By the Committee on Health Regulation; and Senator Bogdanoff

588-03249-11 20111386c1

A bill to be entitled

An act relating to controlled substances; amending s. 400.9905, F.S.; redefining the terms "clinic" and "portable equipment provider" for purposes of the Health Care Clinic Act; amending s. 456.037, F.S.; conforming provisions to changes made by the act; amending s. 456.057, F.S.; authorizing the Department of Health to obtain patient records pursuant to a subpoena and without notification to the patient from a controlled-substance medical clinic under certain circumstances; amending s. 458.3265, F.S.; renaming pain-management clinics as "controlled-substance medical clinics"; prohibiting controlled-substance medical clinics from advertising services related to the dispensing of medication; revising the criteria requiring registration with the department as a controlled-substance medical clinic; conforming provisions to changes made by the act; revising the circumstances in which the department may revoke the certificate of registration for a controlled-substance medical clinic; providing an exception for revoking and suspending a certificate of registration for a controlled-substance medical clinic; revising the responsibilities of a physician who provides professional services in a controlled-substance medical clinic; deleting the requirement that the Board of Medicine adopt a rule establishing the maximum number of prescriptions that can be written for certain controlled substances within a specified

time; revising the rules setting forth the standards of practice that the board is required to adopt; deleting the provision that describes when a physician is primarily engaged in the treatment of pain; amending s. 458.327, F.S.; conforming provisions to changes made by the act; amending s. 458.331, F.S.; conforming provisions to changes made by the act; revising the acts that constitute grounds for disciplinary action for a licensee who serves as a designated physician of a controlled-substance medical clinic; amending s. 459.0137, F.S.; renaming pain-management clinics as "controlled-substance medical clinics"; prohibiting controlled-substance medical clinics from advertising services related to the dispensing of medication; revising the criteria requiring registration with the department as a controlled-substance medical clinic; conforming provisions to changes made by the act; revising the circumstances in which the department may revoke the certificate of registration for a controlled-substance medical clinic; providing an exception for revoking and suspending a certificate of registration for a controlled-substance medical clinic; revising the responsibilities of an osteopathic physician who provides professional services in a controlled-substance medical clinic; deleting the requirement that the Board of Osteopathic Medicine adopt a rule establishing the maximum number of prescriptions that can be written for certain controlled substances

within a specified time; revising the rules setting forth the standards of practice that the board is required to adopt; deleting the provision that describes when an osteopathic physician is primarily engaged in the treatment of pain; amending s. 459.015, F.S.; conforming provisions to changes made by the act; revising the acts that constitute grounds for disciplinary action for a licensee who serves as a designated osteopathic physician of a controlled-substance medical clinic; amending s. 465.0276, F.S.; deleting the provision that prohibits a dispensing practitioner from dispensing a specified amount of a controlled substance under certain circumstances; amending s. 893.055, F.S.; redefining the term "patient advisory report" as it relates to the prescription drug monitoring program; revising the date by which the department is required to establish a comprehensive electronic database system; revising the responsibilities of the dispenser and the prescriber with regard to the electronic database system; revising the circumstances in which the department is required to adopt rules regarding reporting, accessing the database, evaluation, management, development, implementation, operation, security, and storage of information within the electronic database system; deleting the Office of Drug Control as one of the organizations that the department is required to work with in developing rules for the prescription drug monitoring program;

requiring that a dispensed controlled substance be reported to the department within a specified number of hours; authorizing law enforcement agencies to request certain confidential and exempt information from the electronic database system upon determination that probable cause exists that a crime is being committed and issuance of a search warrant; providing that all costs incurred by the department in administering the prescription drug monitoring program be funded through federal grants, dispensing registration fees, or private funding applied for or received by the state; requiring the department rather than the Office of Drug Control to establish a direct-support organization; requiring the State Surgeon General to appoint the board of directors for the direct-support organization; requiring the direct-support organization to operate under written contract with the department; revising requirements for the contract; requiring the activities of the direct-support organization to be consistent with the goals and mission of the department; authorizing the department to permit use of certain services, property, and facilities of the department by the direct-support organization; prohibiting the department from permitting the use of any administrative services, property, or facilities of the state by the direct-support organization under certain conditions; requiring the department rather than the Office of Drug Control to study the

feasibility of enhancing the prescription drug monitoring program for specified purposes; requiring the direct-support organization to provide funding for the department rather than the Office of Drug Control to conduct training in using the prescription drug monitoring program; revising the date in which the department must adopt rules; amending s. 893.0551, F.S.; authorizing a law enforcement agency to disclose certain confidential and exempt information received from the department to a criminal justice agency pursuant to a search warrant; providing an effective date.

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

Section 1. Subsections (4) and (7) of section 400.9905, Florida Statutes, are amended to read:

400.9905 Definitions.—

(4) "Clinic" means an entity at which health care services are provided to individuals and which tenders charges for reimbursement or payment for such services, including a mobile clinic and a portable equipment provider. For purposes of this part, the term does not include and the licensure requirements of this part do not apply to:

(a) Entities licensed or registered by the state under chapter 395; or entities licensed or registered by the state and providing only health care services within the scope of services authorized under their respective licenses granted under ss. 383.30-383.335, chapter 390, chapter 394, chapter 397, this

chapter except part X, chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, part I of chapter 483, chapter 484, or chapter 651; end-stage renal disease providers authorized under 42 C.F.R. part 405, subpart U; or providers certified under 42 C.F.R. part 485, subpart B or subpart H; or any entity that provides neonatal or pediatric hospital-based health care services or other health care services by licensed practitioners solely within a hospital licensed under chapter 395.

(b) Entities that own, directly or indirectly, entities licensed or registered by the state pursuant to chapter 395; or entities that own, directly or indirectly, entities licensed or registered by the state and providing only health care services within the scope of services authorized pursuant to their respective licenses granted under ss. 383.30-383.335, chapter 390, chapter 394, chapter 397, this chapter except part X, chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, part I of chapter 483, chapter 484, chapter 651; end-stage renal disease providers authorized under 42 C.F.R. part 405, subpart U; or providers certified under 42 C.F.R. part 485, subpart B or subpart H; or any entity that provides neonatal or pediatric hospital-based health care services by licensed practitioners solely within a hospital licensed under chapter 395.

(c) Entities that are owned, directly or indirectly, by an entity licensed or registered by the state pursuant to chapter 395; or entities that are owned, directly or indirectly, by an entity licensed or registered by the state and providing only health care services within the scope of services authorized pursuant to their respective licenses granted under ss. 383.30-383.335, chapter 390, chapter 394, chapter 397, this chapter

except part X, chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, part I of chapter 483, chapter 484, or chapter 651; end-stage renal disease providers authorized under 42 C.F.R. part 405, subpart U; or providers certified under 42 C.F.R. part 485, subpart B or subpart H; or any entity that provides neonatal or pediatric hospital-based health care services by licensed practitioners solely within a hospital under chapter 395.

(d) Entities that are under common ownership, directly or indirectly, with an entity licensed or registered by the state pursuant to chapter 395; or entities that are under common ownership, directly or indirectly, with an entity licensed or registered by the state and providing only health care services within the scope of services authorized pursuant to their respective licenses granted under ss. 383.30-383.335, chapter 390, chapter 394, chapter 397, this chapter except part X, chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, part I of chapter 483, chapter 484, or chapter 651; end-stage renal disease providers authorized under 42 C.F.R. part 405, subpart U; or providers certified under 42 C.F.R. part 485, subpart B or subpart H; or any entity that provides neonatal or pediatric hospital-based health care services by licensed practitioners solely within a hospital licensed under chapter 395.

(e) An entity that is exempt from federal taxation under 26 U.S.C. s. 501(c)(3) or (4), an employee stock ownership plan under 26 U.S.C. s. 409 that has a board of trustees not less than two-thirds of which are Florida-licensed health care practitioners and provides only physical therapy services under

physician orders, any community college or university clinic, and any entity owned or operated by the federal or state government, including agencies, subdivisions, or municipalities thereof.

(f) A sole proprietorship, group practice, partnership, or corporation that provides health care services by physicians covered by s. 627.419, that is directly supervised by one or more of such physicians, and that is wholly owned by one or more of those physicians or by a physician and the spouse, parent, child, or sibling of that physician.

(g) A sole proprietorship, group practice, partnership, or corporation that provides health care services by licensed health care practitioners under chapter 457, chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, chapter 466, chapter 467, chapter 480, chapter 484, chapter 486, chapter 490, chapter 491, or part I, part III, part X, part XIII, or part XIV of chapter 468, or s. 464.012, which are wholly owned by one or more licensed health care practitioners, or the licensed health care practitioners set forth in this paragraph and the spouse, parent, child, or sibling of a licensed health care practitioner, so long as one of the owners who is a licensed health care practitioner is supervising the business activities and is legally responsible for the entity's compliance with all federal and state laws. However, a health care practitioner may not supervise services beyond the scope of the practitioner's license, except that, for the purposes of this part, a clinic owned by a licensee in s. 456.053(3)(b) that provides only services authorized pursuant to s. 456.053(3)(b) may be supervised by a licensee specified in s. 456.053(3)(b).

(h) Clinical facilities affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows.

(i) Entities that provide only oncology or radiation therapy services by physicians licensed under chapter 458 or chapter 459 or entities that provide oncology or radiation therapy services by physicians licensed under chapter 458 or chapter 459 which are owned by a corporation whose shares are publicly traded on a recognized stock exchange.

(j) Clinical facilities affiliated with a college of chiropractic accredited by the Council on Chiropractic Education at which training is provided for chiropractic students.

(k) Entities that provide licensed practitioners to staff emergency departments or to deliver anesthesia services in facilities licensed under chapter 395 and that derive at least 90 percent of their gross annual revenues from the provision of such services. Entities claiming an exemption from licensure under this paragraph must provide documentation demonstrating compliance.

(l) Orthotic or prosthetic clinical facilities that are a publicly traded corporation or that are wholly owned, directly or indirectly, by a publicly traded corporation. As used in this paragraph, a publicly traded corporation is a corporation that issues securities traded on an exchange registered with the United States Securities and Exchange Commission as a national securities exchange.

(7) "Portable equipment provider" means an entity that contracts with or employs persons to provide portable equipment to multiple locations performing treatment or diagnostic testing

of individuals~~, that bills third-party payors for those services,~~ and that otherwise meets the definition of a clinic in subsection (4).

Section 2. Subsection (5) of section 456.037, Florida Statutes, is amended to read:

456.037 Business establishments; requirements for active status licenses; delinquency; discipline; applicability.—

(5) This section applies to any business establishment registered, permitted, or licensed by the department to do business. Business establishments include, but are not limited to, dental laboratories, electrology facilities, massage establishments, pharmacies, and controlled-substance medical ~~pain-management~~ clinics required to be registered under s. 458.3265 or s. 459.0137.

Section 3. Paragraph (a) of subsection (9) of section 456.057, Florida Statutes, is amended to read:

456.057 Ownership and control of patient records; report or copies of records to be furnished.—

(9)(a)1. The department may obtain patient records pursuant to a subpoena without written authorization from the patient if the department and the probable cause panel of the appropriate board, if any, find reasonable cause to believe that a health care practitioner has excessively or inappropriately prescribed any controlled substance specified in chapter 893 in violation of this chapter or any professional practice act or that a health care practitioner has practiced his or her profession below that level of care, skill, and treatment required as defined by this chapter or any professional practice act and also find that appropriate, reasonable attempts were made to

obtain a patient release. Notwithstanding the foregoing, the department need not attempt to obtain a patient release when investigating an offense involving the inappropriate prescribing, overprescribing, or diversion of controlled substances and the offense involves a controlled-substance medical ~~pain-management~~ clinic. The department may obtain patient records pursuant to a subpoena and without patient authorization or notification to the patient ~~subpoena~~ from any controlled-substance medical ~~pain-management~~ clinic required to be licensed if the department has probable cause to believe that a violation of any provision of s. 458.3265 or s. 459.0137 is occurring or has occurred and reasonably believes that obtaining such patient authorization is not feasible due to the volume of the dispensing and prescribing activity involving controlled substances and that obtaining patient authorization ~~or the issuance of a subpoena~~ would jeopardize the investigation.

2. The department may obtain patient records and insurance information pursuant to a subpoena without written authorization from the patient if the department and the probable cause panel of the appropriate board, if any, find reasonable cause to believe that a health care practitioner has provided inadequate medical care based on termination of insurance and also find that appropriate, reasonable attempts were made to obtain a patient release.

3. The department may obtain patient records, billing records, insurance information, provider contracts, and all attachments thereto pursuant to a subpoena without written authorization from the patient if the department and probable cause panel of the appropriate board, if any, find reasonable

cause to believe that a health care practitioner has submitted a claim, statement, or bill using a billing code that would result in payment greater in amount than would be paid using a billing code that accurately describes the services performed, requested payment for services that were not performed by that health care practitioner, used information derived from a written report of an automobile accident generated pursuant to chapter 316 to solicit or obtain patients personally or through an agent regardless of whether the information is derived directly from the report or a summary of that report or from another person, solicited patients fraudulently, received a kickback as defined in s. 456.054, violated the patient brokering provisions of s. 817.505, or presented or caused to be presented a false or fraudulent insurance claim within the meaning of s. 817.234(1)(a), and also find that, within the meaning of s. 817.234(1)(a), patient authorization cannot be obtained because the patient cannot be located or is deceased, incapacitated, or suspected of being a participant in the fraud or scheme, and if the subpoena is issued for specific and relevant records.

4. Notwithstanding subparagraphs 1.-3., when the department investigates a professional liability claim or undertakes action pursuant to s. 456.049 or s. 627.912, the department may obtain patient records pursuant to a subpoena without written authorization from the patient if the patient refuses to cooperate or if the department attempts to obtain a patient release and the failure to obtain the patient records would be detrimental to the investigation.

Section 4. Section 458.3265, Florida Statutes, is amended to read:

458.3265 Controlled-substance medical ~~pain-management~~ clinics.—

(1) REGISTRATION.—

(a) A ~~All~~ privately owned controlled-substance medical clinic, facility, or office ~~pain-management clinics, facilities, or offices~~, hereinafter referred to as a "clinic," ~~"clinics,"~~ may not advertise services related to the dispensing of medication. A controlled-substance medical clinic is a facility that employs a physician who prescribes on any given day more than 25 prescriptions of Schedule II or Schedule III controlled substance medications, or a combination thereof, ~~which advertise in any medium for any type of pain-management services,~~ or employs ~~employ~~ a physician who is ~~primarily~~ engaged in ~~the treatment of pain by prescribing or~~ dispensing controlled substance medications. Such a clinic~~,~~ must register with the department unless:

1. That clinic is licensed as a facility pursuant to chapter 395;

2. The majority of the physicians who provide services in the clinic primarily provide interventional pain-management procedures or other surgical services;

3. The clinic is owned by a publicly held corporation whose shares are traded on a national exchange or on the over-the-counter market and whose total assets at the end of the corporation's most recent fiscal quarter exceeded $50 million;

4. The clinic is affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows; or

~~5. The clinic does not prescribe or dispense controlled~~

~~substances for the treatment of pain; or~~

5.~~6.~~ The clinic is owned by a corporate entity exempt from federal taxation under 26 U.S.C. s. 501(c)(3).

(b) Each clinic location shall be registered separately regardless of whether the clinic is operated under the same business name or management as another clinic.

(c) As a part of registration, a clinic must designate a physician who is responsible for complying with all requirements related to registration and operation of the clinic in compliance with this section. Within 10 days after termination of a designated physician, the clinic must notify the department of the identity of another designated physician for that clinic. The designated physician shall have a full, active, and unencumbered license under this chapter or chapter 459 and shall practice at the clinic location for which the physician has assumed responsibility. Failing to have a licensed designated physician practicing at the location of the registered clinic may be the basis for a summary suspension of the clinic registration certificate as described in s. 456.073(8) for a license or s. 120.60(6).

(d) The department shall deny registration to any clinic that is not fully owned by a physician licensed under this chapter or chapter 459 or a group of physicians, each of whom is licensed under this chapter or chapter 459; or that is not a health care clinic licensed under part X of chapter 400.

(e) The department shall deny registration to any controlled-substance medical ~~pain-management~~ clinic owned by or with any contractual or employment relationship with a physician:

1. Whose Drug Enforcement Administration number has ever been revoked.

2. Whose application for a license to prescribe, dispense, or administer a controlled substance has been denied by any jurisdiction.

3. Who has been convicted of or pleaded guilty or nolo contendere to, regardless of adjudication, an offense that constitutes a felony for receipt of illicit and diverted drugs, including a controlled substance listed in Schedule I, Schedule II, Schedule III, Schedule IV, or Schedule V of s. 893.03, in this state, any other state, or the United States.

(f) If the department finds probable cause that a controlled-substance medical ~~pain-management~~ clinic does not meet the requirement of paragraph (d) or is owned, directly or indirectly, by a person meeting any criteria listed in paragraph (e), the department shall revoke the certificate of registration previously issued by the department. As determined by rule, the department may grant an exemption to denying a registration or revoking a previously issued registration if more than 10 years have elapsed since adjudication. As used in this subsection, the term "convicted" includes an adjudication of guilt following a plea of guilty or nolo contendere or the forfeiture of a bond when charged with a crime.

(g) The department may revoke the clinic's certificate of registration and prohibit all physicians associated with that controlled-substance medical ~~pain-management~~ clinic from practicing at that clinic location based upon an annual inspection and evaluation of the factors described in subsection (3) and upon a final determination by the probable cause panel

of the appropriate board that any physician associated with that controlled-substance medical clinic knew or should have known of any violations of the factors described in subsection (3).

(h)1. If the registration of a controlled-substance medical ~~pain-management~~ clinic is revoked or suspended, the designated physician of the controlled-substance medical ~~pain-management~~ clinic, the owner or lessor of the controlled-substance medical ~~pain-management~~ clinic property, the manager, and the proprietor shall cease to operate the facility as a controlled-substance medical ~~pain-management~~ clinic as of the effective date of the suspension or revocation.

2. Notwithstanding subparagraph 1., the clinic's registration shall not be revoked or suspended if the clinic, within 24 hours after notification of suspension or revocation, appoints another designated physician who has a full, active, and unencumbered license under this chapter or chapter 459 to operate a controlled-substance medical clinic.

(i) If a controlled-substance medical ~~pain-management~~ clinic registration is revoked or suspended, the designated physician of the controlled-substance medical ~~pain-management~~ clinic, the owner or lessor of the clinic property, the manager, or the proprietor is responsible for removing all signs and symbols identifying the premises as a controlled-substance medical ~~pain-management~~ clinic.

(j) Upon the effective date of the suspension or revocation, the designated physician of the controlled-substance medical ~~pain-management~~ clinic shall advise the department of the disposition of the medicinal drugs located on the premises. The disposition is subject to the supervision and approval of

the department. Medicinal drugs that are purchased or held by a controlled-substance medical ~~pain-management~~ clinic that is not registered may be deemed adulterated pursuant to s. 499.006.

(k) If the clinic's registration is revoked, any person named in the registration documents of the controlled-substance medical ~~pain-management~~ clinic, including persons owning or operating the controlled-substance medical ~~pain-management~~ clinic, may not, as an individual or as a part of a group, apply to operate a controlled-substance medical ~~pain-management~~ clinic for 5 years after the date the registration is revoked upon a finding of probable cause, and an opportunity to be heard, that the persons operating such clinic knew or should have known of the violations causing such revocation.

(l) The period of suspension for the registration of a controlled-substance medical ~~pain-management~~ clinic shall be prescribed by the department, but may not exceed 1 year.

(m) A change of ownership of a registered controlled-substance medical ~~pain-management~~ clinic requires submission of a new registration application.

(2) PHYSICIAN RESPONSIBILITIES.—These responsibilities apply to any physician who provides professional services in a controlled-substance medical ~~pain-management~~ clinic that is required to be registered in subsection (1).

(a) A physician may not practice medicine in a controlled-substance medical ~~pain-management~~ clinic, as described in subsection (4), if~~:~~

~~1.~~ the controlled-substance medical ~~pain-management~~ clinic is not registered with the department as required by this section.~~; or~~

~~2. Effective July 1, 2012, the physician has not successfully completed a pain-medicine fellowship that is accredited by the Accreditation Council for Graduate Medical Education or a pain-medicine residency that is accredited by the Accreditation Council for Graduate Medical Education or, prior to July 1, 2012, does not comply with rules adopted by the board.~~

~~Any physician who qualifies to practice medicine in a pain-management clinic pursuant to rules adopted by the Board of Medicine as of July 1, 2012, may continue to practice medicine in a pain-management clinic as long as the physician continues to meet the qualifications set forth in the board rules. A physician who violates this paragraph is subject to disciplinary action by his or her appropriate medical regulatory board.~~

(b) A person may not dispense any medication, including a controlled substance, on the premises of a registered controlled-substance medical ~~pain-management~~ clinic unless he or she is a physician licensed under this chapter or chapter 459.

(c) A physician, advanced registered nurse practitioner, or a physician assistant must perform an appropriate medical ~~a physical~~ examination of a patient on the same day that the physician ~~he or she~~ dispenses or prescribes a controlled substance to a patient at a controlled-substance medical ~~pain-management~~ clinic. A ~~If the~~ physician may not dispense ~~prescribes or dispenses~~ more than a 30-day supply ~~72-hour dose~~ of controlled substances to any patient ~~for the treatment of chronic nonmalignant pain, the physician must document in the patient's record the reason for prescribing or dispensing that~~

~~quantity~~.

(d) A physician authorized to prescribe controlled substances who practices at a controlled-substance medical ~~pain-management~~ clinic is responsible for maintaining the control and security of his or her prescription blanks and any other method used for prescribing controlled substance pain medication. The physician shall comply with the requirements for counterfeit-resistant prescription blanks in s. 893.065 and the rules adopted pursuant to that section. The physician shall notify, in writing, the department within 24 hours after discovering ~~following~~ any theft or loss of a prescription blank or breach of any other method for prescribing controlled substances ~~pain medication~~.

(e) The designated physician of a controlled-substance medical ~~pain-management~~ clinic shall notify the applicable board in writing of the date of termination of employment within 10 days after terminating his or her employment with a controlled-substance medical ~~pain-management~~ clinic that is required to be registered under subsection (1).

(3) INSPECTION.—

(a) The department shall inspect the controlled-substance medical ~~pain-management~~ clinic annually, including a review of the patient records, to ensure that it complies with this section and the rules of the Board of Medicine adopted pursuant to subsection (4) unless the clinic is accredited by a nationally recognized accrediting agency approved by the Board of Medicine.

(b) During an onsite inspection, the department shall make a reasonable attempt to discuss each violation with the owner or

designated physician of the controlled-substance medical ~~pain-management~~ clinic before issuing a formal written notification.

(c) Any action taken to correct a violation shall be documented in writing by the owner or designated physician of the controlled-substance medical ~~pain-management~~ clinic and verified by followup visits by departmental personnel.

(4) RULEMAKING.—

(a) The department shall adopt rules necessary to administer the registration and inspection of controlled-substance medical ~~pain-management~~ clinics which establish the specific requirements, procedures, forms, and fees.

(b) The department shall adopt a rule defining what constitutes practice by a designated physician at the clinic location for which the physician has assumed responsibility, as set forth in subsection (1). When adopting the rule, the department shall consider the number of clinic employees, the location of the controlled-substance medical ~~pain-management~~ clinic, the clinic's hours of operation, and the amount of controlled substances being prescribed, dispensed, or administered at the controlled-substance medical ~~pain-management~~ clinic.

~~(c) The Board of Medicine shall adopt a rule establishing the maximum number of prescriptions for Schedule II or Schedule III controlled substances or the controlled substance Alprazolam which may be written at any one registered pain-management clinic during any 24-hour period.~~

(c) ~~(d)~~ The Board of Medicine shall adopt rules setting forth standards of practice for physicians practicing in privately owned controlled-substance medical ~~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:

1. Facility operations;

2. Physical operations;

3. Infection control requirements;

4. Health and safety requirements;

5. Quality assurance requirements;

6. Patient records;

~~7. Training requirements for all facility health care practitioners who are not regulated by another board;~~

7.~~8.~~ Inspections; and

8.~~9.~~ 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) PENALTIES; ENFORCEMENT.—

(a) The department may impose an administrative fine on the clinic of up to $5,000 per violation for violating the requirements of this section; chapter 499, the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug Abuse Prevention and Control Act; chapter 893, the Florida

Comprehensive Drug Abuse Prevention and Control Act; or the rules of the department. In determining whether a penalty is to be imposed, and in fixing the amount of the fine, the department shall consider the following factors:

1. The gravity of the violation, including the probability that death or serious physical or emotional harm to a patient has resulted, or could have resulted, from the controlled-substance medical ~~pain-management~~ clinic's actions or the actions of the physician, the severity of the action or potential harm, and the extent to which the provisions of the applicable laws or rules were violated.

2. What actions, if any, the owner or designated physician took to correct the violations.

3. Whether there were any previous violations at the controlled-substance medical ~~pain-management~~ clinic.

4. The financial benefits that the controlled-substance medical ~~pain-management~~ clinic derived from committing or continuing to commit the violation.

(b) Each day a violation continues after the date fixed for termination of the violation as ordered by the department constitutes an additional, separate, and distinct violation.

(c) The department may impose a fine and, in the case of an owner-operated controlled-substance medical ~~pain-management~~ clinic, revoke or deny a controlled-substance medical ~~pain-management~~ clinic's registration, if the clinic's designated physician knowingly and intentionally misrepresents actions taken to correct a violation.

(d) An owner or designated physician of a controlled-substance medical ~~pain-management~~ clinic who concurrently

operates an unregistered controlled-substance medical ~~pain-management~~ clinic is subject to an administrative fine of $5,000 per day.

(e) If the owner of a controlled-substance medical ~~pain-management~~ clinic that requires registration fails to apply to register the clinic upon a change of ownership and operates the clinic under the new ownership, the owner is subject to a fine of $5,000.

Section 5. Paragraphs (a) and (e) of subsection (1) and paragraph (f) of subsection (2) of section 458.327, Florida Statutes, are amended to read:

458.327 Penalty for violations.—

(1) Each of the following acts constitutes a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084:

(a) The practice of medicine or an attempt to practice medicine without a license to practice in this state ~~Florida~~.

(e) Knowingly operating, owning, or managing a nonregistered controlled-substance medical ~~pain-management~~ clinic that is required to be registered with the Department of Health pursuant to s. 458.3265(1).

(2) Each of the following acts constitutes a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083:

(f) Knowingly prescribing or dispensing, or causing to be prescribed or dispensed, controlled substances in a nonregistered controlled-substance medical ~~pain-management~~ clinic that is required to be registered with the Department of Health pursuant to s. 458.3265(1).

Section 6. Paragraphs (oo) and (pp) of subsection (1) of section 458.331, Florida Statutes, are amended to read:

458.331 Grounds for disciplinary action; action by the board and department.—

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

(oo) Applicable to a licensee who serves as the designated physician of a controlled-substance medical ~~pain-management~~ clinic as defined in s. 458.3265 or s. 459.0137:

1. Registering a controlled-substance medical ~~pain-management~~ clinic through misrepresentation or fraud;

2. Procuring, or attempting to procure, the registration of a controlled-substance medical ~~pain-management~~ clinic for any other person by making or causing to be made, any false representation;

3. Failing to comply with any requirement of chapter 499, the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Drug Abuse Prevention and Control Act; or chapter 893, the Florida Comprehensive Drug Abuse Prevention and Control Act;

4. Being convicted or found guilty of, regardless of adjudication to, a felony or any other crime involving moral turpitude, fraud, dishonesty, or deceit in any jurisdiction of the courts of this state, of any other state, or of the United States;

~~5. Being convicted of, or disciplined by a regulatory agency of the Federal Government or a regulatory agency of another state for, any offense that would constitute a violation of this chapter;~~

5.~~6.~~ Being convicted of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction of the courts of this state, of any other state, or of the United States which relates to the practice of, or the ability to practice, a licensed health care profession;

6.~~7.~~ Being convicted of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction of the courts of this state, of any other state, or of the United States which relates to health care fraud;

7.~~8.~~ Dispensing any medicinal drug based upon a communication that purports to be a prescription as defined in s. 465.003(14) or s. 893.02 if the dispensing practitioner knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship; or

8.~~9.~~ Failing to timely notify the board of the date of his or her termination from a controlled-substance medical ~~pain-management~~ clinic as required by s. 458.3265(2).

(pp) Failing to timely notify the department of the theft of prescription blanks from a controlled-substance medical ~~pain-management~~ clinic or a breach of other methods for prescribing within 24 hours as required by s. 458.3265(2).

Section 7. Section 459.0137, Florida Statutes, is amended to read:

459.0137 Controlled-substance medical ~~pain-management~~ clinics.—

(1) REGISTRATION.—

(a) A ~~All~~ privately owned controlled-substance medical clinic, facility, or office ~~pain-management clinics, facilities, or offices~~, hereinafter referred to as a "clinic," ~~"clinics,"~~

may not advertise services related to the dispensing of medication. A controlled-substance medical clinic is a facility that employs an osteopathic physician who prescribes on any given day more than 25 prescriptions of Schedule II or Schedule III controlled substance medications, or a combination thereof, ~~which advertise in any medium for any type of pain-management services~~, or employs ~~employ~~ an osteopathic physician who is ~~primarily~~ engaged in ~~the treatment of pain by prescribing or~~ dispensing controlled substance medications.~~,~~ Such clinic must register with the department unless:

1. That clinic is licensed as a facility pursuant to chapter 395;

2. The majority of the physicians who provide services in the clinic primarily provide surgical services;

3. The clinic is owned by a publicly held corporation whose shares are traded on a national exchange or on the over-the-counter market and whose total assets at the end of the corporation's most recent fiscal quarter exceeded $50 million;

4. The clinic is affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows; or

~~5. The clinic does not prescribe or dispense controlled substances for the treatment of pain; or~~

5.~~6.~~ The clinic is owned by a corporate entity exempt from federal taxation under 26 U.S.C. s. 501(c)(3).

(b) Each clinic location shall be registered separately regardless of whether the clinic is operated under the same business name or management as another clinic.

(c) As a part of registration, a clinic must designate an

osteopathic, dispensing physician who is responsible for complying with all requirements related to registration and operation of the clinic in compliance with this section. Within 10 days after termination of a designated osteopathic physician, the clinic must notify the department of the identity of another designated physician for that clinic. The designated physician shall have a full, active, and unencumbered license under chapter 458 or this chapter and shall practice at the clinic location for which the physician has assumed responsibility. Failing to have a licensed designated osteopathic physician practicing at the location of the registered clinic may be the basis for a summary suspension of the clinic registration certificate as described in s. 456.073(8) for a license or s. 120.60(6).

(d) The department shall deny registration to any clinic that is not fully owned by a physician licensed under chapter 458 or this chapter or a group of physicians, each of whom is licensed under chapter 458 or this chapter; or that is not a health care clinic licensed under part X of chapter 400.

(e) The department shall deny registration to any controlled-substance medical ~~pain-management~~ clinic owned by or with any contractual or employment relationship with a physician:

1. Whose Drug Enforcement Administration number has ever been revoked.

2. Whose application for a license to prescribe, dispense, or administer a controlled substance has been denied by any jurisdiction.

3. Who has been convicted of or pleaded guilty or nolo

contendere to, regardless of adjudication, an offense that constitutes a felony for receipt of illicit and diverted drugs, including a controlled substance listed in Schedule I, Schedule II, Schedule III, Schedule IV, or Schedule V of s. 893.03, in this state, any other state, or the United States.

(f) If the department finds upon a hearing by the probable cause panel of the appropriate medical board that a controlled-substance medical ~~pain-management~~ clinic does not meet the requirement of paragraph (d) or is owned, directly or indirectly, by a person meeting any criteria listed in paragraph (e), the department shall revoke the certificate of registration previously issued by the department. As determined by rule, the department may grant an exemption to denying a registration or revoking a previously issued registration if more than 10 years have elapsed since adjudication. As used in this subsection, the term "convicted" includes an adjudication of guilt following a plea of guilty or nolo contendere or the forfeiture of a bond when charged with a crime.

(g) The department may revoke the clinic's certificate of registration and prohibit all physicians associated with that controlled-substance medical ~~pain-management~~ clinic from practicing at that clinic location based upon an annual inspection and evaluation of the factors described in subsection (3) and upon a final determination by the probable cause panel of the appropriate medical board that any physician associated with that controlled-substance medical clinic knew or should have known of any violations of the factors described in subsection (3).

(h)1. If the registration of a controlled-substance medical

~~pain-management~~ clinic is revoked or suspended, the designated physician of the controlled-substance medical ~~pain-management~~ clinic, the owner or lessor of the controlled-substance medical ~~pain-management~~ clinic property, the manager, and the proprietor shall cease to operate the facility as a controlled-substance medical ~~pain-management~~ clinic as of the effective date of the suspension or revocation.

2. Notwithstanding subparagraph 1., the clinic's registration shall not be revoked or suspended if the clinic, within 24 hours after notification of suspension or revocation, appoints another designated physician who has a full, active, and unencumbered license under this chapter or chapter 458 to operate a controlled-substance medical clinic.

(i) If a controlled-substance medical ~~pain-management~~ clinic registration is revoked or suspended, the designated physician of the controlled-substance medical ~~pain-management~~ clinic, the owner or lessor of the clinic property, the manager, or the proprietor is responsible for removing all signs and symbols identifying the premises as a controlled-substance medical ~~pain-management~~ clinic.

(j) Upon the effective date of the suspension or revocation, the designated physician of the controlled-substance medical ~~pain-management~~ clinic shall advise the department of the disposition of the medicinal drugs located on the premises. The disposition is subject to the supervision and approval of the department. Medicinal drugs that are purchased or held by a controlled-substance medical ~~pain-management~~ clinic that is not registered may be deemed adulterated pursuant to s. 499.006.

(k) If the clinic's registration is revoked, any person

named in the registration documents of the controlled-substance medical ~~pain-management~~ clinic, including persons owning or operating the controlled-substance medical ~~pain-management~~ clinic, may not, as an individual or as a part of a group, make application for a permit to operate a controlled-substance medical ~~pain-management~~ clinic for 5 years after the date the registration is revoked upon a finding by the probable cause panel, and an opportunity to be heard, the persons operating such clinic knew or should have known of violations causing such revocation.

(l) The period of suspension for the registration of a controlled-substance medical ~~pain-management~~ clinic shall be prescribed by the department, but may not exceed 1 year.

(m) A change of ownership of a registered controlled-substance medical ~~pain-management~~ clinic requires submission of a new registration application.

(2) PHYSICIAN RESPONSIBILITIES.—These responsibilities apply to any osteopathic physician who provides professional services in a controlled-substance medical ~~pain-management~~ clinic that is required to be registered in subsection (1).

(a) An osteopathic physician may not practice medicine in a controlled-substance medical ~~pain-management~~ clinic, as described in subsection (4), if~~:~~

~~1.~~ the controlled-substance medical ~~pain-management~~ clinic is not registered with the department as required by this section.~~; or~~

~~2. Effective July 1, 2012, the physician has not successfully completed a pain-medicine fellowship that is accredited by the Accreditation Council for Graduate Medical~~

~~Education or the American Osteopathic Association or a pain-medicine residency that is accredited by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association or, prior to July 1, 2012, does not comply with rules adopted by the board.~~

~~Any physician who qualifies to practice medicine in a pain-management clinic pursuant to rules adopted by the Board of Osteopathic Medicine as of July 1, 2012, may continue to practice medicine in a pain-management clinic as long as the physician continues to meet the qualifications set forth in the board rules. An osteopathic physician who violates this paragraph is subject to disciplinary action by his or her appropriate medical regulatory board.~~

(b) A person may not dispense any medication, including a controlled substance, on the premises of a registered controlled-substance medical ~~pain-management~~ clinic unless he or she is a physician licensed under this chapter or chapter 458.

(c) An osteopathic physician, an advanced registered nurse practitioner, or a physician assistant must perform an appropriate medical ~~a physical~~ examination of a patient on the same day that the osteopathic physician ~~he or she~~ dispenses or prescribes a controlled substance to a patient at a controlled-substance medical ~~pain-management~~ clinic. An ~~If the~~ osteopathic physician may not dispense ~~prescribes or dispenses~~ more than a 30-day supply ~~72-hour dose~~ of controlled substances to any patient ~~for the treatment of chronic nonmalignant pain, the osteopathic physician must document in the patient's record the reason for prescribing or dispensing that quantity~~.

(d) An osteopathic physician authorized to prescribe controlled substances who practices at a controlled-substance medical ~~pain-management~~ clinic is responsible for maintaining the control and security of his or her prescription blanks and any other method used for prescribing controlled substance pain medication. The osteopathic physician shall comply with the requirements for counterfeit-resistant prescription blanks in s. 893.065 and the rules adopted pursuant to that section. The osteopathic physician shall notify, in writing, the department within 24 hours after discovering ~~following~~ any theft or loss of a prescription blank or breach of any other method for prescribing controlled substances ~~pain medication~~.

(e) The designated osteopathic physician of a controlled-substance medical ~~pain-management~~ clinic shall notify the applicable board in writing of the date of termination of employment within 10 days after terminating his or her employment with a controlled-substance medical ~~pain-management~~ clinic that is required to be registered under subsection (1).

(3) INSPECTION.—

(a) The department shall inspect the controlled-substance medical ~~pain-management~~ clinic annually, including a review of the patient records, to ensure that it complies with this section and the rules of the Board of Osteopathic Medicine adopted pursuant to subsection (4) unless the clinic is accredited by a nationally recognized accrediting agency approved by the Board of Osteopathic Medicine.

(b) During an onsite inspection, the department shall make a reasonable attempt to discuss each violation with the owner or designated physician of the controlled-substance medical ~~pain-~~

~~management~~ clinic before issuing a formal written notification.

(c) Any action taken to correct a violation shall be documented in writing by the owner or designated physician of the controlled-substance medical ~~pain-management~~ clinic and verified by followup visits by departmental personnel.

(4) RULEMAKING.—

(a) The department shall adopt rules necessary to administer the registration and inspection of controlled-substance medical ~~pain-management~~ clinics which establish the specific requirements, procedures, forms, and fees.

(b) The department shall adopt a rule defining what constitutes practice by a designated osteopathic physician at the clinic location for which the physician has assumed responsibility, as set forth in subsection (1). When adopting the rule, the department shall consider the number of clinic employees, the location of the controlled-substance medical ~~pain-management~~ clinic, the clinic's hours of operation, and the amount of controlled substances being prescribed, dispensed, or administered at the controlled-substance medical ~~pain-management~~ clinic.

~~(c) The Board of Osteopathic Medicine shall adopt a rule establishing the maximum number of prescriptions for Schedule II or Schedule III controlled substances or the controlled substance Alprazolam which may be written at any one registered pain-management clinic during any 24-hour period.~~

(c) ~~(d)~~ The Board of Osteopathic Medicine shall adopt rules setting forth standards of practice for osteopathic physicians practicing in privately owned controlled-substance medical ~~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:

1. Facility operations;

2. Physical operations;

3. Infection control requirements;

4. Health and safety requirements;

5. Quality assurance requirements;

6. Patient records;

~~7. Training requirements for all facility health care practitioners who are not regulated by another board;~~

7.~~8.~~ Inspections; and

8.~~9.~~ Data collection and reporting requirements.

~~An osteopathic 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) PENALTIES; ENFORCEMENT.—

(a) The department may impose an administrative fine on the clinic of up to $5,000 per violation for violating the requirements of this section; chapter 499, the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug Abuse Prevention and Control Act; chapter 893, the Florida

Comprehensive Drug Abuse Prevention and Control Act; or the rules of the department. In determining whether a penalty is to be imposed, and in fixing the amount of the fine, the department shall consider the following factors:

1. The gravity of the violation, including the probability that death or serious physical or emotional harm to a patient has resulted, or could have resulted, from the controlled-substance medical ~~pain-management~~ clinic's actions or the actions of the osteopathic physician, the severity of the action or potential harm, and the extent to which the provisions of the applicable laws or rules were violated.

2. What actions, if any, the owner or designated osteopathic physician took to correct the violations.

3. Whether there were any previous violations at the controlled-substance medical ~~pain-management~~ clinic.

4. The financial benefits that the controlled-substance medical ~~pain-management~~ clinic derived from committing or continuing to commit the violation.

(b) Each day a violation continues after the date fixed for termination of the violation as ordered by the department constitutes an additional, separate, and distinct violation.

(c) The department may impose a fine and, in the case of an owner-operated controlled-substance medical ~~pain-management~~ clinic, revoke or deny a controlled-substance medical ~~pain-management~~ clinic's registration, if the clinic's designated osteopathic physician knowingly and intentionally misrepresents actions taken to correct a violation.

(d) An owner or designated osteopathic physician of a controlled-substance medical ~~pain-management~~ clinic who

concurrently operates an unregistered controlled-substance medical ~~pain-management~~ clinic is subject to an administrative fine of $5,000 per day.

(e) If the owner of a controlled-substance medical ~~pain-management~~ clinic that requires registration fails to apply to register the clinic upon a change of ownership and operates the clinic under the new ownership, the owner is subject to a fine of $5,000.

Section 8. Paragraphs (qq) and (rr) of subsection (1) of section 459.015, Florida Statutes, are amended to read:

459.015 Grounds for disciplinary action; action by the board and department.—

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

(qq) Applicable to a licensee who serves as the designated physician of a controlled-substance medical ~~pain-management~~ clinic as defined in s. 458.3265 or s. 459.0137:

1. Registering a controlled-substance medical ~~pain-management~~ clinic through misrepresentation or fraud;

2. Procuring, or attempting to procure, the registration of a pain-management clinic for any other person by making or causing to be made, any false representation;

3. Failing to comply with any requirement of chapter 499, the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Drug Abuse Prevention and Control Act; or chapter 893, the Florida Comprehensive Drug Abuse Prevention and Control Act;

4. Being convicted or found guilty of, regardless of adjudication to, a felony or any other crime involving ~~moral~~

~~turpitude,~~ fraud, dishonesty, or deceit in any jurisdiction of the courts of this state, of any other state, or of the United States;

~~5. Being convicted of, or disciplined by a regulatory agency of the Federal Government or a regulatory agency of another state for, any offense that would constitute a violation of this chapter;~~

5.~~6.~~ Being convicted of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction of the courts of this state, of any other state, or of the United States which relates to the practice of, or the ability to practice, a licensed health care profession;

6.~~7.~~ Being convicted of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction of the courts of this state, of any other state, or of the United States which relates to health care fraud;

7.~~8.~~ Dispensing any medicinal drug based upon a communication that purports to be a prescription as defined in s. 465.003(14) or s. 893.02 if the dispensing practitioner knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship; or

8.~~9.~~ Failing to timely notify the board of the date of his or her termination from a controlled-substance medical ~~pain-management~~ clinic as required by s. 459.0137(2).

(rr) Failing to timely notify the department of the theft of prescription blanks from a controlled-substance medical ~~pain-management~~ clinic or a breach of other methods for prescribing within 24 hours as required by s. 459.0137(2).

Section 9. Subsection (1) of section 465.0276, Florida

Statutes, is amended to read:

465.0276 Dispensing practitioner.—

~~(1)(a)~~ A person may not dispense medicinal drugs unless licensed as a pharmacist or otherwise authorized under this chapter to do so, except that a practitioner authorized by law to prescribe drugs may dispense such drugs to her or his patients in the regular course of her or his practice in compliance with this section.

~~(b) A practitioner registered under this section may not dispense more than a 72-hour supply of a controlled substance listed in Schedule II, Schedule III, Schedule IV, or Schedule V of s. 893.03 for any patient who pays for the medication by cash, check, or credit card in a clinic registered under s. 458.3265 or s. 459.0137. A practitioner who violates this paragraph commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. This paragraph does not apply to:~~

~~1. A practitioner who dispenses medication to a workers' compensation patient pursuant to chapter 440.~~

~~2. A practitioner who dispenses medication to an insured patient who pays by cash, check, or credit card to cover any applicable copayment or deductible.~~

~~3. The dispensing of complimentary packages of medicinal drugs to the practitioner's own patients in the regular course of her or his practice without the payment of a fee or remuneration of any kind, whether direct or indirect, as provided in subsection (5).~~

Section 10. Section 893.055, Florida Statutes, is amended 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, via electronic delivery, or as determined by the department, to a controlled-substance medical clinic and its employed physicians, an advanced registered nurse practitioner, a physician assistant, a ~~prescriber, dispenser,~~ pharmacy, or a patient concerning the dispensing of controlled substances. A controlled-substance medical clinic and its employed physicians, an advanced registered nurse practitioner, a physician assistant, or a pharmacy shall review each patient advisory report before any controlled substance is dispensed to a patient. ~~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) "Controlled-substance medical clinic" means a facility that employs a physician or osteopathic physician who prescribes on any given day more than 25 prescriptions of Schedule II or Schedule III controlled substance medications, or a combination thereof, or employs a physician or an osteopathic physician who is engaged in dispensing controlled substance medications.

(d) ~~(c)~~ "Dispenser" means a pharmacy, dispensing pharmacist, or dispensing health care practitioner.

(e) ~~(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.

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

(g) ~~(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.

(h) ~~(g)~~ "Prescriber" means a prescribing physician, prescribing practitioner, or other prescribing health care practitioner.

(i) ~~(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.

(j)~~(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.

(k)~~(j)~~ "Program manager" means an employee of or a person contracted by the Department of Health who is designated to ensure the integrity of the prescription drug monitoring program in accordance with the requirements established in paragraphs (2)(a) and (b).

(2)(a) By December 1, 2012 ~~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 dispenser and the practitioners employed at or practicing at a controlled-substance medical clinic shall review the comprehensive electronic database system before prescribing or dispensing any controlled substances to a patient. If the dispenser identifies

or has any issues or concerns regarding the dispensing of the controlled substance medications, the dispenser shall immediately contact the prescriber before dispensing the controlled substance medication. 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, if:

1. The direct-support organization receives at least $20,000 in nonstate moneys for the prescription drug monitoring program;

2. The state receives at least $20,000 in federal grants for the prescription drug monitoring program; or

3. The department collects at least $20,000 through registration fees required by the state to dispense controlled substances.

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.

(d) The program manager shall work with professional health care licensure boards and the stakeholders listed in paragraph (b) to develop rules appropriate for identifying indicators of controlled substance abuse and diversion.

(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 24 hours ~~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 upon determination that probable cause exists that a crime is being committed and issuance of a search warrant regarding the ~~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.

(f) The program manager, upon determining a pattern consistent with the rules established under paragraph (2)(d) and having cause to believe a violation of s. 893.13(7)(a)8., (8)(a), or (8)(b) has occurred, may provide relevant information to the applicable law enforcement agency.

(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, registration fees for controlled-substance medical clinics, 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 provided in this subsection. 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(3)(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 State Surgeon General ~~director of the Office of Drug Control~~ shall appoint a board of directors for the direct-support organization. The State Surgeon General ~~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 State Surgeon General ~~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 department ~~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 department ~~Office of Drug Control~~.

2. Submission of an annual budget for the approval of the department ~~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 department ~~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 s. 2,

chapter 2009-198, Laws of Florida, 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 State Surgeon General ~~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 department ~~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.~~

(g) ~~(h)~~ The department ~~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.

(h) ~~(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.

(i) ~~(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. s. 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 December 1, 2011 ~~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 11. Subsection (4) of section 893.0551, Florida Statutes, is amended to read:

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

(4) The department shall disclose such confidential and exempt information to the applicable law enforcement agency in accordance with s. 893.055(7)(f). 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 pursuant to a search warrant ~~as part of an active investigation~~ that is specific to a violation of s. 893.13(7)(a)8., s. 893.13(8)(a), or s. 893.13(8)(b).

Section 12. This act shall take effect July 1, 2011.