**By** the Committee on Health Regulation; and Senator Fasano

588-02461B-11 2011818c1

A bill to be entitled

An act relating to controlled substances; amending s. 400.9905, F.S.; redefining the terms "clinic" and "portable equipment provider" within the Health Care Clinic Act; amending s. 456.013, F.S.; authorizing certain health care practitioners to complete a continuing education course relating to the prescription drug monitoring program; providing requirements for the course; requiring the Department of Health or a board that is authorized to exercise regulatory or rulemaking functions within the department to approve the course offered through a facility licensed under ch. 395, F.S., under certain circumstances; providing for application of the course requirements; requiring a board or the Department of Health to adopt rules; amending s. 458.305, F.S.; defining the term "dispensing physician" as it relates to the practice of medicine in this state; prohibiting certain persons from using titles or displaying signs that would lead the public to believe that they engage in the dispensing of controlled substances; prohibiting certain persons, firms, or corporations from using a trade name, sign, letter, or advertisement that implies that the persons, firms, or corporations are licensed or registered to dispense prescription drugs; prohibiting certain persons, firms, or corporations from holding themselves out to the public as licensed or registered to dispense controlled substances; providing penalties; amending

s. 458.3191, F.S.; revising the information in the physician survey that is submitted by persons who apply for licensure renewal as a physician under ch. 458 or ch. 459, F.S.; amending s. 458.3192, F.S.; requiring the Department of Health to provide nonidentifying information to the prescription drug monitoring program's Implementation and Oversight Task Force regarding the number of physicians that are registered with the prescription drug monitoring program and that use the database from the program in their practice; amending s. 458.3265, F.S.; revising the list of entities that are not required to register as a pain-management clinic; deleting certain requirements for a physician to practice medicine in a pain-management clinic; requiring a physician, an advanced registered nurse practitioner, or a physician assistant to perform an appropriate medical examination of a patient on the same day that the physician dispenses or prescribes a controlled substance to the patient at a pain-management clinic; requiring a physician who works in a pain-management clinic to document the reason a prescription for a certain dosage of a controlled substance is within the proper standard of care; creating a felony of the third degree for any person to register or attempt to register a pain-management clinic through misrepresentation or fraud; amending s. 458.327, F.S.; providing additional penalties; amending s. 458.331, F.S.; providing additional grounds for disciplinary

action by the Board of Medicine; amending s. 459.003, F.S.; defining the term "dispensing physician" as it relates to the practice of osteopathic medicine in this state; amending s. 459.013, F.S.; providing additional penalties; amending s. 459.0137, F.S.; providing an exemption from the requirement that all privately owned pain-management clinics, facilities, or offices that 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, must register with the Department of Health; requiring a physician, an advanced registered nurse practitioner, or a physician assistant to perform an appropriate medical examination of a patient on the same day that the physician dispenses or prescribes a controlled substance to the patient at a pain-management clinic; requiring an osteopathic physician who works in a pain-management clinic to document the reason a prescription for a certain dosage of a controlled substance is within the proper standard of care; creating a felony of the third degree for a licensee or other person who serves as the designated physician of a pain-management clinic to register a pain-management clinic through misrepresentation or fraud; amending s. 459.015, F.S.; providing additional grounds for disciplinary action by the Board of Osteopathic Medicine; amending s. 465.015, F.S.; prohibiting certain persons from

knowingly failing to report to the local county sheriff's office the commission of a felony involving a person who acquires or obtains possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge under certain conditions; providing penalties; providing requirements for reporting the commission of a felony that involves a person who acquires or obtains possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge; providing that a pharmacist, pharmacy intern, or other person employed by or at a pharmacy is not subject to disciplinary action for reporting; amending s. 465.0276, F.S.; requiring a practitioner to register as a dispensing practitioner in order to dispense controlled substances; amending s. 766.101, F.S.; conforming a cross-reference; amending s. 810.02, F.S.; redefining the offense of burglary to include the theft of a controlled substance within a structure or conveyance; amending s. 812.014, F.S.; redefining the offense of theft to include the theft of a controlled substance; creating s. 893.021, F.S.; providing conditions in which a drug is considered adulterated; providing that a physician is not prevented from directing or prescribing a change to the recognized manufactured recommendations for use of any controlled substance for a patient under certain circumstances; requiring a prescribing physician to indicate on the original prescription any deviation of

the recognized manufacturer's recommended use of a controlled substance; requiring a pharmacist or physician to indicate such deviation on the label of the prescription upon dispensing; amending s. 893.04, F.S.; revising the required information that must appear on the face of a prescription or written record of a controlled substance before it is dispensed by a pharmacist; amending s. 893.055, F.S.; requiring that the prescription drug monitoring program comply with the minimum requirements of the National All Schedules Prescription Electronic Reporting Act; requiring the Department of Health to establish a method to allow corrections to the database of the prescription drug monitoring program; requiring the number of refills ordered and whether the drug was dispensed as a refill or a first-time request to be included in the database of the prescription drug monitoring program; revising the number of days in which a dispensed controlled substance must be reported to the department through the prescription drug monitoring program; revising the list of acts of dispensing or administering which are exempt from reporting; requiring a pharmacy, prescriber, practitioner, or dispenser to register with the department by submitting a registering document in order to have access to certain information in the prescription drug monitoring program's database; requiring the department to approve the registering document before granting access to information in the prescription drug

monitoring program's database; requiring criminal background screening for those persons who have direct access to the prescription drug monitoring program's database; authorizing the Attorney General to obtain confidential and exempt information for Medicaid fraud cases and Medicaid investigations; requiring certain documentation to be provided to the program manager in order to release confidential and exempt information from the prescription drug monitoring program's database to a patient, legal guardian, or a designated health care surrogate; authorizing the Agency for Health Care Administration to obtain confidential and exempt information from the prescription drug monitoring program's database for Medicaid fraud cases and Medicaid investigations involving controlled substances; deleting a provision requiring that administrative costs of the prescription drug monitoring program be funded through federal grants and private sources; requiring the State Surgeon General to enter into reciprocal agreements for the sharing of information in the prescription drug monitoring program with other states that have a similar prescription drug monitoring program; requiring the State Surgeon General to annually review a reciprocal agreement to determine its compatibility; providing requirements for compatibility; prohibiting the sharing of certain information; amending s. 893.0551, F.S.; authorizing the Department of Health to disclose certain confidential and exempt

information in the prescription drug monitoring program's database under certain circumstances involving reciprocal agreements with other states; prohibiting the sharing of information from the prescription drug monitoring program's database which is not for the purpose that is statutorily authorized or according to the State Surgeon General's determination of compatibility; amending s. 893.07, F.S.; requiring that a person report to the local sheriff's office the theft or loss of a controlled substance within a specified time; providing penalties; providing legislative intent; 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; authorizing a law enforcement officer to seize as evidence the adulteration or off-label use of a prescribed controlled substance; providing that such adulterated or off-label use of the controlled substance may be returned to its owner only under certain conditions;

providing penalties; prohibiting a prescribing practitioner from writing a prescription for a controlled substance and authorizing or directing the adulteration of the dispensed form of the controlled substance for the purpose of ingestion by means not medically necessary; amending s. 893.138, F.S.; providing circumstances in which a pain-management clinic may be declared a public nuisance; providing definitions; requiring the Board of Pharmacy to create a list of opioid analgesic drugs; providing requirements for the list of opioid analgesic drugs; prohibiting a pharmacist from interchanging or substituting an opioid analgesic drug, brand, or generic for an opioid analgesic drug incorporating a tamper-resistance technology unless certain requirements are met; providing an effective date.

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

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

400.9905 Definitions.—

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

(a) Entities licensed or registered by the state under

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

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

(c) Entities that are owned, directly or indirectly, by an entity licensed or registered by the state pursuant to chapter 395; or entities that are owned, directly or indirectly, by an

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

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

(e) An entity that is exempt from federal taxation under 26

U.S.C. s. 501(c)(3) or (4), an employee stock ownership plan under 26 U.S.C. s. 409 that has a board of trustees not less than two-thirds of which are Florida-licensed health care practitioners and provides only physical therapy services under physician orders, any community college or university clinic, and any entity owned or operated by the federal or state government, including agencies, subdivisions, or municipalities thereof.

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

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

the practitioner's license, except that, for the purposes of this part, a clinic owned by a licensee in s. 456.053(3)(b) that provides only services authorized pursuant to s. 456.053(3)(b) may be supervised by a licensee specified in s. 456.053(3)(b).

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

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

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

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

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

securities exchange.

(7) "Portable equipment provider" means an entity that contracts with or employs persons to provide portable equipment to multiple locations performing treatment or diagnostic testing of individuals~~, that bills third-party payors for those services,~~ and that otherwise meets the definition of a clinic in subsection (4).

Section 2. Subsection (7) of section 456.013, Florida Statutes, is amended to read:

456.013 Department; general licensing provisions.—

(7)(a) The boards, or the department when there is no board, shall require the completion of a 2-hour course relating to prevention of medical errors as part of the licensure and renewal process. The 2-hour course counts ~~shall count~~ towards the total number of continuing education hours required for the profession. The board or department shall approve the course ~~shall be approved by the board or department~~, as appropriate, which must ~~and shall~~ include a study of root-cause analysis, error reduction and prevention, and patient safety. In addition, the course approved by the Board of Medicine and the Board of Osteopathic Medicine must ~~shall~~ include information relating to the five most misdiagnosed conditions during the previous biennium, as determined by the board. If the course is being offered by a facility licensed under ~~pursuant to~~ chapter 395 for its employees, the board may approve up to 1 hour of the 2-hour course to be specifically related to error reduction and prevention methods used in that facility.

(b) As a condition of initial licensure and at each subsequent license renewal, the boards, or the department if

there is no board, shall allow each practitioner licensed under chapter 458, chapter 459, chapter 461, chapter 465, or chapter 466 whose lawful scope of practice authorizes the practitioner to prescribe, administer, or dispense controlled substances to complete a 1-hour continuing education course relating to the prescription drug monitoring program. The course must include, but need not be limited to:

1. The purpose of the prescription drug monitoring program.

2. The practitioners' capabilities for improving the standard of care for patients by using the prescription drug monitoring program.

3. How the prescription drug monitoring program can help practitioners detect doctor shopping.

4. The involvement of law enforcement personnel, the Attorney General's Medicaid Fraud Unit, and medical regulatory investigators with the prescription drug monitoring program.

5. The procedures for registering for access to the prescription drug monitoring program.

The course hours may be included in the total number of hours of continuing education required by the profession and must be approved by the board or by the department if there is no board. The boards, or the department if there is no board, shall approve the course offered through a facility licensed under chapter 395 for its employees if the course is at least 3 hours and covers the education requirements.

(c) The course requirements in paragraph (b) apply to each licensee renewing his or her license on or after July 1, 2012, and to each applicant approved for licensure on or after January

1, 2013.

(d) By October 1, 2011, the boards, or the department if there is no board, shall adopt rules as necessary to administer this subsection.

Section 3. Section 458.305, Florida Statutes, is amended to read:

458.305 Definitions.—As used in this chapter:

(1) "Board" means the Board of Medicine.

(2) "Department" means the Department of Health.

(3) "Dispensing physician" means a physician who is registered as a dispensing practitioner under s. 465.0276.

(4) ~~(3)~~ "Practice of medicine" means the diagnosis, treatment, operation, or prescription for any human disease, pain, injury, deformity, or other physical or mental condition.

(5) ~~(4)~~ "Physician" means a person who is licensed to practice medicine in this state.

Section 4. Advertising of controlled substances by a dispensing physician.—

(1)(a) Only a dispensing physician licensed under chapter 458 or chapter 459, Florida Statutes, may use the title "dispensing physician" or "dispenser" or otherwise lead the public to believe that he or she is engaged in the dispensing of controlled substances.

(b) A person, other than an owner of a:

1. Pain-management clinic registered under chapter 458 or chapter 459, Florida Statutes; or

2. Health clinic licensed under chapter 400, Florida Statutes,

may not display any sign or take any other action that would lead the public to believe that such person is engaged in the business of dispensing a controlled substance. Any advertisement that states "dispensing onsite" or "onsite pharmacy" violates this paragraph. This paragraph does not preclude a person who is not licensed as a medical practitioner from owning a pain-management clinic.

(c) A person, firm, or corporation, unless licensed under chapter 465, Florida Statutes, may not use in a trade name, sign, letter, or advertisement any term, including "drug," "pharmacy," "onsite pharmacy," "dispensing," "dispensing onsite," "prescription drugs," "Rx," or "apothecary," which implies that the person, firm, or corporation is licensed or registered to dispense prescription drugs in this state.

(2) A person who violates paragraph (1)(a) or paragraph (1)(b) commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083, Florida Statutes. A person who violates paragraph (1)(c) commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, Florida Statutes. In any warrant, information, or indictment, it is not necessary to negate any exceptions, and the burden of any exception is upon the defendant.

Section 5. Paragraph (a) of subsection (1) of section 458.3191, Florida Statutes, is amended to read:

458.3191 Physician survey.—

(1) Each person who applies for licensure renewal as a physician under this chapter or chapter 459 must, in conjunction with the renewal of such license under procedures adopted by the Department of Health and in addition to any other information

that may be required from the applicant, furnish the following to the Department of Health in a physician survey:

(a) Licensee information, including, but not limited to:

1. Frequency and geographic location of practice within the state.

2. Practice setting.

3. Percentage of time spent in direct patient care.

4. Anticipated change to license or practice status.

5. Areas of specialty or certification.

6. Whether the department has ever approved or denied the physician's registration for access to a patient's information in the prescription drug monitoring program's database.

7. Whether the physician uses the prescription drug monitoring program with patients in his or her medical practice.

Section 6. Subsection (3) is added to section 458.3192, Florida Statutes, to read:

458.3192 Analysis of survey results; report.—

(3) By November 1 each year, the Department of Health shall provide nonidentifying information to the prescription drug monitoring program's Implementation and Oversight Task Force regarding the number of physicians who are registered with the prescription drug monitoring program and who also use the database from the prescription drug monitoring program for their patients in their medical practice.

Section 7. Paragraph (a) of subsection (1) and paragraphs (a) and (c) of subsection (2) of section 458.3265, Florida Statutes, are amended, and paragraphs (f) and (g) are added to subsection (5) of that section, to read:

458.3265 Pain-management clinics.—

(1) REGISTRATION.—

(a) All privately owned pain-management clinics, facilities, or offices, hereinafter referred to as "clinics," which advertise in any medium for any type of pain-management services, or employ a physician who is primarily engaged in the treatment of pain by prescribing or dispensing controlled substance medications, must register with the department unless:

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

2. The majority of the physicians who provide services in the clinic primarily provide surgical services or interventional pain procedures of the type routinely billed using surgical codes;

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

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

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

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

(2) PHYSICIAN RESPONSIBILITIES.—These responsibilities 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.

(c) A physician, an advanced registered nurse practitioner, or a physician assistant must perform an appropriate medical ~~a physical~~ examination of a patient on the same day that the physician ~~he 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 such dosage is within the standard of care. For the purpose of this paragraph, the standard of care is set forth in rule 64B8-9.013(3), Florida Administrative Code ~~for prescribing~~

~~or dispensing that quantity~~.

(5) PENALTIES; ENFORCEMENT.—

(f) A licensee or other person who serves as the designated physician of a pain-management clinic as defined in this section or s. 459.0137 and registers a pain-management clinic through misrepresentation or fraud or procures or attempts to procure the registration of a pain-management clinic for any other person by making or causing to be made any false or fraudulent representation commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(g) Any person who registers a pain-management clinic through misrepresentation or fraud or who procures or attempts to procure the registration of a pain-management clinic for any other person by making or causing to be made any false or fraudulent representation, commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

Section 8. Paragraphs (f) and (g) are added to subsection (1), paragraphs (g) and (h) are added to subsection (2), and subsection (3) is added to 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) Failing to perform a physical examination of a patient by a physician or a licensed designee acting under the physician's supervision on the same day that the treating physician dispenses or prescribes a controlled substance to the patient at a pain-management clinic occurring three or more

times within a 6-month period, or failing to perform a physical examination on three or more different patients on the same day that the treating physician dispenses or prescribes a controlled substance to each patient at a pain-management clinic within a 6-month period.

(g) Prescribing or dispensing in excess of a 72-hour dose of controlled substances at a pain-management clinic for the treatment of chronic nonmalignant pain of a patient occurring three or more times within a 6-month period without documenting in the patient's record the reason that such dosage is within the standard of care. For the purpose of this paragraph, the standard of care is set forth in rule 64B8-9.013(3), Florida Administrative Code.

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

(g) Failing to perform a physical examination of a patient on the same day that the treating physician dispenses or prescribes a controlled substance to the patient at a pain-management clinic two times in a 6-month period, or failing to perform a physical examination on two different patients on the same day that the treating physician dispenses or prescribes a controlled substance to each patient at a pain-management clinic within a 6-month period.

(h) Prescribing or dispensing in excess of a 72-hour dose of controlled substances at a pain-management clinic for the treatment of chronic nonmalignant pain of a patient occurring two times within a 6-month period without documenting in the patient's record the reason that such dosage is within the

standard of care. For the purpose of this paragraph, the standard of care is set forth in rule 64B8-9.013(3), Florida Administrative Code.

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

(a) A first offense of failing to perform a physical examination of a patient on the same day that the treating physician dispenses or prescribes a controlled substance to the patient at a pain-management clinic.

(b) A first offense of failing to document in a patient's record the reason that such dosage is within the standard of care for prescribing or dispensing in excess of a 72-hour dose of controlled substances at a pain-management clinic for the treatment of chronic nonmalignant pain.

Section 9. Subsection (11) is added to section 458.331, Florida Statutes, to read:

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

(11) Notwithstanding subsection (2), upon finding that a physician has prescribed or dispensed, or caused to be prescribed or dispensed, a controlled substance in a pain-management clinic in a manner that violates the standard of practice as set forth in this chapter or rules adopted pursuant to this chapter, the board shall, at a minimum, suspend the physician's license for at least 6 months and impose a fine of at least $10,000 per count. Repeated violations shall result in increased penalties.

Section 10. Present subsections (3), (4), and (5) of

section 459.003, Florida Statutes, are redesignated as subsections (4), (5), and (6), respectively, and a new subsection (3) is added to that section, to read:

459.003 Definitions.—As used in this chapter:

(3) "Dispensing physician" means an osteopathic physician who is registered as a dispensing practitioner under s. 465.0276.

Section 11. Paragraphs (f) and (g) are added to subsection (1), paragraphs (e) and (f) are added to subsection (2), and paragraphs (d) and (e) are added to subsection (3) 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) Failing to perform a physical examination of a patient on the same day that the osteopathic physician dispenses or prescribes a controlled substance to the patient at a pain-management clinic occurring three or more times within a 6-month period, or failing to perform a physical examination on three or more different patients on the same day that the osteopathic physician dispenses or prescribes a controlled substance to each patient at a pain-management clinic within a 6-month period.

(g) Prescribing or dispensing in excess of a 72-hour dose of controlled substances at a pain-management clinic for the treatment of chronic nonmalignant pain of a patient occurring three or more times within a 6-month period without documenting in the patient's record the reason that such dosage is within the standard of care. For the purpose of this paragraph, the

standard of care is set forth in rule 64B8-9.013(3), Florida Administrative Code.

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

(e) Failing to perform a physical examination of a patient on the same day that the osteopathic physician dispenses or prescribes a controlled substance to the patient at a pain-management clinic occurring two times within a 6-month period, or failing to perform a physical examination on two different patients on the same day that the osteopathic physician dispenses or prescribes a controlled substance to each patient at a pain-management clinic within a 6-month period.

(f) Prescribing or dispensing in excess of a 72-hour dose of controlled substances at a pain-management clinic for the treatment of chronic nonmalignant pain of a patient occurring two times within a 6-month period without documenting in the patient's record the reason that such dosage is within the standard of care. For the purpose of this paragraph, the standard of care is set forth in rule 64B8-9.013(3), Florida Administrative Code.

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

(d) A first offense of failing to perform a physical examination of a patient on the same day that the osteopathic physician dispenses or prescribes a controlled substance to the patient at a pain-management clinic.

(e) A first offense of failing to document in a patient's

record the reason that such dosage is within the standard of care for prescribing or dispensing in excess of a 72-hour dose of controlled substances at a pain-management clinic for the treatment of chronic nonmalignant pain. For the purpose of this paragraph, the standard of care is set forth in rule 64B8-9.013(3), Florida Administrative Code.

Section 12. Paragraph (a) of subsection (1) and paragraph (c) of subsection (2) of section 459.0137, Florida Statutes, are amended, and paragraphs (f) and (g) are added to subsection (5) of that section, to read:

459.0137 Pain-management clinics.—

(1) REGISTRATION.—

(a) 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, must register with the department unless:

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

2. The majority of the physicians who provide services in the clinic primarily provide surgical services or interventional pain procedures of the type routinely billed using surgical codes;

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

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

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

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

(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).

(c) An osteopathic physician, an advanced registered nurse practitioner, or a physician assistant must perform an appropriate medical ~~a physical~~ examination of a patient on the same day that the 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 which prescribing or dispensing a dosage in excess of a 72-hour dose of controlled substances for the treatment of chronic nonmalignant pain is within the standard of care ~~for prescribing or dispensing that quantity~~.

(5) PENALTIES; ENFORCEMENT.—

(f) A licensee or other person who serves as the designated physician of a pain-management clinic as defined in s. 458.3265 or s. 459.0137 and registers a pain-management clinic through intentional misrepresentation or fraud or procures or attempts

to procure the registration of a pain-management clinic for any other person by making or causing to be made any false or fraudulent representation commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(g) Any person who registers a pain-management clinic through misrepresentation or fraud or who procures or attempts to procure the registration of a pain-management clinic for any other person by making or causing to be made any false or fraudulent representation, commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

Section 13. Subsection (11) is added to section 459.015, Florida Statutes, to read:

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

(11) Notwithstanding subsection (2), upon finding that an osteopathic physician has prescribed or dispensed, or caused to be prescribed or dispensed, a controlled substance in a pain-management clinic in a manner that violates the standard of practice as set forth in this chapter or rules adopted pursuant to this chapter, the board shall, at a minimum, suspend the osteopathic physician's license for at least 6 months and impose a fine of at least $10,000 per count. Repeated violations shall result in increased penalties.

Section 14. Present subsections (3) and (4) of section 465.015, Florida Statutes, are renumbered as subsections (4) and (5), respectively, and a new subsection (3) is added to that section, to read:

465.015 Violations and penalties.—

(3)(a) A licensed pharmacist, pharmacy technician, or any

person working under the direction or supervision of a pharmacist or pharmacy technician, may not knowingly fail to timely report to the local county sheriff's office the name of any person who obtains or attempts to obtain a substance controlled by s. 893.03 which the pharmacist, pharmacy intern, or other person employed by or at a pharmacy knows or reasonably should have known was obtained or attempted to be obtained from the pharmacy through any fraudulent method or representation. A pharmacist, pharmacy intern, or other person employed by or at a pharmacy who fails to make such a report within 24 hours after learning of the fraud or attempted fraud commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(b) A sufficient report of the fraudulent obtaining of or attempt to obtain a controlled substance under this section must contain, at a minimum, a copy of the prescription used or presented and a narrative, including all information available to the pharmacy regarding:

1. The transaction, such as the name and telephone number of the prescribing physician;

2. The name, description, and any personal identification information pertaining to the person presenting the prescription; and

3. All other material information, such as photographic or video surveillance of the transaction.

A pharmacist, pharmacy intern, or other person employed by or at a pharmacy is not subject to disciplinary action for reporting under this subsection.

Section 15. Subsection (6) is added to section 465.0276, Florida Statutes, to read:

465.0276 Dispensing practitioner.—

(6) In order to dispense a controlled substance listed in Schedule II, Schedule III, or Schedule IV in s. 893.03, a practitioner authorized by law to prescribe a controlled substance shall register with the Board of Pharmacy as a dispensing practitioner who dispenses controlled substances and pay a fee not to exceed $100. The department shall adopt rules establishing procedures for renewal of the registration every 4 years.

Section 16. Paragraph (a) of subsection (1) of section 766.101, Florida Statutes, is amended to read:

766.101 Medical review committee, immunity from liability.—

(1) As used in this section:

(a) The term "medical review committee" or "committee" means:

1.a. A committee of a hospital or ambulatory surgical center licensed under chapter 395 or a health maintenance organization certificated under part I of chapter 641,

b. A committee of a physician-hospital organization, a provider-sponsored organization, or an integrated delivery system,

c. A committee of a state or local professional society of health care providers,

d. A committee of a medical staff of a licensed hospital or nursing home, provided the medical staff operates pursuant to written bylaws that have been approved by the governing board of the hospital or nursing home,

e. A committee of the Department of Corrections or the Correctional Medical Authority as created under s. 945.602, or employees, agents, or consultants of either the department or the authority or both,

f. A committee of a professional service corporation formed under chapter 621 or a corporation organized under chapter 607 or chapter 617, which is formed and operated for the practice of medicine as defined in s. 458.305(4) ~~s. 458.305(3)~~, and which has at least 25 health care providers who routinely provide health care services directly to patients,

g. A committee of the Department of Children and Family Services which includes employees, agents, or consultants to the department as deemed necessary to provide peer review, utilization review, and mortality review of treatment services provided pursuant to chapters 394, 397, and 916,

h. A committee of a mental health treatment facility licensed under chapter 394 or a community mental health center as defined in s. 394.907, provided the quality assurance program operates pursuant to the guidelines which have been approved by the governing board of the agency,

i. A committee of a substance abuse treatment and education prevention program licensed under chapter 397 provided the quality assurance program operates pursuant to the guidelines which have been approved by the governing board of the agency,

j. A peer review or utilization review committee organized under chapter 440,

k. A committee of the Department of Health, a county health department, healthy start coalition, or certified rural health network, when reviewing quality of care, or employees of these

entities when reviewing mortality records, or

1. A continuous quality improvement committee of a pharmacy licensed pursuant to chapter 465,

which committee is formed to evaluate and improve the quality of health care rendered by providers of health service, to determine that health services rendered were professionally indicated or were performed in compliance with the applicable standard of care, or that the cost of health care rendered was considered reasonable by the providers of professional health services in the area; or

2. A committee of an insurer, self-insurer, or joint underwriting association of medical malpractice insurance, or other persons conducting review under s. 766.106.

Section 17. Subsection (3) of section 810.02, Florida Statutes, is amended 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:

(a) Dwelling, and there is another person in the dwelling at the time the offender enters or remains;

(b) Dwelling, and there is not another person in the dwelling at the time the offender enters or remains;

(c) Structure, and there is another person in the structure at the time the offender enters or remains;

(d) Conveyance, and there is another person in the conveyance at the time the offender enters or remains; ~~or~~

(e) Authorized emergency vehicle, as defined in s. 316.003; or~~.~~

(f) Structure or conveyance when the offense intended to be committed is theft of a substance controlled by s. 893.03. Notwithstanding any contrary provisions of law, separate judgments and sentences for burglary with the intent to commit theft of a controlled substance under this paragraph and for any applicable offense for possession of a controlled substance under s. 893.13, or an offense for trafficking in a controlled substance under s. 893.135, may be imposed if all such offenses involve the same amount or amounts of a controlled substance.

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 18. 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.

5. A firearm.

6. A motor vehicle, except as provided in paragraph (a).

7. Any commercially farmed animal, including any animal of the equine, bovine, or swine class, or other grazing animal, and including aquaculture species raised at a certified aquaculture facility. If the property stolen is aquaculture species raised at a certified aquaculture facility, then a $10,000 fine shall be imposed.

8. Any fire extinguisher.

9. Any amount of citrus fruit consisting of 2,000 or more individual pieces of fruit.

10. Taken from a designated construction site identified by the posting of a sign as provided for in s. 810.09(2)(d).

11. Any stop sign.

12. Anhydrous ammonia.

13. Any amount of a substance controlled by s. 893.03. Notwithstanding any contrary provisions of law, separate judgments and sentences for theft of a controlled substance under this subparagraph, and for any applicable offense for possession of a controlled substance under s. 893.13, or an offense for trafficking in a controlled substance under s. 893.135 may be imposed if all such offenses involve the same amount or amounts of controlled substance.

However, if the property is stolen within a county that is subject to a state of emergency declared by the Governor under chapter 252, the property is stolen after the declaration of emergency is made, and the perpetration of the theft is 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 19. Section 893.021, Florida Statutes, is created to read:

893.021 Adulterated drug.—

(1) As used in this chapter, a drug is adulterated if it is a controlled substance that:

(a) Has been produced, prepared, packed, and marketed for oral consumption by the manufacturer; and

(b) Has had any change to its integrity or composition for use by means of inhalation, injection, or any other form of ingestion not in accordance with the manufacturer's recommended use, and such mode of use has not been previously directed and approved by the prescribing physician.

(2) A physician is not prevented from directing or prescribing a change to the recognized manufactured recommendations for use in a patient who presents a medical need for such a requirement change of any controlled substance. The prescribing physician shall clearly indicate any deviation of the recognized manufacturer's recommended use of a controlled substance on the original prescription, and the licensed pharmacist shall clearly indicate such deviation on the label of the prescription upon dispensing the controlled substance.

Section 20. Paragraphs (c), (d), and (e) of subsection (1) of section 893.04, Florida Statutes, are amended to read:

893.04 Pharmacist and practitioner.—

(1) A pharmacist, in good faith and in the course of professional practice only, may dispense controlled substances upon a written or oral prescription of a practitioner, under the following conditions:

(c) The following information must ~~There shall~~ appear on the face of the prescription or written record of a ~~thereof for the~~ controlled substance ~~the following information~~:

1. The full name and address of the person for whom, or the owner of the animal for which, the controlled substance is dispensed.

2. The full name and address of the prescribing practitioner and the practitioner's federal controlled substance registry number shall be printed thereon.

3. If the prescription is for an animal, the species of animal for which the controlled substance is prescribed.

4. The name of the controlled substance prescribed and the strength, quantity, and directions for use thereof. The directions for use must specify the authorization by the physician, any instructions requiring the adulteration of the dispensed form of the medication, and the medical necessity for the adulteration in accordance with s. 893.021.

5. The number of the prescription, as recorded in the prescription files of the pharmacy in which it is filled.

6. The initials of the pharmacist filling the prescription and the date filled.

(d) The prescription must ~~shall~~ be retained on file by the proprietor of the pharmacy in which it is filled for a period of 2 years.

(e) A label bearing the following information must be affixed to the original container in which a controlled substance is delivered as ~~upon~~ a prescription or authorized refill ~~thereof, as hereinafter provided, there shall be a label bearing the following information~~:

1. The name and address of the pharmacy from which such controlled substance was dispensed.

2. The date on which the prescription for such controlled

substance was filled.

3. The number of such prescription, as recorded in the prescription files of the pharmacy in which it is filled.

4. The name of the prescribing practitioner.

5. The name of the patient for whom, or of the owner and species of the animal for which, the controlled substance is prescribed.

6. The directions for the use of the controlled substance prescribed in the prescription.

7. A clear, concise warning that it is a crime to transfer the controlled substance to any person other than the patient for whom prescribed.

Section 21. 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 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), the National All Schedules Prescription Electronic Reporting (NASPER) Act's minimum requirements for authentication of a practitioner who requests information in the prescription drug monitoring program database and certification of the purpose for which information is requested, 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.

(e) The department shall establish a method to allow corrections to the database when notified by a health care practitioner or pharmacist.

(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.

(h) The number of refills ordered and whether the drug was dispensed as a refill of a prescription or was a first-time request.

(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.~~

(c) ~~(d)~~ A practitioner when administering a controlled

substance in the emergency room of a licensed hospital.

(d) ~~(c)~~ A health care practitioner when administering or dispensing a controlled substance to a person under the age of 16 if the amount of the controlled substance is adequate to treat the patient during that particular treatment session.

(e) ~~(f)~~ A pharmacist or a dispensing practitioner when dispensing a one-time, 48-hour ~~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)1. In order for a pharmacy, prescriber, practitioner, or dispenser to ~~shall~~ have access to information in the prescription drug monitoring program's database which relates to a patient of that pharmacy, prescriber, practitioner, or dispenser, the pharmacy, prescriber, practitioner, or dispenser shall register with the department by submitting a registering document provided by the department. The document and validation of that document shall be determined by the department. Before a

pharmacy, prescriber, practitioner, or dispenser is granted access to information in the database from the prescription drug monitoring program, the department shall approve the submitted document. Upon approval, the department shall grant the registrant access to the appropriate information in the prescription drug monitoring program's database ~~in a manner established by the department as needed for the purpose of reviewing the patient's controlled substance prescription history~~.

2. 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 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 may ~~shall~~ not have ~~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 or Medicaid investigations 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 patient's phone number, current address, and a copy of a government-issued photo identification must be provided in person to the program manager along with the notarized 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.

5. The Agency for Health Care Administration for Medicaid fraud cases or Medicaid investigations involving prescribed controlled substances.

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 may ~~shall~~ not have ~~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.

(11) The Office of Drug Control, in coordination with the department, may establish a direct-support organization that has a board consisting of at least five members to provide assistance, funding, and promotional support for the activities authorized for the prescription drug monitoring program.

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

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

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

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

(c) The director of the Office of Drug Control shall appoint a board of directors for the direct-support

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

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

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

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

3. Certification by the Office of Drug Control in consultation with the department that the direct-support organization is complying with the terms of the contract in a manner consistent with and in furtherance of the goals and purposes of the prescription drug monitoring program and in the best interests of the state. Such certification must be made annually and reported in the official minutes of a meeting of the direct-support organization.

4. The reversion, without penalty, to the Office of Drug Control, or to the state if the Office of Drug Control ceases to

exist, of all moneys and property held in trust by the direct-support organization for the benefit of the prescription drug monitoring program if the direct-support organization ceases to exist or if the contract is terminated.

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

6. The disclosure of the material provisions of the contract to donors of gifts, contributions, or bequests, including such disclosure on all promotional and fundraising publications, and an explanation to such donors of the distinction between the Office of Drug Control and the direct-support organization.

7. The direct-support organization's collecting, expending, and providing of funds to the department for the development, implementation, and operation of the prescription drug monitoring program as described in this section and 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 director of the Office of Drug Control. In addition, the direct-support organization may collect and provide funding to the department in furtherance of the prescription drug monitoring program by:

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

b. Conducting studies on the efficiency and effectiveness

of the program to include feasibility studies as described in subsection (13).

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

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

e. Providing funds for travel expenses.

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

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

(e) The activities of the direct-support organization must be consistent with the goals and mission of the Office of Drug Control, as determined by the office in consultation with the department, and in the best interests of the state. The direct-support organization must obtain a written approval from the director of the Office of Drug Control for any activities in support of the prescription drug monitoring program before undertaking those activities.

(f) The Office of Drug Control, in consultation with the department, may permit, without charge, appropriate use of administrative services, property, and facilities of the Office of Drug Control and the department by the direct-support organization, subject to this section. The use must be directly in keeping with the approved purposes of the direct-support organization and may not be made at times or places that would

unreasonably interfere with opportunities for the public to use such facilities for established purposes. Any moneys received from rentals of facilities and properties managed by the Office of Drug Control and the department may be held by the Office of Drug Control or in a separate depository account in the name of the direct-support organization and subject to the provisions of the letter of agreement with the Office of Drug Control. The letter of agreement must provide that any funds held in the separate depository account in the name of the direct-support organization must revert to the Office of Drug Control if the direct-support organization is no longer approved by the Office of Drug Control to operate in the best interests of the state.

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

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

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

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

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

(13) To the extent that funding is provided for such purpose through federal or private grants or gifts and other types of available moneys, the department, in collaboration with the Office of Drug Control, shall study the feasibility of enhancing the prescription drug monitoring program for the purposes of public health initiatives and statistical reporting that respects the privacy of the patient, the prescriber, and the dispenser. Such a study shall be conducted in order to further improve the quality of health care services and safety by improving the prescribing and dispensing practices for prescription drugs, taking advantage of advances in technology, reducing duplicative prescriptions and the overprescribing of prescription drugs, and reducing drug abuse. The requirements of the National All Schedules Prescription Electronic Reporting (NASPER) Act are authorized in order to apply for federal NASPER funding. In addition, the direct-support organization shall provide funding for the department, in collaboration with the

Office of Drug Control, to conduct training for health care practitioners and other appropriate persons in using the monitoring program to support the program enhancements.

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

(17) After the prescription drug monitoring program has been operational for 12 months, the State Surgeon General shall enter into reciprocal agreements for the sharing of prescription drug monitoring information with any other state that has a compatible prescription drug monitoring program. If the State Surgeon General evaluates the prescription drug monitoring program of another state as authorized in this subsection, priority shall be given to a state that is contiguous with the borders of this state.

(a) In determining compatibility, the State Surgeon General shall consider:

1. The essential purposes of the program and the success of the program in fulfilling those purposes.

2. The safeguards for privacy of patient records and the success of the program in protecting patient privacy.

3. The persons authorized to view the data collected by the program. Comparable organizations and professions for practitioners in other states, law enforcement agencies, the Attorney General's Medicaid Fraud Unit, medical regulatory boards, and, as needed, management staff who have similar duties as management staff who work with the prescription drug monitoring program as authorized in s. 893.0551 are authorized access upon approval by the State Surgeon General.

4. The schedules of the controlled substances that are monitored.

5. The data required to be submitted for each prescription.

6. Any implementing criteria deemed essential for a thorough comparison.

(b) The State Surgeon General shall annually review any agreement to determine its continued compatibility with the prescription drug monitoring program in this state.

(c) Any agreement between the State Surgeon General and another state shall prohibit the sharing of information concerning a resident of this state or a practitioner, pharmacist, or other prescriber for any purpose that is not otherwise authorized by this section or s. 893.0551.

Section 22. Present subsections (4), (5), (6), and (7) of section 893.0551, Florida Statutes, are redesignated as subsections (5), (6), (7), and (8), respectively, and a new subsection (4) is added to that section, to read:

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

(4) The department may disclose confidential and exempt information contained in records held by the department under s. 893.055 if the State Surgeon General has entered into a reciprocal agreement for the sharing of prescription drug monitoring information with any other state that has a compatible prescription drug monitoring program.

(a) The reciprocal agreement may allow the following persons from another state to receive information from the prescription drug monitoring program if approved by the State Surgeon General:

1. A designated representative of a state professional licensing, certification, or regulatory agency charged with

oversight of those persons authorized to prescribe or dispense controlled substances for the purpose of a bona fide, specific investigation of a prescription of a controlled substance which involves a designated person. As required in s. 893.055, this authorization does not preclude the requirement for the program manager to review the request for information and validate it.

2. A health care practitioner or pharmacist licensed in the state from which the request originates. Such health care practitioner or pharmacist shall certify that the requested information is for the purpose of providing medical or pharmaceutical treatment to a bona fide, current patient. The health care practitioner or pharmacist shall follow all the procedures required in s. 893.055 and rules established by the department for a health care practitioner or pharmacist to request information from the database.

3. A law enforcement officer from another state:

a. Who is a member of a sheriff's department or a police department;

b. Who is authorized by law to conduct criminal investigations and make arrests;

c. Whose duty it is to enforce the laws of his or her state relating to controlled substances; and

d. Who is engaged in a bona fide specific, active investigation involving a designated person regarding prescriptions for controlled substances.

As required in s. 893.055, this authorization does not preclude the requirement for the program manager to review the request for information and validate it. This authorization also does

not preclude the ability to provide a report to a law enforcement agency in another state under s. 893.055(7) or this subsection.

(b) Any agreement between the State Surgeon General and another state shall prohibit the sharing of information concerning a resident of this state, a patient whose information is in the program's database, or a practitioner, pharmacy, pharmacist, health care practitioner, or other prescriber for any purpose that is not otherwise authorized by this section or s. 893.055, and the information must be provided according to the State Surgeon General's determination of compatibility as described in s. 893.055(17).

Section 23. Subsections (1), (4), and (5) of section 893.07, Florida Statutes, are amended, and subsection (6) is added to that section, to read:

893.07 Records.—

(1) Notwithstanding any other provision of law and in consonance with the authority of *State v. Carter*, 23 So. 3d 798 (Fla. 1st DCA 2009) and *State v. Tamulonis*, 39 So. 3d 524 (Fla. 2nd DCA 2010), every person who engages in the manufacture, compounding, mixing, cultivating, growing, or by any other process producing or preparing, or in the dispensing, importation, or, as a wholesaler, distribution, of controlled substances shall:

(a) On January 1, 1974, or as soon thereafter as any person first engages in such activity, and every second year thereafter, make a complete and accurate record of all stocks of controlled substances on hand. The inventory may be prepared on the regular physical inventory date which is nearest to, and

does not vary by more than 6 months from, the biennial date that would otherwise apply. As additional substances are designated for control under this chapter, they shall be inventoried as provided for in this subsection.

(b) On and after January 1, 1974, maintain, on a current basis, a complete and accurate record of each substance manufactured, received, sold, delivered, or otherwise disposed of by him or her, except that this subsection shall not require the maintenance of a perpetual inventory.

Compliance with the provisions of federal law pertaining to the keeping of records of controlled substances shall be deemed a compliance with the requirements of this subsection.

(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, such 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. This subsection does not require a law enforcement officer to obtain a subpoena, court order, or search warrant in order to obtain access to or copies of such records.

(5) Each person shall maintain a record that contains ~~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. If a person discovers the theft or loss of a controlled substance, such person shall report the theft or loss to a local county sheriff's office within 48 hours after the discovery of such theft or loss. A person who fails to report the theft or loss of a controlled substance under this subsection commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083. However, a person who fails to report the theft or loss of a Schedule II controlled substance commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(6) The Legislature finds that the opinions rendered in *State v. Carter,* 23 So. 3d 798 (Fla. 1st DCA 2009), and *State v. Tamulonis,* 39 So. 3d 524 (Fla. 2nd DCA 2010), correctly construe this Legislature's intent that the inspection powers previously conferred upon law enforcement officers which allow such officers to access and review pharmacy records concerning controlled substances are to be exercised properly by such law enforcement officers without the requirement of a subpoena or search warrant being sought or issued to examine and copy such records, and without the requirement that those persons to whom particular pharmacy records refer be given notice of the records' examination and copying under this section.

Section 24. Subsections (7) and (8) of section 893.13, Florida Statutes, are 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) Any person who adulterates a controlled substance for directed off-label use without authorization by a prescribing physician violates the provisions of subparagraph (a)1. and causes the issuance of the entire prescription for the controlled substance to become invalid. A law enforcement officer in the performance of his or her official duties may seize the adulterated or off-label prescribed controlled substance as evidence. The controlled substance may be returned to the owner only with a notarized affidavit from the original prescribing practitioner who has knowledge and gave authorization and explicit directions for the adulteration or off-label use of the controlled substance.

(d) ~~(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.

(e) ~~(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.

(f) 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.

(8)(a) Notwithstanding subsection (9), a prescribing practitioner may not:

1. Knowingly assist a patient, other person, or the owner of an animal in obtaining a controlled substance through deceptive, untrue, or fraudulent representations in or related to the practice of the prescribing practitioner's professional practice;

2. Employ a trick or scheme in the practice of the prescribing practitioner's professional practice to assist a patient, other person, or the owner of an animal in obtaining a controlled substance;

3. Knowingly write a prescription for a controlled substance for a fictitious person; ~~or~~

4. Write a prescription for a controlled substance for a patient, other person, or an animal if the sole purpose of writing such prescription is to provide a monetary benefit to, or obtain a monetary benefit for, the prescribing practitioner; or ~~.~~

5. Write a prescription for a controlled substance for a patient, other person, or an animal and authorize or direct the

adulteration of the dispensed form of the controlled substance for the purpose of ingestion by means of inhalation, injection, or any other means not medically necessary for the treatment of the patient.

(b) If the prescribing practitioner wrote a prescription or multiple prescriptions for a controlled substance for the patient, other person, or animal for which there was no medical necessity, or which was in excess of what was medically necessary to treat the patient, other person, or animal, that fact does not give rise to any presumption that the prescribing practitioner violated subparagraph (a)1., but may be considered with other competent evidence in determining whether the prescribing practitioner knowingly assisted a patient, other person, or the owner of an animal to obtain a controlled substance in violation of subparagraph (a)1.

(c) A person who violates paragraph (a) commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(d) Notwithstanding paragraph (c), if a prescribing practitioner has violated paragraph (a) and received $1,000 or more in payment for writing one or more prescriptions or, in the case of a prescription written for a controlled substance described in s. 893.135, has written one or more prescriptions for a quantity of a controlled substance which, individually or in the aggregate, meets the threshold for the offense of trafficking in a controlled substance under s. 893.15, the violation is reclassified as a felony of the second degree and ranked in level 4 of the Criminal Punishment Code.

Section 25. 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 26. (1) DEFINITIONS.—As used in this section, the term:

(a) "Interchange or substitution of an opioid analgesic drug" means the substitution of any opioid analgesic drug, brand or generic, for the opioid analgesic drug incorporating a tamper-resistance technology originally prescribed, irrespective of whether the substituted drug is rated as pharmaceutically and therapeutically equivalent by the United States Food and Drug Administration or the Board of Pharmacy or whether the opioid

analgesic drug with tamper-resistance technology bears a labeling claim with respect to reduction of tampering, abuse, or abuse potential.

(b) "Opioid analgesic drug" means a drug in the opioid analgesic drug class prescribed to treat moderate to severe pain or other conditions, whether in immediate release or extended release form and whether or not combined with other drug substances to form a single tablet or other dosage form.

(c) "Opioid analgesic drug incorporating a tamper-resistance technology" means an opioid analgesic drug listed as such by the Board of Pharmacy based on a submission of evidence by the drug manufacturer or distributor that the drug:

1. Incorporates a tamper-resistance technology; and

2. Has been approved by the United States Food and Drug Administration pursuant to an application that includes at least one study on human tampering or abuse potential or a laboratory study comparing the tamper- or abuse-resistance properties of the drug to one or more opioid analgesic drugs that:

a. Have been approved by the United States Food and Drug Administration; and

b. Serve as a positive control.

(d) "Pharmacist" means any person licensed under chapter 465, Florida Statutes, to practice the profession of pharmacy, including, but not limited to, a community pharmacist and a pharmacist in a hospital-based pharmacy, when filling prescriptions for inpatient or outpatient care.

(2) LIST OF OPIOID ANALGESIC DRUGS INCORPORATING A TAMPER-RESISTANCE TECHNOLOGY.—The Board of Pharmacy shall create a list of opioid analgesic drugs for which information has been

submitted consistent with paragraph (1)(c). Inclusion of a drug on such list does not require that the drug bear a labeling claim with respect to reduction of tampering, abuse, or abuse potential at the time of listing. Such list must also include a determination by the Board of Pharmacy as to which listed opioid analgesic drugs incorporating tamper-resistance technologies provide substantially similar tamper-resistance properties, based solely on studies submitted by the drug manufacturer consistent with paragraph (1)(c).

(3) PROHIBITION.—Notwithstanding s. 465.025, Florida Statutes, a pharmacist may not interchange or substitute an opioid analgesic drug, brand or generic, for an opioid analgesic drug incorporating a tamper-resistance technology which is listed pursuant to subsection (2) without:

(a) Verifying that the opioid analgesic drug has been listed by the Board of Pharmacy under subsection (2) as providing tamper-resistance properties substantially similar to the prescribed opioid analgesic drug incorporating a tamper-resistance technology; or

(b) Obtaining written, signed consent from the prescribing physician for such interchange or substitution.

Section 27. This act shall take effect October 1, 2011.