HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/CS/HB 1081 Controlled Substances
SPONSOR(S): Health & Human Services Committee; Health & Human Services Quality Subcommittee; McBurney
TIED BILLS: None **IDEN./SIM. BILLS:** SB 1364

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health & Human Services Quality Subcommittee	13 Y, 1 N, As CS	Mathieson	Calamas
2) Judiciary Committee	15 Y, 0 N	Thomas	Havlicak
3) Health & Human Services Committee	18 Y, 0 N, As CS	Mathieson	Gormley

CS/CS/HB 1081:

- Provides that knowingly using a Schedule II controlled substance that is intended to be taken orally by a prescriber, in any other manner, is a misdemeanor of the first degree.
- Amends the definition of addiction medicine specialist to include psychiatrist and removes physiatrist.
- Adds rheumatologists to the list of physicians exempted from the standards of practice for pain medicine physicians.
- Amends the definition of chronic pain to remove rheumatoid arthritis.
- Adds the American Board of Medical Specialties to the list of certifying entities for exempt physicians.
- Clarifies which controlled substance schedules trigger the requirement for registration as a controlled substance prescriber (II-IV).
- Adds multi-specialty physician practices to the list of entities that are exempt from pain clinic registration requirements.

The bill has no fiscal impact on the state.

The bill provides for an effective date of October 1, 2012.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Controlled Substances

Controlled substances are drugs with the potential for abuse. Chapter 893, F.S., sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act, and classifies controlled substances into five categories, known as schedules. The distinguishing factor between the schedules is the potential for abuse[1] of the substance and whether there is a currently accepted medical use. These schedules are used to regulate the manufacture, distribution, preparation and dispensing of the substances.[2]

- A **Schedule I** substance has a high potential for abuse and no currently accepted medical use in treatment in the United States and its use under medical supervision does not meet accepted safety standards. Examples: heroin and methaqualone.
- A **Schedule II** substance has a high potential for abuse, a currently accepted but severely restricted medical use in treatment in the United States, and abuse may lead to severe psychological or physical dependence. Examples: cocaine and morphine.
- A **Schedule III** substance has a potential for abuse less than the substances contained in Schedules I and II, a currently accepted medical use in treatment in the United States, and abuse may lead to moderate or low physical dependence or high psychological dependence or, in the case of anabolic steroids, may lead to physical damage. Examples: lysergic acid; ketamine; and some anabolic steroids.
- A **Schedule IV** substance has a low potential for abuse relative to the substances in Schedule III, a currently accepted medical use in treatment in the United States, and abuse may lead to limited physical or psychological dependence relative to the substances in Schedule III. Examples: alprazolam; diazepam; and phenobarbital.
- A **Schedule V** substance has a low potential for abuse relative to the substances in Schedule IV, a currently accepted medical use in treatment in the United States, and abuse may lead to limited physical or psychological dependence relative to the substances in Schedule IV. Examples: low dosage levels of codeine; certain stimulants; and certain narcotic compounds.

Many people who take prescription medications do so responsibly. However, the nonmedical use or abuse of prescription drugs remains a significant public health concern in the United States. Certain prescription drugs – opioid substances, central nervous system depressants and stimulants – when abused can lead to psychological and physiological dependence. According to research by the National Institute on Drug Abuse,[3] the three most abused classes of prescription drugs are:

- Opioids, used to treat pain. Examples include codeine (Schedules II, III, V), oxycodone (OxyContin, Percocet – Schedule II), and morphine (Kadian, Avinza -Schedule II);
- Central nervous system depressants, used to treat anxiety and sleep disorders. Examples include barbiturates (Mebaral, Nembutal) and benzodiazepines (Valium, Xanax) (all in Schedule IV); and
- Stimulants, used to treat ADHD, narcolepsy, and obesity. Examples include dextroamphetamine (Dexedrine, Adderall) and methylphenidate (Ritalin, Concerta) (all in Schedule II).

Pain Clinics

Currently, pain management clinics which prescribe certain controlled substances are required to register with DOH, which certain exemptions:

- Hospital clinics;

[1] Section 893.02(20), F.S.
[2] *See,* s. 893.03, F.S.
[3] *See* http://www.drugabuse.gov/drugs-abuse/prescription-medications (last visited January 25, 2012).

- Clinics in which the majority of the physicians who provide services in the clinic primarily provide surgical services;
- Clinics owned by publicly held corporations 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;
- Clinics affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows;
- Clinics which do not prescribe controlled substances for the treatment of pain;
- Clinics owned by corporate entities exempt from federal taxation under 26 U.S.C. s. 501(c)(3);
- Clinic is wholly owned and operated by one or more board-certified anesthesiologists, physiatrists, or neurologists; and
- Clinics wholly owned and operated by 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.

Physicians

In the 2011 Legislative Session, HB 7095 was enacted, which sought to address Florida's prescription drug abuse issues. The 2011 legislation created new regulatory requirements for physicians who prescribe controlled substances to treat chronic, non-malignant pain, regardless of the setting in which the physician practices. The law defines "chronic non-malignant pain" as "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."[4] Effective January 1, 2012, such physicians were required to register with their respective boards and comply with new standards of care for prescribing controlled substances, including:[5]

- A complete medical history and physical examination of the patient;
- A medical record which documents the medical indications for use of a controlled substance;
- An assessment of the patients' risk for aberrant drug-related behavior, such as abuse, and ongoing monitoring of the patient's risk;
- A written treatment plan for the patient;
- An informed consent agreement;
- Periodic review of the treatment and regular patient visits; and

Referral to certain specialists (board-certified pain management physicians, addiction medicine specialists, or mental health addiction facilities), including addiction medicine specialists, as necessary, with particular attention to certain high-risk patients, and mandatory referral for patients with symptoms of substance abuse.

A "board-certified pain management physician" is defined as:[6]

- 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

- An osteopathic physician who holds a certificate in Pain Management by the American Osteopathic Association.

An "addiction medicine specialist" is defined as:[7]

[4] Ss. 456.44; 458.3265; 459.0137, F.S.
[5] S. 456.44, F.S.
[6] *Id.*
[7] *Id.*

- A board-certified physiatrist with a subspecialty certification in addiction medicine or who is eligible for such subspecialty certification;
- An addiction medicine physician certified or eligible for certification by the American Society of Addiction Medicine; or
- Or an osteopathic physician who holds a certificate of added qualification in Addiction Medicine through the American Osteopathic Association.

Effect of Proposed Changes

The bill amends s. 893.13(7), F.S., to provide that a person who knowingly uses a Schedule II controlled substance, which was intended by their prescriber to be administered orally, in another manner, commits a misdemeanor of the first degree.[8] The bill makes conforming changes for this provision to s. 893.055, F.S., s. 893.0551, F.S., and s. 921.0022, F.S.

The bill amends regulation of physicians who prescribe controlled substances to treat pain, making them applicable to controlled substances in Schedules II-IV. The bill removes physiatrists from, and adds psychiatrists to, the definition of an addiction medicine specialist. Rheumatologists are added to the list of physicians who are exempt from the standards of care, and the definition of chronic nonmalignant pain is amended to remove the reference to rheumatoid arthritis in the physician regulation provisions of s. 456.44, F.S., and in the and pain clinic registration sections of ch. 458, F.S., and ch. 459, F.S.

The bill adds rheumatologists to the list of physician owners who are exempt from the registration requirements of a pain management clinic, making this change to the allopathic and osteopathic physician practice acts. The bill also modifies the registration exemption for physician-own clinics, providing the exemption for clinics owned by a physician multi-specialty practice, where one or more of the board-certified medical specialists has also completed either an approved fellowship in pain medicine, or board certified in pain medicine.

The bill amends the definition of a board certified pain management physician, to include the American Board of Medical Specialties, as a certifying entity for such a physician. The bill amends the definition of board-certified pain management physician to include physicians with board certification or subcertification in pain management by a specialty board recognized by the American Board of Medical Specialties.

B. SECTION DIRECTORY:

Section 1: Amends s. 456.44, F.S., related to controlled substance prescribing.
Section 2: Amends s. 458.3265, F.S., related to pain-management clinics.
Section 3: Amends s. 459.0137, F.S., related to pain-management clinics.
Section 4: Amends s. 893.13, F.S., related to prohibited acts; penalties.
Section 5: Amends s. 893.055, F.S., related to prescription drug monitoring program.
Section 6: Amends s. 893.0551, F.S., related to public records exemption for the prescription drug monitoring program.
Section 7: Amends s. 921.0022, F.S., related to the criminal punishment code; offence severity ranking chart.
Section 8: Provides an effective date.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

[8] A first degree misdemeanor is punishable by a fine not exceeding $1,000 or imprisonment not exceeding one year. Sections. 775.082, 775.083, F.S.

The bill does not appear to have any impact on state government revenues.

2. Expenditures:

The bill does not appear to have any impact on state government expenditures.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

The bill does not appear to have any impact on local government revenues.

2. Expenditures:

The bill creates a first degree misdemeanor offense, which may have a negative jail bed impact on local governments.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill does not appear to have any impact on the private sector.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not Applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On January 31, 2012, the Health and Human Services Quality Subcommittee adopted two amendments to HB 1081. The amendments:

- Provided that knowingly using a Schedule II controlled substance that is intended to be taken orally by a prescriber, in any other manner, is a misdemeanor of the first degree.
- Deleted lines 243-296, removing the provisions of the bill relating to Schedule II opioid drugs that incorporate tamper-resistant technologies.

This bill was reported favorably as a committee substitute. This analysis reflects the committee substitute.

On February 21, 2012, the Health and Human Services Committee adopted a strike-all amendment to CS/HB 1081. The strike-all retained the existing bill:

- Amending the definition of addiction medicine specialist to include psychiatrists (not physiatrists).
- Adding the American Board of Medical Specialties to the list of certifying entities for exempt physicians.
- Adding rheumatologists to the list of physicians exempted from the standards of practice, and removes the exemption for rheumatoid arthritis from the definition of chronic pain.
- Clarifying which controlled substance schedules trigger the requirement for registration as a controlled substance prescriber (II-IV).
- Adding multi-specialty physician practices to the list of entities that are exempt from pain clinic registration requirements.

This bill was reported favorably as a committee substitute. This analysis reflects the committee substitute.