

Akerman Practice Update

HEALTHCARE

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HB 7095 - Bill Requires Wholesalers to Play Role in Reducing Pill Mills

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On May 6, 2011, the Florida Legislature passed House Bill 7095, commonly known as the pill mill law, and Governor Scott signed the legislation on June 3, 2011. The bill includes several new requirements for pharmaceutical wholesalers. The new law will be effective July 1, 2011. The following is a summary of those changes.

Please note this is not intended to be comprehensive. Consult your Akerman lawyer for advice regarding your particular situation.

Reporting Requirements

The bill requires drug manufacturers, in-state and out-of-state wholesalers, repackagers, and retail pharmacy wholesalers to report controlled substance ("CS") (Schedule II, III, IV, and V) drug sales and distributions on a monthly basis by electronic means using the format for ARCOS reporting. Key differences are: ARCOS is quarterly (not monthly); ARCOS is Schedule IIs and some Schedule IIIs (Florida is Schedule II, III, IV and V); ARCOS is just distribution, while Florida includes "receipts." The Department of Health ("Department") has stated that it will model the reporting system after the one used in New York. After transmission to the Department, the wholesaler will receive an acknowledgement page.



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“Any person engaged in wholesale distribution who knowingly distributes controlled substances without making the required report commits a third-degree felony.”

The reports must contain:

- The Wholesaler’s DEA number
- The DEA number of “the entity to which the drugs are distributed or from which the drugs are received”
- The transaction code
- The National Drug Code and quantity of the CS drug distributed or received
- The DEA Form 222 number or Controlled Substances Ordering System identifier for all Schedule II drugs
- The date of the transaction

If no CS distributions were made during a month, the wholesaler must submit a report reflecting a lack of distributions that month. If a wholesaler sells NO controlled substances whatsoever, it must still report.

The Department has indicated that if a manufacturer uses a third party logistics (3PL) provider for its distributions, the 3PL must report and the manufacturer does not have to report.

Any person engaged in wholesale distribution who knowingly distributes controlled substances without making the required report commits a third-degree felony. Additionally, the Department may deny, suspend, or revoke a wholesaler’s permit if that wholesaler has not complied with these reporting requirements.

Credentialing and Monitoring

The bill requires wholesalers to have policies and procedures to “credential” medical doctors, osteopaths, podiatrists, dentists, and pharmacies that purchase Schedule II and III drugs. Records of the actual credentialing have to be maintained and made available to the Department upon request. Wholesalers must also submit documentation of their credentialing policies as part of their permit or renewal applications. It is likely the wholesalers will use the HDMA credentialing format, but each could adapt it to their own operations.

Wholesalers must take reasonable measures to:

- Identify their customers
- Understand the normal and expected transactions conducted by those customers
- Identify those transactions that are suspicious in nature (as set forth in internal policies designed to identify those transactions that are suspicious in nature) and prevent suspicious transactions

“Wholesalers are required to have policies and procedures to identify ‘suspicious’ orders.”

More specifically, the bill requires credentialing to include a determination of the clinical nature of the receiving entity, including any specialty practice area, as well as a review of the purchaser’s Schedule II and III drug purchasing history and whether the purchases are consistent with and reasonable considering the purchaser’s clinical business needs. Wholesalers are required to have policies and procedures to identify “suspicious” orders.

Additionally, the wholesaler must assess orders for greater than 5,000 unit doses of any one controlled substance in any one month to determine whether the purchase is reasonable. The Department has indicated that for solid drugs, “doses” means pills or tablets, but no guidance has been provided yet on liquids. In making the assessments, a wholesaler must consider the purchasing entity’s clinical business needs, location, and population served, in addition to other factors established in the wholesaler’s policies and procedures.

If the wholesaler is aware of any “regulated transaction” involving an “extraordinary quantity” of a “listed chemical” (several of these terms are undefined, but presumably the “regulated transactions” and “listed chemicals” are those defined in 21 CFR 1300 such as ephedrine and pseudoephedrine sales), an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of the law, the wholesaler must report the transaction to the Department. The wholesaler in that situation should maintain records that document the report it submitted to the Department.

The wholesaler must not distribute a CS to any entity if a criminal record check of a person “associated with” that entity shows that person has been convicted of, or entered a plea of guilty or nolo contendere, to a crime in any jurisdiction related to a CS, the practice of pharmacy, or the dispensing of medicinal drugs. To aid in this credentialing, the Department must report to wholesalers the results of annual criminal records checks conducted on certain pharmacy owners and operators. However, at the May 27, 2011 workshop on implementation of the bill, the Department said that there may be a conflict with federal laws that prohibit sharing of criminal background checks.

Finally, the Department may deny, suspend, or revoke a wholesaler’s permit if that wholesaler has not complied with these credentialing requirements.

“Dispensing physicians, with certain exceptions, are prohibited from dispensing Schedule II and III controlled substances.”

Buy Back Program

Dispensing physicians, with certain exceptions, are prohibited from dispensing Schedule II and III controlled substances. By July 11, 2011 non-exempt physicians must either return the drugs to the wholesaler from which they purchased the drugs or turn them in to local law enforcement. Wholesalers are required to buy back the undispensed inventory of Schedule II and III drugs which are in the manufacturer’s original packaging, unopened, and in date, in accordance with the wholesaler’s policies and contractual terms. While at first blush it sounds as if the wholesalers will be buying back these drugs, almost all have “policies and contractual terms” that state that returns (after 7 days) are not allowed. Thus, the physicians may find themselves with legally purchased drug inventory that they are required by law to provide to law enforcement since the wholesalers will not be buying back these drugs. It remains to be seen whether any physicians will challenge this in court as an uncompensated “taking.”

Other Provisions

The Department is required to declare a public health emergency and by July 3, 2011 it is supposed to consult with wholesalers to identify dispensing practitioners who dispensed more than an average of 2,000 unit doses of Schedule II or III drugs per month in the prior 6 months. The Department will use this information to determine which practitioners pose the greatest threat to the public health. There are provisions for law enforcement officials to enter the premises of dispensing practitioners who pose the greatest threat and quarantine the drugs on or after July 4, 2011.

There is also language requiring law enforcement to seize any of these controlled substances still in the possession of physicians on August 1, 2011.

The Department shall include in each medical doctor, osteopath, podiatrist, or dentist practitioner profile whether the practitioner is a controlled substance prescribing practitioner.

For more information, please contact Martin Dix at marty.dix@akerman.com or by phone at (850) 224-9634, or contact a member of our Healthcare practice.

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