Prohibition on Physician Dispensing Schedule IIs and IIs

By Martin R. Dix
marty.dix@akerman.com

Sheryl D. Rosen
sheryl.rosen@akerman.com

On May 6, 2011, the Florida Legislature passed what is commonly known as the pill mill law. The bill includes several new restrictions on physicians’ authority to dispense controlled substances. Physicians can be disciplined and criminally prosecuted (third degree felony) for violating Section 465.0276, FS. While the bill was passed by the legislature, it is still subject to the Governor’s veto power. If the Governor allows it to become law, the effective date is July 1, 2011. The following is a summary of those changes. Please note this is not intended to be comprehensive. Consult your Akerman attorney for advice regarding your particular situation.

Before You Dispense Schedule IIs and IIs.

The new law states that a health care practitioner may not dispense Schedule II or III controlled substances. However, several exceptions apply.

Exception #1 – Drug Samples:
Physicians may still dispense drug samples if:

• the physician gives the samples to the physician’s own patients,
• in the regular course of the physician’s practice, and
• without receiving direct or indirect payment or other remuneration.
**Exception #2 – Dispensing within Department of Corrections:**
Physicians may still dispense Schedule II and III controlled substances in the health care system of the Department of Corrections.

**Exception #3 – Post-Surgery:**
Physicians may still dispense Schedule II and III controlled substances in connection with performance of a surgical procedure as long as:
- the amount dispensed is no more than a 14-day supply; and
- the drugs are dispensed no more than 14 days after the surgical procedure was performed.

A surgical procedure is defined as any procedure in any setting that involves:
- 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
- the use of general anesthesia or major conduction anesthesia and preoperative sedation.

**Exception #4 – Clinical Trials:**
Physicians may still dispense Schedule II and III controlled substances in connection with a clinical trial. The trial either must be funded in whole or part by a state or the federal government or must be conducted under an investigational new drug application reviewed by the U.S. Food and Drug Administration.

**Exception #5 – Methadone:**
Physicians may still dispense methadone in a facility licensed to conduct medication-assisted treatment for opiate addiction.

**Exception #6 – Hospice:**
Physicians may still dispense Schedule II and III controlled substances to a patient of a licensed hospice.

**Disposal of Your Drug Inventory**
Physicians who have Schedule II and III controlled substances in their inventory but do not meet one of the above exceptions must ensure that they do one of the following:
Return the drugs to the wholesale distributors from which they were purchased. The new law requires wholesalers to buy back physicians’ unopened and unexpired inventory in accordance with the established policies of the wholesale distributor or the contractual terms between the wholesale distributor and the physician concerning returns.

Turn the drugs in to a local law enforcement agency.

The drugs must be returned or relinquished to law enforcement by July 11, 2011. (The law confusingly has a 10-day and also a 30-day period after the effective date for return of these drugs, so err on the side of caution and return them by July 11.)

Also, it is unclear at this time whether a pedigree must accompany the returned drugs.

Finally, note that while this bill has passed the Florida Legislature, it cannot become law until it is either signed by Governor Scott or is allowed to become law without his signature.

For more information, please contact a member of our Healthcare practice.

Akerman is ranked among the top 100 law firms in the U.S. by The National Law Journal NLJ 250 (2011) in number of lawyers and is the leading Florida firm. With 500 lawyers and government affairs professionals, Akerman serves clients throughout the U.S. and overseas from Florida, New York, Washington, D.C., California, Virginia, Colorado, Nevada, and Texas.