FLORIDA DEPARTMENT OF
HEALTH

Rick Scott
Governor

H. Frank Farmer, Jr., M.D., Ph.D.
State Surgeon General

June 15, 2011

Dear Licensee:

We want to bring to your attention HB 7095 that passed during the 2011 Legislative Session that may significantly affect your permit. It has been signed by Governor Scott, and unless otherwise noted, will become effective July 1, 2011. We have provided a link to the bill and encourage you to read the full text. We are providing just the highlights below.

CS/CS/HB 7095, 3rd Engrossed/Enrolled-Prescription Drugs

This bill changes the regulation of activities by physicians, pain management clinics, pharmacies and wholesale drug distributors.

On July 1, 2011:

Practitioners, generally, will no longer be authorized to dispense Schedule II or Schedule III controlled substances. A few exceptions are provided:

- Complimentary or sample controlled substances
- In the health care system of the Department of Corrections
- In connection with specified surgical procedures in certain timeframes
- In approved clinical trials
- Methadone in certain licensed treatment facilities
- For licensed hospice facilities

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 must be disposed of by July 11, 2011. Disposal can be achieved by either returning the drugs to the wholesale distributor or turning the inventory in to a local law enforcement agency and abandoning them. Controlled substances not disposed of by August 2 are deemed contraband and are subject to seizure by law enforcement.

Wholesaler 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.

Prescription drug wholesale distributors, out-of-state prescription drug wholesale distributors, retail pharmacy drug wholesale distributors, manufacturers, and repackagers that engage in wholesale distribution of controlled substances as defined in s. 893.02 are required to:

- Submit a report to the department of its receipts and distributions of controlled substances listed in Schedule II, III, IV, or V.
- If there are no distributions for the month, submit a report indicating that no distributions occurred in the period.
- Submit the reports monthly by the 20th of the following month, in the electronic format used for controlled substance reporting to the Automation of Reports and Consolidated Orders System division of the federal Drug Enforcement Administration. Submission must be made in a secured Internet environment that allows for manual or automated transmission and must contain the following:
    - Federal DEA registration number of the wholesale distributing locations
    - Federal DEA registration number of the entity to which the drugs are distributed or from which the drugs are received
    - Transaction code that indicates the type of transaction
    - NDC identifier of the product and the quantity distributed or received
    - DEA Form 222 number of controlled substance Ordering System Identifier on all Schedule II transactions
    - The date of the transaction
- This reporting requirement applies to the following permit types issued by the State of Florida to wholesale distributors of prescription drugs:
    - Prescription Drug Wholesale Distributor
    - Out-of-State Prescription Drug Wholesale Distributor
    - Retail Pharmacy Drug Wholesale Distributor
    - Prescription Drug Manufacturer
    - Non-resident Prescription Drug Manufacturer
    - Third Party Logistics Providers – operating on behalf of a drug manufacturer
    - Prescription Drug Repackager
- Wholesale distributor facilities located within this state shall report all distributions involving controlled substances.
- Wholesale distributor facilities located outside this state shall report all distributions of controlled substances to entities located in Florida.
- The law changes criminal penalties and administrative sanctions for unlawfully distributing controlled substances or submitting false reports pertaining to controlled substance distributions.

Due Diligence is required for the distribution of controlled substances.

- Wholesale distributors must credential and understand the normal business transactions of their customers who purchase certain controlled substances.

  This requirement applies to the following permit types issued by the State of Florida to wholesale distributors of prescription drugs.
    - Prescription Drug Wholesale Distributor
    - Out-of-State Prescription Drug Wholesale Distributor
    - Retail Pharmacy Drug Wholesale Distributor

- Wholesale distributors must identify suspicious orders.

This requirement applies to the following permit types issued by the State of Florida to wholesale distributors of prescription drugs.

- Prescription Drug Wholesale Distributor
- Out-of-State Prescription Drug Wholesale Distributor
- Retail Pharmacy Drug Wholesale Distributor
- Prescription Drug Manufacturer
- Non-resident Prescription Drug Manufacturer
- Third Party Logistics Providers – operating on behalf of drug manufacturer
- Prescription Drug Repackager

- Wholesale distributors must abstain from distributing controlled substances to an entity if any person associated with that entity meets certain disqualifying conditions of any criminal history record check.

  This requirement applies to the following permit types issued by the State of Florida to wholesale distributors of prescription drugs.

  - Prescription Drug Wholesale Distributor
  - Out-of-State Prescription Drug Wholesale Distributor
  - Retail Pharmacy Drug Wholesale Distributor
  - Prescription Drug Manufacturer
  - Non-resident Prescription Drug Manufacturer
  - Third Party Logistics Providers – operating on behalf of a drug manufacturer
  - Prescription Drug Repackager

Counterfeit-proof prescription blanks must be used by practitioners for prescribing of any controlled substance. The department is in the process of compiling a list of approved vendors of counterfeit-proof prescription pads and will post the list to the website.

The State Health Officer, Dr. H. Frank Farmer, 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. The Department of Health, using actual purchasing records from wholesalers and other information, 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 July 5, 2011, law enforcement agencies will enter the business premises of the identified dispensing practitioners and quarantine the inventory on site.

The standards of practice for a controlled substance prescribing practitioner are spelled out in the law and include for each patient, among other things:

- Complete medical history and physical exam
- Written individualized treatment plan
- Written controlled substance agreement
- Regular follow-up appointments at least every 3 months

Criminal and regulatory sanctions for violations of the provisions of this law are modified.

Criteria for required registration as a pain management clinic are revised. 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 opiods, benzodiazepines, barbiturates, or carisoprodol for the treatment of chronic nonmalignant pain. A few additional exemptions from registration are included. New requirements are established for physicians practicing in a pain management clinic, including, among other things, that the physician notify the applicable board within 10 days of beginning or ending practice at the clinic and that the physician ensures compliance with facility and physical operations of the clinic, among other functions. A physician assistant or advanced registered nurse practitioner is authorized to perform the examination of a patient in a pain management clinic.

It is imperative that you review this law in its entirety to understand and comply with new provisions. To access this law and other information that we will post periodically on its implementation, please visit our website at:
www.doh.state.fl.us/mqa/Legislation/legis.htm

Sincerely,

Mark C. Whitten
Executive Director
Florida Department of Health
Board of Pharmacy