By the Committee on Health Regulation; and Senator Bogdanoff

588-02713A-12 20121198c1

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; redefining the term "board-certified pain management physician" to include a physician who possesses board certification or subcertification in pain management by a specialty board recognized by the American Board of Medical Specialties; redefining the term "chronic nonmalignant pain"; providing requirements that a physician who prescribes certain specific controlled substances for the treatment of chronic nonmalignant pain must fulfill; 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 physicians; amending s. 458.3265, F.S.; revising the definition of the term "chronic nonmalignant pain"; requiring that a pain-management clinic register with the Department of Health unless the clinic is wholly owned by certain board-eligible or board-certified physicians or medical specialists, organized as a physician-owned group practice, or wholly owned by physicians who are not board eligible

or board certified but who have completed specified residency programs and have a specified number of years of full-time practice in pain medicine; amending s. 459.0137, F.S.; revising the definition of "chronic nonmalginant pain"; requiring that a pain-management clinic register with the Department of Health unless the clinic is wholly owned by certain health care practitioners; amending s. 465.0276, F.S.; redefining the term "approved clinical trial" as it relates to the Florida Pharmacy Act; amending s. 893.055, F.S.; providing that a pharmacist or health care practitioner is exempt from reporting a dispensed controlled substance to the Department of Health when administering the controlled substance to a patient who is receiving hospice care or to a patient or resident receiving care at certain medical facilities licensed in the state; requiring that a pharmacy, prescriber, or dispenser have access to information in the prescription drug monitoring program's database which relates to a patient, or a potential patient, of that pharmacy, prescriber, or dispenser for the purpose of reviewing the patient's controlled substance prescription history; providing an effective date.

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

Section 1. Section 456.44, Florida Statutes, is 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 certification in addiction medicine or who is eligible for such subspecialty certification in addiction medicine, a ~~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.

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

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

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

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

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

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

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

(3) STANDARDS OF PRACTICE.—The standards of practice in this section do not supersede the level of care, skill, and treatment recognized in general law related to 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 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 must ~~shall~~ state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and must ~~shall~~ indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician shall adjust drug therapy to the individual medical needs of each patient. Other treatment modalities, including a rehabilitation program, shall be considered depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment. The interdisciplinary nature of the treatment plan shall be documented.

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

1. Number and frequency of prescriptions and refills for 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 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.

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

8. Instructions and agreements.

9. Periodic reviews.

10. Results of any drug testing.

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

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

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

(g) Patients with signs or symptoms of substance abuse shall be immediately referred to a board-certified pain management physician, an addiction medicine specialist, or a mental health addiction facility as it pertains to drug abuse or addiction unless the physician is board-certified or board-eligible in pain management. Throughout the period ~~of time~~

before receiving the consultant's report, a prescribing physician shall clearly and completely document medical justification for continued treatment with controlled substances and those steps taken to ensure medically appropriate use of controlled substances by the patient. Upon receipt of the consultant's written report, the prescribing physician shall incorporate the consultant's recommendations for continuing, modifying, or discontinuing 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-eligible or 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-eligible or 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-eligible or board certified in pain medicine by a board approved by the American Board of Pain Medicine, the American Board of Medical Specialties, or the American Osteopathic Association and performs interventional pain procedures of the type routinely billed using surgical codes. This subsection does not apply to a physician certified by the American Board of Medical Specialties in hospice and palliative medicine or to an osteopathic physician who holds a certificate of added qualification in hospice and palliative medicine through the American Osteopathic Association. This subsection does not apply to hospitalists or other physicians who prescribe medically necessary controlled substances for a patient during an inpatient stay or while providing emergency services and care in a hospital licensed under chapter 395. This subsection does not apply to a physician who is treating a patient in accordance with an approved clinical trial.

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, or sickle cell anemia which persists beyond the usual course of disease or beyond 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 pain-management services; or

(II) Where in any month a majority of patients are prescribed opioids, benzodiazepines, barbiturates, or carisoprodol for the treatment of chronic nonmalignant pain.

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-eligible or board-certified anesthesiologists, physiatrists, psychiatrists, rheumatologists, or neurologists; ~~or~~

h. The clinic is wholly owned ~~and operated~~ by one or more board-eligible or 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-eligible or board-certified in pain medicine by a board approved by the American Board of Pain Medicine or the American Board of Medical Specialties and perform interventional pain procedures of the type routinely billed using surgical codes;~~.~~

i. The clinic is organized as a physician-owned group practice as defined in 42 C.F.R. 411,352; or

j. Before June 1, 2011, the clinic was wholly owned by physicians who are not board eligible or board certified but who successfully completed a residency program in anesthesiology, physiatry, psychiatry, rheumatology, or neurology and who have 7 years of documented, full-time practice in pain medicine in this state. For purposes of this paragraph, the term "full-time" is defined as practicing an average of 20 hours per week each year in pain medicine.

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, or sickle cell anemia which persists beyond the usual course of disease or beyond 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 pain-

management services; or

(II) Where in any month a majority of patients are prescribed opioids, benzodiazepines, barbiturates, or carisoprodol for the treatment of chronic nonmalignant pain.

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-eligible or board-certified anesthesiologists, physiatrists, psychiatrists, rheumatologists, or neurologists; or

h. The clinic is wholly owned ~~and operated~~ by one or more board-eligible or 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-eligible or board-certified in pain medicine by a board approved by the American Board of Medical Specialties, the American Association of Physician Specialties, or the American Osteopathic Association and perform interventional pain procedures of the type routinely billed using surgical codes.

Section 4. Paragraph (b) of subsection (1) of section 465.0276, Florida Statutes, is amended to read:

465.0276 Dispensing practitioner.—

(1)

(b) A practitioner registered under this section may not dispense a controlled substance listed in Schedule II or Schedule III as provided in s. 893.03. This paragraph does not apply to:

1. The dispensing of complimentary packages of medicinal drugs which are labeled as a drug sample or complimentary drug as defined in s. 499.028 to the practitioner's own patients in the regular course of her or his practice without the payment of a fee or remuneration of any kind, whether direct or indirect, as provided in subsection (5).

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

3. The dispensing of a controlled substance listed in Schedule II or Schedule III in connection with the performance of a surgical procedure. The amount dispensed pursuant to the subparagraph may not exceed a 14-day supply. This exception does not allow for the dispensing of a controlled substance listed in Schedule II or Schedule III more than 14 days after the performance of the surgical procedure. For purposes of this

subparagraph, the term "surgical procedure" means any procedure in any setting which involves, or reasonably should involve:

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

b. The use of general anesthesia or major conduction anesthesia and preoperative sedation.

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

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

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

Section 5. Paragraph (b) of subsection (5) and paragraph (b) of subsection (7) of section 893.055, Florida Statutes, are amended to read:

893.055 Prescription drug monitoring program.—

(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:

(b) A pharmacist or health care practitioner when administering a controlled substance to a patient who is receiving hospice care or 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.

(7)

(b) A pharmacy, prescriber, or dispenser shall have access to information in the prescription drug monitoring program's database which relates to a patient, or a potential patient, of that pharmacy, prescriber, or dispenser in a manner established by the department as needed for the purpose of reviewing the patient's controlled substance prescription history. Other access to the program's database shall be limited to the program's manager and to the designated program and support staff, who may act only at the direction of the program manager or, in the absence of the program manager, as authorized. Access by the program manager or such designated staff is for prescription drug program management only or for management of the program's database and its system in support of the requirements of this section and in furtherance of the prescription drug monitoring program. Confidential and exempt information in the database shall be released only as provided in paragraph (c) and s. 893.0551. The program manager, designated program and support staff who act at the direction of or in the absence of the program manager, and any individual who has similar access regarding the management 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.

Section 6. This act shall take effect July 1, 2012.