By Senator Gardiner

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A bill to be entitled

An act relating to controlled substances; amending ss. 458.309 and 459.005, F.S.; requiring the Department of Health to deny registration to any clinic that is not fully owned by a physician or group of physicians; requiring the department to deny registration to any clinic that is owned by or under any contractual or employment relationship with a physician whose Drug Enforcement Administration number has ever been suspended or revoked, or against whom the Board of Medicine or the Board of Osteopathic Medicine has taken final administrative action related to the physician's impairment due to the misuse or abuse of alcohol or drugs; requiring the department to deny registration to any clinic in which the ownership or any controlling interest is held by a person who has been convicted of, or has entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony; requiring the department to deny registration to any clinic that has a medical director who is not board-certified in pain medicine; amending ss. 458.331 and 459.015, F.S.; providing that the practice of medicine or osteopathic medicine in an unregistered pain-management clinic is grounds for denial of licensure or disciplinary action; providing that the advertisement of the use, sale, or dispensing of controlled substances is grounds for denial of licensure or disciplinary action; amending s. 465.018, F.S.; prohibiting the department from issuing a permit 9-01263-10 20102722

to operate a community pharmacy unless the applicant demonstrates the ability to participate in a multistate electronic prescribing network; amending 465.023, F.S.; authorizing the department to discipline a pharmacy permittee for failing to participate in a multistate electronic prescribing network; amending s. 465.0276, F.S.; prohibiting registered dispensing practitioners from dispensing more than a specified amount of certain controlled substances; providing an exception; providing an effective date.

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

Section 1. Subsection (4) of section 458.309, Florida Statutes, is amended to read:

458.309 Rulemaking authority.-

(4) 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 by January 4, 2010, unless that clinic is licensed as a facility pursuant to chapter 395. The department shall deny registration to any clinic that is not fully owned by a physician or group of physicians. The department shall deny registration to any clinic owned by or under any contractual or employment relationship with a physician whose Drug Enforcement Administration number

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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 any clinic in which the ownership or any controlling interest is held by a person who has been convicted of, or has entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 893. The department shall deny registration to any clinic that has a medical director who is not board-certified in pain medicine. A physician may not practice medicine in a painmanagement 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

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the physician seeking to register the clinic.

Section 2. 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," 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 that is not fully owned by a physician or group of physicians. The department shall deny registration to any clinic owned by or under 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 any clinic in which the ownership or any controlling interest is held by a person who has been convicted of, or has entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 893. The department shall deny registration to any clinic that has a medical director who is not board-certified in pain medicine. 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

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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.

Section 3. Present paragraph (nn) of subsection (1) of section 458.331, Florida Statutes, is redesignated as paragraph (pp), and new paragraphs (nn) and (oo) are added to that subsection, to read:

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

- (1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):
- (nn) Practicing medicine in a pain-management clinic that is required to register, but that has not registered, with the

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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.

Section 4. Present paragraph (pp) of subsection (1) of section 459.015, Florida Statutes, is redesignated as paragraph (rr), and new paragraphs (pp) and (qq) are added to that subsection, 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 pain-management clinic that is required to register, but that has not registered, with the department pursuant to s. 459.005.
- (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.

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. The department may not 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

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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. The department may not issue the permit unless the applicant demonstrates the ability to participate in a multistate 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 adjudication, of a felony or any other crime involving moral

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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 participate in a multistate electronic prescribing network.

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

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licensed as a pharmacist or otherwise authorized under this chapter to do so, except that a practitioner authorized by law to prescribe drugs may dispense such drugs to her or his patients in the regular course of her or his practice in compliance with this section.

(b) A practitioner registered under this section may not dispense more than a 72-hour supply of a controlled substance listed in Schedule II, Schedule III, or Schedule IV as provided in s. 893.03. 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.