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# Health Care Regulation Policy Committee

**Tuesday, January 12, 2010  
10:00 AM – 12:00 PM  
Morris Hall (17 HOB)**

**MEETING PACKET**

**Larry Cretul  
Speaker**

**Nick Thompson  
Chair**



## House of Representatives

### Health Care Regulation Policy Committee

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#### **A G E N D A**

**January 12, 2010  
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- I. Opening Remarks by the Chairman**
- II. Chapter 2009-197, L.O.F. (SB 440 Public Records) and Chapter 2009-198, L.O.F. (SB 462 Prescription Drugs)**
- III. Presentation by the Department of Health on the Implementation of the Prescription Drug Monitoring Program and Pain Clinic Registration - Chapter 2009-198, L.O.F. (SB 462)**
- IV. Presentation by the Office of Drug Control on the Implementation of the Prescription Drug Monitoring Program - Chapter 2009-198, L.O.F. (SB 462)**
- V. Closing Remarks by the Chairman**
- VI. Adjournment**

**Chapter 2009-  
197, 198, L.O.F.  
(SB 426, SB 440)**

## CHAPTER 2009-198

### Committee Substitute for Committee Substitute for Committee Substitute for Committee Substitute for Senate Bill No. 462

An act relating to prescription drugs; creating s. 893.055, F.S.; providing definitions; requiring the Department of Health to establish a comprehensive electronic database system to monitor the prescribing and dispensing of certain controlled substances; requiring specified prescribing and dispensing information to be reported to the electronic database system; requiring the department to establish policies and procedures for the system; requiring the department, in consultation with the Office of Drug Control and specified organizations, to adopt by rules appropriate for the prescription drug monitoring program; providing reporting requirements; providing a reporting period; providing exemptions from participation in the system; authorizing the department to establish when to suspend and when to resume reporting requirements during declared emergencies; requiring all nonexempt, dispensing pharmacists and practitioners to submit information in a specified format; providing that the cost to the dispenser in submitting the required information may not be material or extraordinary; specifying costs that are not material or extraordinary; providing access to information reported to the system under certain circumstances; providing that information in the database for the electronic prescription drug monitoring system is not discoverable or admissible in any civil or administrative action; providing exceptions; providing for the use of data for specified purposes; providing requirements for verification of information requested; requiring data transmission to comply with state and federal privacy and security laws; authorizing an agency or person to maintain the data for a specified period if the data is pertinent to active health care or law enforcement investigation or prosecution; requiring the annual reporting of certain performance measures to the Governor and Legislature; providing performance measure criteria; providing criminal penalties for violations; requiring that all costs incurred by the department for the program be funded through federal grants or available private funding sources; providing requirements for seeking funding and procuring goods or services; authorizing the Office of Drug Control, in coordination with the department, to establish a direct-support organization; providing a definition; providing for a board of directors appointed by the director of the office; requiring the director to provide guidance to the board regarding acceptance of moneys from appropriate sources; requiring the direct-support organization to operate under written contract with the office; providing contract requirements; providing requirements for the direct-support organization's collecting, expending, and providing of funds; requiring department approval of activities of the direct-support organization; authorizing the office to adopt rules for the use of certain facilities and services; providing for audits; prohibiting the direct-support organization from exercising certain powers; establishing that a prescriber or dispenser is not

liable for good faith use of the department-provided controlled substance prescription information of a patient; requiring the department, in collaboration with the office, to study the feasibility of enhancing the prescription drug monitoring program for specified purposes to the extent that funding is provided for such purpose; requiring certain persons to present specified identification in order to obtain controlled substances; providing for recordkeeping for certain transactions; requiring the Agency for Health Care Administration to continue the promotion of electronic prescribing and an electronic prescribing clearinghouse; requiring the department to adopt rules; establishing a Program Implementation and Oversight Task Force; providing for membership; providing for reimbursement of certain member expenses; providing for meetings; providing the purpose of the task force; requiring reports to the Governor and Legislature; providing for the creation, membership, and duties of subcommittees; authorizing the direct-support organization to collect, expend, and provide funds and other assistance to the department; providing for a final report and the termination of the task force; amending ss. 458.309 and 459.005, F.S.; requiring certain physicians who engage in pain management to register their clinics with the department by a specified date; providing an exception; prohibiting certain physicians from practicing in a pain-management clinic that has not registered with the department; requiring the department to inspect each facility; providing for exceptions; requiring the physician seeking to register the clinic to pay the costs of registration and inspection or accreditation; requiring the Board of Medicine and the Board of Osteopathic Medicine to adopt rules setting forth standards of practice for certain physicians who engage in pain management; providing criteria for the rules; providing an effective date.

WHEREAS, as has been advocated by numerous pain management experts, addiction medicine experts, pharmacists, and law enforcement personnel, a prescription drug monitoring program that provides for reporting and advisory information and other specified information is established pursuant to this act to serve as a means to promote the public health and welfare and to detect and prevent controlled substance abuse and diversion, and

WHEREAS, while the importance and necessity of the proper prescribing, dispensing, and monitoring of controlled substances, particularly pain medication, have been established, controlled prescription drugs are too often diverted in this state, often through fraudulent means, including outright theft, phony pharmacy fronts, loose Internet medical evaluations, and inappropriate importation; in addition, there is a criminal element that facilitates the prescription drug abuse epidemic through illegal profitmaking from the diversion of certain controlled substances that are prescribed or dispensed by physicians, health care practitioners, and pharmacists, and

WHEREAS, in 2007, 8,620 drug-related deaths occurred in this state, 3,159 of which were caused by prescription drugs, an average of nearly 9 Floridians dying each day from prescription drugs; Schedule IV benzodiaze-

pinex, such as Xanax and Valium, were found to be present in more drug-related deaths than cocaine; and opiate pain medications were found to be contributing to the increasing numbers of drug-related deaths, and

WHEREAS, pharmaceutical drug diversion hurts this state significantly in terms of lost lives, increased crime, human misery from addiction, and ballooning health care costs connected to treatment, medical expenses, and Medicaid fraud that all Floridians ultimately bear, and

WHEREAS, the intent of this act is not to interfere with the legitimate medical use of controlled substances; however, the people of this state are in need of and will benefit from a secure and privacy-protected statewide electronic system of specified prescription drug medication information created primarily to encourage safer controlled substance prescription decisions that reduce the number of prescription drug overdoses and the number of drug overdose deaths; to educate and inform health care practitioners and provide an added tool in patient care, including appropriate treatment for patients who have become addicted; to guide public health initiatives to educate the population on the dangers of misusing prescription drugs; to prevent the abuse or diversion of prescribed controlled substances; and to ensure that those who need prescribed controlled substances receive them in a manner that protects patient confidentiality, and

WHEREAS, while certain medicines are very helpful if properly prescribed to a patient in need and then used as prescribed, they may be dangerous or even deadly if improperly dispensed, misused, or diverted, and

WHEREAS, it is the intent of the Legislature to encourage patient safety, responsible pain management, and proper access to useful prescription drugs that are prescribed by a knowledgeable, properly licensed health care practitioner who dispenses prescription drugs and that are dispensed by a pharmacist who is made aware of the patient's prescription drug medication history, thus preventing, in some cases, an abuse or addiction problem from developing or worsening, making such a problem possible or easier to identify, and facilitating the order of appropriate medical treatment or referral, and

WHEREAS, such an electronic system will also aid administrative and law enforcement agencies in an active controlled substance-related investigation and will allow decisions and recommendations for pursuing appropriate administrative or criminal actions while maintaining such information for any such investigation with a reasonable, good faith anticipation of securing an arrest or prosecution in the foreseeable future, and

WHEREAS, a Program Implementation and Oversight Task Force will provide information to the Governor and Legislature regarding the implementation of the program and ensure that privacy and confidentiality of the patient's prescription history is respected, NOW, THEREFORE,

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 893.055, Florida Statutes, is created to read:

893.055 Prescription drug monitoring program.—

(1) As used in this section, the term:

(a) “Patient advisory report” or “advisory report” means information provided by the department in writing, or as determined by the department, to a prescriber, dispenser, pharmacy, or patient concerning the dispensing of controlled substances. All advisory reports are for informational purposes only and impose no obligations of any nature or any legal duty on a prescriber, dispenser, pharmacy, or patient. The patient advisory report shall be provided in accordance with s. 893.13(7)(a)8. The advisory reports issued by the department 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, and a person who participates in preparing, reviewing, issuing, or any other activity related to an advisory report may not be permitted or required to testify in any such civil action as to any findings, recommendations, evaluations, opinions, or other actions taken in connection with preparing, reviewing, or issuing such a report.

(b) “Controlled substance” means a controlled substance listed in Schedule II, Schedule III, or Schedule IV in s. 893.03.

(c) “Dispenser” means a pharmacy, dispensing pharmacist, or dispensing health care practitioner.

(d) “Health care practitioner” or “practitioner” means any practitioner who is subject to licensure or regulation by the department under chapter 458, chapter 459, chapter 461, chapter 462, chapter 464, chapter 465, or chapter 466.

(e) “Health care regulatory board” means any board for a practitioner or health care practitioner who is licensed or regulated by the department.

(f) “Pharmacy” means any pharmacy that is subject to licensure or regulation by the department under chapter 465 and that dispenses or delivers a controlled substance to an individual or address in this state.

(g) “Prescriber” means a prescribing physician, prescribing practitioner, or other prescribing health care practitioner.

(h) “Active investigation” means an investigation that is being conducted with a reasonable, good faith belief that it could lead to the filing of administrative, civil, or criminal proceedings, or that is ongoing and continuing and for which there is a reasonable, good faith anticipation of securing an arrest or prosecution in the foreseeable future.

(i) “Law enforcement agency” means the Department of Law Enforcement, a Florida sheriff’s department, a Florida police department, or a law enforcement agency of the Federal Government which enforces the laws of this state or the United States relating to controlled substances, and which its agents and officers are empowered by law to conduct criminal investigations and make arrests.

(2)(a) By December 1, 2010, the department shall design and establish a comprehensive electronic database system that has controlled substance prescriptions provided to it and that provides prescription information to a patient's health care practitioner and pharmacist who inform the department that they wish the patient advisory report provided to them. Otherwise, the patient advisory report will not be sent to the practitioner, pharmacy, or pharmacist. The system shall be designed to provide information regarding dispensed prescriptions of controlled substances and shall not infringe upon the legitimate prescribing or dispensing of a controlled substance by a prescriber or dispenser acting in good faith and in the course of professional practice. The system shall be consistent with standards of the American Society for Automation in Pharmacy (ASAP). The electronic system shall also comply with the Health Insurance Portability and Accountability Act (HIPAA) as it pertains to protected health information (PHI), electronic protected health information (EPHI), and all other relevant state and federal privacy and security laws and regulations. The department shall establish policies and procedures as appropriate regarding the reporting, accessing the database, evaluation, management, development, implementation, operation, storage, and security of information within the system. The reporting of prescribed controlled substances shall include a dispensing transaction with a dispenser pursuant to chapter 465 or through a dispensing transaction to an individual or address in this state with a pharmacy that is not located in this state but that is otherwise subject to the jurisdiction of this state as to that dispensing transaction. The reporting of patient advisory reports refers only to reports to patients, pharmacies, and practitioners. Separate reports that contain patient prescription history information and that are not patient advisory reports are provided to persons and entities as authorized in paragraphs (7)(b) and (c) and s. 893.0551.

(b) The department, when the direct support organization receives at least \$20,000 in nonstate moneys or the state receives at least \$20,000 in federal grants for the prescription drug monitoring program, and in consultation with the Office of Drug Control, shall adopt rules as necessary concerning the reporting, accessing the database, evaluation, management, development, implementation, operation, security, and storage of information within the system, including rules for when patient advisory reports are provided to pharmacies and prescribers. The patient advisory report shall be provided in accordance with s. 893.13(7)(a)8. The department shall work with the professional health care licensure boards, such as the Board of Medicine, the Board of Osteopathic Medicine, and the Board of Pharmacy; other appropriate organizations, such as the Florida Pharmacy Association, the Office of Drug Control, the Florida Medical Association, the Florida Retail Federation and the Florida Osteopathic Medical Association, including those relating to pain management; and the Attorney General, the Department of Law Enforcement, and the Agency for Health Care Administration to develop rules appropriate for the prescription drug monitoring program.

(c) All dispensers and prescribers subject to these reporting requirements shall be notified by the department of the implementation date for such reporting requirements.



(3) The pharmacy dispensing the controlled substance and each prescriber who directly dispenses a controlled substance shall submit to the electronic system, by a procedure and in a format established by the department and consistent with an ASAP-approved format, the following information for inclusion in the database:

(a) The name of the prescribing practitioner, the practitioner's federal Drug Enforcement Administration registration number, the practitioner's National Provider Identification (NPI) or other appropriate identifier, and the date of the prescription.

(b) The date the prescription was filled and the method of payment, such as cash by an individual, insurance coverage through a third party, or Medicaid payment. This paragraph does not authorize the department to include individual credit card numbers or other account numbers in the database.

(c) The full name, address, and date of birth of the person for whom the prescription was written.

(d) The name, national drug code, quantity, and strength of the controlled substance dispensed.

(e) The full name, federal Drug Enforcement Administration registration number, and address of the pharmacy or other location from which the controlled substance was dispensed. If the controlled substance was dispensed by a practitioner other than a pharmacist, the practitioner's full name, federal Drug Enforcement Administration registration number, and address.

(f) The name of the pharmacy or practitioner, other than a pharmacist, dispensing the controlled substance and the practitioner's National Provider Identification (NPI).

(g) Other appropriate identifying information as determined by department rule.

(4) Each time a controlled substance is dispensed to an individual, the controlled substance shall be reported to the department through the system as soon thereafter as possible, but not more than 15 days after the date the controlled substance is dispensed unless an extension is approved by the department for cause as determined by rule. A dispenser must meet the reporting requirements of this section by providing the required information concerning each controlled substance that it dispensed in a department-approved, secure methodology and format. Such approved formats may include, but are not limited to, submission via the Internet, on a disc, or by use of regular mail.

(5) When the following acts of dispensing or administering occur, the following are exempt from reporting under this section for that specific act of dispensing or administration:

(a) A health care practitioner when administering a controlled substance directly to a patient if the amount of the controlled substance is adequate to treat the patient during that particular treatment session.

(b) A pharmacist or health care practitioner when administering a controlled substance to a patient or resident receiving care as a patient at a hospital, nursing home, ambulatory surgical center, hospice, or intermediate care facility for the developmentally disabled which is licensed in this state.

(c) A practitioner when administering or dispensing a controlled substance in the health care system of the Department of Corrections.

(d) A practitioner when administering a controlled substance in the emergency room of a licensed hospital.

(e) A health care practitioner when administering or dispensing a controlled substance to a person under the age of 16.

(f) A pharmacist or a dispensing practitioner when dispensing a one-time, 72-hour emergency resupply of a controlled substance to a patient.

(6) The department may establish when to suspend and when to resume reporting information during a state-declared or nationally declared disaster.

(7)(a) A practitioner or pharmacist who dispenses a controlled substance must submit the information required by this section in an electronic or other method in an ASAP format approved by rule of the department unless otherwise provided in this section. The cost to the dispenser in submitting the information required by this section may not be material or extraordinary. Costs not considered to be material or extraordinary include, but are not limited to, regular postage, electronic media, regular electronic mail, and facsimile charges.

(b) A pharmacy, prescriber, or dispenser shall have access to information in the prescription drug monitoring program's database which relates to a patient of that pharmacy, prescriber, or dispenser in a manner established by the department as needed for the purpose of reviewing the patient's controlled substance prescription history. Other access to the program's database shall be limited to the program's manager and to the designated program and support staff, who may act only at the direction of the program manager or, in the absence of the program manager, as authorized. Access by the program manager or such designated staff is for prescription drug program management only or for management of the program's database and its system in support of the requirements of this section and in furtherance of the prescription drug monitoring program. Confidential and exempt information in the database shall be released only as provided in paragraph (c) and s. 893.0551.

(c) The following entities shall not be allowed direct access to information in the prescription drug monitoring program database but may request from the program manager and, when authorized by the program manager, the program manager's program and support staff, information that is confidential and exempt under s. 893.0551. Prior to release, the request shall be verified as authentic and authorized with the requesting organization by the program manager, the program manager's program and support staff, or as

determined in rules by the department as being authentic and as having been authorized by the requesting entity:

1. The department or its relevant health care regulatory boards responsible for the licensure, regulation, or discipline of practitioners, pharmacists, or other persons who are authorized to prescribe, administer, or dispense controlled substances and who are involved in a specific controlled substance investigation involving a designated person for one or more prescribed controlled substances.

2. The Attorney General for Medicaid fraud cases involving prescribed controlled substances.

3. A law enforcement agency during active investigations regarding potential criminal activity, fraud, or theft regarding prescribed controlled substances.

4. A patient or the legal guardian or designated health care surrogate of an incapacitated patient as described in s. 893.0551 who, for the purpose of verifying the accuracy of the database information, submits a written and notarized request that includes the patient's full name, address, and date of birth, and includes the same information if the legal guardian or health care surrogate submits the request. The request shall be validated by the department to verify the identity of the patient and the legal guardian or health care surrogate, if the patient's legal guardian or health care surrogate is the requestor. Such verification is also required for any request to change a patient's prescription history or other information related to his or her information in the electronic database.

Information in the database for the electronic prescription drug monitoring system is not discoverable or admissible in any civil or administrative action, except in an investigation and disciplinary proceeding by the department or the appropriate regulatory board.

(d) The following entities shall not be allowed direct access to information in the prescription drug monitoring program database but may request from the program manager and, when authorized by the program manager, the program manager's program and support staff, information that contains no identifying information of any patient, physician, health care practitioner, prescriber, or dispenser and that is not confidential and exempt:

1. Department staff for the purpose of calculating performance measures pursuant to subsection (8).

2. The Program Implementation and Oversight Task Force for its reporting to the Governor, the President of the Senate, and the Speaker of the House of Representatives regarding the prescription drug monitoring program. This subparagraph expires July 1, 2012.

(e) All transmissions of data required by this section must comply with relevant state and federal privacy and security laws and regulations. However, any authorized agency or person under s. 893.0551 receiving such

information as allowed by s. 893.0551 may maintain the information received for up to 24 months before purging it from his or her records or maintain it for longer than 24 months if the information is pertinent to ongoing health care or an active law enforcement investigation or prosecution.

(8) To assist in fulfilling program responsibilities, performance measures shall be reported annually to the Governor, the President of the Senate, and the Speaker of the House of Representatives by the department each December 1, beginning in 2011. Data that does not contain patient, physician, health care practitioner, prescriber, or dispenser identifying information may be requested during the year by department employees so that the department may undertake public health care and safety initiatives that take advantage of observed trends. Performance measures may include, but are not limited to, efforts to achieve the following outcomes:

(a) Reduction of the rate of inappropriate use of prescription drugs through department education and safety efforts.

(b) Reduction of the quantity of pharmaceutical controlled substances obtained by individuals attempting to engage in fraud and deceit.

(c) Increased coordination among partners participating in the prescription drug monitoring program.

(d) Involvement of stakeholders in achieving improved patient health care and safety and reduction of prescription drug abuse and prescription drug diversion.

(9) Any person who willfully and knowingly fails to report the dispensing of a controlled substance as required by this section commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(10) All costs incurred by the department in administering the prescription drug monitoring program shall be funded through federal grants or private funding applied for or received by the state. The department may not commit funds for the monitoring program without ensuring funding is available. The prescription drug monitoring program and the implementation thereof are contingent upon receipt of the nonstate funding. The department and state government shall cooperate with the direct-support organization established pursuant to subsection (11) in seeking federal grant funds, other nonstate grant funds, gifts, donations, or other private moneys for the department so long as the costs of doing so are not considered material. Non-material costs for this purpose include, but are not limited to, the costs of mailing and personnel assigned to research or apply for a grant. Notwithstanding the exemptions to competitive-solicitation requirements under s. 287.057(5)(f), the department shall comply with the competitive-solicitation requirements under s. 287.057 for the procurement of any goods or services required by this section.

(11) The Office of Drug Control, in coordination with the department, may establish a direct-support organization that has a board consisting of

at least five members to provide assistance, funding, and promotional support for the activities authorized for the prescription drug monitoring program.

(a) As used in this subsection, the term "direct-support organization" means an organization that is:

1. A Florida corporation not for profit incorporated under chapter 617, exempted from filing fees, and approved by the Department of State.

2. Organized and operated to conduct programs and activities; raise funds; request and receive grants, gifts, and bequests of money; acquire, receive, hold, and invest, in its own name, securities, funds, objects of value, or other property, either real or personal; and make expenditures or provide funding to or for the direct or indirect benefit of the department in the furtherance of the prescription drug monitoring program.

(b) The direct-support organization is not considered a lobbying firm within the meaning of s. 11.045.

(c) The director of the Office of Drug Control shall appoint a board of directors for the direct-support organization. The director may designate employees of the Office of Drug Control, state employees other than state employees from the department, and any other nonstate employees as appropriate, to serve on the board. Members of the board shall serve at the pleasure of the director of the Office of Drug Control. The director shall provide guidance to members of the board to ensure that moneys received by the direct-support organization are not received from inappropriate sources. Inappropriate sources include, but are not limited to, donors, grantors, persons, or organizations that may monetarily or substantively benefit from the purchase of goods or services by the department in furtherance of the prescription drug monitoring program.

(d) The direct-support organization shall operate under written contract with the Office of Drug Control. The contract must, at a minimum, provide for:

1. Approval of the articles of incorporation and bylaws of the direct-support organization by the Office of Drug Control.

2. Submission of an annual budget for the approval of the Office of Drug Control.

3. Certification by the Office of Drug Control in consultation with the department 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 interests of the state. Such certification must be made annually and reported in the official minutes of a meeting of the direct-support organization.

4. The 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.

5. The fiscal year of the direct-support organization, which must begin July 1 of each year and end June 30 of the following year.

6. 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.

7. The direct-support organization's collecting, expending, and providing of funds to the department for the development, implementation, and operation of the prescription drug monitoring program as described in this section and section 2 of this act as long as the task force is authorized. The direct-support organization may collect and expend funds to be used for the functions of the direct-support organization's board of directors, as necessary and approved by the director of the Office of Drug Control. In addition, the direct-support organization may collect and provide funding to the department in furtherance of the prescription drug monitoring program by:

a. Establishing and administering the prescription drug monitoring program's electronic database, including hardware and software.

b. Conducting studies on the efficiency and effectiveness of the program to include feasibility studies as described in subsection (13).

c. Providing funds for future enhancements of the program within the intent of this section.

d. Providing user training of the prescription drug monitoring program, including distribution of materials to promote public awareness and education and conducting workshops or other meetings, for health care practitioners, pharmacists, and others as appropriate.

e. Providing funds for travel expenses.

f. Providing funds for administrative costs, including personnel, audits, facilities, and equipment.

g. Fulfilling all other requirements necessary to implement and operate the program as outlined in this section.

(e) 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 the department, and in the best interests of the state. 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.

(f) The Office of Drug Control, in consultation with the department, 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, subject to this section. The use must be directly in keeping with the approved purposes of the direct-support organization and may not be made at times or places that would unreasonably interfere with opportunities for the public to use such facilities for established purposes. Any moneys received from rentals of facilities and properties managed by the Office of Drug Control and the department may be held by the Office of Drug Control or in a separate depository account in the name of the direct-support organization and subject to the provisions of the letter of agreement with the Office of Drug Control. The letter of agreement must provide that any funds held in the separate depository account in the name of the direct-support organization must revert to the Office of Drug Control if the direct-support organization is no longer approved by the Office of Drug Control to operate in the best interests of the state.

(g) The Office of Drug Control, in consultation with the department, may adopt rules under s. 120.54 to govern the use of administrative services, property, or facilities of the department or office by the direct-support organization.

(h) The Office of Drug Control may not permit the use of any administrative services, property, or facilities of the state by a direct-support organization if that organization does not provide equal membership and employment opportunities to all persons regardless of race, color, religion, gender, age, or national origin.

(i) The direct-support organization shall provide for an independent annual financial audit in accordance with s. 215.981. Copies of the audit shall be provided to the Office of Drug Control and the Office of Policy and Budget in the Executive Office of the Governor.

(j) The direct-support organization may not exercise any power under s. 617.0302(12) or (16).

(12) A prescriber or dispenser may have access to the information under this section which relates to a patient of that prescriber or dispenser as needed for the purpose of reviewing the patient's controlled drug prescription history. 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. This subsection 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 this subsection for accessing or failing to access such information.

(13) To the extent that funding is provided for such purpose through federal or private grants or gifts and other types of available moneys, the department, in collaboration with the Office of Drug Control, shall 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. Such a study

shall be conducted in order to further improve the quality of health care services and safety by improving the prescribing and dispensing practices for prescription drugs, taking advantage of advances in technology, reducing duplicative prescriptions and the overprescribing of prescription drugs, and reducing drug abuse. The requirements of the National All Schedules Prescription Electronic Reporting (NASPER) Act are authorized in order to apply for federal NASPER funding. In addition, the direct-support organization shall provide funding for the department, in collaboration with the Office of Drug Control, to conduct training for health care practitioners and other appropriate persons in using the monitoring program to support the program enhancements.

(14) A pharmacist, pharmacy, or dispensing health care practitioner or his or her agent, before releasing a controlled substance to any person not known to such dispenser, shall require the person purchasing, receiving, or otherwise acquiring the controlled substance 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 dispenser may verify the validity of the prescription and the identity of the patient with the prescriber or his or her authorized agent. Verification of health plan eligibility through a real-time inquiry or adjudication system will be considered to be proper identification. This subsection does not apply in an institutional setting or to a long-term care facility, including, but not limited to, an assisted living facility or a hospital to which patients are admitted. As used in this subsection, the term "proper identification" means an identification that is issued by a state or the Federal Government containing the person's photograph, printed name, and signature or a document considered acceptable under 8 C.F.R. 274a.2(b)(1)(v)(A) and (B).

(15) The Agency for Health Care Administration shall continue the promotion of electronic prescribing by health care practitioners, health care facilities, and pharmacies under s. 408.0611.

(16) By October 1, 2010, the department shall adopt rules pursuant to ss. 120.536(1) and 120.54 to administer the provisions of this section, which shall include as necessary the reporting, accessing, evaluation, management, development, implementation, operation, and storage of information within the monitoring program's system.

Section 2. (1) The Program Implementation and Oversight Task Force is created within the Executive Office of the Governor. The director of the Office of Drug Control shall be a nonvoting, ex officio member of the task force and shall act as chair. The Office of Drug Control and the Department of Health shall provide staff support for the task force.

(a) The following state officials shall serve on the task force:

1. The Attorney General or his or her designee.
2. The Secretary of Children and Family Services or his or her designee.
3. The Secretary of Health Care Administration or his or her designee.



4. The State Surgeon General or his or her designee.

(b) In addition, the Governor shall appoint 12 members of the public to serve on the task force. Of these 12 appointed members, one member must have professional or occupational expertise in computer security; one member must be a Florida-licensed, board-certified oncologist; two members must be Florida-licensed, fellowship-trained, pain-medicine physicians; one member must be a Florida-licensed primary care physician who has experience in prescribing scheduled prescription drugs; one member must have professional or occupational expertise in e-Prescribing or prescription drug monitoring programs; two members must be a Florida-licensed pharmacists; one member must have professional or occupational expertise in the area of law enforcement and have experience in prescription drug investigations; one member must have professional or occupational expertise as an epidemiologist and have a background in tracking and analyzing drug trends; and two members must have professional or occupational expertise as providers of substance abuse treatment, with priority given to a member who is a former substance abuser.

(c) Members appointed by the Governor shall be appointed to a term of 3 years each. Any vacancy on the task force shall be filled in the same manner as the original appointment, and any member appointed to fill a vacancy shall serve only for the unexpired term of the member's predecessor.

(d) Members of the task force and members of subcommittees appointed under subsection (4) shall serve without compensation, but are entitled to reimbursement for per diem and travel expenses as provided in s. 112.061, Florida Statutes.

(e) The task force shall meet at least quarterly or upon the call of the chair.

(2) The purpose of the task force is to monitor the implementation and safeguarding of the electronic system established for the prescription drug monitoring program under s. 893.055, Florida Statutes, 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.

(3) The Office of Drug Control shall 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 of the task force during that year and the recommendations developed in accordance with the task force's purpose as provided in subsection (2). Interim reports may be submitted at the discretion of the chair.

(4) The chair of the task force may appoint subcommittees that include members of state agencies that are not represented on the task force for the purpose of soliciting input and recommendations from those state agencies as needed by the task force to accomplish its purpose as provided in subsection (2). In addition, the chair may appoint subcommittees as necessary from among the members of the task force in order to efficiently address specific

issues. If a state agency is to be represented on any subcommittee, the representative shall be the head of the agency or his or her designee. The chair may designate lead and contributing agencies within a subcommittee.

(5) The direct-support organization created in s. 893.055, Florida Statutes, may collect, expend, and provide funds and other assistance to the department for the development, implementation, and operation of the task force.

(6) The task force shall provide a final report in accordance with the task force's purpose as provided in subsection (2) on July 1, 2012, to the Governor, the President of the Senate, and the Speaker of the House of Representatives. Such report shall be prepared using only data that does not identify a patient, a prescriber, or a dispenser. The task force shall expire and this section is repealed on that date unless reenacted by the Legislature.

Section 3. Subsections (4), (5), and (6) are added to section 458.309, Florida Statutes, to read:

458.309 Rulemaking authority.—

(4) All privately owned pain-management clinics, facilities, or offices, hereinafter referred to as "clinics," which advertise in any medium for any type of pain-management services, or employ a physician who is primarily engaged in the treatment of pain by prescribing or dispensing controlled substance medications, must register with the department by January 4, 2010, unless that clinic is licensed as a facility pursuant to chapter 395. A physician may not practice medicine in a pain-management clinic that is required to but has not registered with the department. Each clinic location shall be registered separately regardless of whether the clinic is operated under the same business name or management as another clinic. If the clinic is licensed as a health care clinic under chapter 400, the medical director is responsible for registering the facility with the department. If the clinic is not registered pursuant to chapter 395 or chapter 400, the clinic shall, upon registration with the department, designate a physician who is responsible for complying with all requirements related to registration of the clinic. The designated physician shall be licensed under this chapter or chapter 459 and shall practice at the office location for which the physician has assumed responsibility. The department shall inspect the clinic annually to ensure that it complies with rules of the Board of Medicine adopted pursuant to this subsection and subsection (5) unless the office is accredited by a nationally recognized accrediting agency approved by the Board of Medicine. The actual costs for registration and inspection or accreditation shall be paid by the physician seeking to register the clinic.

(5) The Board of Medicine shall adopt rules setting forth standards of practice for physicians practicing in privately owned pain-management clinics that primarily engage in the treatment of pain by prescribing or dispensing controlled substance medications. Such rules shall address, but need not be limited to, the following subjects:

(a) Facility operations;

- (b) Physical operations;
- (c) Infection control requirements;
- (d) Health and safety requirements;
- (e) Quality assurance requirements;
- (f) Patient records;
- (g) Training requirements for all facility health care practitioners who are not regulated by another board;
- (h) Inspections; and
- (i) Data collection and reporting requirements.

A physician is primarily engaged in the treatment of pain by prescribing or dispensing controlled substance medications when the majority of the patients seen are prescribed or dispensed controlled substance medications for the treatment of chronic nonmalignant pain. Chronic nonmalignant pain is 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.

(6) A privately owned clinic, facility, or office that advertises in any medium for any type of pain-management services or employs one or more physicians who are primarily engaged in the treatment of pain by prescribing or dispensing controlled substances is exempt from the registration provisions in subsection (4) if the majority of the physicians who provide services in the clinic, facility, or office primarily provide surgical services.

Section 4. Section 4. Subsections (3), (4), and (5) are added to section 459.005, Florida Statutes, to read:

459.005 Rulemaking authority.—

(3) All privately owned pain-management clinics, facilities, or offices, hereinafter referred to as "clinics," which advertise in any medium for any type of pain-management services, or employ a physician who is licensed under this chapter and who is primarily engaged in the treatment of pain by prescribing or dispensing controlled substance medications, must register with the department by January 4, 2010, unless that clinic is licensed as a facility under chapter 395. A physician may not practice osteopathic medicine in a pain-management clinic that is required to but has not registered with the department. Each clinic location shall be registered separately regardless of whether the clinic is operated under the same business name or management as another clinic. If the clinic is licensed as a health care clinic under chapter 400, the medical director is responsible for registering the facility with the department. If the clinic is not registered under chapter 395 or chapter 400, the clinic shall, upon registration with the department, designate a physician who is responsible for complying with all requirements related to registration of the clinic. The designated physician

shall be licensed under chapter 458 or this chapter and shall practice at the office location for which the physician has assumed responsibility. The department shall inspect the clinic annually to ensure that it complies with rules of the Board of Osteopathic Medicine adopted pursuant to this subsection and subsection (4) unless the office is accredited by a nationally recognized accrediting agency approved by the Board of Osteopathic Medicine. The actual costs for registration and inspection or accreditation shall be paid by the physician seeking to register the clinic.

(4) The Board of Osteopathic Medicine shall adopt rules setting forth standards of practice for physicians who practice in privately owned pain-management clinics that primarily engage in the treatment of pain by prescribing or dispensing controlled substance medications. Such rules shall address, but need not be limited to, the following subjects:

- (a) Facility operations;
- (b) Physical operations;
- (c) Infection control requirements;
- (d) Health and safety requirements;
- (e) Quality assurance requirements;
- (f) Patient records;
- (g) Training requirements for all facility health care practitioners who are not regulated by another board;
- (h) Inspections; and
- (i) Data collection and reporting requirements.

A physician is primarily engaged in the treatment of pain by prescribing or dispensing controlled substance medications when the majority of the patients seen are prescribed or dispensed controlled substance medications for the treatment of chronic nonmalignant pain. Chronic nonmalignant pain is 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.

(5) A privately owned clinic, facility, or office that advertises in any medium for any type of pain-management services or employs one or more physicians who are primarily engaged in the treatment of pain by prescribing or dispensing controlled substances is exempt from the registration provisions in subsection (3) if the majority of the physicians who provide services in the clinic, facility, or office primarily provide surgical services.

Section 5. This act shall take effect July 1, 2009.

Approved by the Governor June 18, 2009.

Filed in Office Secretary of State June 18, 2009.

## CHAPTER 2009-197

### Committee Substitute for Committee Substitute for Senate Bill No. 440

An act relating to public records; creating s. 893.0551, F.S.; providing definitions; exempting from public records requirements information and records reported to the Department of Health under the electronic prescription drug monitoring program for monitoring the prescribing and dispensing of controlled substances listed in Schedules II-IV; authorizing certain persons and entities access to patient-identifying, practitioner-identifying, or pharmacist-identifying information; providing guidelines for the use of such information and penalties for violations; providing for future legislative review and repeal; providing a finding of public necessity; providing a contingent effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 893.0551, Florida Statutes, is created to read:

893.0551 Public-records exemption for the prescription drug monitoring program.—

(1) For purposes of this section, the term:

(a) “Active investigation” has the same meaning as provided in s. 893.055.

(b) “Dispenser” has the same meaning as provided in s. 893.055.

(c) “Health care practitioner” or “practitioner” has the same meaning as provided in s. 893.055.

(d) “Health care regulatory board” has the same meaning as provided in s. 893.055.

(e) “Law enforcement agency” has the same meaning as provided in s. 893.055.

(f) “Pharmacist” means any person licensed under chapter 465 to practice the profession of pharmacy.

(g) “Pharmacy” has the same meaning as provided in s. 893.055.

(h) “Prescriber” has the same meaning as provided in s. 893.055.

(2) The following information of a patient or patient’s agent, a health care practitioner, a dispenser, an employee of the practitioner who is acting on behalf of and at the direction of the practitioner, a pharmacist, or a pharmacy that is contained in records held by the department under s. 893.055 is confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution:

- (a) Name.
- (b) Address.
- (c) Telephone number.
- (d) Insurance plan number.
- (e) Government-issued identification number.
- (f) Provider number.
- (g) Drug Enforcement Administration number.
- (h) Any other unique identifying information or number.

(3) The department shall disclose such confidential and exempt information to the following entities after using a verification process to ensure the legitimacy of that person's or entity's request for the information:

(a) The Attorney General and his or her designee when working on Medicaid fraud cases involving prescription drugs or when the Attorney General has initiated a review of specific identifiers of Medicaid fraud regarding prescription drugs. The Attorney General or his or her designee may disclose the confidential and exempt information received from the department to a criminal justice agency as defined in s. 119.011 as part of an active investigation that is specific to a violation of prescription drug abuse or prescription drug diversion law as it relates to controlled substances. The Attorney General's Medicaid fraud investigators may not have direct access to the department's database.

(b) The department's relevant health care regulatory boards responsible for the licensure, regulation, or discipline of a practitioner, pharmacist, or other person who is authorized to prescribe, administer, or dispense controlled substances and who is involved in a specific controlled substances investigation for prescription drugs involving a designated person. The health care regulatory boards may request information from the department but may not have direct access to its database. The health care regulatory boards may provide such information to a law enforcement agency pursuant to ss. 456.066 and 456.073.

(c) A law enforcement agency that has initiated an active investigation involving a specific violation of law regarding prescription drug abuse or diversion of prescribed controlled substances. The law enforcement agency may disclose the confidential and exempt information received from the department to a criminal justice agency as defined in s. 119.011 as part of an active investigation that is specific to a violation of prescription drug abuse or prescription drug diversion law as it relates to controlled substances. A law enforcement agency may request information from the department but may not have direct access to its database.

(d) A health care practitioner who certifies that the information is necessary to provide medical treatment to a current patient in accordance with ss. 893.05 and 893.055.

(e) A pharmacist who certifies that the requested information will be used to dispense controlled substances to a current patient in accordance with ss. 893.04 and 893.055.

(f) A patient or the legal guardian or designated health care surrogate for an incapacitated patient, if applicable, making a request as provided in s. 893.055(7)(c)4.

(g) The patient's pharmacy, prescriber, or dispenser who certifies that the information is necessary to provide medical treatment to his or her current patient in accordance with s. 893.055.

(4) Any agency or person who obtains such confidential and exempt information pursuant to this section must maintain the confidential and exempt status of that information.

(5) Any person who willfully and knowingly violates this section commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(6) This section is subject to the Open Government Sunset Review Act in accordance with s. 119.15 and shall stand repealed on October 2, 2014, unless reviewed and saved from repeal through reenactment by the Legislature.

Section 2. The Legislature finds that it is a public necessity that certain identification and location information of a patient or patient's agent; a health care practitioner as defined in s. 893.055, Florida Statutes; a dispenser as defined in s. 893.055, Florida Statutes; an employee of the practitioner who is acting on behalf of and at the direction of the practitioner; a pharmacist; or a pharmacy as defined in s. 893.055, Florida Statutes, that is contained in records that are held by the Department of Health under s. 893.055, Florida Statutes, the electronic prescription drug monitoring system for the monitoring of the prescribing and dispensing of controlled substances, be made confidential and exempt from public records requirements. Specifically, the Legislature finds that it is a public necessity to make confidential and exempt the name, address, telephone number, insurance plan number, government-issued identification number, provider number, Drug Enforcement Administration number, and any other unique identifying information or number. Information concerning the prescriptions that have been prescribed or dispensed to a patient is a private, personal matter between the patient, the practitioner, and the pharmacist. Nevertheless, the reporting of prescriptions on a timely and accurate basis by dispensing practitioners and pharmacists will ensure the ability of the state to review and provide oversight of prescribing and dispensing practices. Further, the reporting of this information will facilitate investigations and prosecutions of violations of state drug laws by patients, practitioners, and pharmacists, thereby increasing compliance with those laws. However, if in the process the information that would identify a patient is not made confidential and exempt from disclosure, any person could inspect and copy the record and be aware of the patient's prescriptions. The availability of such information to the public would result in the invasion of the patient's privacy. If the identity of the patient could be correlated with his or her prescriptions and

his or her prescription dispensing history, it would be possible for the public to become aware of the diseases or other medical concerns for which a patient is being treated by his or her physician. This knowledge could be used to embarrass or to humiliate a patient or to discriminate against him or her. Requiring the reporting of prescribing and dispensing information while protecting a patient's personal identifying information will facilitate efforts to maintain compliance with the state's drug laws and will facilitate the sharing of information between health care practitioners and pharmacists while maintaining and ensuring patient privacy. Additionally, exempting from disclosure the personal identifying information of practitioners will ensure that an individual will not be able to identify which practitioners prescribe the largest amount of a particular type of drug and to seek out those practitioners in order to increase the likelihood of obtaining a particular prescribed substance. Further, protecting personal identifying information of pharmacists and dispensers ensures that an individual will not be able to identify which pharmacists, pharmacies, or dispensing health care practitioners dispense the largest amount of a particular controlled substance and identify that pharmacy or dispensing health care practitioner as a potential target for a robbery or burglary. Thus, the Legislature finds that it is a public necessity to make confidential and exempt from public records requirements certain identification and location information of a patient or patient's agent, a health care practitioner, a dispenser, an employee of the practitioner who is acting on behalf of and at the direction of the practitioner, a pharmacist, or a pharmacy.

Section 3. This act shall take effect July 1, 2009, if CS for CS for CS for CS for SB 462, or similar legislation establishing an electronic system to monitor the prescribing and dispensing of controlled substances, is adopted in the same legislative session or an extension thereof and becomes law.

Approved by the Governor June 18, 2009.

Filed in Office Secretary of State June 18, 2009.



**DOH**

**Presentation**

PL2009 – 198  
Implementation of the  
**Prescription Drug Monitoring Program**  
&  
**Pain Clinic Registration**  
Florida Department of Health

House  
Health Regulation Policy Committee  
January 12, 2010

# Prescription Monitoring Program Plan Status

- **Establishment of the Program  
Implementation and Oversight Task Force**
  - Complete – first meeting held on December 17, 2009
- **Establishment of the Direct Support  
Organization**
  - Not complete

# Prescription Monitoring Program Plan Status

- **Rule Promulgation – rules specifying how to access the system, reporting, etc. (due by 10/1/2010)**
  - Chapter 64K, F.A.C. has been established.
  - Draft rule in process to set thresholds for patient advisory reports
  - Operational rules will be drafted when vendor for system is procured

# Prescription Monitoring Program Plan Status

- **Procuring the system in preparation for the December 1, 2010 implementation**
  - A Request for Information (RFI) was released.
  - Eight responses have been obtained from vendors as of October 30th.
  - Four vendors are currently operating a PMP for other states.
  - A Request for Proposal (competitive procurement) is scheduled to be released no later than April 1, 2010.

# Prescription Monitoring Program Plan Status

- **Funding to implement by December 1, 2010**
  - A federal Harold Rogers Implementation grant of \$400,000 has been awarded to DCF.
  - By February:
    - The grant will be transferred to DOH; and
    - Amended according to our spending needs

# DOH Funding Requirements for the PDMP

|                       | <u>Non-recurring</u> | <u>Recurring</u> |
|-----------------------|----------------------|------------------|
| • DOH Staff Positions | 25,560               | 243,234          |
| • Project Manager     | 112,667              |                  |
| • Rule-making         | 40,690               |                  |
| • Promotion           | 89,498               | 43,499           |
| • System Procurement  | <u>181,250</u>       | <u>193,750</u>   |
| <b>TOTALS</b>         | <b>\$449,665</b>     | <b>\$480,483</b> |

# Cost Estimates from RFI Responses

## **Eight Responses**

- Four from vendors who are operating/hosting systems for other states

## **Range of estimated cost to implement a system for Florida by Dec. 1, 2010:**

- \$35,000 to \$225,000

## **Range of estimated annual operational costs after implementation:**

- \$175,000 to \$400,000



# Prescription Drug Monitoring Systems in Other States

- 37 other states have operating systems; five states (including Florida) are under development
- 22 of the 37 states have non-state, vendor hosted systems

# Prescription Drug Monitoring Systems in Other States

- **Interstate Exchange of Prescription Data**

- The Alliance of States with Prescription Monitoring Programs (ASPMP) is working a project with funds provided by the Bureau of Justice Assistance (BJA) enlisting states to participate in a hub-based interstate exchange of prescription data.
- Currently Ohio and Kentucky have exchanged data and are preparing to participate.

# Prescription Drug Monitoring Systems in Other States

- **NASPER**

- The National All Schedules Prescription Electronic Reporting Act of 2005 (NASPER) awarded grant money to 13 states in 2009.
- NASPER is administered by the Substance Abuse and Mental Health Services Administration (SAMHSA) of HHS to foster state-administered PDMPs.
- Only states whose PDMP statutes meet the requirements of NASPER can apply for and receive NASPER funding.

# Statutory Barriers to Florida Participation in NASPER

## 1. Interoperability

- NASPER: Must show a plan to exchange data with at least one other state PMP using NIEM XML standards
- FLORIDA: Requires change to s. 893.055(7) and s. 893.0551(3) to allow data sharing with other states and to establish standards

## 2. Data elements collected

- NASPER: Requires collection of the number of refills ordered and whether the drug was dispensed as a refill or as a first-time request
- FLORIDA: Reporting these elements not mandated; requires amendment to s. 893.055(3)

# Statutory Barriers to Florida Participation in NASPER

## **3. Information required for patient inquiry of the data**

- NASPER: Patient must submit a phone number and a copy of a government issued photo identification
- FLORIDA: Above items not required; amendment needed to s. 893.055(7)(c)4.

## **4. Background checks for program operation personnel**

- NASPER: The administrator and any other persons with access to the database must received a security clearance or background check.
- FLORIDA: Requires amendment to s. 893.055(7)(b)

# Statutory Barriers to Florida Participation in NASPER

## 5. Reporting time frame

- NASPER: Information must be reported from dispenser to the state not later than one week after dispensing
- FLORIDA: Reporting period is not more than 15 days; requires amendment to s.893.055(4)

## 6. Unsolicited reporting to practitioners and dispensers

- NASPER: PMP must establish a program to notify practitioners and dispensers of information that will help identify and prevent the unlawful diversion or misuse of controlled substances
- FLORIDA: Information from the PMP is sent to practitioners and dispensers only upon request; requires amendment to s 893.055(2)

# Statutory Barriers to Florida Participation in NASPER

## 7. Exclusions for reporters

- NASPER: Does not exclude patients in the health care system of the Dept. of Corrections
  - FLORIDA: Excludes patients in the health care system of the Dept. of Corrections; requires amendment to s.893.055(5)(c)
- 
- NASPER: Does not exclude reporting of dispensing to persons under 16
  - FLORIDA: Excludes reporting of dispensing to persons under 16; requires amendment to s. 893.055(5)(e)
- 
- NASPER: Excludes quantities prescribed for 48 hours or less
  - FLORIDA: Excludes quantities prescribed for 72 hours or less; requires amendment to s. 893.055(5)(f)

# Statutory Barriers to Florida Participation in NASPER

## 8. Authentication of data requesters

- NASPER: Requires practitioners/pharmacists to submit hard copy, written, signed, notarized requests in order to obtain data
- FLORIDA: Not mandated; requires language authorizing



# Pain Management Clinic Registration & Inspection Program

- **Developing Standards of Practice For MD and DO licensees practicing in Pain Management Clinics**
  - Develop DOH Rules | Fees | Application for Clinic Registration | Inspection
  - Educate licensees
  - Register clinics
  - BOM/BOOM Develop Rules
  - Conduct Inspections

# Pain Management Clinic Registration & Inspection Program

**STEP 1: Develop DOH business processes and conduct rulemaking on Registration, Fees, and Application Form**

- Business processes developed
- Rules developed, adopted and in effect
- Rules and application on-line
- \$150.00 one time registration fee
- \$1,5000 annual inspection fee, if not certified by a nationally accredited organization

# Pain Management Clinic Registration & Inspection Program

## **STEP 2: Educate licensees**

- E-mails
- FOMA and FMA Notification
- Letters to dispensing practitioners
- DOH Investigators visiting pain clinics with info sheet
- DOH Investigators visiting local occupational licensing offices with info
- Press Release
- Letters to all others not covered by the above

# Pain Management Clinic Registration & Inspection Program

## **STEP 3: Register clinics**

- 584 applications received by January 6, 2010
- 173 applications approved by January 6, 2010
- Remainder pending review/other action
- Status list of applicants on-line

# Pain Management Clinic Registration & Inspection Program

## Step 5: Conduct Inspections

- Inspections, paid for by the clinic, will be conducted annually
- Inspections will be to determine compliance with standards of practice developed by the BOM/BOOM
- It is planned that inspections will be conducted by a DOH inspector and practitioner/risk manager team.
- Inspections will commence after standards are developed

# Questions?

Diane Orcutt, Deputy Director  
Florida Department of Health  
Division of Medical Quality Assurance  
Enforcement  
(850) 245-4123  
Diane\_Orcutt@doh.state.fl.us

**Office of Drug  
Control  
Presentation**

A grayscale photograph of the Florida State Capitol building, showing its iconic dome and classical architecture, serving as a background for the top portion of the slide.

**Florida Office of Drug Control**  
**January 12, 2009**

**Prescription Drug Monitoring Program**  
**PL2009 – 198**  
**Implementation Status Plan**

**Florida House**  
**Health Regulation Policy Committee**

**“A Program to Improve Patient Quality of Care  
and Reduce Prescription Drug Diversion in Florida”**





# Responsibilities

- Statute: May establish Direct Support Organization (DSO)
- Statute: “Chair” the Implementation and Oversight Task Force (TF)
  - Implied task: Assist Governor’s Appointment Office with obtaining applicants for the TF and provide administrative support for the TF meetings
    - TF appointed; first meeting held December 17th
- Implied task: Assist Department of Health (DOH) with Implementation of database system



# Purpose of DSO

“Organized and operated to conduct programs and activities; raise funds; request and receive grants, gifts, and bequests of money; acquire, receive, hold, and invest, in its own name, securities, funds, objects of value, or other property, either real or personal; and make expenditures or provide funding to or for the direct or indirect benefit of the department in the furtherance of the prescription drug monitoring program.”

Note: Per statute state government shall cooperate with seeking federal grant funds, other non-state grant funds, gifts, donations, or other private moneys



# Direct Support Organization (DSO)

- Director of the Office of Drug Control shall appoint a board of directors for the direct-support organization
- Direct-support organization shall operate under written contract with the Office of Drug Control
- Director of the Office of Drug Control must approve all activities
- The minimum of five Directors required for the DSO board per the statute have been identified:
  - Jim Slattery: Chairman
  - David Bowen II: Vice-chairman
  - Rodman Steele: Treasurer
  - Sheriff Lamberti: Secretary
  - William Janes: Member



# Direct Support Organization (DSO)

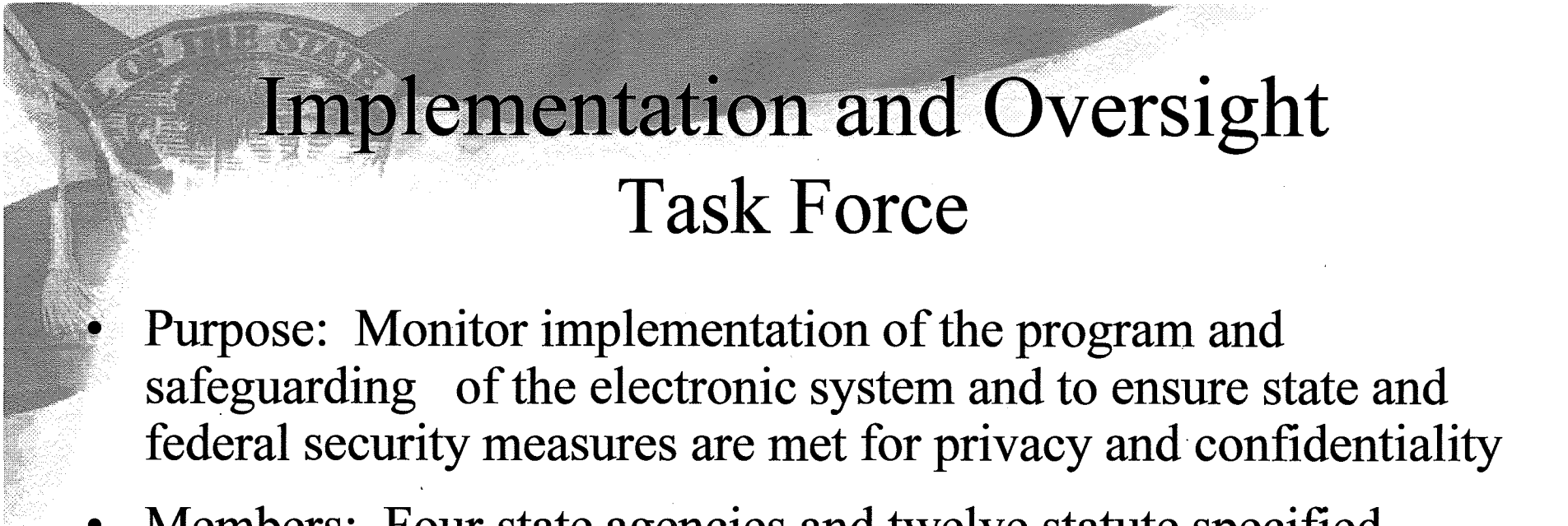
- Articles of Incorporation awaiting signatures
  - Signatures completed by January 8th
  - Articles of Incorporation
    - Submitted No Later Than 1-2 days after signatures obtained
    - Approval normally takes 1 – 2 weeks at Dept of State
- Contract and By-laws for the DSO
  - Submitted at first DSO meeting by the end of January
  - DSO operational by February



# Federal Grant Funding

- Harold Rogers PDMP grant was awarded by the federal Bureau of Justice Assistance (BJA)
  - DCF was awarded PDMP Implementation grant
    - \$400,000 grant; two years
    - Intent is to transfer to DOH for their use
    - Request to transfer goes through BJA; has to be approved by federal Assistant Attorney General
    - BJA has recommended approval; at US Comptroller for approval prior to being sent to Assistant AG for final approval

Note: The awarding of this grant met the statute requirement to have \$20,000 in non-state funding to begin rule-making



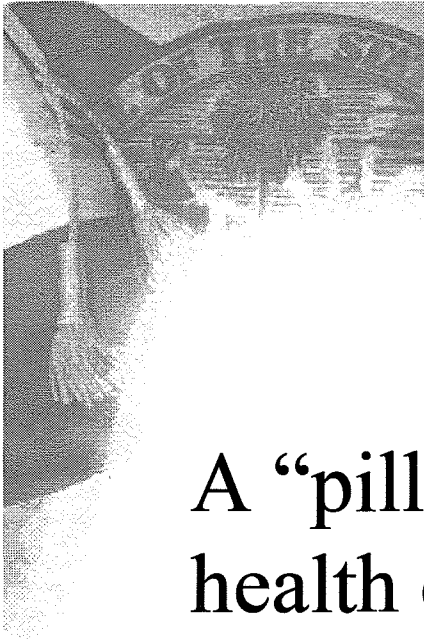
# Implementation and Oversight Task Force

- Purpose: Monitor implementation of the program and safeguarding of the electronic system and to ensure state and federal security measures are met for privacy and confidentiality
- Members: Four state agencies and twelve statute specified interdisciplinary members selected by the Governor
- Director of ODC “Chairs” the Task Force meeting
- December 17<sup>th</sup> was the first Task Force meeting; meets quarterly
  - Next meeting is scheduled for February 18<sup>th</sup>
- ODC provides Governor, President of Senate and Speaker of the House an annual Task Force report summarizing its work and providing recommendations based upon its Purpose

The top left corner of the slide features a portion of the Florida state flag, showing the words "FLORIDA STATE" and a palm tree emblem.

# Prescription Drug Update

- Most significant drug problem in Florida
- Six (6) die per day
- Pain clinics in South Florida



## Office of Drug Control's definition of a “pill mill

A “pill mill” is a doctor’s office, clinic, or health care facility that routinely conspires in the prescribing and dispensing of controlled substances outside the scope of the prevailing standards of medical practice in the community or violates the laws of the state of Florida regarding the prescribing or dispensing of controlled prescription drugs.



The top left corner of the slide features a grayscale, semi-transparent image of the Florida State Seal. The seal is partially visible, showing the words "FLORIDA STATE" and a central emblem with a sun, a palm tree, and a ship. The seal is set against a dark, curved background that resembles a banner or a draped cloth.

# Questions?

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[Bruce.Grant@MyFlorida.com](mailto:Bruce.Grant@MyFlorida.com)