

June 15, 2011

Dear Pharmacist/Pharmacy Manager/Pharmacy:

We want to bring to your attention HB 7095 and HB 1319 that passed during the 2011 Legislative Session that will significantly affect your pharmacy practice. They have been signed by Governor Scott, and unless otherwise noted, will become effective July 1, 2011. We have provided links 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 pharmacies, pharmacists, pain management clinics, 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.

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. Many of the approved vendors are currently approved with AHCA for the Medicaid program. The list will be posted on the board website prior to July 1, 2011. You can access the Board of Pharmacy website at:

<http://www.doh.state.fl.us/mqa/pharmacy/index.html>

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 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 opioids, 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.

Violations and penalties for pharmacists are expanded to include:

- It is unlawful for any pharmacist to knowingly fail to report to the sheriff or other chief law enforcement agency of the county where the pharmacy is located within 24 hours after learning of any instance in which a person obtained or attempted to obtain a controlled substance through fraudulent methods or representations. The content of the report is set forth in the law. Failure to report constitutes a misdemeanor.
- Disciplinary action grounds are expanded to include committing errors or omissions during the performance of certain prescription drug processing.

Community pharmacy permit application requirements are changed and include existing pharmacy permittees.

- The Board of Pharmacy may suspend, revoke or refuse to issue a permit to persons who have been disciplined, abandoned a permit, or allowed a permit to become void after written notice that disciplinary proceedings had been or would be brought against the permit.
- Other reasons for denial, suspension or revocation include failure to pay all outstanding fines, liens or overpayments assessed by final order of the department.
- Passing an onsite inspection is a prerequisite to the issuance of an initial permit.

Community pharmacies that dispense controlled substances must maintain a record of all controlled substance dispensing consistent with the requirements of s. 893.07, F.S., and must make the record available to the department and law enforcement agencies upon request.

In order to dispense controlled substances listed in Schedule II or Schedule III on or after July 1, 2012, a community pharmacy permittee must be permitted pursuant to new requirements set forth in the law. The changes in permitting requirements that must be met for a pharmacy to dispense Schedule II or Schedule II prescriptions after July 1, 2012 included, but are not limited to, fingerprinting requirements and written policies and procedures for preventing controlled substance dispensing based upon fraudulent representations or invalid practitioner-patient relationships. The law sets forth certain convictions and termination from Medicaid as reasons for which application for a permit must be denied. The new application, and all requirements will be available on line in the near future.

A pharmacy permittee must notify the department within 10 days after any change in the prescription department manager or consultant pharmacist of record.

The prescription department manager must:

- Obtain and maintain all drug records required by any state or federal law to be obtained by a pharmacy, including, but not limited to, records required by chapters 465, 499 or 893. The manager must also insure compliance with all rules adopted under those chapters as they relate to the practice of the profession of pharmacy and the sale of prescription drugs.
- Ensure the security of the prescription department and notify the board of any theft or significant loss of any controlled substances within 1 day after discovery of the theft or loss.
- All required records documenting prescription drug distributions shall be readily available or immediately retrievable during an inspection by the department and must be maintained for 4 years after the creation or receipt of the record, whichever is later.

A pharmacist may not serve as the prescription department manager in more than one location unless approved by the board.

The Prescription Drug Monitoring Program (which is scheduled to be operational by October 1, 2011) requirements for reporting have been modified from 15 days to 7 days by when a controlled substance dispensed to an individual must be reported. Be sure to visit the EFORCSE website for updates and details on the program at:
<http://drugcontrol.flgov.com/pdmp/index.html>

A number of changes were made to s. 893.13, F.S. related to prohibited acts and penalties, two of which are:

- Discovery of a theft or significant loss of controlled substances must be reported to law enforcement within 24 hours of the discovery. Failure to do so will result in a misdemeanor of the first degree.
- 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, 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. Material fact includes whether the patient has an existing prescription

for a controlled substance issued for the same period of time by another practitioner. A health care practitioner who violates this provision commits a felony of the third degree.

CS/CS/CS/HB 1319 Enrolled-Certificates/Licenses/Health Care Practitioners

This bill authorizes the department to issue a temporary license to a health care practitioner whose spouse is stationed in Florida on active duty with the Armed Forces if the applicant meets the eligibility requirements for a full license and is qualified to take the licensure examination. It also requires the applicant for a temporary license to pay for fingerprint processing for a criminal history check in addition to the application fee.

It is imperative that you review HB 7095 in its entirety to understand and comply with new provisions. To access this law, ongoing information on its implementation, information on the Prescription Drug Monitoring Program, and other information that we will post periodically on bills that are signed by the Governor, please visit our website at:

www.doh.state.fl.us/mqa/Legislation/legis.htm

Sincerely,

A handwritten signature in black ink, appearing to read "Mark C. Whitten", with a large, stylized flourish extending to the right.

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