By Senator Bogdanoff

25-01224-12 20121198

A bill to be entitled

An act relating to the prescribing of controlled substances; amending s. 456.44, F.S.; revising the definition of the term "addiction medicine specialist" to include a board-certified psychiatrist, rather than a physiatrist; providing that the management of pain in certain patients requires consultation with or referral to a psychiatrist, rather than a physiatrist; providing that a prescription is deemed compliant with the standards of practice and is valid for dispensing when a pharmacy receives it; providing that the standards of practice regarding the prescribing of controlled substances do not apply to certain boardcertified psychiatrists and rheumatologists; amending ss. 458.3265 and 459.0137, F.S.; requiring that a pain-management clinic register with the Department of Health unless the clinic is wholly owned and operated by certain health care professionals, including a board-certified psychiatrist or rheumatologist; 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. Paragraph (a) of subsection (1) and subsection (3) of section 456.44, Florida Statutes, are amended to read: 456.44 Controlled substance prescribing.—
 - (1) DEFINITIONS.-
- (a) "Addiction medicine specialist" means a board-certified psychiatrist who holds physiatrist with a subspecialty

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certification in addiction medicine or who is eligible for such subspecialty certification in addiction medicine, an addiction medicine physician who is certified or eligible for certification by the American Society of Addiction Medicine, or an osteopathic physician who holds a certificate of added qualification in Addiction Medicine through the American Osteopathic Association.

- (3) STANDARDS OF PRACTICE.—The standards of practice in this section do not supersede the level of care, skill, and treatment recognized in general law related to health care licensure.
- (a) A complete medical history and a physical examination must be conducted before beginning any treatment and must be documented in the medical record. The exact components of the physical examination shall be left to the judgment of the clinician who is expected to perform a physical examination proportionate to the diagnosis that justifies a treatment. The medical record must, at a minimum, document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, a review of previous medical records, previous diagnostic studies, and history of alcohol and substance abuse. The medical record must shall also document the presence of one or more recognized medical indications for the use of a controlled substance. Each registrant must develop a written plan for assessing each patient's risk of aberrant drug-related behavior, which may include patient drug testing. Registrants must assess each patient's risk for aberrant drug-related behavior and monitor

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that risk on an ongoing basis in accordance with the plan.

- (b) Each registrant must develop a written individualized treatment plan for each patient. The treatment plan <u>must shall</u> state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and <u>must shall</u> indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician shall adjust drug therapy to the individual medical needs of each patient. Other treatment modalities, including a rehabilitation program, shall be considered depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment. The interdisciplinary nature of the treatment plan shall be documented.
- (c) The physician shall discuss the risks and benefits of the use of controlled substances, including the risks of abuse and addiction, as well as physical dependence and its consequences, with the patient, persons designated by the patient, or the patient's surrogate or guardian if the patient is incompetent. The physician shall use a written controlled substance agreement between the physician and the patient outlining the patient's responsibilities, including, but not limited to:
- 1. Number and frequency of <u>prescriptions and refills for</u> controlled substances substance prescriptions and refills.
- 2. Patient compliance and reasons for which drug therapy may be discontinued, such as a violation of the agreement.
- 3. An agreement that controlled substances for the treatment of chronic nonmalignant pain shall be prescribed by a

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single treating physician unless otherwise authorized by the treating physician and documented in the medical record.

- (d) The patient shall be seen by the physician at regular intervals, not to exceed 3 months, to assess the efficacy of treatment, ensure that controlled-substance controlled substance therapy remains indicated, evaluate the patient's progress toward treatment objectives, consider adverse drug effects, and review the etiology of the pain. Continuation or modification of therapy depends shall depend on the physician's evaluation of the patient's progress. If treatment goals are not being achieved, despite medication adjustments, the physician shall reevaluate the appropriateness of continued treatment. The physician shall monitor patient compliance in medication usage, related treatment plans, controlled substance agreements, and indications of substance abuse or diversion at a minimum of 3-month intervals.
- (e) The physician shall refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention shall be given to those patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder requires extra care, monitoring, and documentation and requires consultation with or referral to an addictionologist or psychiatrist physiatrist.
- (f) A physician registered under this section must maintain accurate, current, and complete records that are accessible and readily available for review and comply with the requirements of

this section, the applicable practice act, and applicable board rules. The medical records must include, but are not limited to:

- 1. The complete medical history and a physical examination, including history of drug abuse or dependence.
 - 2. Diagnostic, therapeutic, and laboratory results.
 - 3. Evaluations and consultations.
 - 4. Treatment objectives.
 - 5. Discussion of risks and benefits.
- 6. Treatments.

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- 7. Medications, including date, type, dosage, and quantity prescribed.
 - 8. Instructions and agreements.
 - 9. Periodic reviews.
 - 10. Results of any drug testing.
- 131 11. A photocopy of the patient's government-issued photo identification.
 - 12. If a written prescription for a controlled substance is given to the patient, a duplicate of the prescription.
 - 13. The physician's full name presented in a legible manner.
 - shall be immediately referred to a board-certified pain management physician, an addiction medicine specialist, or a mental health addiction facility as it pertains to drug abuse or addiction unless the physician is board-certified or board-eligible in pain management. Throughout the period of time before receiving the consultant's report, a prescribing physician shall clearly and completely document medical justification for continued treatment with controlled substances

and those steps taken to ensure medically appropriate use of controlled substances by the patient. Upon receipt of the consultant's written report, the prescribing physician shall incorporate the consultant's recommendations for continuing, modifying, or discontinuing the controlled-substance controlled substance therapy. The resulting changes in treatment shall be specifically documented in the patient's medical record. Evidence or behavioral indications of diversion shall be followed by discontinuation of the controlled-substance controlled substance therapy, and the patient shall be discharged, and all results of testing and actions taken by the physician shall be documented in the patient's medical record.

(h) When a pharmacy subject to this section receives a prescription, the prescription is deemed compliant with the standards of practice under this section and, therefore, valid for dispensing.

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

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Section 2. Paragraph (a) of subsection (1) of section 458.3265, Florida Statutes, is amended to read:

458.3265 Pain-management clinics.

- (1) REGISTRATION. -
- (a) 1. As used in this section, the term:
- a. "Chronic nonmalignant pain" means pain unrelated to cancer or rheumatoid arthritis which persists beyond the usual course of disease or <u>beyond</u> the injury that is the cause of the pain or which persists more than 90 days after surgery.
- b. "Pain-management clinic" or "clinic" means any publicly
 or privately owned facility:
- (I) That advertises in any medium for any type of painmanagement services; or
- (II) Where in any month a majority of patients are prescribed opioids, benzodiazepines, barbiturates, or carisoprodol for the treatment of chronic nonmalignant pain.
- 2. Each pain-management clinic must register with the department unless:
- a. The That clinic is licensed as a facility pursuant to chapter 395;
- b. The majority of the physicians who provide services in the clinic primarily provide primarily surgical services;
- c. The clinic is owned by a publicly held corporation whose shares are traded on a national exchange or on the over-the-counter market and whose total assets at the end of the corporation's most recent fiscal quarter exceeded \$50 million;
- d. The clinic is affiliated with an accredited medical school at which training is provided for medical students,

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- e. The clinic does not prescribe controlled substances for the treatment of pain;
- f. The clinic is owned by a corporate entity exempt from federal taxation under 26 U.S.C. s. 501(c)(3);
- g. The clinic is wholly owned and operated by one or more board-certified anesthesiologists, physiatrists, <u>psychiatrists</u>, <u>rheumatologists</u>, or neurologists; or
- h. The clinic is wholly owned and operated by one or more board-certified medical specialists who have also completed fellowships in pain medicine approved by the Accreditation Council for Graduate Medical Education, or who are also board-certified in pain medicine by a board approved by the American Board of Medical Specialties and perform interventional pain procedures of the type routinely billed using surgical codes.
- Section 3. Paragraph (a) of subsection (1) of section 459.0137, Florida Statutes, is amended to read:
 - 459.0137 Pain-management clinics.
 - (1) REGISTRATION.-
 - (a) 1. As used in this section, the term:
- a. "Chronic nonmalignant pain" means pain unrelated to cancer or rheumatoid arthritis which persists beyond the usual course of disease or <u>beyond</u> the injury that is the cause of the pain or which persists more than 90 days after surgery.
- b. "Pain-management clinic" or "clinic" means any publicly
 or privately owned facility:
- (I) That advertises in any medium for any type of painmanagement services; or
 - (II) Where in any month a majority of patients are

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prescribed opioids, benzodiazepines, barbiturates, or carisoprodol for the treatment of chronic nonmalignant pain.

- 2. Each pain-management clinic must register with the department unless:
- a. The That clinic is licensed as a facility pursuant to chapter 395;
- b. The majority of the physicians who provide services in the clinic primarily provide primarily surgical services;
- c. The clinic is owned by a publicly held corporation whose shares are traded on a national exchange or on the over-the-counter market and whose total assets at the end of the corporation's most recent fiscal quarter exceeded \$50 million;
- d. The clinic is affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows;
- e. The clinic does not prescribe controlled substances for the treatment of pain;
- f. The clinic is owned by a corporate entity exempt from federal taxation under 26 U.S.C. s. 501(c)(3);
- g. The clinic is wholly owned and operated by one or more board-certified anesthesiologists, physiatrists, <u>psychiatrists</u>, rheumatologists, or neurologists; or
- h. The clinic is wholly owned and operated by one or more board-certified medical specialists who have also completed fellowships in pain medicine approved by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association, or who are also board-certified in pain medicine by a board approved by the American Board of Medical Specialties or the American Osteopathic Association and perform

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262	interventional pain procedures of the type routinely bi	illed
263	using surgical codes.	
264	Section 4. This act shall take effect July 1, 2012	2.