229192

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/31/2009	.	
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The Committee on Governmental Oversight and Accountability (Jones) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

893.055 Prescription drug monitoring program.—

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

(a) "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

229192

nature or any legal duty on a prescriber, dispenser, pharmacy, or patient. 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 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 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.


229192

(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 reporting of prescribed controlled substances shall include a dispensing transaction with a dispenser pursuant to chapter 465 or through a dispensing transaction with a pharmacy that is not located in this state but who is otherwise subject to the jurisdiction of this state as to that dispensing transaction. The reporting of patient advisories only refers to reports to pharmacists and practitioners. Separate reports that have patient prescription history information 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 shall adopt rules as necessary concerning the reporting, accessing, evaluation, management, development, implementation, operation, and storage of information within the system, including rules for when patient advisory reports and patient information is provided to pharmacies, prescribers, and health care practitioners and rules for when health care regulatory boards, law enforcement agencies, and other persons or organizations authorized in this section and s. 893.0551 are provided patient prescription history information from the database unless provision of such information is otherwise described in this section. Such rules shall be developed with a reasonable-person standard for controlled prescription drug dispensers, prescribers, and patients. The department shall work with the professional health care licensure boards, such as the Board of Medicine and the Board of Pharmacy; other appropriate organizations, such as the Florida Pharmacy Association and the Florida 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 the reasonable-person standard for 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

229192

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 or insurance through a third party. This paragraph does not authorize the department to include individual credit card 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 and address of the pharmacy or other location from which the controlled substance was dispensed.

(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

229192

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) The following are exempt from this section when administering or dispensing a controlled substance:

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

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

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

(f) A pharmacist or a dispensing practitioner 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.


229192

(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 direct 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. 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,

229192

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's 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, as described in s. 893.0551(2)(c), during ongoing investigations as provided in s. 893.07 or during active investigations as defined in s. 119.011 regarding potential criminal activity, fraud, or theft regarding prescribed controlled substances. The database information is available only for criminal cases.

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


229192

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.

(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


229192

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 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


229192

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. Nonmaterial 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


229192

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 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

229192

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 subsections (2), (3), and (4). 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

229192

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, software, and personnel.

b. Conducting studies on the efficiency and effectiveness of the program.

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.

229192

(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.


229192

(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


229192

prescription drugs, taking advantage of advances in technology, reducing duplicative prescriptions and the overprescribing of prescription drugs, and reducing drug abuse. 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. 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 implementation of electronic prescribing by health care practitioners, health care facilities, and pharmacies under


229192

s. 408.061 and the electronic prescribing clearinghouse collaboration with the private sector 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.

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 11 members of the public to serve on the task force. Of these 11 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, board-certified, fellowship-trained physicians who have experience in pain management; 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


229192

prescription drug monitoring programs; one member must be a Florida-licensed pharmacist; 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.


229192

(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 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) and (5) are added to section 458.309, Florida Statutes, to read:

458.309 Rulemaking authority.—


229192

(4) Each privately owned pain-management clinic that employs a physician licensed under this chapter and who is primarily engaged in the treatment of pain by prescribing controlled substance medications must be registered with the department unless that clinic is licensed as a facility under chapter 395. Each clinic location shall be licensed 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 shall be responsible for registering the facility with the department. If the clinic is not licensed 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 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 board rules adopted pursuant to this subsection and subsection (5) unless the clinic is accredited by a nationally recognized accrediting agency approved by the board. The actual costs for registration and inspection or accreditation shall be paid by the physician seeking to register the clinic.

(5) The board 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 controlled substance medications. Such rules shall address, but need not be limited to, the following

229192

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;

(h) Inspections; and

(i) Data collection and reporting requirements.

A physician is primarily engaged in the treatment of pain by prescribing controlled substance medications if the majority of the patients seen on any day the facility is open are issued 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 disease or injury. It may or may not be associated with a pathologic disease.

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

459.005 Rulemaking authority.—

(3) Each privately owned pain-management clinic that employs a physician licensed under this chapter and who is primarily engaged in the treatment of pain by prescribing controlled substance medications must be registered with the department unless that clinic is licensed as a facility under chapter 395. Each clinic location shall be licensed 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 shall be responsible for registering the facility with the department. If the clinic is not licensed 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 board rules adopted pursuant to this subsection and subsection (4) unless the clinic is accredited by a nationally recognized accrediting agency approved by the board. The actual costs for registration and inspection or accreditation shall be paid by the physician seeking to register the clinic.

(4) The board 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 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;


229192

(f) Patient records;

(g) Training requirements for all facility health care practitioners;

(h) Inspections; and

(i) Data collection and reporting requirements.

A physician is primarily engaged in the treatment of pain by prescribing controlled substance medications if the majority of the patients seen on any day the facility is open are issued 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 disease or injury. It may or may not be associated with a pathologic disease.

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

========== T I T L E A M E N D M E N T ==========

And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

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, in conjunction with

specified organizations, to adopt by rule a reasonable-person standard 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 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 ongoing health care or an active 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


229192

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


229192

Administration to continue implementation 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; 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; 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 benzodiazepines, 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


229192

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 and

ongoing 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,