A bill to be entitled

An act relating to prescription drugs; amending s. 456.44, F.S.; removing physiatrist; adding psychiatrist and rheumatologist; amending definition of chronic non-malignant pain; adding the American Board of Medical Specialties to recognized certification entities; amending definition of controlled substances; amending s. 458.3265, F.S.; amending definition of chronic non-malignant pain; permitting a rheumatologist to own pain clinics; adding multi-specialty practice to permitted ownership forms of pain clinics; amending s. 459.0137, F.S.; amending definition of chronic non-malignant pain; permitting a rheumatologist to own pain clinics; adding multi-specialty practice to permitted ownership forms of pain clinics; amending s. 499.003, F.S.; revising the definitions of the terms "distribute" or "distribution," "drug," "establishment," and "prescription drug"; amending s. 499.01, F.S.; deleting provisions relating to an exemption from nonresident prescription drug manufacturer permit requirements; deleting provisions relating to an exemption from out-of-state prescription drug wholesale distributor permit requirements for intracompany sale or transfer of prescription drugs; providing an exemption from permit requirements for the distribution into this state of prescription drug active pharmaceutical ingredients for incorporation

into prescription drugs in finished dosage form; requiring a distributor claiming such exemption to maintain a valid license, permit, or registration in the state from which the prescription drug was distributed; requiring compliance with certain recordkeeping requirements; exempting compliance with pedigree paper requirements; providing an exemption from permit requirements for distribution into this state of limited quantities of a prescription drug that has not been repackaged, for research and development or to a holder of a letter of exemption issued by the Department of Business and Professional Regulation for research, teaching, or testing; granting the department authority to define "limited quantities" by rule and limit therein the number of transactions and amount of prescription drugs distributed into the state; requiring a distributor claiming such exemption to maintain a valid license, permit, or registration in the state from which the prescription drug was distributed; requiring all purchasers and recipients of such prescription drugs to ensure the products are not resold or used on humans except in lawful clinical trials and biostudies; requiring compliance with certain recordkeeping requirements; exempting compliance from pedigree paper requirements; providing labeling requirements for active pharmaceutical ingredients distributed within the state for teaching, testing,

research, and development; exempting from out-of-state prescription drug wholesale distributor permit requirements intracompany transactions or the sale of prescription drugs from an out-of-state distributor to a distributor in this state if both distributors conduct wholesale distributions under the same business name; requiring compliance with recordkeeping and pedigree paper requirements; allowing distributors and recipients of prescription drugs claiming exemption from certain permitting requirements to maintain on file their FDA registration number, resident state distributor license or permit number, and most recent resident state or FDA inspection report; providing that persons claiming such exemptions are subject to part I of chapter 499, F.S., the Florida Drug and Cosmetic Act; requiring persons claiming such exemptions to make all records regarding prescription drug distribution available to the department, upon request, within 48 hours; requiring submission of a report of mishandled or adulterated prescription drugs within 14 days after receipt of such drugs; authorizing the department to adopt rules; providing that failure to comply with requirements or rules governing such exemptions constitutes unlawful purchase or receipt of a prescription drug from a person not authorized to distribute prescription drugs to that purchaser or recipient; providing that knowing failure to comply with such requirements constitutes

unlawful sale, distribution, purchase, trade, holding, or offering of a drug; providing penalties; providing construction with respect to federal and state laws relating to controlled substances; providing an effective date.

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

Section 1. Paragraphs (a),(c) and (d)of subsection (1), paragraph (a) of subsection (2), and paragraph (e) of 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 ~~physiatrist~~ 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.

(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~~ 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.

(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 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.

(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.

(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~~.

This subsection does not apply to a 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 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 billed using surgical codes.

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 the injury that is the cause of the pain or 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. 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 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, rheumatologists, or neurologists; or

h. The clinic is wholly owned and operated by a physician multi-specialty practice where 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 the injury that is the cause of the pain or 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. 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 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, rheumatologists, or neurologists; or

h. The clinic is wholly owned and operated by a physician multi-specialty practice where 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 interventional pain procedures of the type routinely billed using surgical codes.

Section 4. Subsections (17), (19), (20), and (43) of section 499.003, Florida Statutes, are amended to read:

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

(17) "Distribute" or "distribution" means to sell; offer to sell; give away; transfer, whether by passage of title, physical movement, or both; deliver; or offer to deliver. The term does not mean to administer or dispense and does not include administrative billing, invoicing, and payment collection and

processing activities that commonly evidence a distribution transaction.

(19) "Drug" means an article that is:

(a) Recognized in the current edition of the United States Pharmacopoeia and National Formulary, official Homeopathic Pharmacopoeia of the United States, or any supplement to any of those publications;

(b) Intended for use in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals;

(c) Intended to affect the structure or any function of the body of humans or other animals; or

(d) Intended for use as a component of any article specified in paragraph (a), paragraph (b), or paragraph (c), and includes active pharmaceutical ingredient, but does not include devices or their non-drug components, parts, or accessories. For purposes of this paragraph, an "active pharmaceutical ingredient" includes any substance or mixture of substances intended, represented, or labeled for use in drug manufacturing that furnishes or is intended to furnish in a finished dosage form any pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals, or to affect the structure or any function of the body of humans or other animals.

(20) "Establishment" means a place of business at one general physical location that may extend to one or more contiguous buildings or building subdivisions, including suites,

units, or floors, or to one or more buildings situated on a single controlled-access property owned or operated by a single entity or entities under common operational control. To be contiguous, buildings or building subdivisions must adjoin or share a sufficient common boundary to allow full and free access to the whole establishment without crossing a public roadway, public waterway, or similar barrier. A permit issued under this part applies only to those buildings and building subdivisions identified on the most recent application for or to renew that permit, and an establishment may not expand to include other buildings or building subdivisions without an approved change of address application under s. 499.012(6)(a).

(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(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 Florida are also prescription drugs.

Section 5. Paragraphs (c) and (e) of subsection (2) of section 499.01, Florida Statutes, are amended, and subsections (3) and (4) of section 499.01, Florida Statutes, are created to read:

499.01 Permits.-

(2) The following permits are established:

(c) Nonresident prescription drug manufacturer permit.—A nonresident prescription drug manufacturer permit is required for any person that is a manufacturer of prescription drugs, unless permitted as a third party logistics provider, located outside of this state or outside the United States and that engages in the wholesale distribution in this state of such prescription drugs. Each such manufacturer must be permitted by the department and comply with all of the provisions required of a wholesale distributor under this part, except s. 499.01212.

1. A person that distributes prescription drugs for which the person is not the manufacturer must also obtain an out-of-state prescription drug wholesale distributor permit or third party logistics provider permit pursuant to this section to engage in the wholesale distribution of such prescription drugs. This subparagraph does not apply to a manufacturer as defined in s. 499.003(31)(e).

2. Any such person must comply with the licensing or permitting requirements of the jurisdiction in which the establishment is located and the federal act, and any product wholesaled into this state must comply with this part. If a person intends to import prescription drugs from a foreign country into this state, the nonresident prescription drug manufacturer must provide to the department a list identifying each prescription drug it intends to import and document approval by the United States Food and Drug Administration for such importation.

~~3. A nonresident prescription drug manufacturer permit is not required for a manufacturer to distribute a prescription~~

~~drug active pharmaceutical ingredient that it manufactures to a prescription drug manufacturer permitted in this state in limited quantities intended for research and development and not for resale, or human use other than lawful clinical trials and biostudies authorized and regulated by federal law. A manufacturer claiming to be exempt from the permit requirements of this subparagraph and the prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall comply with the recordkeeping requirements of s. 499.0121(6), but not the requirements of s. 499.01212. The prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall maintain on file a record of the FDA registration number; the out-of-state license, permit, or registration number; and, if available, a copy of the most current FDA inspection report, for all manufacturers from whom they purchase active pharmaceutical ingredient under this section. The department shall specify by rule the allowable number of transactions within a given period of time and the amount of active pharmaceutical ingredient that qualify as limited quantities for purposes of this exemption. The failure to comply with the requirements of this subparagraph, or rules adopted by the department to administer this subparagraph, for the purchase of prescription drug active pharmaceutical ingredients is a violation of s. 499.005(14).~~

(e) Out-of-state prescription drug wholesale distributor permit.—An out-of-state prescription drug wholesale distributor is a wholesale distributor located outside this state which engages in the wholesale distribution of prescription drugs into

this state and which must be permitted by the department and comply with all the provisions required of a wholesale distributor under this part. An out-of-state prescription drug wholesale distributor that applies to the department for a new permit or the renewal of a permit must submit a bond of $100,000, or other equivalent means of security acceptable to the department, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to the Florida Drug, Device, and Cosmetic Trust Fund. The purpose of the bond is to secure payment of any administrative penalties imposed by the department and any fees and costs incurred by the department regarding that permit which are authorized under state law and which the permittee fails to pay 30 days after the fine or costs become final. The department may make a claim against such bond or security until 1 year after the permittee's license ceases to be valid or until 60 days after any administrative or legal proceeding authorized in this part which involves the permittee is concluded, including any appeal, whichever occurs later.

~~1.~~ The out-of-state prescription drug wholesale distributor must maintain at all times a license or permit to engage in the wholesale distribution of prescription drugs in compliance with laws of the state in which it is a resident.

~~2. An out-of-state prescription drug wholesale distributor permit is not required for an intracompany sale or transfer of a prescription drug from an out-of-state establishment that is duly licensed as a prescription drug wholesale distributor, in its state of residence, to a licensed prescription drug~~

~~wholesale distributor in this state, if both wholesale distributors conduct wholesale distributions of prescription drugs under the same business name. The recordkeeping requirements of ss. 499.0121(6) and 499.01212 must be followed for this transaction.~~

(3) Exemptions.

(a) A nonresident prescription drug manufacturer permit is not required for a manufacturer to distribute a prescription drug active pharmaceutical ingredient that it manufactures to a prescription drug manufacturer permitted in this state in limited quantities intended for research and development and not for resale, or human use other than lawful clinical trials and biostudies authorized and regulated by federal law. A manufacturer claiming to be exempt from the permitting requirements of this part under this paragraph and the prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall comply with the recordkeeping requirements of s. 499.0121(6), but not the requirements of s. 499.01212. The prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall maintain on file a record of the FDA registration number; the out-of-state license, permit, or registration number; and, if available, a copy of the most current FDA inspection report, for all manufacturers from whom active pharmaceutical ingredient is purchased under this paragraph. The department shall define "limited quantities" by rule, and may include the allowable number of transactions within a given period of time and the amounts of prescription drugs distributed into the state for

purposes of this exemption. The failure to comply with the requirements of this paragraph, or rules adopted by the department to administer this paragraph, for the purchase of prescription drug active pharmaceutical ingredients is a violation of s. 499.005(14), and a knowing failure is a violation of s. 499.0051(4).

(b) Subject to the requirements of paragraph (d), a permit issued under this part is not required to distribute prescription drug active pharmaceutical ingredient that has not been repackaged from an establishment located in the United States to an establishment located in this state permitted as a prescription drug manufacturer under this part for use solely by or for the recipient in preparing, deriving, processing, producing, or fabricating a prescription drug finished dosage form at the establishment in this state where the product is received under an approved and otherwise valid New Drug Application, Abbreviated New Drug Application, New Animal Drug Application, Therapeutic Biologic Application, or Biologics License Application, provided that the application, active pharmaceutical ingredient, or finished dosage form has not been withdrawn or removed from the market in this country for public health reasons.

(c) Subject to the requirements of paragraph (d), a permit issued under this part is not required to distribute limited quantities of a prescription drug that has not been repackaged from an establishment located in the United States to an establishment located in this state permitted as a prescription drug manufacturer under this part for research and development

or to a holder of a letter of exemption issued by the department under s. 499.03(4) for research, teaching, or testing. The department shall define "limited quantities" by rule, and may include the allowable number of transactions within a given period of time and the amounts of prescription drugs distributed into the state for purposes of this exemption.

1. All purchasers and recipients of any prescription drugs distributed pursuant to this paragraph shall ensure that the products are not resold or used, directly or indirectly, on humans except in lawful clinical trials and biostudies authorized and regulated by federal law.

2. The immediate package or container of any prescription drug distributed into the state intended for teaching, testing, research, or development shall bear a label prominently displaying the statement "Caution: Research, Teaching, or Testing Only – Not for Commercial Use, Distribution, or Resale."

(d) The persons and activities described in paragraphs (b) and (c) shall comply with the following requirements, and except as provided in this subsection, the requirements of this part and rules adopted under this part:

1. The distributor claimed to be exempt from the permitting requirements of this part shall maintain a license, permit or registration as a manufacturer or wholesale distributor of prescription drugs under the laws of the state from which the product is distributed.

2. Persons purchasing or receiving prescription drugs from a distributor claimed to be exempt from the permitting requirements of this part shall maintain on file, for each such

prescription drug and distributor, a record of the FDA establishment registration number where the prescription drugs were manufactured; the distributing establishment's resident state prescription drug manufacturer or wholesale distributor license, permit, or registration number; and a copy of the distributing establishment's most recent resident state or FDA inspection report, if available.

3. Distributors claimed to be exempt from the permitting requirements of this part, and the purchaser and recipient of the prescription drugs purchased or received from such sources, shall comply with the recordkeeping requirements of s. 499.0121(6), but not the requirements of s. 499.01212.

(e) An out-of-state prescription drug wholesale distributor permit is not required for an intracompany sale or transfer of a prescription drug from an out-of-state establishment that is duly licensed as a prescription drug wholesale distributor, in its state of residence, to a licensed prescription drug wholesale distributor in this state, if both wholesale distributors conduct wholesale distributions of prescription drugs under the same business name. The recordkeeping requirements of ss. 499.0121(6) and 499.01212 must be followed for such transactions.

(f) All persons distributing prescription drugs in or into the state, regardless of any exemption from permitting requirements, are subject to this part, including ss. 499.005 and 499.0051, and the rules adopted under this part, and shall make available, within 48 hours, to the department on request all records related to any prescription drugs distributed under

this subsection, including those records described in s. 499.051(4), regardless of the location where the records are stored.

(g) A person purchasing and receiving a prescription drug from a person claimed to be exempt from licensing requirements pursuant to this subsection shall report to the department in writing within 14 days of receiving any product that is misbranded or adulterated or that fails to meet minimum standards for identity, purity, potency, or sterility set forth in the official compendium or in state or federal good manufacturing practices, regardless of whether the product is thereafter rehabilitated, quarantined, returned, or destroyed.

(h) The department may adopt rules to administer this subsection, which rules are necessary for the protection of the public health, safety, and welfare. The failure to comply with the requirements of this subsection, or rules adopted by the department to administer this subsection, is a violation of s. 499.005(14), and a knowing failure is a violation of s. 499.0051(4).

(i) This subsection does not relieve any person from any requirement prescribed by law with respect to controlled substances as defined in the applicable federal and state laws.

(4) A prescription drug repackager permit issued under this part is not required for a restricted prescription drug distributor permit holder that is a health care entity to repackage prescription drugs in this state for its own use or for distribution to hospitals or other health care entities in

the state for their own use pursuant to s. 499.003(54)(a)3., provided:

(a) The prescription drug distributor notifies the department, in writing, of its intention to engage in repackaging under this exemption thirty days prior to actually engaging in the repackaging of prescription drugs at the permitted establishment;

(b) The prescription drug distributor is under common control with the hospitals or other health care entities to which the prescription drug distributor is distributing prescription drugs. For purposes of this subparagraph, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, by voting rights, by contract, or otherwise;

(c) The prescription drug distributor repackages the prescription drugs in accordance with current state and federal good manufacturing practices; and

(d) The prescription drug distributor labels the prescription drug it repackages in accordance with state and federal laws and rules.

The prescription drug distributor is exempt from the product registration requirements of s. 499.015, with regard to the prescription drugs that it repackages and distributes under this subsection.

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