FLORIDA OSTEOPATHIC MEDICAL ASSOCIATION

8-2011: CS/CS/HB 7095 Engrossed 3 (2011 Legislative Session)

REQUIREMENTS FOR PHYSICIANS AND CLINICS -

PLEASE NOTE: The following are excerpts from the language in HB 7095. For the complete language contained in the bill, we have provided you with the page and line(s) numbers so that you may read the entire language if you so desire. The excerpts are to provide you with a brief introduction to the REQUIREMENTS for Physicians in the bill.

You may access a copy of the bill at:

http://www.flsenate.gov/

- Go to the top middle of the page to "Go To Bill"
- Put the number of the bill in and click on "Go"
- Scroll down to "Bill History" and click on "Bill Text"
- Scroll down to the last bill listed "h 7075 er 5/9/2011 and click on "PDF"
- That will bring the bill up for review

Language UNDERLINED is NEW language

Page 8; Section 1; Lines 209-219

- 456.072, FS; GROUNDS FOR DISCIPLINE; **TO PARAPHRASE**: If a physician prescribes or dispenses a controlled substance or causes a controlled substance to be prescribed or dispensed in a manner that violates this bill, the physician will be suspended for a period of not less than 6 months and pay a fine of not less than $10,000 per count.

NOTE: A "violation" of this bill would be disregarding any of the requirements of the bill such as provisions which prohibit physicians from dispensing Schedule II or III drugs, not designating themselves as a controlled substance prescribing practitioner on the physician's practitioner profile, etc.

Page 9; Section 2; Lines 243-250

- 456.42, FS; (2) A written prescription for a controlled substance listed in chapter 893 must have the quantity of the drug prescribed in both textual

and numerical formats, must be dated with the abbreviated month written out on the face of the prescription, and must be either written on a standardized counterfeit-proof prescription pad produced by a vendor approved by the department or electronically prescribed as that term is used in s. 408.0611.

NOTE: On July 7, 2011, the FOMA sent out a "Newswire" alert to all members telling them that the Dept. of Health suspended the requirement for physicians to use new counterfeit-proof prescription pads. The suspension is valid until September 1, 2011.

Page 11; Section 3; Lines 285-293

- 456.44, FS; (2) REGISTRATION.—Effective January 1, 2012, a physician licensed under chapter 458, chapter 459, chapter 461, or chapter 466 who prescribes any controlled substance, 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.
  (b) Comply with the requirements of this section and applicable board rules.

NOTE: We have been told by the Dept. of Health that they are working on a Memo to go out in October to all Physicians detailing how and where they are to place this information on their profile

Pages 11-16; Section 3; Lines 294-427

- 456.44, FS; (3) STANDARDS OF PRACTICE; (a) A complete medical history and a physical examination must be conducted before beginning any treatment and must be documented in the medical record.

- The medical record must, at a minimum, document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, a review of previous medical records, previous diagnostic studies, and history of alcohol and substance abuse. The medical record shall also document the presence of one or more recognized medical indications for the use of a controlled substance. Each registrant must develop a written plan for assessing each patient's risk of aberrant drug-related behavior, which may include patient drug testing. Registrants must assess each patient's risk for aberrant drug-related behavior and monitor that risk on an ongoing basis in accordance with the plan.

- Each registrant must develop a written individualized treatment plan for each patient.

- The physician shall discuss the risks and benefits of the use of controlled substances, including the risks of abuse and addiction, as well as physical dependence and its consequences, with the patient, persons designated by the patient, or the patient's surrogate or guardian if the patient is incompetent.

- The physician shall use a written controlled 335 substance agreement between the physician and the patient outlining the patient's responsibilities,…

- (d) The patient shall be seen by the physician at regular intervals, not to exceed 3 months, to assess the efficacy of treatment, ensure that controlled substance therapy remains indicated, evaluate the patient's progress toward treatment objectives, consider adverse drug effects, and review the etiology of the pain.

- The physician shall monitor patient compliance in medication usage, related treatment plans, controlled substance agreements, and indications of substance abuse or diversion at a minimum of 3-month intervals.

- 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 physiatrist.

- (f) A physician registered under this section must maintain accurate, current, and complete records that are accessible and readily available for review and comply with the requirements of this section, the applicable practice act, and applicable board rules.

- Throughout the period of time before receiving the consultant's report, a prescribing physician shall clearly and completely document medical justification for continued treatment with controlled substances and those steps taken to ensure medically appropriate use of controlled substances by the patient.

- ***This subsection does not apply to*** a board-certified anesthesiologist, physiatrist, 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.

The following language states requirements for both Chapter 458 and 459 – We are citing references to Chapter 459, Florida Statutes

Pages 30-45; Section 7; Lines 837-1239

- 459.0137, FS; (1) REGISTRATION;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.

- g. The clinic is wholly owned and operated by one or more board-certified anesthesiologists, physiatrists, or neurologists; or
  h. The clinic is 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.

- Each physician practicing in a pain-management clinic shall advise the Board of Medicine, in writing, within 10 calendar days after beginning or ending his or her practice at a pain-management clinic.

- (f) Each physician practicing in a pain-management clinic is responsible for ensuring compliance with the following facility and physical operations requirements:
  1. A pain-management clinic shall be located and operated at a publicly accessible fixed location and must:
  a. Display a sign that can be viewed by the public that contains the clinic name, hours of operations, and a street address.

b. Have a publicly listed telephone number and a dedicated phone number to send and receive faxes with a fax machine that shall be operational 24 hours per day.
c. Have emergency lighting and communications.
d. Have a reception and waiting area.
e. Provide a restroom.
f. Have an administrative area, including room for storage of medical records, supplies, and equipment.
g. Have private patient examination rooms.
h. Have treatment rooms, if treatment is being provided to the patients.
i. Display a printed sign located in a conspicuous place in the waiting room viewable by the public with the name and contact information of the clinic's designated physician and the names of all physicians practicing in the clinic.
j. If the clinic stores and dispenses prescription drugs, comply with ss. 499.0121 and 893.07.
2. This section does not excuse a physician from providing any treatment or performing any medical duty without the proper equipment and materials as required by the standard of care. This section does not supersede the level of care, skill, and treatment recognized in general law related to healthcare licensure.

- The designated physician is responsible for ensuring compliance with the following quality assurance requirements. Each pain-management clinic shall have an ongoing quality assurance program that objectively and systematically monitors and evaluates the quality and appropriateness of patient care, evaluates methods to improve patient care, identifies and corrects deficiencies within the facility, alerts the designated physician to identify and resolve recurring problems, and provides for opportunities to improve the facility's performance and to enhance and improve the quality of care provided to the public. The designated physician shall establish a quality assurance program…

Page 45; Section 8 and 9; Lines 1240-1255

- 459.013, FS; Penalty for Violations; (1) Each of the following acts constitutes a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084:
  (f) Dispensing a controlled substance listed in Schedule II or Schedule III in violation of s. 465.0276.

Page 45; Section 8 and 9; Lines 1248-1255

- 459.015, FS; Grounds for disciplinary action; (1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

(tt) Dispensing a controlled substance listed in Schedule II or Schedule III in violation of s. 465.0276.

Pages 58-59; Section 15; Lines 1597-1652

- 465.0276, FS; Dispensing Practitioner; **TO PARAPHASE:** A practitioner registered under this section may not dispense a controlled substance listed in Schedule II or Schedule III. **This paragraph does not apply to:**

- 1.The dispensing of complimentary packages of medicinal drugs which are labeled as a drug sample or complimentary drug as defined in s. 499.028 to the practitioner's own patients in the regular course of her or his practice without the payment of a fee or remuneration of any kind, whether direct or indirect, as provided in subsection (5).
  2. The dispensing of controlled substances in the health care system of the Department of Corrections.
  3. The dispensing of a controlled substance listed in Schedule II or Schedule III in connection with the performance of a surgical procedure. The amount dispensed pursuant to the subparagraph may not exceed a 14-day supply. This exception does not allow for the dispensing of a controlled substance listed in Schedule II or Schedule III more than 14 days after the performance of the surgical procedure. For purposes of this subparagraph, the term "surgical procedure" means any procedure in any setting which involves, or reasonably should involve:
  a. Perioperative medication and sedation that allows the patient to tolerate unpleasant procedures while maintaining adequate cardiorespiratory function and the ability to respond purposefully to verbal or tactile stimulation and makes intra- and post-operative monitoring necessary; or
  b. The use of general anesthesia or major conduction anesthesia and preoperative sedation.
  4. The dispensing of a controlled substance listed in Schedule II or Schedule III pursuant to an approved clinical trial. For purposes of this subparagraph, the term "approved clinical trial" means a clinical research study or clinical investigation that, in whole or in part, is state or federally funded or is conducted under an investigational new drug application that is reviewed by the United States Food and Drug Administration.
  5. The dispensing of methadone in a facility licensed under s. 397.427 where medication-assisted treatment for opiate addiction is provided.
  6. The dispensing of a controlled substance listed in Schedule II or Schedule III to a patient of a facility licensed under part IV of chapter 400.

Pages 88-89; Section 24; Lines 2461-2475

- 893.065, FS; Counterfeit-resistant prescription blanks for controlled substances listed in Schedule II, Schedule III, or Schedule IV.—The Department of Health shall develop and adopt by rule the form and content for a counterfeit-resistant prescription blank which must be used by practitioners for the purpose of prescribing a controlled substance listed in Schedule II, Schedule III, or Schedule IV, or Schedule V pursuant to s. 456.42. The Department of Health may require the prescription blanks to be printed on distinctive, watermarked paper and to bear the preprinted name, address, and category of professional licensure of the practitioner and that practitioner's federal registry number for controlled substances. The prescription blanks may not be transferred.

Page 89-90; Section 25; Lines 2476-2511

- 893.07, FS; RECORDS; (4) Every inventory or record required by this chapter, including prescription records, shall be maintained:
  (a) Separately from all other records of the registrant, or
  (b) Alternatively, in the case of Schedule III, IV, or V controlled substances, in such form that information required by 2484 this chapter is readily retrievable from the ordinary business records of the registrant.
  In either case, the records described in this subsection shall be kept and made available for a period of at least 2 years for inspection and copying by law enforcement officers whose duty it is to enforce the laws of this state relating to controlled substances. Law enforcement officers are not required to obtain a subpoena, court order, or search warrant in order to obtain access to or copies of such records.
  (5) Each person described in subsection (1) shall:
  (a) Maintain a record which shall contain a detailed list of controlled substances lost, destroyed, or stolen, if any; the kind and quantity of such controlled substances; and the date of the discovering of such loss, destruction, or theft.
  (b) In the event of the discovery of the theft or significant loss of controlled substances, report such theft or significant loss to the sheriff of that county within 24 hours after discovery. A person who fails to report a theft or significant loss of a substance listed in s. 893.03(3), (4), or (5) within 24 hours after discovery as required in this paragraph commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083. A person who fails to report a theft or significant loss of a substance listed in s. 893.03(2) within 24 hours after discovery as required in this paragraph commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

Pages 90-93; Section 26; Lines 2512-2599

- 893.13, FS; Prohibited acts; penalties; (7)(a) A person **may not:**

1. Distribute or dispense a controlled substance in violation of this chapter.

- (b) A health care practitioner, with the intent to provide a controlled substance or combination of controlled substances that are not medically necessary to his or her patient or an amount of controlled substances that are not medically necessary for his or her patient, may not provide a controlled substance or a prescription for a controlled substance by misrepresentation, fraud, forgery, deception, subterfuge, or concealment of a material fact. For purposes of this paragraph, a material fact includes whether the patient has an existing prescription for a controlled substance issued for the same period of time by another practitioner or as described in subparagraph (a)8.

- (e) A person or health care practitioner who violates the provisions of paragraph (b) or subparagraph (a)13. commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, if any controlled substance that is the subject of the offense is listed in Schedule II, Schedule III, or Schedule IV.

Pages 93-94; Section 27; Lines 2600-2620

- Section 893.138, FS; (3) Any pain-management clinic, as described in s. 458.3265 or s. 459.0137, which has been used on more than two occasions within a 6-month period as the site of a violation of:
  (a) Section 784.011, s. 784.021, s. 784.03, or s. 784.045, relating to assault and battery;
  (b) Section 810.02, relating to burglary;
  (c) Section 812.014, relating to dealing in theft;
  (d) Section 812.131, relating to robbery by sudden snatching; or
  (e) Section 893.13, relating to the unlawful distribution of controlled substances,
  may be declared to be a public nuisance, and such nuisance may be abated pursuant to the procedures provided in this section.

Pages 94-98; Section 28; Lines 2621-2643

HAVE YOU DISPENSED YOUR INVENTORY OF CONTROLED SUBSTANCES?

UNDER THE REQUIREMENTS OF THIS BILL, YOU HAD TO DO SO BY JULY 11, 2011 UNLESS YOU MEET EXCEPTION REQUIREMENTS

- DISPOSITION OF CONTROLLED SUBSTANCES.—
  (a) Within 10 days after the effective date of this act, each physician licensed under chapter 458, chapter 459, chapter 461, or chapter 466, Florida Statutes, unless he or she meets one of the exceptions for physician who dispenses under s. 465.0276, Florida Statutes, shall ensure that the undispensed inventory of controlled substances listed in Schedule II or Schedule III as provided in s. 893.03, Florida Statutes, purchased under the physician's Drug Enforcement Administration number for dispensing is:
  1. Returned in compliance with the laws and rules adopted under chapter 499, Florida Statutes, to the wholesale distributor, as defined in s. 499.003, Florida Statutes, which distributed the controlled substances to the physician; or
  2. Turned in to local law enforcement agencies and abandoned.
  (b) Wholesale distributors shall buy back the undispensed inventory of controlled substances listed in Schedule II or Schedule III as provided in s. 893.03, Florida Statutes, which are in the manufacturer's original packing, unopened, and in date, in accordance with the established policies of the wholesale distributor or the contractual terms between the wholesale distributor and the physician concerning returns.