Rx AND THE LAW

By Don. R. McGuire Jr., R.Ph., J.D.

This series, **Pharmacy and the Law**, is presented by Pharmacists Mutual Insurance Company and your State Pharmacy Association through Pharmacy Marketing Group, Inc., a company dedicated to providing quality products and services to the pharmacy community.

CONTROLLED SUBSTANCES

The opioid crisis has brought a lot of attention to the prescribing and dispensing of opioids. This attention has also extended to the prescribing and dispensing of all controlled substances. I recently attended a seminar which contained a number of sessions on opioids and controlled substances. One of these sessions suggested that every pharmacist should read the DEA's Pharmacist's Manual.[1] That suggestion caused me to ask myself when was the last time I had read it. One human trait is that we tend to forget details over time and our memory becomes a little less sharp. There have been a number of times when I was sure what a contract provision said, only to go back, read the document, and find that what it stated was slightly different from my memory. This same phenomenon applies to the Pharmacist's Manual. The manual is about 80 pages, but it is much more readable than the actual statute and regulations.

The speaker at the seminar explained that many pharmacists feel their duty is to make sure that a controlled substance prescription isn't forged or altered. While that is true, the duty is much broader. For a controlled substance prescription to be valid, it must be issued for a legitimate medical purpose in the usual course of the prescriber's professional practice. The law does not require a pharmacist to dispense a questionable prescription. The DEA has provided some red flags that may indicate diversion. Those are discussed in 2018 decision and order.[2] Corresponding Responsibility is a topic that requires its own forum so I won't delve more deeply into it now.

The Pharmacist's Manual contains information on a number of topics. Besides a basic introduction to the Schedules, there is a lot of practical information in the manual. There is a section on the transfer and disposal of controlled substances. This covers transfer to another pharmacy, the original manufacturer, or a reverse distributor. There are numerous reminders to use the triplicate DEA Form 222 to transfer Schedule II substances. Another reason to refresh our memories periodically is that requirements change and if we rely only on our memories, we may not be current. The DEA recently announced the phase out of the triplicate form over the next two years.

The DEA Form 222 is also mentioned in the section of the manual on ordering of controlled substances. Topics here include how to order the Form 222, who is authorized to sign the forms, and what to do if the forms are lost or stolen. The manual also contains useful

1 https://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf

2 https://www.deadiversion.usdoj.gov/fed_regs/actions/2018/fr0220_4.pdf#search=red%20flag%20diversion

information on what to do when controlled substances are stolen or lost. The DEA must be notified, in writing, within one business day of the discovery of the theft or loss. Completion of the DEA Form 106 in this situation can be made easier by using the biennial inventory and prescription records because you can use these records to determine how much product was stolen or lost. There is also an entire section of recordkeeping requirements. While many pharmacies are using a perpetual inventory system today, that does not replace the required biennial inventories. Physical inventories are required for a new registrant (either opening a new pharmacy or taking over an existing one) and for products that are newly added to a schedule.

The manual also contains helpful information for the review and dispensing of controlled substance prescriptions. It provides what information is required to be on the prescription itself and the information required to be on the prescription label. Partial fill situations are addressed as is the dispensing of controlled substances without a prescription. The record of over the counter sales of controlled substances is required to be kept in a bound record book. These types of sales must be made by a pharmacists and cannot be delegated to a non-pharmacist. While the manual contains a lot of practical information, there are some uncommon provisions also. Sometimes these less common situations are problem-prone because we aren't as familiar with the situation. Suppose one of your patients has a valid prescription for a C-IV medication and requests that you send a refill to their vacation home in Bermuda. Can you send that refill to a foreign country? Not unless you are registered with the DEA as an exporter and have obtained the necessary permits or submitted the necessary declarations for export. The pharmacist might assume it is permissible to send the refill because there is a valid prescription on file. This is an example where a seemingly reasonable conclusion is incorrect.

The periodic review of the DEA's Pharmacist's Manual is a good risk management tool. During my years of practice, none of my employers recommended or required that I review it. My working knowledge of the DEA regulations was what I drew from my pharmacy law class and any updates that I may have read and retained. Given the scrutiny that is currently being given to the dispensing of controlled substances, an annual review of the Pharmacist's Manual is an excellent risk management tool to help the pharmacist and pharmacy avoid a potential problem brought on by foggy memory of the requirements. In addition, a review of your state statutes and regulations should also be done because your state may have more restrictive standards which you are required to follow.

© Don R. McGuire Jr., R.Ph., J.D., is General Counsel, Senior Vice President, Risk Management & Compliance at Pharmacists Mutual Insurance Company.

This article discusses general principles of law and risk management. It is not intended as legal advice. Pharmacists should consult their own attorneys and insurance companies for specific advice. Pharmacists should be familiar with policies and procedures of their employers and insurance companies, and act accordingly.