IMPORTANT INFORMATIONS REGARDING
CONTROL DRUG SALES & DISTRIBUTION IN FLORIDA

Amendments to the controlled substance laws related to the Florida Controlled Substance Act and Pain Management Clinic Act took effect July 1, 2011. The law, Laws Of Florida 2011-141, contains a number of requirements as well as criminal provisions related to the pharmaceutical wholesale industry that will affect the way in which wholesalers do business. In the past, the legal requirements for due diligence of a wholesale distributor with respect to their clients could be as minimal as a copy of a license and DEA number. Increasingly over the last several years, the State and Federal governments have been holding wholesale distributors responsible for the conduct of their client providers. This responsibility to police the client's activity is now both necessary and required to avoid not only a loss of licensure but perhaps to avoid criminal prosecution.

Under Florida law, manufacturers, wholesalers, retail pharmacy wholesale distributors and repackagers (wholesale distributors) now have reporting and statutory due diligence requirements. First as to reporting:

Under Florida Statutes § 499.0121(14), wholesale distributors will now be required to report to the State of Florida distribution information in the same manner as currently reported to the DEA ARCOS. The State will then share that information with the FDLE and law enforcement so that they can track those providers that order large amounts of controlled substances. Out of state wholesale distributor are required to send information regarding controlled substances sent into the state of Florida or received from the State of Florida; Florida in-state wholesale distributors are required to send the information for all distributions. A false statement made in a report is a third degree felony. The reporting is required by the 20th of each month, even if there are no distributions. The reporting can be done electronically here:

https://ww2.doh.state.fl.us/CSR/login.aspx

Wholesale distributors should make sure to keep and store an electronic receipt for that report. Other state agencies have had previous problems in other areas related to electronic reporting and the administrative agencies have somewhat consistently taken the position that if a person required to report doesn't keep a record not only of the report, but or the receipt of the report by the agency, the reporting did not happen.

Under Florida Statutes § 499.067(8), a wholesale distributor can have their license revoked, suspended or denied if they fail to comply with the reporting requirements.

There is a second type of reporting under the new law related to due diligence. A wholesale distributor is required to report "suspicious" orders or transactions under Florida Statute § 499.0121(15). Wholesale distributors must take efforts to identify suspicious transactions and develop policies and procedures to identify suspicious transactions based on the nature of the client's order history, clinical business needs, location, the population served, manner of payment or uncommon delivery requests. Any order over 5,000 unit dosages of any one controlled substance must be investigated by a wholesale distributor for the reasonableness of the order. A wholesaler is required to report suspicious orders to the DOH and keep records of any report.

Due diligence and records of that due diligence must also be used prior to any distribution. Under Florida Statute § 499.0121(15), wholesale distributors are now also required under law to undertake certain due diligence measures which include specific steps to credential providers, physicians and pharmacies prior to distributing Schedule II and III controlled substance medications. The interesting part of this requirement is that with certain limited exceptions, physicians are no longer permitted to dispense CII and CIII medications in the State of Florida. However, since Florida distributors are required to report all distributions, out of state physicians fall into this category. The minimum credentialing requirements include:

1. A determination of the clinical nature of the receiving entity, including any specialty practice area.
2. A review of the receiving entity's history of Schedule II and Schedule III controlled substance purchasing from the wholesale distributor.
3. A determination that the receiving entity's Schedule II and Schedule III controlled substance purchasing history, if any, is consistent with and reasonable for that entity's clinical business needs.

Under Florida Statutes § 499.067(9), a wholesale distributor can have their license revoked, suspended or denied if they fail to comply with the due diligence or reporting requirements. The entire law can be found here:

http://laws.flrules.org/2011/141

Bernard M. Cassidy
legal@usmeds.com