

2010 Legislative Update

SB 2272

Senate Bill 462, passed during the 2009 Legislative Session, required the registration and inspection of pain management clinics. The Department of Health (Department) developed rules for registration and set the inspection fee. The Boards of Medicine and Osteopathic Medicine are developing standards of practice rules for physicians practicing in pain management clinics. You can view the draft rule at the board website: www.flhealthsource.com.

In addition to the ongoing rulemaking process, new statutory provisions affecting pain management clinics, SB 2272, were signed into law by Governor Crist on June 4, 2010. These new provisions become effective on October 1, 2010. Most of the new provisions are in s. 458.3265, Florida Statutes.

Currently, all privately owned pain-management clinics/facilities/offices (clinics) which advertise in any medium for any type of pain services, or employ a physician who is primarily engaged in the treatment of pain by prescribing or dispensing controlled substance medications are required to register with the Department. There are over 1,000 clinics registered. Below is a summary of the new pain management clinics provisions, which are effective October 1, 2010.

SB 2272 includes major changes that will impact the ownership and practice of pain management clinics. If you practice in this area, it is imperative that you carefully review the entire bill. To view the entire pain management clinic law, go to:

- www.leg.state.fl.us
- Select "Senate"
- In the bill field, enter "2272".

The following is a summary of some of the changes. These are only highlights of the bill and you are urged to read the entire bill:

Clinic Responsibilities

The following four new exemptions to registration were created. In addition to the current exemptions, clinics do not have to register if:

- 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;
- clinic is affiliated with an accredited medical school at which training is provided for medical students, residents or fellows;
- clinic does not prescribe or dispense controlled substances for the treatment of pain; and
- clinic is owned by a corporate entity exempt from federal taxation under 26 U.S.C. § 501(c)(3).

Each clinic location must register separately even if the clinic is operated under the same business name or management as another. A new registration is also required for changes

in ownership. The law creates new restrictions on ownership, including certain convictions and the law allows the Department to grant exemptions for criminal adjudications over 10 years old.

The clinic must designate a physician to register the clinic and the designated physician must practice at the clinic. The term “practice at the clinic” will be defined in rule by the Department. The designated physician must be a medical doctor licensed under Chapter 458, F.S., or an osteopathic physician licensed under Chapter 459, F.S., that has a full, active and unencumbered license. Notification of changes in designated physician must be made within 10 days by the clinic and the outgoing designated physician.

The Department shall deny registration to any clinic that is not fully owned by an MD, DO, or group of MD and DO licensees, unless the clinic is licensed as a health care clinic with the Agency for Health Care Administration pursuant to Chapter 400, F.S.

The Department will conduct annual inspections of clinics that will include medical records review. Clinics must demonstrate compliance with s. 458.3265, F.S., as well as the rules of the Department and the Boards’ standards of practice rules after rulemaking is complete and the rules are in effect. [Rules 64B8-9.0131 & 64B15-14.0051, FAC – not yet in effect].

Physician Responsibilities

Physicians may not practice in a clinic that should be registered but is not registered as required.

Any physician who qualifies to practice medicine in a pain management clinic pursuant to rules adopted by the Board as of July 1, 2012, may continue to practice medicine in a pain-management clinic as long as the physician continues to meet the qualifications set forth by board rules.

On July 1, 2012, physicians practicing in a registered pain management clinic must have:

- successfully completed a pain medicine fellowship accredited by ACGME; or
- successfully completed a pain medicine residency accredited by ACGME; or
- practicing in a pain clinic and in compliance with qualifications set forth in the Boards’ standards of practice rules.

Only physicians licensed under Chapters 458 (MD) and 459 (DO), F.S., may dispense medications in a pain management clinic.

A physical examination must be performed by the physician on the day that the physician prescribes or dispenses a controlled substance for a patient at a pain management clinic. If the physician prescribes in excess of a 72-hour supply of a controlled substance, the physician must document the reason in the patient’s medical record.

The Board shall adopt a rule establishing the maximum number of prescriptions for Schedule II or Schedule III controlled substances or the controlled substance Alprazolam which may be written at any one registered pain management clinic during any 24 hour period.

Physicians are responsible for maintaining control and security of his/her prescription blanks and any other method used for prescribing controlled substances. This includes using counterfeit resistant prescriptions and notifying the Department within 24 hours of a theft or loss of a prescription blank or breach of any other method used for prescribing.

Dispensing Practitioners

Dispensing practitioners (all dispensing practitioners not just dispensing practitioners at pain management clinics) may not dispense more than a 72 hour supply of schedule II-V medications for a patient that pays by cash, check, or credit card. However, there are exemptions:

- workers compensation patient;
- cash, check or credit card is used only to cover the applicable co-payment or deductible; and
- complimentary packs of medications to the practitioner's own patients.

Penalties and Grounds for Discipline

New grounds for criminal violations have been established for:

- operating/owning/managing an unregistered clinic, and
- knowingly prescribing or dispensing controlled substances from an unregistered clinic.

New grounds for discipline for designated physicians have also been established for violations of their responsibilities.

New grounds for discipline have been created for MD licensees, including:

- failing to notify the Department of theft of prescriptions from a pain management clinic within 24 hours, and
- promoting or advertising, through any communication media, the use, sale or dispensing of any controlled substance appearing on any schedule in Chapter 893, F.S.

This article is an overview of the new laws. It is important that physicians who practice pain management stay abreast of these current events and are encouraged to go online to read the new law in its entirety. If you are unsure whether you should register, it is important that you contact your private counsel. And as always, stay tuned to our web site for more information on pain management clinics.

HB 573

This bill deleted the law that requires PA's to complete 3 months of clinical experience prior to being approved to be a prescribing PA and allows forms to be submitted electronically. This change is effective July 1, 2010.

HB 5311

This bill, in sections 32 and 33, provides licensure avenues for retired military physicians to be eligible to receive an area of critical need license. Many physicians often give up their medical license when they retire then decide they want to practice, often as a volunteer, but do not want to go through the full licensure process again. The bill also provides the board additional authority to place conditions on the license.