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:	SB 1198
INTRODUCER:	Senator Bogandoff
SUBJECT:	Prescribing of Controlled Substances
DATE:	January 28, 2012 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Davlantes	Stovall	HR	**Pre-meeting**
2.			CJ	
3.			BC	
4.				
5.				
6.				

I. Summary:

This bill redefines "addiction medicine specialist" to include psychiatrists instead of physiatrists. 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.

Psychiatrists and rheumatologists are added to the list of physician specialists exempt from the standards of practice for prescribing controlled substances in s. 456.44(3), F.S., and from registering their offices as pain management clinics.

This bill substantially amends ss. 456.44, 458.3265, and 459.0137, 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 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]

---

[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).
[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).

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 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

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

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;
- 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

[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.

- 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]

III. Effect of Proposed Changes:

Section 1 amends s. 456.44, F.S., to define addiction medicine specialists as board-certified psychiatrists, not board-certified physiatrists. 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. Psychiatrists and rheumatologists are added to the list of physician specialists who are exempt from the provisions of this section related to the standards of practice.

Sections 2 and 3 amend ss. 458.3265, and 459.0137, F.S., to add psychiatrists and rheumatologists to the list of physician specialists who are exempt from registering their offices as pain management clinics under this section.

Section 4 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.

[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.

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 oversight over the controlled substance prescribing activity of these physicians.

VI. Technical Deficiencies:

Line 33 defines an addiction medicine specialist as including someone 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.

"Addictionologist" in line 112 is not a term defined in statute. Perhaps this should be changed to "addiction medicine specialist." This term is in existing law.

VII. Related Issues:

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

Lines 158-161 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.[18]

Language requiring physicians to maintain the integrity of prescription blanks is provided in ss. 458.3625 and 459.0137, F.S. If the intention of this amendment is to protect pharmacists from liability relating to physicians who do not follow controlled substance prescription protocol, perhaps similar language should be inserted into these statutes.

VIII. Additional Information:

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

None.

B. Amendments:

None.

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