

Committee on Health Regulation

CS/CS/HB 7095, 3rd Engrossed— Prescription Drugs

by Appropriations Committee; Judiciary Committee; Health and Human Services Committee; and Rep. Schenck (CS/CS/SB 818, 1st Engrossed by Criminal Justice Committee; Health Regulation Committee; and Senators Fasano, Lynn, and Margolis)

This bill provides a more comprehensive approach to address the epidemic of prescription drug abuse and the untimely deaths that result from such abuse in this state. The approach includes the regulation of activities by physicians, pain management clinics, pharmacies, and wholesale drug distributors. The bill also provides minor revisions to the prescription drug monitoring program.

Physicians Generally

On July 1, 2011, practitioners will no longer be authorized to dispense controlled substances. However, there are exceptions. These include dispensing:

- Complimentary or sample controlled substances.
- In the health care system of the Department of Corrections.
- In connection with certain surgical procedures within certain timeframes.
- Pursuant to participation in an approved clinical trial.
- Methadone in a licensed treatment program.
- For hospice patients.

On July 1, 2011, when this law goes into effect, the State Health Officer will declare a public health emergency concerning the possession of controlled substances for dispensing by practitioners who are no longer authorized to dispense controlled substances. Any controlled substance inventory that was acquired for dispensing that is still in the possession of a practitioner who will no longer be authorized to dispense controlled substances once this act goes into effect, must be disposed of by July 11, 2011. The drugs can be disposed of by returning them to the wholesale distributor or turning the inventory in to a local law enforcement agency and abandoning them. If this does not happen by August 2, the controlled substances are deemed contraband and are subject to seizure by law enforcement agencies.

Wholesale distributors are required to buy back the inventory of controlled substances listed in Schedule II or Schedule III which are in the manufacturer's original packaging, 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.

In addition, using actual purchasing records from wholesalers and other information, the Department of Health (department) will identify those practitioners who pose the greatest threat to the public health and risk that the controlled substances may not be disposed of in accordance with this act. Beginning on the 3rd day after this act goes into effect, law enforcement agencies will enter the business premises of the identified dispensing practitioners and quarantine the inventory on site. A \$3 million appropriation is available for law enforcement for this effort, to

maintain the security of the quarantined inventory until final disposition, and to investigate and prosecute crimes related to prescribed controlled substances.

Effective January 1, 2012, each medical physician, osteopathic physician, podiatrist, or dentist who prescribes controlled substances for the treatment of chronic nonmalignant pain must designate on his or her practitioner profile that he or she is a controlled substance prescribing practitioner.

The standards of practice for a controlled substance prescribing practitioner are spelled out in the law. These standards of practice do not supersede the level of care, skill, and treatment recognized in general law. The standards of practice in this bill include, among other things:

- A complete medical history and physical examination, the exact components of the exam are left to the judgment of the clinician;
- Development of a written individualized treatment plan for each patient, with objectives for treatment success and other treatment modalities;
- Discussion with the patient concerning the risks and benefits of the use of controlled substances;
- A written controlled substance agreement between the physician and the patient that includes reasons for which drug therapy may be discontinued and that controlled substances shall be prescribed by a single treating physician, unless otherwise authorized and documented in the medical record;
- Regular follow-up appointments at least every 3 months to assess the efficacy and appropriateness of treatment;
- Referrals to specialists when indicated; and
- Maintenance of accurate and complete records on each patient.

Certain specialists and surgeons are exempted from these standards of practice.

Additional disciplinary or criminal sanctions are established for physicians who violate the controlled substances laws, including:

- Failing to comply with the controlled substance prescribing and dispensing requirements.
- If a physician violates the standard of practice for prescribing or dispensing a controlled substance as set forth in the bill, then the physician will be suspended for at least 6 months and pay a fine of at least \$10,000. Repeat offenses result in increased penalties.

The department will approve vendors of counterfeit-proof prescription pads. The approved vendors will report monthly to the department on the number of pads sold and the purchasers of the pads. The counterfeit-resistant prescription blanks must be used by practitioners for the purpose of prescribing any controlled substance.

Pain Management Clinics

The bill revises the criteria for required registration as a pain management clinic. Registration is required if the clinic advertises in any medium for any type of pain management services or where, in any month, a majority of patients are prescribed opioids, benzodiazepines, barbiturates, or carisoprodol for the treatment of chronic nonmalignant pain (pain unrelated to cancer or rheumatoid arthritis which persists beyond the usual period or more than 90 days after surgery). The bill includes additional exemptions from registration.

Physicians practicing in pain management clinics must:

- Notify the applicable board within 10 days after beginning or ending practice at a pain management clinic.
- Ensure compliance with facility and physical operations of the clinic, infection control requirements, and health and safety requirements.

The designated physician is also responsible for certain additional functions, including quality assurance requirements to evaluate the quality and appropriateness of patient care and reporting aggregated patient statistics.

Provisions and requirements under the regulation of pain management clinics do not supersede the level of care, skill, and treatment recognized in general law related to healthcare licensure.

The amendment authorizes a physician assistant or advanced registered nurse practitioner under both the medical practice act and the osteopathic practice act to perform the physician examination of a patient in a pain management clinic.

The amendment strikes the requirement that passed last year requiring physicians practicing in pain management clinics after July 1, 2012 to meet certain training and education requirements.

The laws pertaining to the regulation of pain management clinics are set to expire on January 1, 2016.

A pain management clinic which has been used on more than two occasions within a 6-month period as a site in which certain criminal violations occur may be declared a public nuisance.

Pharmacies / Pharmacists

Community pharmacies must be re-licensed under the provisions of this act and rules adopted thereunder by July 1, 2012. Additional licensure requirements are intended to prevent felons and other nefarious persons from owning or operating pharmacies. In addition, pharmacies will be required to develop policies and procedures to minimize dispensing based on fraudulent representations or invalid practitioner-patient relationships.

A pharmacist must report to a local law enforcement officer any person who obtains or attempts to obtain a controlled substance through fraudulent methods or representations. The failure to report is a misdemeanor of the first degree.

Principals associated with a pharmacy must undergo annual criminal background screening. The department must forward the results to wholesale distributors permitted under ch. 499, F.S., for purposes of complying with the requirements related to due diligence of purchasers.

The amendment includes additional requirements and disciplinary action related to activities in pharmacies and by pharmacists.

Drug Wholesalers

Licensed drug wholesalers are required to:

- Credential and understand the normal business transactions of their customers who purchase certain controlled substances.
- Report to the department on wholesale distributions of unusual quantities of controlled substances. Unusual purchasing levels for the purchasing entity's clinical needs will be investigated by law enforcement.
- Abstain from distributing controlled substances to an entity if any person associated with that entity meets certain disqualifying conditions in the criminal history record check.

The department is required to identify the national average of distributions per pharmacy of certain controlled substances and report to the Governor and Legislature by November 1, 2012.

The amendment provides for stiffer criminal penalties and administrative sanctions for unlawfully distributing controlled substances or submitting false reports pertaining to controlled substance distributions.

Prescription Drug Monitoring Program

The bill reduces the timeframe for dispensers to report to the prescription drug monitoring program database from 15 days to 7 days. The bill also requires persons who have access to the database to submit fingerprints for background screening. Department staff are prohibited from having direct access to information in the database.

Funds provided by prescription drug manufacturers may not be used to implement the prescription drug monitoring program. References to the department and State Surgeon General are substituted for the Office of Drug Control and the director of the Office of Drug Control.

Other Provisions

The bill specifies that law enforcement officers may obtain access to or copy records that are required to be maintained under ch. 893, F.S., without a subpoena, court order, or search warrant.

Upon the discovery of the theft or significant loss of controlled substances, a manufacturer, importer, distributor, or dispenser must report the theft or significant loss to a law enforcement officer. The failure to report is a misdemeanor.

Fraudulently obtaining, attempting to obtain, or providing a prescription for a controlled substance by concealment of a material fact (the existence of another prescription for a controlled substance for the same time period) when the controlled substance is not medically necessary for the patient is a third degree felony.

The bill enhances criminal offenses relating to theft and burglary involving controlled substances.

If approved by the Governor, these provisions take effect on July 1, 2011.

Vote: Senate 39-0; House 118-0