A bill to be entitled 1 2 An act relating to controlled substances; creating s. 3 408.0512; requiring the Agency for Health Care 4 Administration to enter into a contract with a multi-state 5 electronic prescribing network to provide access to 6 certain information on certain controlled substances; 7 providing for access to controlled substance information 8 in the network by a criminal justice agency and the Department of Health or relevant regulatory board; 9 10 requiring the agency to seek grants and donations to implement the act; amending s. 458.309, F.S.; ownership of pain management clinics; amending s. 458.331, 12 F.S.; making the practice of medicine in an unregistered 13 pain management clinic grounds for licensure disciplinary 15 action; making advertising the use, sale, or dispensing of 16 controlled substances grounds for physician licensure disciplinary action; amending s. 459.005, F.S.; limiting 17 ownership of pain management clinics; amending s. 459.015, 18 19 F.S.; making the practice of osteopathic medicine in an unregistered pain management clinic grounds for 20 osteopathic physician licensure disciplinary action; 22 making advertising the use, sale, or dispensing of 23 controlled substances grounds for licensure disciplinary action; amending s. 465.018, F.S.; requiring community 24 25 pharmacy permit applicants to demonstrate ability to 26 participate in and transmit dispensing information through 27 a multi-state electronic prescribing network; requiring 28 community pharmacies to transmit dispensing information on

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certain controlled substance prescriptions through a multi-state electronic prescribing network; providing effective dates; amending 465.023, F.S.; making failure to transmit certain dispensing information through a multistate electronic prescribing network grounds for community pharmacy permit disciplinary action; amending s. 465.0276, F.S.; prohibiting registered dispensing practitioners from dispensing more than a specified amount of certain controlled substances; providing penalties; providing exceptions; providing an effective date.

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

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Section 1. Section 408.0513, Florida Statutes, is created to read:

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408.0513 Access to prescription drug medication history.-

The agency shall, by December 1, 2010, contract with

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an entity that operates a multi-state electronic prescribing network to provide access to Schedule II and III controlled

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substance information available on the network to:

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A criminal justice agency, as defined in s. 119.011, which enforces the laws of this state or the United States and which has initiated an active investigation involving a specific

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violation of law.

(a)

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(b) The Department of Health or the relevant health regulatory board responsible for the licensure, regulation, or discipline of practitioners, pharmacists, or other persons who

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are authorized to prescribe, administer, or dispense controlled

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substances and who are involved in a specific investigation involving a designated person.

- (2) The agency shall adopt rules under ss. 120.536(1) and 120.54 to administer the provisions of this section, including the method and terms of access to the information provided under subsection (1).
- (3) The agency shall seek federal grants and donations from private entities to implement this section.
- Section 2. Subsection (4) of section 458.309, Florida Statutes, is amended to read:

458.309 Rulemaking authority.-

All privately owned pain-management clinics, facilities, or offices, hereinafter referred to as "clinics," primarily engaged in the treatment of pain by prescribing or dispensing controlled substances, and which advertise in any medium for any type of pain-management services, or employ a physician who is primarily engaged in the treatment of pain by prescribing or dispensing controlled substance medications, must register with the department by January 4, 2010, unless that clinic is licensed as a facility pursuant to chapter 395. The department shall deny registration to any clinic not fully owned by a physician or group of physicians. The department shall deny registration to any clinic owned by or with any contractual or employment relationship with a physician whose Drug Enforcement Administration number has ever been suspended or revoked, or against whom the board has taken final administrative action related to the physician's impairment due to the misuse or abuse of alcohol or drugs. The department shall deny registration to

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any clinic in which ownership or any controlling interest is held by any person who was convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 893. A physician may not practice medicine in a pain-management clinic that is required to but has not registered with the department. Each clinic location shall be registered separately regardless of whether the clinic is operated under the same business name or management as another clinic. If the clinic is licensed as a health care clinic under chapter 400, the medical director is responsible for registering the facility with the department. If the clinic is not registered pursuant to chapter 395 or chapter 400, the clinic shall, upon registration with the department, designate a physician who is responsible for complying with all requirements related to registration of the clinic. The designated physician shall be licensed under this chapter or chapter 459 and shall practice at the office location for which the physician has assumed responsibility. The department shall inspect the clinic annually to ensure that it complies with rules of the Board of Medicine adopted pursuant to this subsection and subsection (5) unless the office is accredited by a nationally recognized accrediting agency approved by the Board of Medicine. The actual costs for registration and inspection or accreditation shall be paid by the physician seeking to register the clinic. Section 2. Paragraph (nn) of subsection (1) of section 458.331, Florida Statutes, is amended to read: Grounds for disciplinary action; action by the

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board and department. -

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- (1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):
- (nn) Practicing medicine in a clinic that is required to but has not registered with the department pursuant to s. 458.309.
- (oo) Using any communication media to promote or advertise the use, sale, or dispensing of any controlled substance appearing in any schedule in chapter 893.
- (pp) Violating any provision of this chapter or chapter
 456, or any rules adopted pursuant thereto.
- Section 3. Subsection (3) of section 459.005, Florida Statutes, is amended to read:
 - 459.005 Rulemaking authority.-
- (3) All privately owned pain-management clinics, facilities, or offices, hereinafter referred to as "clinics," primarily engaged in the treatment of pain by prescribing or dispensing controlled substances, and which advertise in any medium for any type of pain-management services, or employ a physician who is licensed under this chapter and who is primarily engaged in the treatment of pain by prescribing or dispensing controlled substance medications, must register with the department by January 4, 2010, unless that clinic is licensed as a facility under chapter 395. The department shall deny registration to any clinic not fully owned by a physician or group of physicians. The department shall deny registration to any clinic owned by or with any contractual or employment relationship with a physician whose Drug Enforcement

 Administration number has ever been suspended or revoked, or

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against whom the board has taken final administrative action related to the physician's impairment due to the misuse or abuse of alcohol or drugs. The department shall deny registration to any clinic in which ownership or any controlling interest is held by any person who was convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 893. A physician may not practice osteopathic medicine in a pain-management clinic that is required to but has not registered with the department. Each clinic location shall be registered separately regardless of whether the clinic is operated under the same business name or management as another clinic. If the clinic is licensed as a health care clinic under chapter 400, the medical director is responsible for registering the facility with the department. If the clinic is not registered under chapter 395 or chapter 400, the clinic shall, upon registration with the department, designate a physician who is responsible for complying with all requirements related to registration of the clinic. The designated physician shall be licensed under chapter 458 or this chapter and shall practice at the office location for which the physician has assumed responsibility. The department shall inspect the clinic annually to ensure that it complies with rules of the Board of Osteopathic Medicine adopted pursuant to this subsection and subsection (4) unless the office is accredited by a nationally recognized accrediting agency approved by the Board of Osteopathic Medicine. The actual costs for registration and inspection or accreditation shall be paid by the physician seeking to register the clinic.

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Section 4. Paragraph (pp) of subsection (1) of section 459.015, Florida Statutes, is amended to read:

- 459.015 Grounds for disciplinary action; action by the board and department.—
- (1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):
- (pp) Practicing osteopathic medicine in a clinic that is required to but has not registered with the department pursuant to s. 458.309.
- (qq) Using any communication media to promote or advertise the use, sale, or dispensing of any controlled substance appearing in any schedule in chapter 893.
- (rr) Violating any provision of this chapter or chapter 456, or any rules adopted pursuant thereto.
- Section 5. Section 465.018, Florida Statutes, is amended to read:

465.018 Community pharmacies; permits.—Any person desiring a permit to operate a community pharmacy shall apply to the department. If the board office certifies that the application complies with the laws of the state and the rules of the board governing pharmacies, the department shall issue the permit. No permit shall be issued unless a licensed pharmacist is designated as the prescription department manager responsible for maintaining all drug records, providing for the security of the prescription department, and following such other rules as relate to the practice of the profession of pharmacy. The permittee and the newly designated prescription department manager shall notify the department within 10 days of any change

in prescription department manager. Effective July 1, 2012, no permit shall be issued unless the applicant demonstrates ability to participate in and transmit dispensing information through a multi-state electronic prescribing network. Effective January 1, 2013, all permittees shall transmit dispensing information for all Schedule II and III controlled substance prescriptions through a multi-state electronic prescribing network.

Section 6. Subsection (1) of section 465.023, Florida Statutes, is amended to read:

465.023 Pharmacy permittee; disciplinary action.-

- (1) The department or the board may revoke or suspend the permit of any pharmacy permittee, and may fine, place on probation, or otherwise discipline any pharmacy permittee if the permittee, or any affiliated person, partner, officer, director, or agent of the permittee, including a person fingerprinted under s. 465.022(3), has:
- (a) Obtained a permit by misrepresentation or fraud or through an error of the department or the board;
- (b) Attempted to procure, or has procured, a permit for any other person by making, or causing to be made, any false representation;
- (c) Violated any of the requirements of this chapter or any of the rules of the Board of Pharmacy; of chapter 499, known as the "Florida Drug and Cosmetic Act"; of 21 U.S.C. ss. 301-392, known as the "Federal Food, Drug, and Cosmetic Act"; of 21 U.S.C. ss. 821 et seq., known as the Comprehensive Drug Abuse Prevention and Control Act; or of chapter 893;
 - (d) Been convicted or found guilty, regardless of

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adjudication, of a felony or any other crime involving moral turpitude in any of the courts of this state, of any other state, or of the United States;

- (e) Been convicted or disciplined by a regulatory agency of the Federal Government or a regulatory agency of another state for any offense that would constitute a violation of this chapter;
- (f) Been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, the profession of pharmacy;
- (g) Been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud; $\frac{\partial f}{\partial x}$
- (h) Dispensed any medicinal drug based upon a communication that purports to be a prescription as defined by s. 465.003(14) or s. 893.02 when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship that includes a documented patient evaluation, including history and a physical examination adequate to establish the diagnosis for which any drug is prescribed and any other requirement established by board rule under chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, or chapter 466;— or
- (i) Failed to transmit dispensing information for all Schedule II and III controlled substance prescriptions through a multi-state electronic prescribing network pursuant to s. 465.018.

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Section 7. Subsection (1) of section 465.0276, Florida Statutes, is amended to read:

465.0276 Dispensing practitioner.-

- (1) (a) A person may not dispense medicinal drugs unless licensed as a pharmacist or otherwise authorized under this chapter to do so, except that a practitioner authorized by law to prescribe drugs may dispense such drugs to her or his patients in the regular course of her or his practice in compliance with this section.
- (b) A practitioner registered under this section may not dispense more than a 72-hour supply of a controlled substance listed in Schedule II or Schedule III as provided in s. 893.03. It is unlawful for a practitioner registered under this section to dispense more than a 72-hour supply of a controlled substance listed in Schedule II or Schedule III as provided in s. 893.03. A practitioner who violates this provision commits a felony of the third degree, punishable as provided in s. 775.082 or s 775.083. This paragraph does not apply to the dispensing of complimentary packages of medicinal drugs to the practitioner's own patients in the regular course of her or his practice, without the payment of fee or remuneration of any kind, whether direct or indirect, and in conformity with the requirements of subsection (5). This paragraph does not apply to controlled substances dispensed in the health care system of the Department of Corrections.
 - Section 8. This act shall take effect July 1, 2010.

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