

Beware Pharmacy Record-Keeping Violations

Law360, New York (April 09, 2013, 1:54 PM ET) -- On April 3, the United States Attorney's Office in Oklahoma and the Drug Enforcement Administration announced a civil settlement with nationwide chain CVS Pharmacy Inc., whereby CVS agreed to pay \$11 million to the federal government to resolve allegations of deficient record-keeping in regard to prescriptions for controlled substances. This settlement was hailed by the U.S. Department of Justice in its press release as "one of the largest settlements ever paid for record-keeping violations by a retail pharmacy chain related to controlled pharmaceuticals."

Although the allegations involved several of CVS's pharmacies located in Oklahoma, the deficiencies noted have application to all pharmacies and could result in civil fines and administrative actions against other pharmacies committing similar practices.

Accordingly, it is useful to review these condemned practices so that the lessons of history and financial exposure are not lost:

1. Filling Prescriptions for Expired DEA Numbers

In several instances, CVS pharmacies were filling prescriptions for a physician whose DEA number had recently expired. The government noted that each such instance constituted an act of improper dispensing under Title 21 U. S. Code and subjected the pharmacy to a \$25,000 fine per prescription.

This same allegation was at issue in the recent Florida CVS cases which resulted in two CVS pharmacies in Florida having their DEA registrations revoked in 2012. (77 Fed. Reg. 62315-62346) (Holiday CVS)

While at least one pharmacist explained that it was very difficult to attempt to verify the accuracy and continued validity of each DEA prescriber number prior to dispensing by consulting the DEA website, those comments did not find an hospitable ear from the government, which took the position that it is the lawful duty of the pharmacist to ensure that every prescription is issued by a physician authorized to prescribe the medication by possessing a valid DEA number.

Pharmacists are expected to regularly check the DEA database to ensure that each prescriber is a valid DEA registrant at the time such prescription is issued and filled. In the CVS matter, one prescriber had 80 or so prescriptions filled after expiration, and a few other prescribers had one or two scripts filled after expiration.

The lesson appears that regardless of the number, the DEA will be very unforgiving and views each

instance as amounting to a \$25,000 penalty.

2. Labeling Prescription and Reporting to Monitoring Program Under Name of Supervising Physician Rather Than Prescriber

In several instances, the CVS pharmacies were receiving valid prescriptions written by a registered nurse practitioner (RNP) or physician's assistant (PA), but were recording the prescriptions internally and to the state's Prescription Drug Monitoring Program under the DEA number of a supervising physician. They stated they were doing this for insurance reasons. The label would bear the name and DEA of the supervising physician rather than the name and DEA number of the prescribing RNP or PA.

In no instance was it alleged that the drugs were being improperly diverted or had been improperly prescribed. Nevertheless, each instance was condemned and worth a \$10,000 fine.

The simple lesson is that regardless of innocent motive, prescriptions must always be filled and filed under the name and DEA number of the prescriber.

3. Wrong DEA Number

An audit revealed that several prescriptions were filled using a valid DEA number, but the number belonged to a physician different than prescriber, similar to the RNP and PA issue above. In addition, in some instances, the DEA number used was invalid, which error may have been the result of transcription or other internal error. Each instance was viewed as a \$10,000 violation. This happened in several instances and was widespread according to the civil complaint. The reasons that this was occurring are not clear.

Advice

Actions such as this one involving CVS show the DEA's continued vigilance and insistence upon strict and rigorous compliance with all of the provisions of Title 21, Code of Federal Regulations, 1301, et. seq. Substantial fines and penalties, including restriction of DEA registration can result from a failure to do so. In addition, although not at issue in the CVS case, there are many instances where CMS and other private insurers have taken the position that a prescription which does not conform to the law in all respects is not a valid prescription, is not a valid dispensing, and therefore they won't reimburse. In such instances, pharmacies must either litigate to try and recover or simply abandon the payment.

Title 21, United States Code, Section 1306.05, makes plain that all prescriptions for controlled substances, in order to be valid, whether written or oral, must bear the name and address of the patient, the name, address and DEA registration of the prescriber, and information relating to the drug, dosage, quantity and directions for use. Failure to adhere to these technical requirements may render the prescription invalid and subject the pharmacy to financial penalties, restriction of registration, and potential criminal charges.

Given the above, pharmacies are well-advised to treat such issues with utmost seriousness. And it really does not matter whether one thinks it fair or unfair; the point is it can be a very costly event for any pharmacy or pharmacy chain.

With this in mind, it is paramount to have policies and procedures in place to ensure that each script is technically complete, and that the DEA number is valid and belongs to the prescriber. Scheduled self-

audits, consisting of regularly inspecting the prescriptions are also a very good idea. Such audits will inform the pharmacy as to how well it is doing. Records of the results of such audits should be maintained as the mere conduct of such audits shows diligence.

—By Ronald J. Friedman, Lane Powell PC

Ronald Friedman is a shareholder in Lane Powell's Seattle office and former federal prosecutor who regularly advises pharmacies and other DEA registrants regarding regulatory compliance and provides representation in enforcement actions.

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