The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Health Regulation Committee

BILL:	CS/SB 1198
INTRODUCER:	Health Regulation Committee and Senator Bogandoff
SUBJECT:	Prescribing of Controlled Substances
DATE:	February 2, 2012 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Davlantes	Stovall	HR	**Fav/CS**
2.			CJ	
3.			BC	
4.				
5.				
6.				

I. Summary:

This bill redefines "addiction medicine specialist," "board-certified pain management physician," and "chronic nonmalignant pain." Only physicians who prescribe Schedule II, Schedule III, or Schedule IV controlled substances for the treatment of chronic nonmalignant pain are required to register as controlled substance prescribing practitioners. Patients who are prescribed controlled substances who are especially at risk for substance abuse must be co-managed by the prescribing physician and either an addictionologist or a psychiatrist, rather than a physiatrist. The bill states that when a pharmacy subject to s. 456.44, F.S., receives a prescription, the prescription is deemed compliant with the standards of practice under this section and, therefore, valid for dispensing.

Additional physicians are exempted from following the standards of practice for prescribing controlled substances found in ch. 456, F.S. Additional clinics are exempted from registration as pain-management clinics under chs. 458 or 459, F.S.

A pharmacy, prescriber, or dispenser is allowed to have access to information in the prescription drug monitoring program's database which relates to a potential patient in a manner established by the department as needed for the purpose of reviewing the patient's controlled substance prescription history. Pharmacists or health care practitioners who are administering controlled substances to patients who are receiving hospice care or to patients or residents receiving care at certain licensed health care facilities are exempted from provisions of the prescription drug monitoring program.

This bill substantially amends ss. 456.44, 458.3265, 459.0137, 465.0276, and 893.055, F.S.

II. Present Situation:

Physician Specialties

Physiatrists, or rehabilitation physicians, are medical doctors who specialize in nerve, muscle, and bone injuries and illnesses which affect the way patients move. Physiatrists focus on treating the whole patient, not just symptoms, and aim to restore maximum function after strokes, limb amputations, and other conditions. Physiatrists also treat patients with chronic pain and do not perform surgery.[1] To practice as a physiatrist, a physician must complete at least 3 years of residency training in physical medicine and rehabilitation.[2]

Rheumatologists are physicians who focus on diseases of the joints, muscles, and bones.[3] Rheumatologists mainly diagnose and manage the progress of immune-mediated or degenerative diseases, as opposed to physiatrists, who emphasize rehabilitation of patients following injuries. Common conditions treated by rheumatologists include osteoarthritis, rheumatoid arthritis, and lupus. Rheumatologists must complete 3 years of residency training in either pediatrics or internal medicine as well as a 2- to 3-year fellowship in rheumatology.[4]

Psychiatrists are physicians who specialize in the prevention, diagnosis, and treatment of mental, addictive, and emotional disorders. Psychiatrists are trained in the medical, psychological, and social components of mental, emotional, and behavioral disorders and utilize a broad range of treatment modalities to treat such disorders, including medication, psychotherapy, and support services for helping patients and their families cope with stress and crises.[5] Disorders managed by psychiatrists include autism, schizophrenia, and attention-deficit hyperactive disorder (ADHD). Residency training programs for psychiatry are 4 years in length.[6]

Addiction medicine physicians have expertise in the recognition and treatment of patients with addictive disorders, including both physical and psychological addiction. They are certified by the American Board of Addiction Medicine and must have completed at least 1 year of fellowship training in addiction medicine or 1,920 hours of practical experience in the field.[7] Addiction medicine physicians usually have a background in psychiatry, but some fellowship

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[1] American Academy of Physical Medicine and Rehabilitation, *What is a Physiatrist?*, available at: http://www.aapmr.org/patients/aboutpmr/pages/physiatrist.aspx (last visited on January 27, 2012).
[2] American Medical Association, *FREIDA Online Program Information*, available at: https://freida.ama-assn.org/Freida/user/programSearchDispatch.do (last visited on January 27, 2012).
[3] American College of Rheumatology, *What is a Rheumatologist?*, available at: http://www.rheumatology.org/practice/clinical/patients/rheumatologist.asp (last visited on January 27, 2012).
[4] *Supra* fn. 2.
[5] Michigan Psychiatric Society, *What is a Psychiatrist?*, available at: http://www.mpsonline.org/psychiatry/Pages/WhatisaPsychiatrist.aspx (last visited on January 27, 2012).
[6] *Supra* fn. 2.
[7] American Board of Addiction Medicine, *Booklet for the 2012 Certification Examination and the 2012 Recertification Examination*, available at: http://www.abam.net/wp-content/uploads/2011/08/ABAM-Exam-Book-2012Final2.pdf (last visited on January 27, 2012).

programs are open to all physician specialties.[8] Certification of specifically osteopathic addiction medicine specialists is also available as through the board of family medicine.[9]

Controlled Substances

"Controlled substance" means any substance named or described in Schedules I-V of s. 839.03, F.S.[10] Drug schedules are specified by the United States Department of Justice Drug Enforcement Administration (DEA) in 21 C.F.R. ss. 1308.11-15 and in s. 893.03, F.S.

Schedule I controlled substances currently have no accepted medical use in treatment in the United States and therefore may not be prescribed, administered, or dispensed for medical use. These substances have a high potential for abuse and include heroin, lysergic acid diethylamide (LSD), and marijuana. Schedule II controlled substances have a high potential for abuse which may lead to severe psychological or physical dependence, including morphine and its derivatives, amphetamines, cocaine, and pentobarbital. Schedule III controlled substances have lower abuse potential than Schedule II substances but may still cause psychological or physical dependence. Schedule III substances include products containing less than 15 milligrams (mg) of hydrocodone (such as Vicodin) or less than 90 mg of codeine per dose (such as Tylenol #3), ketamine, and anabolic steroids. Schedule IV substances have a low potential for abuse and include propoxyphene (Darvocet), alprazolam (Xanax), and lorazepam (Ativan). Schedule V controlled substances have an extremely low potential for abuse and primarily consist of preparations containing limited quantities of certain narcotics, such as cough syrup.[11]

Any health care professional wishing to prescribe controlled substances must apply for a prescribing number from the DEA. Prescribing numbers are linked to state licenses and may be suspended or revoked upon any disciplinary action taken against a licensee. The DEA will grant prescribing numbers to a wide range of health care professionals, including physicians, nurse practitioners, physician assistants, optometrists, dentists, and veterinarians, but such professionals may only prescribe controlled substances which have been authorized to them under state law. Prescribing numbers must be renewed every 3 years.[12]

Controlled Substance Prescribing

As of January 1, 2012, every physician, podiatrist, or dentist who prescribes controlled substances in the state for the treatment of chronic nonmalignant pain[13] must register as a

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[8] American Society of Addiction Medicine, *Addiction Medicine Fellowships*, available at: http://www.asam.org/membership/resident-and-student-center/addiction-medicine-fellowships (last visited on January 27, 2012).
[9] American Osteopathic Board of Family Physicians, *Welcome*, available at: http://www.aobfp.org/home.html (last visited on January 27, 2012).
[10] Section 893.02(4), F.S.
[11] DEA, Office of Diversion Control, *Controlled Substance Schedules*, available at: http://www.deadiversion.usdoj.gov/schedules/#define (last visited on January 25, 2012).
[12] DEA, *Questions and Answers*, available at: http://www.deadiversion.usdoj.gov/drugreg/faq.htm (last visited on January 26, 2012).
[13] As defined in s. 456.44, F.S., chronic nonmalignant pain means pain unrelated to cancer or rheumatoid arthritis which persists beyond the usual course of disease or injury which caused the pain or for more than 90 days after surgery.

controlled substance prescribing practitioner and comply with certain practice standards specified in statute and rule.[14]

Before prescribing any controlled substances for the treatment of chronic nonmalignant pain, a practitioner must document certain characteristics about the nature of the pain, success of past treatments, any underlying health problems, and history of alcohol and substance abuse. The practitioner must develop a written plan for assessing the patient's risk for aberrant drug-related behavior and monitor such behavior throughout the course of controlled substance treatment. Each practitioner must also enter into a controlled substance agreement with their patients; such agreements must include the risks and benefits of controlled substance use, including the risk for addiction or dependence; the number and frequency of permitted prescriptions and refills; a statement of reasons for discontinuation of therapy, including violation of the agreement; and the requirement that patients' chronic nonmalignant pain only be treated by one practitioner at a time unless otherwise authorized and documented. This agreement must be signed by the patient or his or her legal representative and by the prescribing practitioner.

Patients treated with controlled substances must been seen by their prescribing practitioners at least once every 3 months to monitor progress and compliance, and detailed medical records relating to such treatment must be maintained. Patients at special risk for drug abuse or diversion may require co-monitoring by an addiction medicine physician or a psychiatrist. Anyone with signs or symptoms of substance abuse must be immediately referred to a pain management physician, an addiction medicine specialist, or an addiction medicine facility.[15]

Anesthesiologists, physiatrists, neurologists, and surgeons are exempt from all these provisions. Physicians who hold certain credentials relating to pain medicine are also exempt.

Pain Management Clinics

A pain management clinic is any facility that advertises pain management services or where a majority of patients are prescribed opioids, benzodiazepines, barbiturates, or carisoprodol for the treatment of chronic nonmalignant pain. Until January 1, 2016, all pain management clinics must register as such with the Department of Health (the department) and meet certain provisions concerning staffing, sanitation, recordkeeping, and quality assurance.[16] Clinics are exempt from these provisions if they are:

- Licensed under ch. 395, F.S., as a hospital, ambulatory surgical center, or mobile surgical facility;
- Staffed primarily by surgeons;

[14] Section 456.44(3), F.S., and Rules 64B8-9.013 and 64B15-14.005, F.A.C.

[15] According to s. 456.44(1), F.S., an addiction medicine specialist is a board-certified 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. A board-certified pain management physician is 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 sub-certification in pain management by a specialty board recognized by the American Association of Physician Specialists or an osteopathic physician who holds a certificate in pain management by the American Osteopathic Association. A mental health addiction facility means a facility licensed under ch. 394 or ch. 397, F.S.

[16] *See* ss. 458.3265 and 459.0137, F.S.

- 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;
- Affiliated with an accredited medical school at which training is provided for medical student, residents, or fellows;
- Not involved in prescribing controlled substances for the treatment of pain;
- Owned by a corporate entity exempt from federal taxation under 26 U.S.C. s. 501(c)(3); or
- Wholly owned and operated by anesthesiologists, physiatrists, or neurologists, or physicians holding certain credentials in pain medicine.

All clinics must be owned by at least one licensed physician or be licensed as a health care clinic under part X or ch. 400, F.S., to be eligible for registration. Physicians connected with a pain management clinic must be free of past disciplinary action against their medical licenses and DEA numbers in any jurisdiction as well as any convictions or pleas for illicit drug felonies within the past 10 years.

Pain management clinics are inspected annually by the department unless they hold current certification from a department-approved national accrediting agency. The department may suspend or revoke clinic registration or impose administrative fines of up to $5000 per violation for any offenses against state pain management clinic provisions or related federal laws and rules.

If the registration for a pain management clinic is revoked for any reason, the clinic must cease to operate immediately, remove all signs or symbols identifying the facility as a pain management clinic, and dispose of any medication on the premises. No owner or operator of the clinic may own or operate another pain clinic for 5 years after revocation of registration.[17]

Board Certification Organizations

The gold standard for certification of a physician in a medical subspecialty is certification by the American Board of Medical Specialties (ABMS). ABMS member boards certify physicians in more than 150 different specialties and subspecialties. Major national healthcare organizations such as The Joint Commission, the National Committee for Quality Assurance, hospitals, and insurance companies use ABMS board certification as an essential tool to assess physician specialty credentials, and numerous studies have demonstrated that physicians who are board-certified by an ABMS member board deliver higher-quality care and have better patient outcomes than those certified by other organizations.[18] ABMS board certification is available to both allopathic and osteopathic physicians. Another gold standard of certification for osteopathic physicians is receiving a certificate of added qualification through the American Osteopathic Association (AOA).

[17] Section 458.3265, F.S. Similar language is found in s. 459.0137, F.S. Related rules are found in Rules 64B8-9 and 64B15-14, F.A.C.
[18] ABMS, *The Highest Standard*, available at: http://www.certificationmatters.org/about-board-certified-doctors/the-highest-standard.aspx (last visited on February 2, 2012).

III. Effect of Proposed Changes:

Section 1 amends s. 456.44, F.S., to define an addiction medicine specialist as a board-certified psychiatrist, not a board-certified physiatrist. The definition of "board-certified pain management physician" is amended to include a physician certified in pain management by the ABMS, and the definition of "chronic nonmalignant pain" is amended to exclude pain related to sickle-cell anemia.

Instead of requiring certain physicians to register as controlled substance prescribing practitioners if any controlled substances are prescribed for the treatment of chronic nonmalignant pain, registration is required only if controlled substances in schedules II-IV are prescribed. The bill also requires that patients prescribed controlled substances who are especially at risk for substance abuse be co-managed by the prescribing physician and an addictionologist or a psychiatrist, rather than a physiatrist. The bill states that 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.

The following physicians are exempted from following the standards of practice for prescribing controlled substances in this bill:

- Board-eligible, in addition to board-certified, physicians in certain specialties and holding certain certifications. The certain specialties are expanded to include psychiatrists and rheumatologists, and the certain certifications are expanded to include pain medicine certification by a board approved by the American Board of Pain Medicine;
- Physicians who are certified in hospice and palliative medicine by the ABMS or who hold a certificate of added qualification in hospice and palliative medicine through the AOA;
- Physicians treating patients in accordance with an approved clinical trial; and
- Physicians who prescribe medically-necessary controlled substances for patients during inpatient stays or while providing emergency services and care in hospitals licensed under ch. 395, F.S.

Section 2 amends s. 458.3265, F.S., to amend the definition of "chronic nonmalignant pain" to exclude pain related to sickle-cell anemia. The following clinics are exempted from registration as pain-management clinics:

- Clinics wholly owned by one or more board-eligible or board-certified anesthesiologists, physiatrists, psychiatrists, rheumatologists, or neurologists. The requirement that the clinics must also be operated by one or more of these physicians is removed;
- Clinics wholly owned by one or more board-eligible medical specialists in areas already listed in statute. The requirement that the clinics must also be operated by one or more of these physicians is removed, and the American Board of Pain Medicine is added as an approved board for certification of pain medicine specialists;
- Clinics organized as physician-owned group practices as defined in 42 C.F.R. 411.352; and
- Clinics which, before June 1, 2011, were wholly owned by physicians who are not board-eligible or board-certified but who successfully completed residency programs in anesthesiology, physiatry, psychiatry, rheumatology, or neurology and who have 7 years of documented, full-time practice in pain medicine in this state. "Full-time" is defined as practicing an average of 20 hours per week each year in pain medicine.

Section 3 amends s. 459.0137, F.S., to amend the definition of "chronic nonmalignant pain" to exclude pain related to sickle-cell anemia. The following clinics are exempted from registration as pain-management clinics:

- Clinics wholly owned by one or more board-eligible or board-certified anesthesiologists, physiatrists, psychiatrists, rheumatologists, or neurologists. The requirement that the clinics must also be operated by one or more of these physicians is removed; and
- Clinics wholly owned by one or more board-eligible medical specialists who hold certain qualifications relating to pain medicine. The requirement that the clinics must also be operated by one or more of these physicians is removed, and the American Association of Physician Specialties is added as an approved board for certification of pain medicine specialists.

Section 4 amends s. 465.0276, F.S., to revise the language that authorizes physicians to dispense Schedule II or III controlled substances as part of clinical research conducted under protocols approved by the United States Food and Drug Administration (FDA).

Section 5 amends s. 893.055, F.S., to allow a pharmacy, prescriber, or dispenser to have access to information in the prescription drug monitoring program's database which relates to a potential patient in a manner established by the department as needed for the purpose of reviewing the patient's controlled substance prescription history. Pharmacists or health care practitioners who are administering controlled substances to patients who are receiving hospice care or to patients or residents receiving care at certain licensed health care facilities are exempted from reporting pursuant to the prescription drug monitoring program.

Section 6 provides an effective date of July 1, 2012.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of the bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Psychiatrists, rheumatologists, and practitioners who work under their supervision will be exempt from certain controlled substance prescribing and pain management clinic registration provisions.

C. Government Sector Impact:

The department may experience a decrease in workload related to applications for pain management clinic certifications from physician offices newly exempt from statutory requirements, although this will be offset by a corresponding decrease in fees related to these services. The department will also lose some oversight over the controlled substance prescribing activity of these physicians.

VI. Technical Deficiencies:

Lines 61-69 define an addiction medicine specialist as including a medicine physician who has been certified by the American Society of Addiction Medicine. However, the American Board of Addiction Medicine, rather than the American Society of Addiction Medicine, is responsible for certifying physicians in this field. This language is in existing law. Furthermore, "medicine physician" in line 65 is a technically incorrect term and should be changed to "physician."

"Addictionologist" in line 173 is not a term defined in statute. Perhaps this should be changed to "addiction medicine specialist." This term is in existing law.

"Hospitalists or other physicians" in lines 243-244 is redundant. Hospitalists are physicians. This phrase could be reduced to "physicians" for clarity.

Line 293 states that physicians who are board-certified in pain medicine by a board approved by the American Board of Pain Medicine may be exempt from registering their clinics as pain-management clinics under ch. 458, F.S. However, the American Board of Pain Medicine is itself a certifying board; it does not approve other boards for certification.

"Physiatry" as mentioned in line 302 is not the name of any residency program. Physiatrists complete their residency training in Physical Medicine and Rehabilitation.

The definitions of "chronic nonmalignant pain" in chs. 456, 458, and 459, F.S., are amended to read "pain unrelated to cancer, 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." The second "beyond" in that definition should be deleted for clarity.

The AMBS certifies physicians in pain medicine, not in pain management as is often mentioned in the bill.

VII. Related Issues:

This bill is entitled "an act relating to the prescribing of controlled substances." However, statutes related to controlled substance prescribing, controlled substance dispensing, the prescription drug monitoring program, and registration and regulation of pain management clinics are amended in this bill.

The bill allows certain board-certified or board-eligible physicians to be exempted from registering their offices as pain-management clinics under chs. 458 or 459, F.S. Board certification in a medical specialty is an industry-recognized standard for expertise in that specialty. To become board-certified, physicians must complete residency and sometimes fellowship training in specialty areas, pass a rigorous examination, hold a valid medical license in a state, and meet certain practice requirements. It is unclear how many of these criteria a physician must fulfill to be considered "board-eligible" by statute.

Language in sections 1, 2, and 3 of the bill references board-certified physicians, although the specifications for which boards must certify them are inconsistent or sometimes absent. For example, lines 224-227 exempt board-certified anesthesiologists, physiatrists, psychiatrists, and rheumatologists from provisions of ch. 456, F.S., but there is no mention of what board must certify such individuals. This language is in current statute, but similar problems exist in lines 284-290, 299-306, and 341-346.

Furthermore, criteria for exempting physicians from registering their clinics as pain-management clinics are inconsistent between allopathic and osteopathic physicians. Clinics organized as physician-group practices, owned by physicians board-eligible or board-certified in pain medicine by a board approved by the American Board of Pain Medicine, or owned by certain anesthesiologists, physiatrists, rheumatologists, or neurologists prior to June 1, 2011, are exempt from registration as pain-management clinics under ch. 458, F.S. However, such clinics are not eligible for exemption from registration under ch. 459, F.S. Clinics owned by physicians board-eligible or board-certified in pain medicine by a board approved by the American Association of Physician Specialties are eligible for exemption, although these are not eligible for exemption under ch. 458, F.S.

Lines 219-222 state that when a pharmacy subject to s. 456.44, F.S., receives a prescription, the prescription is deemed compliant with the standards of practice under this section and, therefore, valid for dispensing. However, prescribing practitioners, not pharmacists or prescriptions, are subject to the provisions of s. 456.44, F.S. Clearer language to convey the intention of this amendment might be, "when a pharmacy receives a prescription written by a practitioner subject to this section, the prescription is deemed valid for dispensing." However, this language does not absolve pharmacists from the requirement to be vigilant against patients obtaining or attempting to obtain controlled substances through fraudulent means.[19]

Lines 243-247 exempt physicians who prescribe medically necessary controlled substances while providing emergency services and care in a hospital licensed under ch. 395, F.S., from standards of practice for controlled substance prescribing in ch. 456, F.S. Like hospital emergency

[19] Section 465.015(3), F.S.

departments, urgent care clinics also provide episodic care to patients, and physicians working there are unlikely to see their patients more than once. However, physicians in urgent care clinics are not exempted from the standards of practice for controlled substance prescribing.

Lines 387-394 state that pharmacists may dispense controlled substances as part of an approved clinical trial conducted under protocols approved by the FDA. The FDA is charged with approving new drugs for sale in the United States and sometimes approves clinical trial protocols related to testing of new drugs. However, the FDA is not part of approving clinical trials which concern drugs which have already been FDA-approved; such trials are instead approved by an institutional review board. If this provision in the bill is intended to allow controlled substances to be prescribed in Florida as part of any clinical trial, not just trials which are part of the process of gaining FDA approval, then this aim has not been accomplished.

Lines 415-420 state that a pharmacy, prescriber, or dispenser may 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. However, this language might be so broad as to violate privacy laws. Anyone might at some point be a potential patient of a pharmacy, including those who are not currently prescribed pain medications, but their privacy should be respected until they seek medical care or try to fill a prescription for controlled substances.

VIII. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Regulation on January 31, 2012:
The CS makes the following changes from the original bill:

- Requires physicians who prescribe Schedules II-IV controlled substances for the treatment of chronic nonmalignant pain to register as controlled substance prescribing practitioners under ch. 456, F.S.
- Adds physicians certified in pain management by the American Board of Medical Specialties to the definition of "board-certified pain management physician" in ch. 456, F.S.
- Adds sickle-cell anemia to diseases exempted from the definition of "chronic nonmalignant pain" in chs. 456, 458, and 459, F.S.
- Exempts the following physicians from the standards of practice for prescribing controlled substances in ch. 456, F.S.:
  - Board-eligible, in addition to board-certified, physicians in certain specialties and holding certain certifications. The certain specialties are expanded to include psychiatrists and rheumatologists, and the certain certifications are expanded to include pain medicine certification by a board approved by the American Board of Pain Medicine;
  - Physicians who are certified in hospice and palliative medicine by the American Board of Medical Specialties or who hold a certificate of added qualification in hospice and palliative medicine through the American Osteopathic Association;

- Physicians treating patients in accordance with an approved clinical trial; and
- Physicians who prescribe medically-necessary controlled substances for patients during inpatient stays or while providing emergency services and care in hospitals licensed under ch. 395, F.S.

- Exempts the following clinics from registration as pain-management clinics under ch. 458, F.S.:
  - Clinics wholly owned (no longer requires that they also be operated) by one or more board-eligible or board-certified anesthesiologists, physiatrists, psychiatrists, rheumatologists, or neurologists;
  - Clinics wholly owned (no longer requires that they also be operated) by one or more board-eligible medical specialists in areas already listed in statute. The American Board of Pain Medicine is added as an approved board for certification of pain medicine specialists;
  - Clinics organized as physician-owned group practices as defined in 42 C.F.R. 411.352; and
  - Clinics which, before June 1, 2011, were wholly owned by physicians who are not board-eligible or board-certified but who successfully completed residency programs in anesthesiology, physiatry, psychiatry, rheumatology, or neurology and who have 7 years of documented, full-time practice in pain medicine in this state. "Full-time" is defined as practicing an average of 20 hours per week each year in pain medicine.
- Exempts the following clinics from registration as pain-management clinics under ch. 459, F.S.:
  - Clinics wholly owned (no longer requires that they also be operated) by one or more board-eligible or board-certified anesthesiologists, physiatrists, psychiatrists, rheumatologists, or neurologists; and
  - Clinics wholly owned (no longer requires that they also be operated) by one or more board-eligible medical specialists who hold certain qualifications relating to pain medicine. The American Association of Physician Specialties is added as an approved board for certification of pain medicine specialists.
- Allows pharmacists to dispense Schedule II or Schedule III controlled substances as part of clinical research conducted under protocols approved by the FDA.
- Allows a pharmacy, prescriber, or dispenser to have access to information in the prescription drug monitoring program's database which relates to a potential patient. Pharmacists or health care practitioners who are administering controlled substances to patients who are receiving hospice care or to patients or residents receiving care at certain licensed health care facilities are exempted from provisions of the prescription drug monitoring program.

B. Amendments:

None.