A bill to be entitled

An act relating to the provision of health care with controlled substances; amending s. 456.44, F.S.; limiting the application of requirements for prescribing controlled substances; requiring a physician to consult the prescription drug monitoring program database before prescribing certain controlled substances; authorizing the Board of Medicine and the Board of Osteopathic Medicine to adopt a penalty for failure to consult the database; exempting nursing home residents and certain physicians from requirements regarding prescriptions of controlled substances; amending s. 465.003, F.S.; defining a term; conforming a cross-reference; creating s. 465.0065, F.S.; providing notice requirements for inspection of a pharmacy; amending s. 465.016, F.S.; providing additional grounds for disciplinary action; conforming a cross-reference; amending s. 465.022, F.S.; conforming a cross-reference; requiring a pharmacy permittee to commence operations within 180 days after permit issuance or show good cause why operations were not commenced; requiring the Board of Pharmacy to establish rules; requiring a pharmacy permittee to be supervised by a prescription department manager or consultant pharmacist of record; amending s. 465.023, F.S.; providing additional grounds for disciplinary action; conforming a cross-reference; creating s. 465.1902, F.S.; providing that the regulation of pharmacies and pharmacists is

preempted to the state; providing that a local ordinance, rule, or regulation may not be enacted or remain in effect which regulates or attempts to regulate pharmacies or pharmacists in subject matters regulated under ch. 465, F.S.; amending s. 893.055, F.S.; deleting obsolete provisions; requiring a designated agent under the supervision of a health care practitioner to have access to information in the prescription drug monitoring program's database; deleting a provision that prohibits funds from prescription drug manufacturers to be used to implement the prescription drug monitoring program; authorizing the prescription drug monitoring program to be funded by state funds; revising the sources of money which are inappropriate for the direct-support organization of the prescription drug monitoring program to receive; amending s. 893.0551, F.S.; requiring the Department of Health to disclose certain confidential and exempt information to a designated agent of a health care practitioner or pharmacist under certain circumstances; creating s. 893.0552, F.S.; providing that regulation of the licensure, standards of practice, and operation of pain-management clinics is preempted to the state under certain circumstances; authorizing a local government or political subdivision to enact certain ordinances; amending ss. 409.9201, 458.331, 459.015, 465.014, 465.015, 465.0156, 465.0197, 465.1901, 499.003, and 893.02, F.S.; conforming cross-references; 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 with a subspecialty certification in addiction medicine or who is eligible for such subspecialty certification in addiction medicine, an addiction medicine physician 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 or pain medicine 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) "Board eligible" means successful completion of an

anesthesia, physical medicine and rehabilitation, rheumatology, or neurology residency program approved by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association for a period of 6 years from successful completion of such residency program.

(e) "Chronic nonmalignant pain" means pain unrelated to cancer which persists beyond the usual course of disease or the injury that is the cause of the pain or more than 90 days after surgery.

(f) "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 more than a 30-day supply of any controlled substance, listed in Schedule II, Schedule III, or Schedule IV as defined in s. 893.03, over a 6-month period to any one patient 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 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) Before or during a new patient's visit for services for the treatment of pain at a pain-management clinic registered under s. 458.3265 or s. 459.0137, a physician shall consult the prescription drug monitoring program database provided under s. 893.055(2)(a) before prescribing a controlled substance listed in Schedule II or Schedule III in s. 893.03. The physician may designate an agent under his or her supervision to consult the database. The Board of Medicine under chapter 458 and the Board of Osteopathic Medicine under chapter 459 shall adopt rules to establish a penalty for a physician who does not comply with this subsection.

(c) ~~(b)~~ Each registrant must develop a written individualized treatment plan for each patient. The treatment

plan shall state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and 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.

(d) ~~(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 controlled 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.

(e) ~~(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 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 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.

(f) ~~(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 addiction medicine specialist or psychiatrist.

(g) ~~(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.

(h) ~~(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 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 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.

This section ~~subsection~~ does not apply to a board-eligible or board-certified anesthesiologist, physiatrist, 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 section ~~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 the American Board of Pain Medicine or a board approved by 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 section ~~subsection~~ does not apply to a physician who prescribes medically necessary controlled substances for a patient during an inpatient stay in a hospital licensed under chapter 395 or to a resident in a facility licensed under part II of chapter 400. This section does not apply to a physician

licensed under chapter 458 or chapter 459 who writes fewer than 50 prescriptions for a controlled substance for all of his or her patients during a 1-year period.

Section 2. Present subsections (1) through (17) of section 465.003, Florida Statutes, are renumbered as subsections (2) through (18), respectively, paragraph (a) of present subsection (11) of that section is amended, and a new subsection (1) is added to that section, to read:

465.003 Definitions.—As used in this chapter, the term:

(1) "Abandoned" means the status of a pharmacy permit of a person or entity that was issued the permit but fails to commence pharmacy operations within 180 days after issuance of the permit without good cause or fails to follow pharmacy closure requirements as set by the board.

(12) ~~(11)~~(a) "Pharmacy" includes a community pharmacy, an institutional pharmacy, a nuclear pharmacy, a special pharmacy, and an Internet pharmacy.

1. The term "community pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.

2. The term "institutional pharmacy" includes every location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility, hereinafter referred to as "health care institutions," where medicinal drugs are compounded, dispensed, stored, or sold.

3. The term "nuclear pharmacy" includes every location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold.

The term "nuclear pharmacy" does not include hospitals licensed under chapter 395 or the nuclear medicine facilities of such hospitals.

4. The term "special pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold if such locations are not otherwise defined in this subsection.

5. The term "Internet pharmacy" includes locations not otherwise licensed or issued a permit under this chapter, within or outside this state, which use the Internet to communicate with or obtain information from consumers in this state and use such communication or information to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy in this state. Any act described in this definition constitutes the practice of pharmacy as defined in subsection (14) ~~(13)~~.

Section 3. Section 465.0065, Florida Statutes, is created to read:

465.0065 Notices; form and service.—Each notice served by the department pursuant to this chapter must be in writing and must be delivered personally by an agent of the department or by certified mail to the pharmacy permittee or licensee. If the pharmacy permittee or licensee refuses to accept service or evades service or if the agent is otherwise unable to carry out service after due diligence, the department may post the notice in a conspicuous place at the pharmacy or at the home or business address for the licensee.

Section 4. Paragraphs (e) and (s) of subsection (1) of section 465.016, Florida Statutes, are amended, and paragraph (u) is added to that subsection, to read:

465.016 Disciplinary actions.—

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

(e) Violating chapter 499; 21 U.S.C. ss. 301-392, known as the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq., known as the Comprehensive Drug Abuse Prevention and Control Act; or chapter 893 or rules adopted thereunder.

(s) Dispensing any medicinal drug based upon a communication that purports to be a prescription as defined by s. 465.003 ~~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.

(u) Misappropriating drugs, supplies, or equipment from a pharmacy permittee.

Section 5. Paragraph (j) of subsection (5) of section 465.022, Florida Statutes, is amended, present subsections (10) through (14) are renumbered as subsections (11) through (15), respectively, present subsection (10) of that section is amended, and a new subsection (10) is added to that section, to read:

465.022 Pharmacies; general requirements; fees.—

(5) The department or board shall deny an application for a pharmacy permit if the applicant or an affiliated person, partner, officer, director, or prescription department manager or consultant pharmacist of record of the applicant:

(j) Has dispensed any medicinal drug based upon a communication that purports to be a prescription as defined by s. 465.003 ~~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.

For felonies in which the defendant entered a plea of guilty or nolo contendere in an agreement with the court to enter a pretrial intervention or drug diversion program, the department shall deny the application if upon final resolution of the case the licensee has failed to successfully complete the program.

(10) The permittee shall commence pharmacy operations within 180 days after issuance of the permit, or show good cause to the department why pharmacy operations were not commenced. Commencement of pharmacy operations includes, but is not limited to, acts within the scope of the practice of pharmacy, ordering or receiving drugs, and other similar activities. The board shall establish rules regarding commencement of pharmacy operations.

(11) ~~(10)~~ A pharmacy permittee shall be supervised by a prescription department manager or consultant pharmacist of record at all times. A permittee must notify the department, on a form approved by the board, within 10 days after any change in prescription department manager or consultant pharmacist of record.

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 or rules adopted thereunder;

(d) Been convicted or found guilty, regardless of 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; or

(h) Dispensed any medicinal drug based upon a communication that purports to be a prescription as defined by s. 465.003 ~~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.

Section 7. Section 465.1902, Florida Statutes, is created to read:

465.1902 Preemption.—The regulation of pharmacies and pharmacists is expressly preempted to the state. No local ordinance, rule, or regulation shall be enacted or remain in effect which regulates or attempts to regulate pharmacies or pharmacists in subject matters regulated under this chapter, including, but not limited to, licensure, discipline, pharmacy permitting, and the dispensing of controlled substances.

Section 8. Paragraph (b) of subsection (2), paragraph (b) of subsection (7), subsection (10), and paragraph (c) of subsection (11) of section 893.055, Florida Statutes, are amended to read:

893.055 Prescription drug monitoring program.—

(2)

(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,~~ 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 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.

(7)

(b) A pharmacy, prescriber, <u>designated agent under the supervision of a health care practitioner,</u> or dispenser shall have access to information in the prescription drug monitoring program's database which relates to a 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.

(10) All costs incurred by the department in administering the prescription drug monitoring program shall be funded through state funds, 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 state funds, federal grant funds, other nonstate grant

funds, gifts, donations, or other private moneys for the department if ~~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. ~~Funds provided, directly or indirectly, by prescription drug manufacturers may not be used to implement the program.~~

(11) 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.

(c) The State Surgeon General shall appoint a board of directors for the direct-support organization. Members of the board shall serve at the pleasure of the State Surgeon General. The State Surgeon General 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, or pharmaceutical companies, that may monetarily or substantively benefit from the purchase of goods or services by the department in furtherance of the prescription drug monitoring program.

Section 9. Paragraphs (d) and (e) of subsection (3) of section 893.0551, Florida Statutes, are amended to read:

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

(3) The department shall disclose such confidential and exempt information to the following entities after using a verification process to ensure the legitimacy of that person's or entity's request for the information:

(d) A health care practitioner or a designated agent under his or her supervision who certifies that the information is necessary to provide medical treatment to a current patient in accordance with ss. 893.05 and 893.055.

(e) A pharmacist or a designated agent under his or her supervision who certifies that the requested information will be used to dispense controlled substances to a current patient in accordance with ss. 893.04 and 893.055.

Section 10. Section 893.0552, Florida Statutes, is created to read:

893.0552 Preemption of regulation.—

(1) This section preempts to the state all regulation of the licensure, standards of practice, and operation of pain-management clinics as defined in ss. 458.3265 and 459.0137 in the following circumstances:

(a) The clinic is wholly owned and operated by a physician who performs interventional pain procedures of the type routinely billed using surgical codes, who has never been suspended or revoked for prescribing a controlled substance in Schedule II or Schedule III of s. 893.03 and drugs containing Alprazolam in excessive or inappropriate quantities that are not in the best interest of a patient, and who:

1. Has completed a fellowship in pain medicine which is

approved by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association;

2. Is board-certified in pain medicine by the American Board of Pain Medicine, board-certified by the American Board of Interventional Pain Physicians; or

3. Has a board certification or subcertification in pain management or pain medicine by a specialty board approved by the American Board of Medical Specialties or the American Osteopathic Association.

(b) The clinic is wholly owned and operated by a physician-multispecialty practice if one or more board-eligible or board-certified medical specialists has one of the qualifications specified in subparagraph (a)1., subparagraph (a)2., or subparagraph (a)3., performs interventional pain procedures of the type routinely billed using surgical codes, and has never been suspended or revoked for prescribing a controlled substance in Schedule II or Schedule III of s. 893.03 and drugs containing Alprazolam in excessive or inappropriate quantities that are not in the best interest of a patient.

(2) Notwithstanding subsection (1), the preemption does not prohibit a local government or political subdivision from enacting an ordinance regarding local business taxes adopted pursuant to chapter 205, any other local levy, charge, or fee applied to businesses currently authorized by general law or the Florida Constitution, and land use development regulations adopted pursuant to chapter 163. A pain-management clinic in which the regulation of its licensure, standards of practice, and operation is preempted to the state pursuant to subsection (1) is a permissible use in a land use or zoning category that

permits hospitals and other health care facilities or clinics as defined in chapter 395 or s. 408.07. Upon the request of a local government, a pain-management clinic must annually demonstrate that it qualifies for preemption pursuant to subsection (1).

Section 11. Subsection (1) of section 409.9201, Florida Statutes, is amended to read:

409.9201 Medicaid fraud.—

(1) As used in this section, the term:

(a) "Prescription drug" means any drug, including, but not limited to, finished dosage forms or active ingredients that are subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act or by s. 465.003 ~~s. 465.003(8)~~, s. 499.003(46) or (53) or s. 499.007(13).

(b) "Value" means the amount billed to the Medicaid program for the property dispensed or the market value of a legend drug or goods or services at the time and place of the offense. If the market value cannot be determined, the term means the replacement cost of the legend drug or goods or services within a reasonable time after the offense.

The value of individual items of the legend drugs or goods or services involved in distinct transactions committed during a single scheme or course of conduct, whether involving a single person or several persons, may be aggregated when determining the punishment for the offense.

Section 12. Paragraph (pp) of subsection (1) of section 458.331, Florida Statutes, is amended 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):

(pp) Applicable to a licensee who serves as the designated physician of a pain-management clinic as defined in s. 458.3265 or s. 459.0137:

1. Registering a pain-management clinic through misrepresentation or fraud;

2. Procuring, or attempting to procure, the registration of a pain-management clinic for any other person by making or causing to be made, any false representation;

3. Failing to comply with any requirement of chapter 499, the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Drug Abuse Prevention and Control Act; or chapter 893, the Florida Comprehensive Drug Abuse Prevention and Control Act;

4. Being convicted or found guilty of, regardless of adjudication to, a felony or any other crime involving moral turpitude, fraud, dishonesty, or deceit in any jurisdiction of the courts of this state, of any other state, or of the United States;

5. Being convicted of, 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;

6. Being convicted of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction of the courts of this state, of any other state, or of the United States which relates to the practice of, or the ability to practice, a licensed health care profession;

7. Being convicted of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction of the courts of this state, of any other state, or of the United States which relates to health care fraud;

8. Dispensing any medicinal drug based upon a communication that purports to be a prescription as defined in s. 465.003 ~~s. 465.003(14)~~ or s. 893.02 if the dispensing practitioner knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship; or

9. Failing to timely notify the board of the date of his or her termination from a pain-management clinic as required by s. 458.3265(2).

Section 13. Paragraph (rr) 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):

(rr) Applicable to a licensee who serves as the designated physician of a pain-management clinic as defined in s. 458.3265 or s. 459.0137:

1. Registering a pain-management clinic through misrepresentation or fraud;

2. Procuring, or attempting to procure, the registration of a pain-management clinic for any other person by making or causing to be made, any false representation;

3. Failing to comply with any requirement of chapter 499, the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq.,

the Drug Abuse Prevention and Control Act; or chapter 893, the Florida Comprehensive Drug Abuse Prevention and Control Act;

4. Being convicted or found guilty of, regardless of adjudication to, a felony or any other crime involving moral turpitude, fraud, dishonesty, or deceit in any jurisdiction of the courts of this state, of any other state, or of the United States;

5. Being convicted of, 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;

6. Being convicted of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction of the courts of this state, of any other state, or of the United States which relates to the practice of, or the ability to practice, a licensed health care profession;

7. Being convicted of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction of the courts of this state, of any other state, or of the United States which relates to health care fraud;

8. Dispensing any medicinal drug based upon a communication that purports to be a prescription as defined in s. 465.003 ~~s. 465.003(14)~~ or s. 893.02 if the dispensing practitioner knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship; or

9. Failing to timely notify the board of the date of his or her termination from a pain-management clinic as required by s. 459.0137(2).

Section 14. Subsection (1) of section 465.014, Florida

Statutes, is amended to read:

465.014 Pharmacy technician.—

(1) A person other than a licensed pharmacist or pharmacy intern may not engage in the practice of the profession of pharmacy, except that a licensed pharmacist may delegate to pharmacy technicians who are registered pursuant to this section those duties, tasks, and functions that do not fall within the purview of s. 465.003 ~~s. 465.003(13)~~. All such delegated acts shall be performed under the direct supervision of a licensed pharmacist who shall be responsible for all such acts performed by persons under his or her supervision. A pharmacy registered technician, under the supervision of a pharmacist, may initiate or receive communications with a practitioner or his or her agent, on behalf of a patient, regarding refill authorization requests. A licensed pharmacist may not supervise more than one registered pharmacy technician unless otherwise permitted by the guidelines adopted by the board. The board shall establish guidelines to be followed by licensees or permittees in determining the circumstances under which a licensed pharmacist may supervise more than one but not more than three pharmacy technicians.

Section 15. Paragraph (c) of subsection (2) of section 465.015, Florida Statutes, is amended to read:

465.015 Violations and penalties.—

(2) It is unlawful for any person:

(c) To sell or dispense drugs as defined in s. 465.003 ~~s. 465.003(8)~~ without first being furnished with a prescription.

Section 16. Subsection (8) of section 465.0156, Florida Statutes, is amended to read:

465.0156 Registration of nonresident pharmacies.—

(8) Notwithstanding s. 465.003 ~~s. 465.003(10)~~, for purposes of this section, the registered pharmacy and the pharmacist designated by the registered pharmacy as the prescription department manager or the equivalent must be licensed in the state of location in order to dispense into this state.

Section 17. Subsection (4) of section 465.0197, Florida Statutes, is amended to read:

465.0197 Internet pharmacy permits.—

(4) Notwithstanding s. 465.003 ~~s. 465.003(10)~~, for purposes of this section, the Internet pharmacy and the pharmacist designated by the Internet pharmacy as the prescription department manager or the equivalent must be licensed in the state of location in order to dispense into this state.

Section 18. Section 465.1901, Florida Statutes, is amended to read:

465.1901 Practice of orthotics and pedorthics.—The provisions of chapter 468 relating to orthotics or pedorthics do not apply to any licensed pharmacist or to any person acting under the supervision of a licensed pharmacist. The practice of orthotics or pedorthics by a pharmacist or any of the pharmacist’s employees acting under the supervision of a pharmacist shall be construed to be within the meaning of the term “practice of the profession of pharmacy” as set forth in s. 465.003 ~~s. 465.003(13)~~, and shall be subject to regulation in the same manner as any other pharmacy practice. The Board of Pharmacy shall develop rules regarding the practice of orthotics and pedorthics by a pharmacist. Any pharmacist or person under the supervision of a pharmacist engaged in the practice of

orthotics or pedorthics is not precluded from continuing that practice pending adoption of these rules.

Section 19. Subsection (43) of section 499.003, Florida Statutes, is amended to read:

499.003 Definitions of terms used in this part.—As used in this part, the term:

(43) "Prescription drug" means a prescription, medicinal, or legend drug, including, but not limited to, finished dosage forms or active pharmaceutical ingredients subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act or s. 465.003 ~~s. 465.003(8)~~, s. 499.007(13), or subsection (11), subsection (46), or subsection (53), except that an active pharmaceutical ingredient is a prescription drug only if substantially all finished dosage forms in which it may be lawfully dispensed or administered in this state are also prescription drugs.

Section 20. Subsection (22) of section 893.02, Florida Statutes, is amended to read:

893.02 Definitions.—The following words and phrases as used in this chapter shall have the following meanings, unless the context otherwise requires:

(22) "Prescription" means and includes an order for drugs or medicinal supplies written, signed, or transmitted by word of mouth, telephone, telegram, or other means of communication by a duly licensed practitioner licensed by the laws of the state to prescribe such drugs or medicinal supplies, issued in good faith and in the course of professional practice, intended to be filled, compounded, or dispensed by another person licensed by the laws of the state to do so, and meeting the requirements of

s. 893.04. The term also includes an order for drugs or medicinal supplies so transmitted or written by a physician, dentist, veterinarian, or other practitioner licensed to practice in a state other than Florida, but only if the pharmacist called upon to fill such an order determines, in the exercise of his or her professional judgment, that the order was issued pursuant to a valid patient-physician relationship, that it is authentic, and that the drugs or medicinal supplies so ordered are considered necessary for the continuation of treatment of a chronic or recurrent illness. However, if the physician writing the prescription is not known to the pharmacist, the pharmacist shall obtain proof to a reasonable certainty of the validity of said prescription. A prescription order for a controlled substance shall not be issued on the same prescription blank with another prescription order for a controlled substance which is named or described in a different schedule, nor shall any prescription order for a controlled substance be issued on the same prescription blank as a prescription order for a medicinal drug, as defined in s. 465.003 ~~s. 465.003(8)~~, which does not fall within the definition of a controlled substance as defined in this act.

Section 21. This act shall take effect July 1, 2013.