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LEGISLATIVE ACTION

Senate	.	House
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05/06/2011 04:09 PM	.	
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Senator Fasano moved the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Paragraph (mm) is added to subsection (1) of section 456.072, Florida Statutes, subsection (7) is redesignated as subsection (8), and a new subsection (7) is added to that section, to read:

456.072 Grounds for discipline; penalties; enforcement.—

(1) The following acts shall constitute grounds for which the disciplinary actions specified in subsection (2) may be taken:

(mm) Failure to comply with controlled substance

prescribing requirements of s. 456.44.

(7) Notwithstanding subsection (2), upon a finding that a physician has prescribed or dispensed a controlled substance, or caused a controlled substance to be prescribed or dispensed, in a manner that violates the standard of practice set forth in s. 458.331(1)(q) or (t), s. 459.015(1)(t) or (x), s. 461.013(1)(o) or (s), or s. 466.028(1)(p) or (x), the physician shall be suspended for a period of not less than 6 months and pay a fine of not less than $10,000 per count. Repeated violations shall result in increased penalties.

Section 2. Section 456.42, Florida Statutes, is amended to read:

456.42 Written prescriptions for medicinal drugs.—

(1) A written prescription for a medicinal drug issued by a health care practitioner licensed by law to prescribe such drug must be legibly printed or typed so as to be capable of being understood by the pharmacist filling the prescription; must contain the name of the prescribing practitioner, the name and strength of the drug prescribed, the quantity of the drug prescribed, and the directions for use of the drug; must be dated; and must be signed by the prescribing practitioner on the day when issued. ~~A written prescription for a controlled substance listed in chapter 893 must have the quantity of the drug prescribed in both textual and numerical formats and must be dated with the abbreviated month written out on the face of the prescription.~~ However, a prescription that is electronically generated and transmitted must contain the name of the prescribing practitioner, the name and strength of the drug prescribed, the quantity of the drug prescribed in numerical

format, and the directions for use of the drug and must be dated and signed by the prescribing practitioner only on the day issued, which signature may be in an electronic format as defined in s. 668.003(4).

(2) A written prescription for a controlled substance listed in chapter 893 must have the quantity of the drug prescribed in both textual and numerical formats, must be dated with the abbreviated month written out on the face of the prescription, and must be either written on a standardized counterfeit-proof prescription pad produced by a vendor approved by the department or electronically prescribed as that term is used in s. 408.0611. As a condition of being an approved vendor, a prescription pad vendor must submit a monthly report to the department which, at a minimum, documents the number of prescription pads sold and identifies the purchasers. The department may, by rule, require the reporting of additional information.

Section 3. Section 456.44, Florida Statutes, is created to read:

456.44 Controlled substance prescribing.—

(1) DEFINITIONS.—

(a) "Addiction medicine specialist" means a board-certified physiatrist with a subspecialty certification in addiction medicine or who is eligible for such subspecialty certification in addiction medicine, an addiction medicine physician certified or eligible for certification by the American Society of Addiction Medicine, or an osteopathic physician who holds a certificate of added qualification in Addiction Medicine through the American Osteopathic Association.

(b) "Adverse incident" means any incident set forth in s. 458.351(4)(a)-(e) or s. 459.026(4)(a)-(e).

(c) "Board-certified pain management physician" means a physician who possesses board certification in pain medicine by the American Board of Pain Medicine, board certification by the American Board of Interventional Pain Physicians, or board certification or subcertification in pain management by a specialty board recognized by the American Association of Physician Specialists or an osteopathic physician who holds a certificate in Pain Management by the American Osteopathic Association.

(d) "Chronic nonmalignant pain" means pain unrelated to cancer or rheumatoid arthritis which persists beyond the usual course of disease or the injury that is the cause of the pain or more than 90 days after surgery.

(e) "Mental health addiction facility" means a facility licensed under chapter 394 or chapter 397.

(2) REGISTRATION.—Effective January 1, 2012, a physician licensed under chapter 458, chapter 459, chapter 461, or chapter 466 who prescribes any controlled substance, as defined in s. 893.03, for the treatment of chronic nonmalignant pain, must:

(a) Designate himself or herself as a controlled substance prescribing practitioner on the physician's practitioner profile.

(b) Comply with the requirements of this section and applicable board rules.

(3) STANDARDS OF PRACTICE.—The standards of practice in this section do not supersede the level of care, skill, and treatment recognized in general law related to healthcare

licensure.

(a) A complete medical history and a physical examination must be conducted before beginning any treatment and must be documented in the medical record. The exact components of the physical examination shall be left to the judgment of the clinician who is expected to perform a physical examination proportionate to the diagnosis that justifies a treatment. The medical record must, at a minimum, document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, a review of previous medical records, previous diagnostic studies, and history of alcohol and substance abuse. The medical record shall also document the presence of one or more recognized medical indications for the use of a controlled substance. Each registrant must develop a written plan for assessing each patient's risk of aberrant drug-related behavior, which may include patient drug testing. Registrants must assess each patient's risk for aberrant drug-related behavior and monitor that risk on an ongoing basis in accordance with the plan.

(b) Each registrant must develop a written individualized treatment plan for each patient. The treatment plan shall state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and shall indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician shall adjust drug therapy to the individual medical needs of each patient. Other treatment modalities, including a rehabilitation program, shall be

considered depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment. The interdisciplinary nature of the treatment plan shall be documented.

(c) The physician shall discuss the risks and benefits of the use of controlled substances, including the risks of abuse and addiction, as well as physical dependence and its consequences, with the patient, persons designated by the patient, or the patient's surrogate or guardian if the patient is incompetent. The physician shall use a written controlled substance agreement between the physician and the patient outlining the patient's responsibilities, including, but not limited to:

1. Number and frequency of controlled substance prescriptions and refills.

2. Patient compliance and reasons for which drug therapy may be discontinued, such as a violation of the agreement.

3. An agreement that controlled substances for the treatment of chronic nonmalignant pain shall be prescribed by a single treating physician unless otherwise authorized by the treating physician and documented in the medical record.

(d) The patient shall be seen by the physician at regular intervals, not to exceed 3 months, to assess the efficacy of treatment, ensure that controlled substance therapy remains indicated, evaluate the patient's progress toward treatment objectives, consider adverse drug effects, and review the etiology of the pain. Continuation or modification of therapy shall depend on the physician's evaluation of the patient's progress. If treatment goals are not being achieved, despite

medication adjustments, the physician shall reevaluate the appropriateness of continued treatment. The physician shall monitor patient compliance in medication usage, related treatment plans, controlled substance agreements, and indications of substance abuse or diversion at a minimum of 3-month intervals.

(e) The physician shall refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention shall be given to those patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder requires extra care, monitoring, and documentation and requires consultation with or referral to an addictionologist or physiatrist.

(f) A physician registered under this section must maintain accurate, current, and complete records that are accessible and readily available for review and comply with the requirements of this section, the applicable practice act, and applicable board rules. The medical records must include, but are not limited to:

1. The complete medical history and a physical examination, including history of drug abuse or dependence.

2. Diagnostic, therapeutic, and laboratory results.

3. Evaluations and consultations.

4. Treatment objectives.

5. Discussion of risks and benefits.

6. Treatments.

7. Medications, including date, type, dosage, and quantity

prescribed.

8. Instructions and agreements.

9. Periodic reviews.

10. Results of any drug testing.

11. A photocopy of the patient's government-issued photo identification.

12. If a written prescription for a controlled substance is given to the patient, a duplicate of the prescription.

13. The physician's full name presented in a legible manner.

(g) Patients with signs or symptoms of substance abuse shall be immediately referred to a board-certified pain management physician, an addiction medicine specialist, or a mental health addiction facility as it pertains to drug abuse or addiction unless the physician is board-certified or board-eligible in pain management. Throughout the period of time before receiving the consultant's report, a prescribing physician shall clearly and completely document medical justification for continued treatment with controlled substances and those steps taken to ensure medically appropriate use of controlled substances by the patient. Upon receipt of the consultant's written report, the prescribing physician shall incorporate the consultant's recommendations for continuing, modifying, or discontinuing controlled substance therapy. The resulting changes in treatment shall be specifically documented in the patient's medical record. Evidence or behavioral indications of diversion shall be followed by discontinuation of controlled substance therapy and the patient shall be discharged and all results of testing and actions taken by the physician

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shall be documented in the patient's medical record.

This subsection does not apply to a board-certified anesthesiologist, physiatrist, or neurologist, or to a board-certified physician who has surgical privileges at a hospital or ambulatory surgery center and primarily provides surgical services. This subsection does not apply to a board-certified medical specialist who has also completed a fellowship in pain medicine approved by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association, or who is board certified in pain medicine by a board approved by the American Board of Medical Specialties or the American Osteopathic Association and performs interventional pain procedures of the type routinely billed using surgical codes.

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

458.3265 Pain-management clinics.—

(1) REGISTRATION.—

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

a. "Chronic nonmalignant pain" means pain unrelated to cancer or rheumatoid arthritis which persists beyond the usual course of disease or the injury that is the cause of the pain or more than 90 days after surgery.

b. "Pain-management clinic" or "clinic" means any publicly or privately owned facility:

(I) That advertises in any medium for any type of pain-management services; or

(II) Where in any month a majority of patients are prescribed opioids, benzodiazepines, barbiturates, or


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carisoprodol for the treatment of chronic nonmalignant pain. ~~All privately owned pain-management clinics, facilities, or offices, hereinafter referred to as "clinics," which advertise in any medium for any type of pain-management services, or employ a physician who is primarily engaged in the treatment of pain by prescribing or dispensing controlled substance medications,~~

2. Each pain-management clinic must register with the department unless:

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

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

c.~~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;

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

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

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

g. The clinic is wholly owned and operated by one or more board-certified anesthesiologists, physiatrists, or neurologists; or

h. The clinic is wholly owned and operated by one or more board-certified medical specialists who have also completed fellowships in pain medicine approved by the Accreditation

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Council for Graduate Medical Education, or who are also board-certified in pain medicine by a board approved by the American Board of Medical Specialties and perform interventional pain procedures of the type routinely billed using surgical codes.

(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 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 that a 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 pain-management clinic from practicing at that clinic location based upon an annual inspection and evaluation of the factors described in subsection (3).

(h) If the registration of a pain-management clinic is revoked or suspended, the designated physician of the pain-

management clinic, the owner or lessor of the pain-management clinic property, the manager, and the proprietor shall cease to operate the facility as a pain-management clinic as of the effective date of the suspension or revocation.

(i) If a pain-management clinic registration is revoked or suspended, the designated physician of the 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 pain-management clinic.

(j) Upon the effective date of the suspension or revocation, the designated physician of the 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 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 pain-management clinic, including persons owning or operating the pain-management clinic, may not, as an individual or as a part of a group, apply to operate a pain-management clinic for 5 years after the date the registration is revoked.

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

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

(2) PHYSICIAN RESPONSIBILITIES.—These responsibilities


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apply to any physician who provides professional services in a pain-management clinic that is required to be registered in subsection (1).

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

~~1.~~ The 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 pain-management clinic unless he or she is a physician licensed under this chapter or chapter 459.

(c) A physician, a physician assistant, or an advanced registered nurse practitioner must perform a physical examination of a patient on the same day that the physician ~~he~~


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~~or she dispenses or~~ prescribes a controlled substance to a patient at a pain-management clinic. If the physician prescribes ~~or dispenses~~ more than a 72-hour dose of controlled substances 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 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 following any theft or loss of a prescription blank or breach of any other method for prescribing pain medication.

(e) The designated physician of a 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 pain-management clinic that is required to be registered under subsection (1). Each physician practicing in a pain-management clinic shall advise the Board of Medicine, in writing, within 10 calendar days after beginning or ending his or her practice at a pain-management clinic.

(f) Each physician practicing in a pain-management clinic is responsible for ensuring compliance with the following facility and physical operations requirements:

1. A pain-management clinic shall be located and operated


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at a publicly accessible fixed location and must:

a. Display a sign that can be viewed by the public that contains the clinic name, hours of operations, and a street address.

b. Have a publicly listed telephone number and a dedicated phone number to send and receive faxes with a fax machine that shall be operational 24 hours per day.

c. Have emergency lighting and communications.

d. Have a reception and waiting area.

e. Provide a restroom.

f. Have an administrative area, including room for storage of medical records, supplies, and equipment.

g. Have private patient examination rooms.

h. Have treatment rooms, if treatment is being provided to the patients.

i. Display a printed sign located in a conspicuous place in the waiting room viewable by the public with the name and contact information of the clinic's designated physician and the names of all physicians practicing in the clinic.

j. If the clinic stores and dispenses prescription drugs, comply with ss. 499.0121 and 893.07.

2. This section does not excuse a physician from providing any treatment or performing any medical duty without the proper equipment and materials as required by the standard of care. This section does not supersede the level of care, skill, and treatment recognized in general law related to healthcare licensure.

(g) Each physician practicing in a pain-management clinic is responsible for ensuring compliance with the following


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infection control requirements.

1. The clinic shall maintain equipment and supplies to support infection prevention and control activities.

2. The clinic shall identify infection risks based on the following:

a. Geographic location, community, and population served.

b. The care, treatment, and services it provides.

c. An analysis of its infection surveillance and control data.

3. The clinic shall maintain written infection prevention policies and procedures that address the following:

a. Prioritized risks.

b. Limiting unprotected exposure to pathogens.

c. Limiting the transmission of infections associated with procedures performed in the clinic.

d. Limiting the transmission of infections associated with the clinic's use of medical equipment, devices, and supplies.

(h) Each physician practicing in a pain-management clinic is responsible for ensuring compliance with the following health and safety requirements:

1. The clinic, including its grounds, buildings, furniture, appliances, and equipment shall be structurally sound, in good repair, clean, and free from health and safety hazards.

2. The clinic shall have evacuation procedures in the event of an emergency, which shall include provisions for the evacuation of disabled patients and employees.

3. The clinic shall have a written facility-specific disaster plan setting forth actions that will be taken in the event of clinic closure due to unforeseen disasters and shall

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include provisions for the protection of medical records and any controlled substances.

4. Each clinic shall have at least one employee on the premises during patient care hours who is certified in Basic Life Support and is trained in reacting to accidents and medical emergencies until emergency medical personnel arrive.

(i) The designated physician is responsible for ensuring compliance with the following quality assurance requirements. Each pain-management clinic shall have an ongoing quality assurance program that objectively and systematically monitors and evaluates the quality and appropriateness of patient care, evaluates methods to improve patient care, identifies and corrects deficiencies within the facility, alerts the designated physician to identify and resolve recurring problems, and provides for opportunities to improve the facility's performance and to enhance and improve the quality of care provided to the public. The designated physician shall establish a quality assurance program that includes the following components:

1. The identification, investigation, and analysis of the frequency and causes of adverse incidents to patients.

2. The identification of trends or patterns of incidents.

3. The development of measures to correct, reduce, minimize, or eliminate the risk of adverse incidents to patients.

4. The documentation of these functions and periodic review no less than quarterly of such information by the designated physician.

(j) The designated physician is responsible for ensuring compliance with the following data collection and reporting

requirements:

1. The designated physician for each pain-management clinic shall report all adverse incidents to the department as set forth in s. 458.351.

2. The designated physician shall also report to the Board of Medicine, in writing, on a quarterly basis the following data:

a. Number of new and repeat patients seen and treated at the clinic who are prescribed controlled substance medications for the treatment of chronic, nonmalignant pain.

b. The number of patients discharged due to drug abuse.

c. The number of patients discharged due to drug diversion.

d. The number of patients treated at the pain clinic whose domicile is located somewhere other than in this state. A patient’s domicile is the patient’s fixed or permanent home to which he or she intends to return even though he or she may temporarily reside elsewhere.

(3) INSPECTION.—

(a) The department shall inspect the 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 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 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 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 pain-management clinic, the clinic's hours of operation, and the amount of controlled substances being prescribed, dispensed, or administered at the 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.~~

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

~~1. Facility operations;~~


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~~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.~~;~~
~~8. Inspections; and~~
~~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 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 pain-management clinic.

4. The financial benefits that the 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 pain-management clinic, revoke or deny a 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 pain-management clinic who concurrently operates an unregistered pain-management clinic is subject to an administrative fine of $5,000 per day.

(e) If the owner of a 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.

(6) EXPIRATION.—This section expires January 1, 2016.

Section 5. Paragraph (f) is added to subsection (1) of

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section 458.327, Florida Statutes, 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:

(f) Dispensing a controlled substance listed in Schedule II or Schedule III in violation of s. 465.0276.

Section 6. Paragraph (rr) is added to subsection (1) of section 458.331, Florida Statutes, 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):

(rr) Dispensing a controlled substance listed in Schedule II or Schedule III in violation of s. 465.0276.

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

459.0137 Pain-management clinics.—

(1) REGISTRATION.—

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

a. "Chronic nonmalignant pain" means pain unrelated to cancer or rheumatoid arthritis which persists beyond the usual course of disease or the injury that is the cause of the pain or more than 90 days after surgery.

b. "Pain-management clinic" or "clinic" means any publicly or privately owned facility:

(I) That advertises in any medium for any type of pain-management services; or

(II) Where in any month a majority of patients are

prescribed opioids, benzodiazepines, barbiturates, or carisoprodol for the treatment of chronic nonmalignant pain. ~~All privately owned pain-management clinics, facilities, or offices, hereinafter referred to as "clinics," which advertise in any medium for any type of pain-management services, or employ an osteopathic physician who is primarily engaged in the treatment of pain by prescribing or dispensing controlled substance medications,~~

2. Each pain-management clinic must register with the department unless:

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

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

c.~~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;

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

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

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

g. The clinic is wholly owned and operated by one or more board-certified anesthesiologists, physiatrists, or neurologists; or

h. The clinic is wholly owned and operated by one or more


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board-certified medical specialists who have also completed fellowships in pain medicine approved by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association, or who are also board-certified in pain medicine by a board approved by the American Board of Medical Specialties or the American Osteopathic Association and perform interventional pain procedures of the type routinely billed using surgical codes.

(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 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 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 that a 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 pain-management clinic from practicing at that clinic location

based upon an annual inspection and evaluation of the factors described in subsection (3).

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

(i) If a pain-management clinic registration is revoked or suspended, the designated physician of the 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 pain-management clinic.

(j) Upon the effective date of the suspension or revocation, the designated physician of the 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 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 pain-management clinic, including persons owning or operating the pain-management clinic, may not, as an individual or as a part of a group, make application for a permit to operate a pain-management clinic for 5 years after the date the registration is revoked.

(l) The period of suspension for the registration of a


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pain-management clinic shall be prescribed by the department, but may not exceed 1 year.

(m) A change of ownership of a registered 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 pain-management clinic that is required to be registered in subsection (1).

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

~~1.~~ the 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.

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

(c) An osteopathic physician, a physician assistant, or an advanced registered nurse practitioner must perform 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 pain-management clinic. If the osteopathic physician prescribes ~~or dispenses~~ more than a 72-hour dose of controlled substances 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 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 following any theft or loss of a prescription blank or breach of any other method for prescribing pain medication.

(e) The designated osteopathic physician of a 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 pain-management clinic that is required to be registered under subsection (1). Each

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osteopathic physician practicing in a pain-management clinic shall advise the Board of Osteopathic Medicine in writing within 10 calendar days after beginning or ending his or her practice at a pain-management clinic.

(f) Each osteopathic physician practicing in a pain-management clinic is responsible for ensuring compliance with the following facility and physical operations requirements:

1. A pain-management clinic shall be located and operated at a publicly accessible fixed location and must:

a. Display a sign that can be viewed by the public that contains the clinic name, hours of operations, and a street address.

b. Have a publicly listed telephone number and a dedicated phone number to send and receive faxes with a fax machine that shall be operational 24 hours per day.

c. Have emergency lighting and communications.

d. Have a reception and waiting area.

e. Provide a restroom.

f. Have an administrative area including room for storage of medical records, supplies and equipment.

g. Have private patient examination rooms.

h. Have treatment rooms, if treatment is being provided to the patient.

i. Display a printed sign located in a conspicuous place in the waiting room viewable by the public with the name and contact information of the clinic-designated physician and the names of all physicians practicing in the clinic.

j. If the clinic stores and dispenses prescription drug, comply with ss. 499.0121 and 893.07.

2. This section does not excuse an osteopathic physician from providing any treatment or performing any medical duty without the proper equipment and materials as required by the standard of care. This section does not supersede the level of care, skill, and treatment recognized in general law related to healthcare licensure.

(g) Each osteopathic physician practicing in a pain-management clinic is responsible for ensuring compliance with the following infection control requirements.

1. The clinic shall maintain equipment and supplies to support infection prevention and control activities.

2. The clinic shall identify infection risks based on the following:

a. Geographic location, community, and population served.

b. The care, treatment and services it provides.

c. An analysis of its infection surveillance and control data.

3. The clinic shall maintain written infection prevention policies and procedures that address the following:

a. Prioritized risks.

b. Limiting unprotected exposure to pathogen.

c. Limiting the transmission of infections associated with procedures performed in the clinic.

d. Limiting the transmission of infections associated with the clinic’s use of medical equipment, devices, and supplies.

(h) Each osteopathic physician practicing in a pain-management clinic is responsible for ensuring compliance with the following health and safety requirements.

1. The clinic, including its grounds, buildings, furniture,

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appliances, and equipment shall be structurally sound, in good repair, clean, and free from health and safety hazards.

2. The clinic shall have evacuation procedures in the event of an emergency which shall include provisions for the evacuation of disabled patients and employees.

3. The clinic shall have a written facility-specific disaster plan which sets forth actions that will be taken in the event of clinic closure due to unforeseen disasters and shall include provisions for the protection of medical records and any controlled substances.

4. Each clinic shall have at least one employee on the premises during patient care hours who is certified in Basic Life Support and is trained in reacting to accidents and medical emergencies until emergency medical personnel arrive.

(i) The designated physician is responsible for ensuring compliance with the following quality assurance requirements. Each pain-management clinic shall have an ongoing quality assurance program that objectively and systematically monitors and evaluates the quality and appropriateness of patient care, evaluates methods to improve patient care, identifies and corrects deficiencies within the facility, alerts the designated physician to identify and resolve recurring problems, and provides for opportunities to improve the facility's performance and to enhance and improve the quality of care provided to the public. The designated physician shall establish a quality assurance program that includes the following components:

1. The identification, investigation, and analysis of the frequency and causes of adverse incidents to patients.

2. The identification of trends or patterns of incidents.

3. The development of measures to correct, reduce, minimize, or eliminate the risk of adverse incidents to patients.

4. The documentation of these functions and periodic review no less than quarterly of such information by the designated physician.

(j) The designated physician is responsible for ensuring compliance with the following data collection and reporting requirements:

1. The designated physician for each pain-management clinic shall report all adverse incidents to the department as set forth in s. 459.026.

2. The designated physician shall also report to the Board of Osteopathic Medicine, in writing, on a quarterly basis, the following data:

a. Number of new and repeat patients seen and treated at the clinic who are prescribed controlled substance medications for the treatment of chronic, nonmalignant pain.

b. The number of patients discharged due to drug abuse.

c. The number of patients discharged due to drug diversion.

d. The number of patients treated at the pain clinic whose domicile is located somewhere other than in this state. A patient’s domicile is the patient’s fixed or permanent home to which he or she intends to return even though he or she may temporarily reside elsewhere.

(3) INSPECTION.—

(a) The department shall inspect the 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

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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 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 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 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 pain-management clinic, the clinic's hours of operation, and the amount of controlled substances being prescribed, dispensed, or administered at the 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~~


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~~pain-management clinic during any 24-hour period.~~

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

~~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.~~;~~

~~8. Inspections; and~~

~~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 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 pain-management clinic.

4. The financial benefits that the 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 pain-management clinic, revoke or deny a pain-management clinic's registration, if the clinic's designated osteopathic physician knowingly and intentionally misrepresents actions taken to correct a violation.

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(d) An owner or designated osteopathic physician of a pain-management clinic who concurrently operates an unregistered pain-management clinic is subject to an administrative fine of $5,000 per day.

(e) If the owner of a 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.

(6) EXPIRATION.—This section expires January 1, 2016.

Section 8. Paragraph (f) is added to subsection (1) of section 459.013, Florida Statutes, to read:

459.013 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:

(f) Dispensing a controlled substance listed in Schedule II or Schedule III in violation of s. 465.0276.

Section 9. Paragraph (tt) is added to subsection (1) of section 459.015, Florida Statutes, 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):

(tt) Dispensing a controlled substance listed in Schedule II or Schedule III in violation of s. 465.0276.

Section 10. Subsections (3) and (4) of section 465.015, Florida Statutes, are renumbered as subsections (4) and (5), respectively, a new subsection (3) is added to that section, and present subsection (4) of that section is amended, to read:

465.015 Violations and penalties.—

(3) It is unlawful for any pharmacist to knowingly fail to report to the sheriff or other chief law enforcement agency of the county where the pharmacy is located within 24 hours after learning of any instance in which a person obtained or attempted to obtain a controlled substance, as defined in s. 893.02, or at the close of business on the next business day, whichever is later, that the pharmacist knew or believed was obtained or attempted to be obtained through fraudulent methods or representations from the pharmacy at which the pharmacist practiced pharmacy. Any pharmacist who knowingly fails to make such a report within 24 hours after learning of the fraud or attempted fraud or at the close of business on the next business day, whichever is later, commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083. A sufficient report of the fraudulent obtaining of controlled substances under this subsection must contain, at a minimum, a copy of the prescription used or presented and a narrative, including all information available to the pharmacist concerning the transaction, such as the name and telephone number of the prescribing physician; the name, description, and any personal identification information pertaining to the person who presented the prescription; and all other material information, such as photographic or video surveillance of the transaction.

(5) ~~(4)~~ Any person who violates any provision of subsection (1) or subsection (4) ~~(3)~~ commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083. Any person who violates any provision of subsection (2) commits a felony of the third degree, punishable as provided in s.

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775.082, s. 775.083, or s. 775.084. In any warrant, information, or indictment, it shall not be necessary to negative any exceptions, and the burden of any exception shall be upon the defendant.

Section 11. Paragraph (t) is added to subsection (1) of section 465.016, Florida Statutes, to read:

465.016 Disciplinary actions.—

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

(t) Committing an error or omission during the performance of a specific function of prescription drug processing, which includes, for purposes of this paragraph:

1. Receiving, interpreting, or clarifying a prescription.

2. Entering prescription data into the pharmacy's record.

3. Verifying or validating a prescription.

4. Performing pharmaceutical calculations.

5. Performing prospective drug review as defined by the board.

6. Obtaining refill and substitution authorizations.

7. Interpreting or acting on clinical data.

8. Performing therapeutic interventions.

9. Providing drug information concerning a patient's prescription.

10. Providing patient counseling.

Section 12. Section 465.018, Florida Statutes, is amended to read:

465.018 Community pharmacies; permits.—

(1) Any person desiring a permit to operate a community pharmacy shall apply to the department.


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(2) If the board office certifies that the application complies with the laws of the state and the rules of the board governing pharmacies, the department shall issue the permit. No permit shall be issued unless a licensed pharmacist is designated as the prescription department manager ~~responsible for maintaining all drug records, providing for the security of the prescription department, and following such other rules as relate to the practice of the profession of pharmacy~~. ~~The permittee and the newly designated prescription department manager shall notify the department within 10 days of any change in prescription department manager.~~

(3) The board may suspend or revoke the permit of, or may refuse to issue a permit to:

(a) Any person who has been disciplined or who has abandoned a permit or allowed a permit to become void after written notice that disciplinary proceedings had been or would be brought against the permit;

(b) Any person who is an officer, director, or person interested directly or indirectly in a person or business entity that has had a permit disciplined or abandoned or become void after written notice that disciplinary proceedings had been or would be brought against the permit; or

(c) Any person who is or has been an officer of a business entity, or who was interested directly or indirectly in a business entity, the permit of which has been disciplined or abandoned or become null and void after written notice that disciplinary proceedings had been or would be brought against the permit.

(4) In addition to any other remedies provided by law, the

board may deny the application or suspend or revoke the license, registration, or certificate of any entity regulated or licensed by it if the applicant, licensee, registrant, or licenseholder, or, in the case of a corporation, partnership, or other business entity, if any officer, director, agent, or managing employee of that business entity or any affiliated person, partner, or shareholder having an ownership interest equal to 5 percent or greater in that business entity, has failed to pay all outstanding fines, liens, or overpayments assessed by final order of the department, unless a repayment plan is approved by the department, or has failed to comply with any repayment plan.

(5) In reviewing any application requesting a change of ownership or a change of licensee or registrant, the transferor shall, before board approval of the change, repay or make arrangements to repay any amounts owed to the department. If the transferor fails to repay or make arrangements to repay the amounts owed to the department, the license or registration may not be issued to the transferee until repayment or until arrangements for repayment are made.

(6) Passing an onsite inspection is a prerequisite to the issuance of an initial permit or a permit for a change of location. The department must make the inspection within 90 days before issuance of the permit.

(7) Community pharmacies that dispense controlled substances must maintain a record of all controlled substance dispensing consistent with the requirements of s. 893.07 and must make the record available to the department and law enforcement agencies upon request.

Section 13. In order to dispense controlled substances

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listed in Schedule II or Schedule III, as provided in s. 893.03, Florida Statutes, on or after July 1, 2012, a community pharmacy permittee must be permitted pursuant to chapter 465, Florida Statutes, as amended by this act and any rules adopted thereunder.

Section 14. Section 465.022, Florida Statutes, is amended to read:

465.022 Pharmacies; general requirements; fees.—

(1) The board shall adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this chapter. Such rules shall include, but shall not be limited to, rules relating to:

(a) General drug safety measures.

(b) Minimum standards for the physical facilities of pharmacies.

(c) Safe storage of floor-stock drugs.

(d) Functions of a pharmacist in an institutional pharmacy, consistent with the size and scope of the pharmacy.

(e) Procedures for the safe storage and handling of radioactive drugs.

(f) Procedures for the distribution and disposition of medicinal drugs distributed pursuant to s. 499.028.

(g) Procedures for transfer of prescription files and medicinal drugs upon the change of ownership or closing of a pharmacy.

(h) Minimum equipment which a pharmacy shall at all times possess to fill prescriptions properly.

(i) Procedures for the dispensing of controlled substances to minimize dispensing based on fraudulent representations or


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invalid practitioner-patient relationships.

(2) A pharmacy permit may ~~shall~~ be issued only to a natural person who is at least 18 years of age, to a partnership comprised of at least one natural person and all of whose partners are ~~all~~ at least 18 years of age, to a governmental agency, or to a business entity that is properly registered with the Secretary of State, if required by law, and has been issued a federal employer tax identification number ~~corporation that is registered pursuant to chapter 607 or chapter 617 whose officers, directors, and shareholders are at least 18 years of age~~. Permits issued to business entities may be issued only to entities whose affiliated persons, members, partners, officers, directors, and agents, including persons required to be fingerprinted under subsection (3), are not less than 18 years of age.

(3) Any person or business entity, ~~partnership, or corporation~~ before engaging in the operation of a pharmacy, shall file with the board a sworn application on forms provided by the department. For purposes of this section, any person required to provide fingerprints under this subsection is an affiliated person within the meaning of s. 465.023(1).

(a) An application for a pharmacy permit must include a set of fingerprints from each person having an ownership interest of 5 percent or greater and from any person who, directly or indirectly, manages, oversees, or controls the operation of the applicant, including officers and members of the board of directors of an applicant that is a corporation. The applicant must provide payment in the application for the cost of state and national criminal history records checks.


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1. For corporations having more than $100 million of business taxable assets in this state, in lieu of these fingerprint requirements, the department shall require the prescription department manager or consultant pharmacist of record who will be directly involved in the management and operation of the pharmacy to submit a set of fingerprints.

2. A representative of a corporation described in subparagraph 1. satisfies the requirement to submit a set of his or her fingerprints if the fingerprints are on file with the department or the Agency for Health Care Administration, meet the fingerprint specifications for submission by the Department of Law Enforcement, and are available to the department.

(b) The department shall annually submit the fingerprints provided by the applicant to the Department of Law Enforcement for a state criminal history records check. The Department of Law Enforcement shall annually forward the fingerprints to the Federal Bureau of Investigation for a national criminal history records check. The department shall report the results of annual criminal history records checks to wholesale distributors permitted under chapter 499 for the purposes of s. 499.0121(15).

(c) In addition to those documents required by the department or board, each applicant having any financial or ownership interest greater than 5 percent in the subject of the application must submit a signed affidavit disclosing any financial or ownership interest greater than 5 percent in any pharmacy permitted in the past 5 years, which pharmacy has closed voluntarily or involuntarily, has filed a voluntary relinquishment of its permit, has had its permit suspended or revoked, or has had an injunction issued against it by a


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regulatory agency. The affidavit must disclose the reason such entity was closed, whether voluntary or involuntary.

(4) An application for a pharmacy permit must include the applicant's written policies and procedures for preventing controlled substance dispensing based on fraudulent representations or invalid practitioner-patient relationships. The board must review the policies and procedures and may deny a permit if the policies and procedures are insufficient to reasonably prevent such dispensing. The department may phase in the submission and review of policies and procedures over one 18-month period beginning July 1, 2011.

(5) ~~(4)~~ The department or board shall deny an application for a pharmacy permit if the applicant or an affiliated person, partner, officer, director, or prescription department manager or consultant pharmacist of record of the applicant ~~has~~:

(a) Has obtained a permit by misrepresentation or fraud.~~;~~

(b) Has attempted to procure, or has procured, a permit for any other person by making, or causing to be made, any false representation.~~;~~

(c) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, the profession of pharmacy.~~;~~

(d) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud.~~;~~

(e) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 409, chapter 817, or chapter 893, or a similar felony

offense committed in another state or jurisdiction, since July 1, 2009. ~~Been terminated for cause, pursuant to the appeals procedures established by the state or Federal Government, from any state Medicaid program or the federal Medicare program, unless the applicant has been in good standing with a state Medicaid program or the federal Medicare program for the most recent 5 years and the termination occurred at least 20 years ago; or~~

(f) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396 since July 1, 2009.

(g) Has been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the applicant has been in good standing with the Florida Medicaid program for the most recent 5-year period.

(h) Has been terminated for cause, pursuant to the appeals procedures established by the state, from any other state Medicaid program, unless the applicant has been in good standing with a state Medicaid program for the most recent 5-year period and the termination occurred at least 20 years before the date of the application.

(i) Is currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities.

(j) ~~(f)~~ Has dispensed any medicinal drug based upon a communication that purports to be a prescription as defined by s. 465.003(14) or s. 893.02 when the pharmacist knows or has reason to believe that the purported prescription is not based

upon a valid practitioner-patient relationship that includes a documented patient evaluation, including history and a physical examination adequate to establish the diagnosis for which any drug is prescribed and any other requirement established by board rule under chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, or chapter 466.

For felonies in which the defendant entered a plea of guilty or nolo contendere in an agreement with the court to enter a pretrial intervention or drug diversion program, the department shall deny the application if upon final resolution of the case the licensee has failed to successfully complete the program.

(6) The department or board may deny an application for a pharmacy permit if the applicant or an affiliated person, partner, officer, director, or prescription department manager or consultant pharmacist of record of the applicant has violated or failed to comply with any provision of this chapter; chapter 499, the Florida Drug and Cosmetic Act; chapter 893; 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; or any rules or regulations promulgated thereunder unless the violation or noncompliance is technical.

(7) ~~(5)~~ After the application has been filed with the board and the permit fee provided in this section has been received, the board shall cause the application to be fully investigated, both as to the qualifications of the applicant and the prescription department manager or consultant pharmacist designated to be in charge and as to the premises and location described in the application.


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(8) ~~(6)~~ The Board of Pharmacy shall have the authority to determine whether a bona fide transfer of ownership is present and that the sale of a pharmacy is not being accomplished for the purpose of avoiding an administrative prosecution.

(9) ~~(7)~~ Upon the completion of the investigation of an application, the board shall approve or deny ~~disapprove~~ the application. If approved, the permit shall be issued by the department.

(10) ~~(8)~~ A permittee must notify the department, on a form approved by the board, within 10 days after any change in prescription department manager or consultant pharmacist of record. ~~Permits issued by the department are not transferable.~~

(11) A permittee must notify the department of the identity of the prescription department manager within 10 days after employment. The prescription department manager must comply with the following requirements:

(a) The prescription department manager of a permittee must obtain and maintain all drug records required by any state or federal law to be obtained by a pharmacy, including, but not limited to, records required by or under this chapter, chapter 499, or chapter 893. The prescription department manager must ensure the permittee’s compliance with all rules adopted under those chapters as they relate to the practice of the profession of pharmacy and the sale of prescription drugs.

(b) The prescription department manager must ensure the security of the prescription department. The prescription department manager must notify the board of any theft or significant loss of any controlled substances within 1 business day after discovery of the theft or loss.


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(c) A registered pharmacist may not serve as the prescription department manager in more than one location unless approved by the board.

(12) The board shall adopt rules that require the keeping of such records of prescription drugs as are necessary for the protection of public health, safety, and welfare.

(a) All required records documenting prescription drug distributions shall be readily available or immediately retrievable during an inspection by the department.

(b) The records must be maintained for 4 years after the creation or receipt of the record, whichever is later.

(13) Permits issued by the department are not transferable.

(14) ~~(9)~~ The board shall set the fees for the following:

(a) Initial permit fee not to exceed $250.

(b) Biennial permit renewal not to exceed $250.

(c) Delinquent fee not to exceed $100.

(d) Change of location fee not to exceed $100.

Section 15. Paragraph (b) of subsection (1) of section 465.0276, Florida Statutes, is amended to read:

465.0276 Dispensing practitioner.—

(1)

(b)1. A practitioner registered under this section may not dispense ~~more than a 72-hour supply of~~ a controlled substance listed in Schedule II or~~,~~ Schedule III as provided in~~, 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.~~

1.~~3.~~ The dispensing of complimentary packages of medicinal drugs which are labeled as a drug sample or complimentary drug as defined in s. 499.028 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).

2. The dispensing of controlled substances in the health care system of the Department of Corrections.

3. The dispensing of a controlled substance listed in Schedule II or Schedule III in connection with the performance of a surgical procedure. The amount dispensed pursuant to the subparagraph may not exceed a 14-day supply. This exception does not allow for the dispensing of a controlled substance listed in Schedule II or Schedule III more than 14 days after the performance of the surgical procedure. For purposes of this subparagraph, the term "surgical procedure" means any procedure in any setting which involves, or reasonably should involve:

a. Perioperative medication and sedation that allows the patient to tolerate unpleasant procedures while maintaining adequate cardiorespiratory function and the ability to respond purposefully to verbal or tactile stimulation and makes intra- and post-operative monitoring necessary; or

b. The use of general anesthesia or major conduction

anesthesia and preoperative sedation.

4. The dispensing of a controlled substance listed in Schedule II or Schedule III pursuant to an approved clinical trial. For purposes of this subparagraph, the term "approved clinical trial" means a clinical research study or clinical investigation that, in whole or in part, is state or federally funded or is conducted under an investigational new drug application that is reviewed by the United States Food and Drug Administration.

5. The dispensing of methadone in a facility licensed under s. 397.427 where medication-assisted treatment for opiate addiction is provided.

6. The dispensing of a controlled substance listed in Schedule II or Schedule III to a patient of a facility licensed under part IV of chapter 400.

Section 16. Subsections (16) and (17) are added to section 499.0051, Florida Statutes, to read:

499.0051 Criminal acts.—

(16) FALSE REPORT.—Any person who submits a report required by s. 499.0121(14) knowing that such report contains a false statement commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(17) CONTROLLED SUBSTANCE DISTRIBUTION.—Any person who engages in the wholesale distribution of prescription drugs and who knowingly distributes controlled substances in violation of s. 499.0121(14) commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. In addition to any other fine that may be imposed, a person convicted of such a violation may be sentenced to pay a fine

that does not exceed three times the gross monetary value gained from such violation, plus court costs and the reasonable costs of investigation and prosecution.

Section 17. Paragraph (o) is added to subsection (8) of section 499.012, Florida Statutes, to read:

499.012 Permit application requirements.—

(8) An application for a permit or to renew a permit for a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor submitted to the department must include:

(o) Documentation of the credentialing policies and procedures required by s. 499.0121(14).

Section 18. Subsections (14) and (15) are added to section 499.0121, Florida Statutes, to read:

499.0121 Storage and handling of prescription drugs; recordkeeping.—The department shall adopt rules to implement this section as necessary to protect the public health, safety, and welfare. Such rules shall include, but not be limited to, requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.

(14) DISTRIBUTION REPORTING.—Each prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, retail pharmacy drug wholesale distributor, manufacturer, or repackager that engages in the wholesale distribution of controlled substances as defined in s. 893.02 shall submit a report to the department of its receipts and distributions of controlled substances listed in Schedule II, Schedule III, Schedule IV, or Schedule V as provided in s.

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893.03. Wholesale distributor facilities located within this state shall report all transactions involving controlled substances, and wholesale distributor facilities located outside this state shall report all distributions to entities located in this state. If the prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, retail pharmacy drug wholesale distributor, manufacturer, or repackager does not have any controlled substance distributions for the month, a report shall be sent indicating that no distributions occurred in the period. The report shall be submitted monthly by the 20th of the next month, in the electronic format used for controlled substance reporting to the Automation of Reports and Consolidated Orders System division of the federal Drug Enforcement Administration. Submission of electronic data must be made in a secured Internet environment that allows for manual or automated transmission. Upon successful transmission, an acknowledgement page must be displayed to confirm receipt. The report must contain the following information:

(a) The federal Drug Enforcement Administration registration number of the wholesale distributing location.

(b) The federal Drug Enforcement Administration registration number of the entity to which the drugs are distributed or from which the drugs are received.

(c) The transaction code that indicates the type of transaction.

(d) The National Drug Code identifier of the product and the quantity distributed or received.

(e) The Drug Enforcement Administration Form 222 number or Controlled Substance Ordering System Identifier on all schedule

II transactions.

(f) The date of the transaction.

The department must share the reported data with the Department of Law Enforcement and local law enforcement agencies upon request and must monitor purchasing to identify purchasing levels that are inconsistent with the purchasing entity's clinical needs. The Department of Law Enforcement shall investigate purchases at levels that are inconsistent with the purchasing entity's clinical needs to determine whether violations of chapter 893 have occurred.

(15) DUE DILIGENCE OF PURCHASERS.—

(a) Each prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, and retail pharmacy drug wholesale distributor must establish and maintain policies and procedures to credential physicians licensed under chapter 458, chapter 459, chapter 461, or chapter 466 and pharmacies that purchase or otherwise receive from the wholesale distributor controlled substances listed in Schedule II or Schedule III as provided in s. 893.03. The prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, or retail pharmacy drug wholesale distributor shall maintain records of such credentialing and make the records available to the department upon request. Such credentialing must, at a minimum, include:

1. A determination of the clinical nature of the receiving entity, including any specialty practice area.

2. A review of the receiving entity's history of Schedule II and Schedule III controlled substance purchasing from the

1551 wholesale distributor.
1552 3. A determination that the receiving entity's Schedule II
1553 and Schedule III controlled substance purchasing history, if
1554 any, is consistent with and reasonable for that entity's
1555 clinical business needs.
1556 (b) A wholesale distributor must take reasonable measures
1557 to identify its customers, understand the normal and expected
1558 transactions conducted by those customers, and identify those
1559 transactions that are suspicious in nature. A wholesale
1560 distributor must establish internal policies and procedures for
1561 identifying suspicious orders and preventing suspicious
1562 transactions. A wholesale distributor must assess orders for
1563 greater than 5,000 unit doses of any one controlled substance in
1564 any one month to determine whether the purchase is reasonable.
1565 In making such assessments, a wholesale distributor may consider
1566 the purchasing entity's clinical business needs, location, and
1567 population served, in addition to other factors established in
1568 the distributor's policies and procedures. A wholesale
1569 distributor must report to the department any regulated
1570 transaction involving an extraordinary quantity of a listed
1571 chemical, an uncommon method of payment or delivery, or any
1572 other circumstance that the regulated person believes may
1573 indicate that the listed chemical will be used in violation of
1574 the law. The wholesale distributor shall maintain records that
1575 document the report submitted to the department in compliance
1576 with this paragraph.
1577 (c) A wholesale distributor may not distribute controlled
1578 substances to an entity if any criminal history record check for
1579 any person associated with that entity shows that the person has

been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction related to controlled substances, the practice of pharmacy, or the dispensing of medicinal drugs.

(d) The department shall assess national data from the Automation of Reports and Consolidated Orders System of the federal Drug Enforcement Administration, excluding Florida data, and identify the national average of grams of hydrocodone, morphine, oxycodone, and methadone distributed per pharmacy registrant per month in the most recent year for which data is available. The department shall report the average for each of these drugs to the Governor, the President of the Senate, and the Speaker of the House of Representatives by November 1, 2011. The department shall assess the data reported pursuant to subsection (14) and identify the statewide average of grams of each benzodiazapine distributed per community pharmacy per month. The department shall report the average for each benzodiazapine to the Governor, the President of the Senate, and the Speaker of the House of Representatives by November 1, 2011.

Section 19. Paragraphs (o) and (p) are added to subsection (1) of section 499.05, Florida Statutes, to read:

499.05 Rules.—

(1) The department shall adopt rules to implement and enforce this part with respect to:

(o) Wholesale distributor reporting requirements of s. 499.0121(14).

(p) Wholesale distributor credentialing and distribution requirements of s. 499.0121(15).

Section 20. Subsections (8) and (9) are added to section

499.067, Florida Statutes, to read:

499.067 Denial, suspension, or revocation of permit, certification, or registration.—

(8) The department may deny, suspend, or revoke a permit if it finds the permittee has not complied with the credentialing requirements of s. 499.0121(15).

(9) The department may deny, suspend, or revoke a permit if it finds the permittee has not complied with the reporting requirements of, or knowingly made a false statement in a report required by, s. 499.0121(14).

Section 21. Paragraph (f) is added to subsection (3) of section 810.02, Florida Statutes, to read:

810.02 Burglary.—

(3) Burglary is a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, if, in the course of committing the offense, the offender does not make an assault or battery and is not and does not become armed with a dangerous weapon or explosive, and the offender enters or remains in a:

(f) Structure or conveyance when the offense intended to be committed therein is theft of a controlled substance as defined in s. 893.02. Notwithstanding any other law, separate judgments and sentences for burglary with the intent to commit theft of a controlled substance under this paragraph and for any applicable possession of controlled substance offense under s. 893.13 or trafficking in controlled substance offense under s. 893.135 may be imposed when all such offenses involve the same amount or amounts of a controlled substance.

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However, if the burglary is committed within a county that is subject to a state of emergency declared by the Governor under chapter 252 after the declaration of emergency is made and the perpetration of the burglary is facilitated by conditions arising from the emergency, the burglary is a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. As used in this subsection, the term "conditions arising from the emergency" means civil unrest, power outages, curfews, voluntary or mandatory evacuations, or a reduction in the presence of or response time for first responders or homeland security personnel. A person arrested for committing a burglary within a county that is subject to such a state of emergency may not be released until the person appears before a committing magistrate at a first appearance hearing. For purposes of sentencing under chapter 921, a felony offense that is reclassified under this subsection is ranked one level above the ranking under s. 921.0022 or s. 921.0023 of the offense committed.

Section 22. Paragraph (c) of subsection (2) of section 812.014, Florida Statutes, is amended to read:

812.014 Theft.—

(2)

(c) It is grand theft of the third degree and a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, if the property stolen is:

1. Valued at $300 or more, but less than $5,000.

2. Valued at $5,000 or more, but less than $10,000.

3. Valued at $10,000 or more, but less than $20,000.

4. A will, codicil, or other testamentary instrument.

1667 5. A firearm.
1668 6. A motor vehicle, except as provided in paragraph (a).
1669 7. Any commercially farmed animal, including any animal of
1670 the equine, bovine, or swine class, or other grazing animal, and
1671 including aquaculture species raised at a certified aquaculture
1672 facility. If the property stolen is aquaculture species raised
1673 at a certified aquaculture facility, then a $10,000 fine shall
1674 be imposed.
1675 8. Any fire extinguisher.
1676 9. Any amount of citrus fruit consisting of 2,000 or more
1677 individual pieces of fruit.
1678 10. Taken from a designated construction site identified by
1679 the posting of a sign as provided for in s. 810.09(2)(d).
1680 11. Any stop sign.
1681 12. Anhydrous ammonia.
1682 13. Any amount of a controlled substance as defined in s.
1683 893.02. Notwithstanding any other law, separate judgments and
1684 sentences for theft of a controlled substance under this
1685 subparagraph and for any applicable possession of controlled
1686 substance offense under s. 893.13 or trafficking in controlled
1687 substance offense under s. 893.135 may be imposed when all such
1688 offenses involve the same amount or amounts of a controlled
1689 substance.
1690
1691 However, if the property is stolen within a county that is
1692 subject to a state of emergency declared by the Governor under
1693 chapter 252, the property is stolen after the declaration of
1694 emergency is made, and the perpetration of the theft is
1695 facilitated by conditions arising from the emergency, the

offender commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, if the property is valued at $5,000 or more, but less than $10,000, as provided under subparagraph 2., or if the property is valued at $10,000 or more, but less than $20,000, as provided under subparagraph 3. As used in this paragraph, the term "conditions arising from the emergency" means civil unrest, power outages, curfews, voluntary or mandatory evacuations, or a reduction in the presence of or the response time for first responders or homeland security personnel. For purposes of sentencing under chapter 921, a felony offense that is reclassified under this paragraph is ranked one level above the ranking under s. 921.0022 or s. 921.0023 of the offense committed.

Section 23. 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, or as determined by the department, to a prescriber, dispenser, pharmacy, or patient concerning the dispensing of controlled substances. All advisory reports are for informational purposes only and impose no obligations of any nature or any legal duty on a prescriber, dispenser, pharmacy, or patient. The patient advisory report shall be provided in accordance with s. 893.13(7)(a)8. The advisory reports issued by the department are not subject to discovery or introduction into evidence in any civil or administrative action against a prescriber, dispenser, pharmacy, or patient arising out of matters that are the subject

of the report; and a person who participates in preparing, reviewing, issuing, or any other activity related to an advisory report may not be permitted or required to testify in any such civil action as to any findings, recommendations, evaluations, opinions, or other actions taken in connection with preparing, reviewing, or issuing such a report.

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

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

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

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

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

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

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


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arrest or prosecution in the foreseeable future.

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

(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, 2010,~~ The department shall design and establish a comprehensive electronic database system that has controlled substance prescriptions provided to it and that provides prescription information to a patient's health care practitioner and pharmacist who inform the department that they wish the patient advisory report provided to them. Otherwise, the patient advisory report will not be sent to the practitioner, pharmacy, or pharmacist. The system shall be designed to provide information regarding dispensed prescriptions of controlled substances and shall not infringe upon the legitimate prescribing or dispensing of a controlled substance by a prescriber or dispenser acting in good faith and in the course of professional practice. The system shall be consistent with standards of the American Society for Automation in Pharmacy (ASAP). The electronic system shall also comply with the Health Insurance Portability and Accountability Act (HIPAA)

as it pertains to protected health information (PHI), electronic protected health information (EPHI), and all other relevant state and federal privacy and security laws and regulations. The department shall establish policies and procedures as appropriate regarding the reporting, accessing the database, evaluation, management, development, implementation, operation, storage, and security of information within the system. The reporting of prescribed controlled substances shall include a dispensing transaction with a dispenser pursuant to chapter 465 or through a dispensing transaction to an individual or address in this state with a pharmacy that is not located in this state but that is otherwise subject to the jurisdiction of this state as to that dispensing transaction. The reporting of patient advisory reports refers only to reports to patients, pharmacies, and practitioners. Separate reports that contain patient prescription history information and that are not patient advisory reports are provided to persons and entities as authorized in paragraphs (7)(b) and (c) and s. 893.0551.

(b) The department, when the direct support organization receives at least $20,000 in nonstate moneys or the state receives at least $20,000 in federal grants for the prescription drug monitoring program, ~~and in consultation with the Office of Drug Control,~~ shall adopt rules as necessary concerning the reporting, accessing the database, evaluation, management, development, implementation, operation, security, and storage of information within the system, including rules for when patient advisory reports are provided to pharmacies and prescribers. The patient advisory report shall be provided in accordance with s. 893.13(7)(a)8. The department shall work with the professional

health care licensure boards, such as the Board of Medicine, the Board of Osteopathic Medicine, and the Board of Pharmacy; other appropriate organizations, such as the Florida Pharmacy Association, ~~the Office of Drug Control,~~ the Florida Medical Association, the Florida Retail Federation, and the Florida Osteopathic Medical Association, including those relating to pain management; and the Attorney General, the Department of Law Enforcement, and the Agency for Health Care Administration to develop rules appropriate for the prescription drug monitoring program.

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

(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.

(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 7 ~~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. The program manager, designated program and support staff who act at the direction of or in the absence of the program manager, and any individual who has similar access regarding the management


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of the database from the prescription drug monitoring program shall submit fingerprints to the department for background screening. The department shall follow the procedure established by the Department of Law Enforcement to request a statewide criminal history record check and to request that the Department of Law Enforcement forward the fingerprints to the Federal Bureau of Investigation for a national criminal history record check.

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

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

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

3. A law enforcement agency during active investigations

regarding potential criminal activity, fraud, or theft regarding prescribed controlled substances.

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

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

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

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

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

(e) All transmissions of data required by this section must comply with relevant state and federal privacy and security laws and regulations. However, any authorized agency or person under s. 893.0551 receiving such information as allowed by s. 893.0551 may maintain the information received for up to 24 months before purging it from his or her records or maintain it for longer than 24 months if the information is pertinent to ongoing health care or an active law enforcement investigation or prosecution.

(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 or private funding applied for or received by the state. The department may not commit funds for the monitoring program without ensuring funding is available. The prescription drug monitoring program and the implementation thereof are contingent upon receipt of the nonstate funding. The department and state government shall cooperate with the direct-support organization established pursuant to subsection (11) in seeking federal grant funds, other nonstate grant funds, gifts, donations, or other private moneys for the department so long as the costs of doing so are not considered material. Nonmaterial

costs for this purpose include, but are not limited to, the costs of mailing and personnel assigned to research or apply for a grant. Notwithstanding the exemptions to competitive-solicitation requirements under s. 287.057(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. Funds provided, directly or indirectly, by prescription drug manufacturers may not be used to implement the program.

(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.


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(c) The State Surgeon General ~~director of the Office of Drug Control~~ shall appoint a board of directors for the direct-support organization. ~~The director may designate employees of the Office of Drug Control, state employees other than state employees from the department, and any other nonstate employees as appropriate, to serve on the board.~~ Members of the board shall serve at the pleasure of ~~the director of~~ the State Surgeon General ~~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 department ~~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 department ~~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:

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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 department ~~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~~


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~~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 department ~~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 department ~~Office of Drug Control~~ if the direct-support organization is no longer approved by the department ~~Office of Drug Control~~ to operate in the best interests of the state.

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

(h) The 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.

(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 department ~~Office of Drug Control~~ and the Office of Policy and Budget in the Executive Office of the Governor.

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

(12) A prescriber or dispenser may have access to the information under this section which relates to a patient of that prescriber or dispenser as needed for the purpose of reviewing the patient's controlled drug prescription history. A prescriber or dispenser acting in good faith is immune from any civil, criminal, or administrative liability that might otherwise be incurred or imposed for receiving or using information from the prescription drug monitoring program. This subsection does not create a private cause of action, and a person may not recover damages against a prescriber or dispenser authorized to access information under this subsection for accessing or failing to access such information.

(13) To the extent that funding is provided for such purpose through federal or private grants or gifts and other types of available moneys, the department~~, in collaboration with the Office of Drug Control,~~ shall study the feasibility of enhancing the prescription drug monitoring program for the purposes of public health initiatives and statistical reporting that respects the privacy of the patient, the prescriber, and the dispenser. Such a study shall be conducted in order to further improve the quality of health care services and safety by improving the prescribing and dispensing practices for prescription drugs, taking advantage of advances in technology, reducing duplicative prescriptions and the overprescribing of


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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 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 24. Section 893.065, Florida Statutes, is amended to read:

893.065 Counterfeit-resistant prescription blanks for controlled substances listed in Schedule II, Schedule III, or Schedule IV.—The Department of Health shall develop and adopt by rule the form and content for a counterfeit-resistant prescription blank which must ~~may~~ be used by practitioners for the purpose of prescribing a controlled substance listed in Schedule II, Schedule III, ~~or~~ Schedule IV, or Schedule V pursuant to s. 456.42. The Department of Health may require the prescription blanks to be printed on distinctive, watermarked paper and to bear the preprinted name, address, and category of professional licensure of the practitioner and that practitioner's federal registry number for controlled substances. The prescription blanks may not be transferred.

Section 25. Subsections (4) and (5) of section 893.07, Florida Statutes, are amended to read:

893.07 Records.—

(4) Every inventory or record required by this chapter, including prescription records, shall be maintained:

(a) Separately from all other records of the registrant, or

(b) Alternatively, in the case of Schedule III, IV, or V controlled substances, in such form that information required by this chapter is readily retrievable from the ordinary business records of the registrant.

In either case, the records described in this subsection shall be kept and made available for a period of at least 2 years for inspection and copying by law enforcement officers whose duty it is to enforce the laws of this state relating to controlled substances. Law enforcement officers are not required to obtain a subpoena, court order, or search warrant in order to obtain access to or copies of such records.

(5) Each person described in subsection (1) shall:

(a) Maintain a record which shall contain a detailed list of controlled substances lost, destroyed, or stolen, if any; the kind and quantity of such controlled substances; and the date of the discovering of such loss, destruction, or theft.

(b) In the event of the discovery of the theft or significant loss of controlled substances, report such theft or significant loss to the sheriff of that county within 24 hours after discovery. A person who fails to report a theft or significant loss of a substance listed in s. 893.03(3), (4), or (5) within 24 hours after discovery as required in this paragraph commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083. A person who fails to report a theft or significant loss of a substance listed in s. 893.03(2) within 24 hours after discovery as required in this paragraph commits a misdemeanor of the first degree, punishable

as provided in s. 775.082 or s. 775.083.

Section 26. Subsection (7) of section 893.13, Florida Statutes, is amended to read:

893.13 Prohibited acts; penalties.—

(7)(a) A ~~It is unlawful for any~~ person may not:

1. ~~To~~ Distribute or dispense a controlled substance in violation of this chapter.

2. ~~To~~ Refuse or fail to make, keep, or furnish any record, notification, order form, statement, invoice, or information required under this chapter.

3. ~~To~~ Refuse ~~an~~ entry into any premises for any inspection or ~~to~~ refuse to allow any inspection authorized by this chapter.

4. ~~To~~ Distribute a controlled substance named or described in s. 893.03(1) or (2) except pursuant to an order form as required by s. 893.06.

5. ~~To~~ Keep or maintain any store, shop, warehouse, dwelling, building, vehicle, boat, aircraft, or other structure or place which is resorted to by persons using controlled substances in violation of this chapter for the purpose of using these substances, or which is used for keeping or selling them in violation of this chapter.

6. ~~To~~ Use to his or her own personal advantage, or ~~to~~ reveal, any information obtained in enforcement of this chapter except in a prosecution or administrative hearing for a violation of this chapter.

7. ~~To~~ Possess a prescription form which has not been completed and signed by the practitioner whose name appears printed thereon, unless the person is that practitioner, is an agent or employee of that practitioner, is a pharmacist, or is a

supplier of prescription forms who is authorized by that practitioner to possess those forms.

8. ~~To~~ Withhold information from a practitioner from whom the person seeks to obtain a controlled substance or a prescription for a controlled substance that the person making the request has received a controlled substance or a prescription for a controlled substance of like therapeutic use from another practitioner within the previous 30 days.

9. ~~To~~ Acquire or obtain, or attempt to acquire or obtain, possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge.

10. ~~To~~ Affix any false or forged label to a package or receptacle containing a controlled substance.

11. ~~To~~ Furnish false or fraudulent material information in, or omit any material information from, any report or other document required to be kept or filed under this chapter or any record required to be kept by this chapter.

12. ~~To~~ Store anhydrous ammonia in a container that is not approved by the United States Department of Transportation to hold anhydrous ammonia or is not constructed in accordance with sound engineering, agricultural, or commercial practices.

13. With the intent to obtain a controlled substance or combination of controlled substances that are not medically necessary for the person or an amount of a controlled substance or substances that are not medically necessary for the person, obtain or attempt to obtain from a practitioner a controlled substance or a prescription for a controlled substance by misrepresentation, fraud, forgery, deception, subterfuge, or concealment of a material fact. For purposes of this

subparagraph, a material fact includes whether the person has an existing prescription for a controlled substance issued for the same period of time by another practitioner or as described in subparagraph 8.

(b) A health care practitioner, with the intent to provide a controlled substance or combination of controlled substances that are not medically necessary to his or her patient or an amount of controlled substances that are not medically necessary for his or her patient, may not provide a controlled substance or a prescription for a controlled substance by misrepresentation, fraud, forgery, deception, subterfuge, or concealment of a material fact. For purposes of this paragraph, a material fact includes whether the patient has an existing prescription for a controlled substance issued for the same period of time by another practitioner or as described in subparagraph (a)8.

(c) ~~(b)~~ Any person who violates the provisions of subparagraphs (a)1.-7. commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083; except that, upon a second or subsequent violation, the person commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(d) ~~(c)~~ Any person who violates the provisions of subparagraphs (a)8.-12. commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(e) A person or health care practitioner who violates the provisions of paragraph (b) or subparagraph (a)13. commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, if any controlled substance

that is the subject of the offense is listed in Schedule II, Schedule III, or Schedule IV.

Section 27. Present subsections (3) through (10) of section 893.138, Florida Statutes, are redesignated as subsections (4) through (11), respectively, and a new subsection (3) is added to that section, to read:

893.138 Local administrative action to abate drug-related, prostitution-related, or stolen-property-related public nuisances and criminal gang activity.—

(3) Any pain-management clinic, as described in s. 458.3265 or s. 459.0137, which has been used on more than two occasions within a 6-month period as the site of a violation of:

(a) Section 784.011, s. 784.021, s. 784.03, or s. 784.045, relating to assault and battery;

(b) Section 810.02, relating to burglary;

(c) Section 812.014, relating to dealing in theft;

(d) Section 812.131, relating to robbery by sudden snatching; or

(e) Section 893.13, relating to the unlawful distribution of controlled substances,

may be declared to be a public nuisance, and such nuisance may be abated pursuant to the procedures provided in this section.

Section 28. (1) DISPOSITION OF CONTROLLED SUBSTANCES.—

(a) Within 10 days after the effective date of this act, each physician licensed under chapter 458, chapter 459, chapter 461, or chapter 466, Florida Statutes, unless he or she meets one of the exceptions for physician who dispenses under s. 465.0276, Florida Statutes, shall ensure that the undispensed

inventory of controlled substances listed in Schedule II or Schedule III as provided in s. 893.03, Florida Statutes, purchased under the physician's Drug Enforcement Administration number for dispensing is:

1. Returned in compliance with the laws and rules adopted under chapter 499, Florida Statutes, to the wholesale distributor, as defined in s. 499.003, Florida Statutes, which distributed the controlled substances to the physician; or

2. Turned in to local law enforcement agencies and abandoned.

(b) Wholesale distributors shall buy back the undispensed inventory of controlled substances listed in Schedule II or Schedule III as provided in s. 893.03, Florida Statutes, which are in the manufacturer's original packing, unopened, and in date, in accordance with the established policies of the wholesale distributor or the contractual terms between the wholesale distributor and the physician concerning returns.

(2) PUBLIC HEALTH EMERGENCY.—

(a) The Legislature finds that:

1. Prescription drug overdose has been declared a public health epidemic by the United States Centers for Disease Control and Prevention.

2. Prescription drug abuse results in an average of seven deaths in this state each day.

3. Physicians in this state purchased more than 85 percent of the oxycodone purchased by all practitioners in the United States in 2006.

4. Physicians in this state purchased more than 93 percent of the methadone purchased by all practitioners in the United

States in 2006.

5. Some physicians in this state dispense medically unjustifiable amounts of controlled substances to addicts and to people who intend to illegally sell the drugs.

6. Physicians in this state who have purchased large quantities of controlled substances may have significant inventory 30 days after the effective date of this act.

7. Thirty days after the effective date of this act, the only legal method for a dispensing practitioner to sell or otherwise transfer controlled substances listed in Schedule II or Schedule III as provided in s. 893.03, Florida Statutes, purchased for dispensing, is through the abandonment procedures of subsection (1) or as authorized under s. 465.0276, Florida Statutes.

8. It is likely that the same physicians who purchase and dispense medically unjustifiable amounts of drugs will not legally dispose of the remaining inventory.

9. The actions of such dispensing practitioners may result in substantial injury to the public health.

(b) Immediately upon the effective date of this act, the State Health Officer shall declare a public health emergency pursuant to s. 381.00315, Florida Statutes. Pursuant to that declaration, the Department of Health, the Attorney General, the Department of Law Enforcement, and local law enforcement agencies shall take the following actions:

1. Within 2 days after the effective date of this act, in consultation with wholesale distributors as defined in s. 499.003, Florida Statutes, the Department of Health shall identify dispensing practitioners who purchased more than an

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average of 2,000 unit doses of controlled substances listed in Schedule II or Schedule III as provided in s. 893.03, Florida Statutes, per month in the previous 6 months, and shall identify the dispensing practitioners in that group who pose the greatest threat to the public health based on an assessment of:

a. The risk of noncompliance with subsection (1).

b. The purchase amounts.

c. The manner of medical practice.

d. Any other factor set by the State Health Officer.

The Attorney General shall consult and coordinate with federal law enforcement agencies. The Department of Law Enforcement shall coordinate the efforts of local law enforcement agencies.

2. On the 3rd day after the effective date of this act, the Department of Law Enforcement or local law enforcement agencies shall enter the business premises of the dispensing practitioners identified as posing the greatest threat to public health and quarantine any inventory of controlled substances listed in Schedule II or Schedule III as provided in s. 893.03, Florida Statutes, of such dispensing practitioners on site.

3. The Department of Law Enforcement or local law enforcement agencies shall ensure the security of such inventory 24 hours a day until the inventory is seized as contraband or deemed to be lawfully possessed for dispensing by the physician in accordance with s. 465.0276, Florida Statutes.

4. On the 31st day after the effective date of this act, any remaining inventory of controlled substances listed in Schedule II or Schedule III as provided in s. 893.03, Florida Statutes, purchased for dispensing by practitioners is deemed

contraband under s. 893.12, Florida Statutes. The Department of Law Enforcement or local law enforcement agencies shall seize the inventory and comply with the provisions of s. 893.12, Florida Statutes, to destroy it.

(c) In order to implement this subsection, the sum of $3 million of nonrecurring funds from the General Revenue Fund is appropriated to the Department of Law Enforcement for the 2010-2011 fiscal year. The Department of Law Enforcement shall expend the appropriation by reimbursing local law enforcement agencies for the overtime-hour costs associated with securing the quarantined controlled substance inventory as provided in paragraph (b) and activities related to investigation and prosecution of crimes related to prescribed controlled substances. If requests for reimbursement exceed the amount appropriated, the reimbursements shall be prorated by the hours of overtime per requesting agency at a maximum of one law enforcement officer per quarantine site.

(3) REPEAL.—This section expires January 1, 2013.

Section 29. The Department of Health shall establish a practitioner profile for dentists licensed under chapter 466, Florida Statutes, for a practitioner's designation as a controlled substance prescribing practitioner as provided in s. 456.44, Florida Statutes.

Section 30. If any provision of this act or its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the act which can be given effect without the invalid provision or application, and to this end the provisions of this act are severable.

Section 31. This act shall take effect July 1, 2011.

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

And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to prescription drugs; amending s. 456.072, F.S.; making failure to comply with the requirements of s. 456.44, F.S., grounds for disciplinary action; providing mandatory administrative penalties for certain violations related to prescribing; amending s. 456.42, F.S.; requiring prescriptions for controlled substances to be written on a counterfeit-resistant pad produced by an approved vendor or electronically prescribed; providing conditions for being an approved vendor; creating s. 456.44, F.S.; providing definitions; requiring certain physicians to designate themselves as controlled substance prescribing practitioners on their practitioner profiles; providing an effective date; requiring registered physicians to meet certain standards of practice; requiring a physical examination; requiring a written protocol; requiring an assessment of risk for aberrant behavior; requiring a treatment plan; requiring specified informed consent; requiring consultation and referral in certain circumstances; requiring medical records meeting certain criteria; providing an exemption for

physicians meeting certain criteria; amending s. 458.3265, F.S., relating to regulation of pain-management clinics and medical doctors; redefining the term "pain-management clinic"; providing definitions; providing an exemption from registration for clinics owned and operated by physicians or medical specialists meeting certain criteria; revising responsibilities of physicians in pain-management clinics; allowing physician assistants and advanced registered nurse practitioners to perform physical examinations; requiring physicians in pain-management clinics to ensure compliance with certain requirements; imposing facility and physical operations requirements; imposing infection control requirements; imposing health and safety requirements; imposing quality assurance requirements; imposing data collection and reporting requirements; revising rulemaking authority; conforming provisions to changes made by the act; providing for future expiration of provisions; amending s. 458.327, F.S.; providing that dispensing certain controlled substances in violation of specified provisions is a third-degree felony; providing penalties; amending s. 458.331, F.S.; providing that dispensing certain controlled substances in violation of specified provisions is grounds for disciplinary action; providing penalties; amending s. 459.0137, F.S., relating to regulation of pain-management clinics and osteopathic physicians; providing definitions; providing an exemption from

registration for clinics owned and operated by physicians meeting certain criteria; revising responsibilities of osteopathic physicians in pain-management clinics; allowing physician assistants and advanced registered nurse practitioners to perform physical examinations; requiring osteopathic physicians in pain-management clinics to ensure compliance with certain requirements; imposing facility and physical operations requirements; imposing infection control requirements; imposing health and safety requirements; imposing quality assurance requirements; imposing data collection and reporting requirements; revising rulemaking authority; conforming provisions to changes made by the act; providing for future expiration of provisions; amending s. 459.013, F.S.; providing that dispensing certain controlled substances in violation of specified provisions is a third-degree felony; providing penalties; amending s. 459.015, F.S.; providing that dispensing certain controlled substances in violation of specified provisions is grounds for disciplinary action; providing penalties; amending s. 465.015, F.S.; requiring a pharmacist to report to the sheriff within a specified period any instance in which a person fraudulently obtained or attempted to fraudulently obtain a controlled substance; providing criminal penalties; providing suggested criteria for the reports; amending s. 465.016, F.S.; providing additional grounds for denial

of or disciplinary action against a pharmacist license; amending s. 465.018, F.S.; providing grounds for permit denial or discipline; requiring applicants to pay or make arrangements to pay amounts owed to the Department of Health; requiring an inspection; requiring permittees to maintain certain records; requiring a community pharmacy to be permitted under ch. 465, F.S., on or after a specified date in order to dispense Schedule II or Schedule III controlled substances; amending s. 465.022, F.S.; requiring the Department of Health to adopt rules related to procedures for dispensing controlled substances; providing requirements for the issuance of a pharmacy permit; requiring disclosure of financial interests; requiring submission of policies and procedures and providing for grounds for permit denial based on such policies and procedures; authorizing the Department of Health to phase in the policies and procedures requirement over an 18-month period beginning July 1, 2011; requiring the Department of Health to deny a permit to applicants under certain circumstances; requiring permittees to provide notice of certain management changes; requiring prescription department managers to meet certain criteria; imposing duties on prescription department managers; limiting the number of locations a prescription department manager may manage; requiring the board to adopt rules related to recordkeeping; providing that permits are not transferable; amending s. 465.0276, F.S.; deleting a

provision establishing a 72-hour supply limit on dispensing certain controlled substances; prohibiting registered dispensing practitioners from dispensing certain controlled substances; revising the list of exceptions that allow registered dispensing practitioners to dispense certain controlled substances; amending s. 499.0051, F.S.; providing criminal penalties for violations of certain provisions of s. 499.0121, F.S.; amending s. 499.012, F.S.; requiring wholesale distributor permit applicants to submit documentation of credentialing policies; amending s. 499.0121, F.S.; providing reporting requirements regarding certain controlled substances for prescription drug wholesale distributors, out-of-state prescription drug wholesale distributors, retail pharmacy drug wholesale distributors, manufacturers, or repackagers that engage in the wholesale distribution of controlled substances to a retail pharmacy; requiring the Department of Health to share the reported data with law enforcement agencies; requiring the Department of Law Enforcement to make investigations based on the reported data; providing credentialing requirements for distribution of controlled substances to certain entities by wholesale distributors; requiring distributors to identify suspicious transactions; requiring distributors to determine the reasonableness of orders for controlled substances over certain amounts; requiring distributors to maintain documents

that support the report submitted to the Department of Health; requiring the department to assess data; requiring the department to report certain data to the Governor, President of the Senate, and Speaker of the House of Representatives by certain dates; prohibiting distribution to entities with certain criminal backgrounds; amending s. 499.05, F.S.; authorizing rulemaking concerning specified controlled substance wholesale distributor reporting requirements and credentialing requirements; amending s. 499.067, F.S.; authorizing the Department of Health to take disciplinary action against wholesale distributors failing to comply with specified credentialing or reporting requirements; amending s. 810.02, F.S.; authorizing separate judgments and sentences for burglary with the intent to commit theft of a controlled substance under specified provisions and for any applicable possession of controlled substance offense under specified provisions in certain circumstances; amending s. 812.014, F.S.; authorizing separate judgments and sentences for theft of a controlled substance under specified provisions and for any applicable possession of controlled substance offense under specified provisions in certain circumstances; amending s. 893.055, F.S., relating to the prescription drug monitoring program; deleting obsolete dates; deleting references to the Office of Drug Control; requiring reports to the prescription drug monitoring system to be made in 7 days rather

than 15 days; prohibiting the use of certain funds to implement the program; requiring criminal background screening for those persons who have direct access to the prescription drug monitoring program's database; requiring the State Surgeon General to appoint a board of directors for the direct-support organization; conforming provisions to changes made by the act; amending s. 893.065, F.S.; conforming provisions to changes made by the act; amending s. 893.07, F.S.; providing that law enforcement officers are not required to obtain a subpoena, court order, or search warrant in order to obtain access to or copies of specified controlled substance inventory records; requiring reporting of the discovery of the theft or loss of controlled substances to the sheriff within a specified period; providing criminal penalties; amending s. 893.13, F.S.; prohibiting a person from obtaining or attempting to obtain from a practitioner a controlled substance or a prescription for a controlled substance by misrepresentation, fraud, forgery, deception, subterfuge, or concealment of a material fact; prohibiting a health care provider from providing a controlled substance or a prescription for a controlled substance by misrepresentation, fraud, forgery, deception, subterfuge, or concealment of a material fact; prohibiting a person from adulterating a controlled substance for certain use without authorization by a prescribing physician; providing penalties; amending s. 893.138, F.S.; providing

circumstances in which a pain-management clinic may be declared a public nuisance; providing for the disposition of certain controlled substance inventory held by specified licensed physicians; providing certain requirements for a physician returning inventory to a distributor; requiring wholesale distributors to buy back certain undispensed inventory of controlled substances; providing for a declaration of a public health emergency; requiring certain actions relating to dispensing practitioners identified as posing the greatest threat to public health; providing an appropriation; providing for future expiration of program provisions; requiring the Department of Health to establish a practitioner profile for dentists; providing for severability; providing an effective date.