

# Akerman Practice Update

HEALTHCARE

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## Pharmacy Practice Impacted by the Pill Mill Bill- House Bill 7095

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### Introduction

On May 6, 2011, the Florida Legislature passed House Bill 7095, commonly known as the pill mill law. The bill includes several new requirements affecting Florida pharmacies and pharmacists. “Changes” already in law or rule are not addressed here. The requirements take effect July 1, 2011 if allowed to become law by the Governor. The bill addresses the following areas affecting pharmacy:

- Reporting Requirements
- Controlled Substance Records Requirements
- Pharmacy Permits
- Dispensing and Drug Processing Errors
- Written Prescriptions for Controlled Substances
- Purchases from Wholesalers

### Reporting Requirements:

When a pharmacist knows a person obtained or attempted to obtain a controlled substance through fraudulent means, the pharmacist must report



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“The failure  
to report  
is a  
first-degree  
misdemeanor”

the incident to a law enforcement agency of the county in which the pharmacy is located. This must be done within 24 hours of learning of the incident or at the close of business on the next business day, whichever is later. The failure to report is a first-degree misdemeanor.

The prescription department manager must notify the Board of Pharmacy of any theft or significant loss of any controlled substances within 1 business day after discovery of the theft or loss. DEA still requires that such thefts and losses be reported “immediately” upon discovery.

### **Controlled Substance Records Requirements:**

Community pharmacies must maintain a record of all controlled substances dispensed and make the record available to the Department of Health and law enforcement upon request.

All required records documenting prescription drug distributions shall be readily available or immediately retrievable during an inspection. The records must be retained for 4 years after creation or receipt of the record, whichever is later.

### **Pharmacy Permits:**

The Department of Health may issue a pharmacy permit to:

1. A natural person at least 18 years old;
2. A partnership consisting of at least one natural person when the natural partners are all at least 18 years old;
3. A governmental agency; and
4. A business entity whose affiliated persons are at least 18 years old.

Before the Department of Health will issue an initial permit or a permit for change of location, the pharmacy must pass an onsite inspection conducted within 90 days before issuance of the permit.

Each applicant with a 5% or greater financial interest in the pharmacy seeking a permit must submit a signed affidavit disclosing any 5% or greater interest in any permitted pharmacy in the past 5 years that has closed voluntarily or involuntarily, has voluntarily relinquished its permit, has had its permit suspended or revoked, or has had an injunction issued against it by a regulatory agency.

“The wholesalers cannot sell controlled substances to ‘any entity’ if any associated person has ‘been convicted of, or entered a plea of guilty or nolo contendere to . . . a crime . . . related to controlled substances...”

An application for a pharmacy permit must include written policies and procedures for preventing controlled substance dispensing based on fraudulent representations or invalid. An 18 month phase in is allowed.

The Board of Pharmacy may suspend, revoke, or refuse to issue a permit to:

1. Any person who has been disciplined, has abandoned a permit, or has allowed a permit to become void;
2. Any officer, director, or person directly or indirectly interested in a person or organization that has had a permit disciplined, abandoned, or voided;
3. Any former officer of an organization that has had a permit disciplined, abandoned, or voided; and
4. Any entity if the applicant, licensee, officer, director, agent, or managing employee or owner of 5% or more has failed to pay all outstanding fines, liens, or overpayments declared by the Department of Health, unless a repayment plan is ongoing.

The Department of Health or Board of Pharmacy shall deny an application for a pharmacy permit if the applicant or an affiliated person:

1. Has been convicted of or entered a guilty plea or nolo contendere to a felony for fraud or a crime involving a controlled substance since July 1, 2009;
2. Has been terminated from the Florida Medicaid program; or
3. Has been terminated for cause from any other state’s Medicaid program (with exceptions).

The Department of Health must annually submit permit applicants’ fingerprints to the Department of Law Enforcement for a state criminal records check. The Department of Law Enforcement must annually forward the fingerprints to the FBI for a national criminal records check. The Department of Health must report the results of the annual criminal records checks to licensed drug wholesale distributors. The wholesalers cannot sell controlled substances to “any entity” if any associated person has “been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction related to controlled substances, the practice of pharmacy, or the dispensing of medicinal drugs.”

“[A] pharmacy purchasing 5,000 doses per month of any one controlled substance should ensure its distributors are aware of the pharmacy’s clinical need, location, population, and any other factors.”

### **Dispensing and Drug Processing Errors:**

Committing an error or omission during the performance of a specific function of prescription drug processing is grounds for denial of a license or disciplinary action. Specific functions of prescription drug processing include:

1. Receiving, interpreting, or clarifying a prescription;
2. Entering prescription data into the pharmacy’s record;
3. Verifying or validating a prescription;
4. Performing pharmaceutical calculations;
5. Performing prospective drug review as defined by the Board of Pharmacy;
6. Obtaining refill and substitution authorizations;
7. Interpreting or acting on clinical data;
8. Performing therapeutic interventions;
9. Providing drug information concerning a patient’s prescription; and
10. Providing patient counseling.

### **Written Prescriptions for Controlled Substances:**

The requirements for controlled substance prescriptions have been changed so pharmacies should review these to make sure that the prescriptions are valid. The prescription must:

- have the quantity in both textual and numerical formats
- be dated with the abbreviated month written out on the face of the prescription;
- 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.

### **Purchases from Wholesalers:**

The new law requires that wholesalers credential pharmacies and pay special attention to orders for more than 5,000 unit doses of any one controlled substance. They must make a determination of whether the purchase is reasonable and report any suspicions. While not entirely clear, it appears that a wholesaler could deny a request the wholesaler deems to be unreasonable or suspicious. Therefore, a pharmacy purchasing 5,000 doses per month of any one controlled substance should ensure its distributors are aware of the pharmacy’s clinical need, location, population, and any other factors.

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.

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