word payment is substituted for the word *reimbursement*. The definition of "portable medical equipment provider" deletes the modifier that a portable equipment provider bills third-party payors for providing portable equipment to multiple locations performing treatment or diagnostic testing of individuals.

Section 2 amends s. 456.013, F.S., related to general licensing provisions for the professions licensed by the Department or a board. The bill allows allopathic physicians, osteopathic physicians, podiatrists, pharmacists, and dentists to complete a 1-hour continuing education course relating to the PDMP upon license renewal on or after July 1, 2012. Each applicant for licensure in one of these professions that is approved for licensure on or after January 1, 2013, must also complete a course. The course must address the purpose of the PDMP; the practitioners' capabilities for improving the standard of care for patients by using the PDMP; how the PDMP can help practitioners detect doctor shopping; the involvement of law

[16] *See* HealthCentral Chronic Pain Connection.com: Tamper Resistant Opioid Medicines by Will Rowe, May 4, 2009, available at:<http://www.healthcentral.com/chronic-pain/c/3025/69656/medicines/>, (Last visited on March 16, 2011).
[17] *See* Intellipharmaceutics, The Future of Drug Delivery, Rexista™ (oxycodone), available at: <http://www.intellipharmaceutics.com/oxycodone.cfm>, and Federal Food and Drug Administration, OxyContin - Questions and Answers, available at: <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm207196.htm> (Last visited on March 16, 2010).

enforcement personnel, the Attorney General's Medicaid Fraud Control Unit, and medical regulatory investigators with the PDMP; and the procedures for registering for access to the PDMP.

The course may be included in the total number of hours of required continuing education and must be approved by the board or by the Department if there is no board. The boards or the Department is required to approve a course offered through a Florida-licensed hospital, ambulatory surgical center, or mobile surgical facility. The boards or the Department must adopt rules as necessary to implement these provisions by October 1, 2011.

Sections 3 and 10 amend s. 458.305, F.S., and s. 459.003, respectively, to add a definition for "dispensing physician" to the terms used under the practice act for the respective professions. "Dispensing physician" is defined to mean a physician who is registered as a dispensing practitioner under the Pharmacy Practice Act in s. 465.0276, F.S.

Section 4 creates an unnumbered section of law relating to advertising controlled substances by a dispensing physician. This section prohibits a person, other than a dispensing physician, from using the title "dispensing physician" or "dispenser" or otherwise leading the public to believe that he or she is engaged in the dispensing of controlled substances. A person, other than the owner of a registered pain-management clinic or health clinic licensed under ch. 400, F.S., may not display any sign or take any other action that would lead the public to believe that the person is engaged in the business of dispensing a controlled substance. This could be construed as authorizing a registered pain-management clinic or any other health clinic licensed under ch. 400, F.S., to display a sign or otherwise communicate that the entity is in the business of dispensing a controlled substance and authorizes them to advertise that the entity dispenses onsite. The bill provides that any advertisement that states "dispensing onsite" or "onsite pharmacy" violates the prohibition. A person who violates any of these provisions commits a misdemeanor of the first degree.

A person, firm, or corporation that is not licensed as a pharmacy may not use in a trade name, sign, letter, or advertisement any term, including "drug," "pharmacy," "onsite pharmacy," "dispensing," "dispensing onsite," "prescription drugs," "Rx," or "apothecary," which implies that the person, firm, or corporation is licensed or registered to dispense prescription drugs in this state. A person who violates this provision commits a felony of the third degree.

The bill provides that in any warrant, information, or indictment, it is not necessary to negate any exceptions, and the burden of any exception is upon the defendant.

Section 5 amends s. 458.3191, F.S., to add to the information collected by the Department in the physician survey that is completed upon licensure renewal. The additional information includes:

- Whether the Department has ever approved or denied the physician's registration for access to a patient's information in the PDMP database, and
- Whether the physician uses the PDMP with patients in his or her medical practice.

Section 6 amends s. 458.3192, F.S., to require the Department, by November 1 of each year, to provide non-identifying information to the PDMP's Implementation and Oversight Task Force

regarding the number of physicians who are registered with the PDMP and who also use the database from the PDMP for their patients in their medical practice.

Sections 7 and 12 amend s. 458.3265, F.S., and s. 459.0137, F.S., respectively, to add to the list of clinics that are exempt from registration as a pain-management clinic, a clinic where the majority of the physicians who provide services in the clinic primarily provide interventional pain procedures of the type routinely billed using surgical codes.

The bill removes the requirement that effective July 1, 2012, unless grandfathered in, a physician practicing in a pain-management clinic must have completed a pain-management fellowship or residency.

A physician, advanced registered nurse practitioner, or physician assistant must perform an appropriate medical examination prior to or on the same day that the physician dispenses or prescribes a controlled substance in a pain management clinic.

Additionally, the bill clarifies the physician's responsibilities with respect to prescribing or dispensing more than a 72-hour dose of controlled substance for the treatment of chronic nonmalignant pain when practicing in a pain-management clinic that is required to be registered. The bill requires a physician to document in the patient's record the reason that dosage is within the standard of care as set forth in Rule 64B8-9.013(3), Florida Administrative Code. Current law requires the physician to document in the patient's record the reason for prescribing or dispensing that quantity.

This section also creates a new crime for a licensee or other person who serves as the designated physician of a pain-management clinic to register a pain-management clinic through misrepresentation or fraud or procure or attempt to procure the registration of a pain-management clinic for any other person by making or causing to be made any false or fraudulent representation. This is a felony of the third degree.

Sections 8 and 11 amend s. 458.327, F.S., and s. 459.013, F.S., respectively, to designate the commission of certain acts criminal acts. These include:
Acts that are a felony of the third degree:

- Failing to perform a physical examination of a patient on the same day that the treating physician dispenses or prescribes a controlled substance to the patient at a pain-management clinic three or more times within a 6-month period;
- Failing to perform a physical examination on three or more different patients on the same day that the treating physician dispenses or prescribes a controlled substance to each patient at a pain-management clinic within a 6-month period; and
- Prescribing or dispensing in excess of a 72-hour dose of controlled substances for the treatment of chronic nonmalignant pain of a patient without documenting in the patient's record the reason that such dosage is within the standard of care, three or more times within a 6-month period.

Acts that are a misdemeanor of the first degree:

- Failing to perform a physical examination of a patient on the same day that the treating physician dispenses or prescribes a controlled substance to the patient at a pain-management clinic two times within a 6-month period;
- Failing to perform a physical examination on two different patients on the same day that the treating physician dispenses or prescribes a controlled substance to each patient at a pain-management clinic within a 6-month period; and
- Prescribing or dispensing in excess of a 72-hour dose of controlled substances for the treatment of chronic nonmalignant pain of a patient without documenting in the patient's record the reason that such dosage is within the standard of care, two times within a 6-month period.

Acts that are a misdemeanor of the second degree:

- A first offense of failing to perform a physical examination of a patient on the same day that the treating physician dispenses or prescribes a controlled substance to the patient at a pain-management clinic; and
- A first offense of prescribing or dispensing in excess of a 72-hour dose of controlled substances for the treatment of chronic nonmalignant pain of a patient without documenting in the patient's record the reason that such dosage is within the standard of care.

Sections 9 and 13 amend s. 458.331, F.S., and s. 459.015, F.S., respectively, to provide for additional disciplinary action when the board finds that a physician has prescribed or dispensed a controlled substance in a pain-management clinic in a manner that violates the standard of practice as set forth in the practice act or rules. This includes at a minimum, suspending the physician's license for at least 6 months and imposing a fine of at least $10,000 per count. Increased penalties are required for repeated violations.

Section 14 amends s. 465.015, F.S., to prohibit a licensed pharmacist, pharmacy technician or any person working under the direction or supervision of a pharmacist or pharmacy technician, from knowingly failing to timely report to the local county sheriff's office the name of any person who obtains or attempts to obtain a controlled substance which the person knows or reasonably should have known was obtained or attempted to be obtained from the pharmacy through a fraudulent method or representation. A pharmacy, pharmacy intern or other person employed by or at a pharmacy is required to report within 24 hours after learning of the fraud or attempted fraud, otherwise he or she commits a misdemeanor of the first degree.

The report must contain, at a minimum, a copy of the prescription used or presented and a narrative, including all information available to the pharmacy regarding:

- The transaction, such as the name and telephone number of the prescribing physician;
- The name, description, and any personal identification information pertaining to the person presenting the prescription; and
- All other material information, such as photographic or video surveillance of the transaction.

Section 15 amends s. 465.0276, F.S., relating to dispensing practitioners under the Pharmacy Practice Act. The bill requires a practitioner to register with the Board of Pharmacy as a dispensing practitioner who dispenses controlled substances in order to dispense controlled

substances that are listed in Schedules II – V and pay a fee that is not to exceed $100. The Department is required to adopt rules for renewal of the registration every four years.

Section 16 amends s. 766.101, F.S., related to medical review committees to conform a cross-reference.

Section 17 amends s. 810.02, F.S., to modify the elements of burglary that is a felony of the second degree. This occurs if, in the course of committing the offense, the offender does not make an assault or battery and is not and does not become armed with a dangerous weapon or explosive, and the offender enters or remains in a structure or conveyance when the offense intended to be committed is theft of a substance controlled by s. 893.03, F.S. Further, the bill provides that notwithstanding any contrary provisions of law, separate judgments and sentences for burglary with the intent to commit theft of a controlled substance and for any applicable offense for possession of a controlled substance or an offense for trafficking in a controlled substance, may be imposed if all such offenses involve the same amount or amounts of a controlled substance.

Section 18 amends s. 812.014, F.S., to modify the elements of grand theft of the third degree that is a felony of the third degree. This occurs if the property stolen is any amount of a controlled substance. Further, the bill provides that notwithstanding any contrary provisions of law, separate judgments and sentences for theft of a controlled substance and for any applicable offense for possession of a controlled substance or an offense for trafficking in a controlled substance, may be imposed if all such offenses involve the same amount or amounts of a controlled substance.

Section 19 creates s. 893.021, F.S., to define an adulterated drug for purposes of ch. 893, F.S., related to Drug Abuse Prevention and Control. An adulterated drug includes a controlled substance that:

- Has been produced, prepared, packed, and marketed for oral consumption by the manufacturer; and
- Has had any change to its integrity or composition for off-label use by means of inhalation, injection, or any other form of ingestion not in accordance with the manufacturer's recommended use, and such off-label use has not been previously directed and approved by the prescribing physician.

The bill provides that a physician is not prevented from directing or prescribing a change to the recognized manufactured recommendations for use in a patient who presents a medical need for the changed controlled substance. The prescribing physician is required to clearly indicate any deviation of the recognized manufacturer's recommended use of a controlled substance on the original prescription, and the licensed pharmacist is required to clearly indicate the deviation on the label of the prescription upon dispensing the controlled substance.

Section 20 amends s. 893.04, F.S., to require that in addition to existing required elements for a prescription for a controlled substance, the directions for use must specify the authorization by the physician, any instructions requiring the adulteration of the dispensed form of the medication, and the medical necessity for the adulteration as provided in s. 893.021, F.S., which is created in this bill.

Section 21 amends s. 893.055, F.S., relating to the PDMP to require:

- The electronic system (database) comply with the National All Schedules Prescription Electronic Reporting (NASPER) Act's minimum requirements for authentication of a practitioner who requests information in the PDMP database and certification of the purpose for which information is requested;
- The Department to establish a method to allow corrections to the database when notified by a health care practitioner or pharmacist;
- Information that is reported by the dispenser to include the number of refills ordered and whether the drug was dispensed as a refill of a prescription or was a first-time request; and
- The reporting of a dispensed controlled substance within 7 days as opposed to 15 days.

This section also modifies the exemptions from reporting to the PDMP to:

- Delete the exemption for a practitioner when administering or dispensing a controlled substance in the health care system of the Department of Corrections, so that if this provision is enacted, this event must be reported;
- Exempt reporting by a health care practitioner when administering or dispensing a controlled substance to a person under the age of 16, but only if the amount of the controlled substance is adequate to treat the patient during that particular treatment session; and
- Reduce the timeframe for a pharmacist or a dispensing practitioner when dispensing a one-time emergency resupply of a controlled substance to a patient from a 72-hour emergency resupply to a 48-hour emergency resupply.

The bill requires a pharmacy, prescriber, practitioner, or dispenser to register with the Department in order to access the information in the PDMP database related to his or her patient. The Department must approve the documentation submitted for registration prior to granting the person access to the appropriate information in the PDMP database.

The PDMP program manager and persons who have access to the database for management purposes must submit fingerprints for a statewide and federal criminal background screening.

The bill expands the authority of the Attorney General to access the database, through the program manager, for Medicaid investigations involving prescribed controlled substances. It also authorizes the Agency similar access for Medicaid fraud cases or Medicaid investigations involving prescribed controlled substances.

The bill requires additional identifying information related to a patient or the patient's legal guardian or surrogate to access the database to verify the accuracy of the information in the database. The additional information includes the patient's phone number and a copy of a government-issued photo identification which must be provided in person to the program manager along with the notarized request.

The bill eliminates the requirement that all costs incurred by the Department in administering the PDMP be funded through federal grants or private funding.

After the PDMP has been operational for 12 months, the State Surgeon General is required to enter into reciprocal agreements for the sharing of prescription drug monitoring information with other states that have a compatible program. The factors to consider when determining compatibility include:

- The essential purposes of the program and the success of the program in fulfilling those purposes;
- The safeguards for privacy of patient records and the success of the program in protecting patient privacy;
- The persons authorized to view the data. The bill lists those who are authorized access upon approval by the State Surgeon General;
- The schedules of controlled substances that are monitored;
- The data required to be submitted for each prescription; and
- Any implementing criteria deemed essential for a thorough comparison.

Priority for access by another state shall be given to a state that is contiguous with the borders of this state. The State Surgeon General is required to annually review the agreement to determine continued compatibility. Any agreement between states must prohibit the sharing of information for any purpose that is not otherwise authorized in Florida Statutes relating to the PDMP and its confidentiality and public records exemptions.

Section 22 amends s. 893.0551, F.S., to authorize additional exemptions for disclosures related to the reciprocal agreement for the sharing of prescription drug monitoring information with another state that has a compatible PDMP. The bill specifies who the reciprocal agreement may authorize to receive information from the PDMP and for what purpose. These individuals include:

- State regulators of professionals authorized to prescribe or dispense controlled substances from the investigation of a designated person;
- A health care practitioner or pharmacist licensed in that state for providing medical or pharmaceutical treatment to a current patient; and
- A law enforcement officer whose duty it is to enforce the laws of his or her state relating to controlled substances and who is engaged in a specific, active investigation involving a designated person.

The program manager may review the request for information received from one of these individuals and validate it.

Section 23 amends s. 893.07, F.S., to require a person who engages in the manufacture, compounding, mixing, cultivating, growing, or by other means producing or preparing, or in the dispensing, importation, or as a wholesaler or distributor of controlled substance to report a theft or loss of a controlled substance to a local county sheriff's office within 48 hours after the discovery of the theft or loss. A person who fails to report the loss or theft as required commits a misdemeanor of the first degree.

The bill adopts into law two judicial opinions that the inspection powers previously conferred upon law enforcement officer which allow them to access and review pharmacy records concerning controlled substances are to be exercised properly by the law enforcement officers

without the requirement of a subpoena or search warrant. Further, the officer may examine and copy such records without the requirement that those persons to whom particular pharmacy records refer be given notice of the records' examination and copying.

Section 24 amends s. 893.13, F.S., to add the following prohibited acts:

- A person may not, with the intent to obtain a controlled substance, or amount of controlled substance, that is not medically necessary for the person, obtain or attempt to obtain from a practitioner a controlled substance or prescription for a controlled substance by misrepresentation, fraud, forgery, deception, subterfuge, or concealment of a material fact. A material fact includes whether the person has an existing prescription for a controlled substance issued for the same period of time by another practitioner or withholding information from a practitioner that the person has received a controlled substance or a prescription for a controlled substance of like therapeutic use from another practitioner within the previous 30 days;
- A health care practitioner, with the intent to provide a controlled substance or an amount of controlled substances that is not medically necessary to his or her patient, may not provide a controlled substance or a prescription for a controlled substance by misrepresentation, fraud, forgery, deception, subterfuge, or concealment of a material fact.
- Any person who adulterates a controlled substance for directed off-label use without authorization by a prescribing physician, violates existing provisions of law and causes the issuance of the entire prescription for the controlled substance to become invalid. A law enforcement officer in the performance of his or her duties may seize the adulterated or off-label prescribed controlled substance as evidence. The controlled substance may be returned to the owner only with a notarized affidavit from the original prescribing practitioner who gave authorization and explicit directions for the adulteration or off-label use of the controlled substance.

A person or health care practitioner who violates any of these new prohibited acts commits a felony of the third degree if any controlled substance that is the subject of the offense is listed in Schedule II, Schedule III, or Schedule IV.

A prescribing practitioner may not write a prescription for a controlled substance for a patient, other person, or an animal and authorize or direct the adulteration of the dispensed form of the controlled substance for the purpose of ingestion by means of inhalation, injection, or any other means that is not medically necessary for the treatment of that patient. To do so, the practitioner commits a felony of the third degree.

Section 25 amends s. 893.138, F.S., to authorize any pain-management clinic which has been used on more than two occasions within a 6-month period as the site of a violation of state laws related to assault and battery, burglary, dealing in theft, robbery by sudden snatching, or unlawful distribution of controlled substance to be declared a public nuisance. As such it may be abated pursuant to the procedures provided in s. 893.138, F.S. Under that statute, a county or municipality may create an administrative board to hear complaints regarding nuisances as defined in that statute and take action such as ordering the closure of the business or activity on the premises. Such an order expires after one year or at an earlier time if so stated in the order.

Section 26 creates a new unnumbered section of law related to the interchange or substitution of an opioid analgesic drug. This is defined as the substitution of any opioid analgesic drug, which is either a brand or generic drug, for the opioid analgesic drug incorporating a tamper-resistance technology that was originally prescribed, regardless of whether the substituted drug is rated as pharmaceutically and therapeutically equivalent or whether the opioid analgesic drug with tamper-resistance technology bears a labeling claim with respect to reduction of tempering, abuse, or abuse potential.

The bill defines an "opioid analgesic drug" and "opioid analgesic drug incorporating a tamper-resistance technology."

The Board of Pharmacy is required to create a list of opioid analgesic drugs incorporating a temper-resistance technology, along with the identification of those drugs that provide substantially similar tamper-resistance properties.

A pharmacist is prohibited from interchanging or substituting an opioid analgesic drug for an opioid analgesic drug incorporating a tamper-resistance technology which is listed by the Board of Pharmacy unless the pharmacist verifies that the opioid analgesic drug has been identified on the list as one that provides substantially similar tamper-resistance properties or obtains written, signed consent from the prescribing physician for the interchange or substitution.

Section 27 provides an effective date of October 1, 2011.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of the bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

D. Other Constitutional Issues:

The advertising restriction in lines 403 through 427 may violate the First Amendment to the United States Constitution and Article I, Section 4 of the Florida Constitution.

The Central Hudson Test is the standard used for determining the constitutionality of a restriction on commercial speech.[18] The four prongs of the *Central Hudson* test, as modified by *Board of Trustees of State Univ. of New York v. Fox*, 492 U.S. 469, 109 S.Ct. 3028, 106 L.Ed.2d 388 (1989), are: (1) whether the speech at issue is not misleading and concerns lawful activity; (2) whether the government has a substantial interest in restricting that speech; (3) whether the regulation directly advances the asserted governmental interest; and (4) whether the regulation is narrowly tailored, but not necessarily the least restrictive means available, to serve the asserted governmental interest.

Article I, Section 4 of the Florida Constitution, related to Freedom of speech and press states:

> Every person may speak, write and publish sentiments on all subjects but shall be responsible for the abuse of that right. No law shall be passed to restrain or abridge the liberty of speech or of the press. In all criminal prosecutions and civil actions for defamation the trust may be given in evidence. If the matter charged as defamatory is true and was published with good motives, the party shall be acquitted or exonerated.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

The bill requires a $100 fee to register as a dispensing practitioner who dispenses controlled substances. This registration must be renewed every 4 years.

B. Private Sector Impact:

All practitioners who are authorized under their practice act to dispense controlled substances and who choose to do so will be required to register with the Board of Pharmacy and pay a $100 registration fee initially and every 4 years thereafter to renew the registration.

Pharmacy employees will be required to report to law enforcement persons who have allegedly engaged in fraud or deception to obtain or attempt to obtain a controlled substance from the pharmacy.

Certain persons who are required to maintain records of controlled substances will be required to report losses or thefts to law enforcement.

Due to the additional criminal violations established in this bill, medical practitioners, pain management clinics, and the general public are all potentially impacted.

[18] *See:* ***Central Hudson Gas*** *& Elec. Corp. v. Public Service Com'n*, 447 U.S. 557, 100 S.Ct. 2343, 65 L.Ed.2d 341 (1980)

C. Government Sector Impact:

The Department and the boards will be required to adopt rules to implement provisions in the bill. Additional criminal violations will impact resources for law enforcement, the court system, and jails and prisons. The impact of this bill has not been determined. The PDMP database may require modification, if completed before this law is enacted, to capture the additional information required to be reported.

VI. Technical Deficiencies:

Line 1629 provides for certain action after the PDMP has been operational for 12 months. It probably should require the action after the PDMP *database* has been operational for 12 months.

Section 14 of the bill refers to a pharmacy technician in one place and a pharmacy intern in others. Since this section relates to criminal violations, the person to which the provision applies should be consistent and clarified.

Section 21 of the bill expands the purposes for which the Attorney General may access information in the PDMP database (see lines 1325-1327) and authorizes the Agency to access information in the PDMP for certain purposes (see lines 1347 – 1349). However, a corresponding exception is not provided in s. 893.0551, F.S., related to the confidentiality of information in the PDMP database.

VII. Related Issues:

The Department advises that it is authorized to comply with all requirements of the NASPER Act. However, the bill fails to authorize the PDMP program manager to provide health care practitioners with unsolicited reports. This authority is necessary for the Department / PDMP to be eligible to receive federal grant funding under the NASPER Act.

VIII. Additional Information:

Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Regulation o March 14, 2011:

- Reduces the continuing education hours from 3 hours to 1 hour;
- Includes an exception from registration as a pain-management clinic in both ch. 458, F.S., and ch. 459, F.S., when a majority of the physicians who provide services in the clinic primarily provide interventional pain procedures of the type routinely billed using surgical codes;
- Strikes the requirement in existing law that allopathic physicians working in a pain-management clinic effective July 1, 2012 must have completed a pain medicine fellowship or a pain-medicine residency;
- Authorizes an ARNP or a PA, to perform an appropriate medical examination of a patient, in lieu of the allopathic physician or osteopathic physician on the same day

that the physician dispenses or prescribes a controlled substance to a patient at a pain-management clinic and changes the terminology for the examination performed by a physician that is in current law to an appropriate medical examination rather than a physician examination;

- Specifies the standard of care that must be met is set forth in a specific rule when a physician prescribing or dispensing more than a 72-hour dose of controlled substances for the treatment of chronic nonmalignant pain at a pain-management clinic documents in the patient record that the dosage is within the standard of care;
- Removes FDLE as a report recipient when an employee in a pharmacy reports identifying information concerning a person obtaining or attempting to obtain a controlled substance through fraud or misrepresentation or when a person who is required to maintain records and inventories of controlled substances under ch. 893, F.S., discovers a loss or theft of controlled substances;
- Removes a dwelling as a location in which the new element for the crime of burglary may occur;
- Deletes one of the conditions that defines an adulterated controlled substance;
- Removes the new misdemeanor offense created in the bill as filed for a person or health care practitioner who performs a prohibited act with an adulterated controlled substance that is listed in Schedule V;
- Clarifies and exempts a law enforcement officer from securing a subpoena, court order, or search warrant in order to obtain access to or copies of records required to be maintained under ch. 893, F.S., relating to controlled substances; and
- Prohibits the substitution of an opioid analgesic drug with tamper-resistance technology under certain circumstances.

A. Amendments:

None.