An Update on "Constructive Transfer" Under the Controlled Substances Act

Alliance for Pharmacy Compounding

The issue: For at least 20 years, DEA has taken the legal position that the Controlled Substances Act (CSA) prohibits a pharmacist from transferring a controlled substance to the prescribing/treating physician or veterinarian for safekeeping and administration.

The DEA's position is based on the CSA's definition of "dispense," which requires "delivery" of a controlled substance to the "ultimate user" of the drug (defined as the patient or a member of the patient's household).

Despite the fact that the CSA defines "delivery" to include "the actual, constructive, or attempted transfer of a controlled substance […] whether or not an agency relationship exists," DEA has interpreted the statute to require "manufacturer" registration before a pharmacy may transfer a controlled substance to a physician for office administration. This, despite that fact that some controlled substances, including compounded controlled substances, are sterile drugs that must be injected or otherwise administered by the prescribing physician.

DEA's position is that a member of the patient's household is somehow less of a threat to their mission to prevent diversion of dangerous drugs than the prescribing physician or veterinarian. Although DEA policy does allow a practitioner to obtain controlled substances for office stock from a pharmacy under a 5 percent cap without distributor or manufacturer registration, that policy as it relates to compounded controlled substances now conflicts with FDA's interpretation of the FDCA's prescription requirement for 503A pharmacies.

Legal and Legislative History

Unfortunately, DEA's position on constructive transfer of controlled substances to prescribing physicians has not been fully adjudicated to date. The closest case on point is Wedgewood Village Pharmacy v DEA (DC Cir 2007) which was remanded back to DEA by the appellate court and then eventually settled. However, the opinion did produce some strong language questioning DEA's position on constructive transfer, especially patient-specific transfers to the prescribing physician, and also questioning DEA's dubious claim that Congress intended that section of the law to only apply in criminal context of drug kingpins not making the actual drug transfers themselves.

Congress also began taking note. In the 110th and 111th Congresses, bills were introduced that would have specifically allowed for the constructive transfer of intrathecal pain pump drugs to physicians. These bills caused a split in the compounding community with concerns raised that the narrow legislation would be used by DEA to exclude all other controlled substance constructive transfers.

The industry united in the 112th Congress behind efforts to get DEA to undertake rulemaking on the issue, and behind a broader bipartisan bill in the 113th Congress — S.2825 introduced in 2014 by Senator Cornyn (R-TX) and Senator Brown (D-OH) — that would have amended the statute to expressly allow these transfers under certain circumstances. This seemed to get DEA's attention, and at that point the agency issued a letter to attorney Linden Barber, a former DEA agent and attorney, outlining the circumstances by which it would consider a constructive transfer to the prescribing physician appropriate. Since this letter was issued in July of 2016, enforcement actions by DEA have all but ceased to our knowledge.

Update: The New Mexico DEA office has notified the state's board of pharmacy that pharmacies making transfers to prescribing physicians are in violation of the CSA, jeopardizing pharmacy licensing with the BOP. APC is working to address this matter directly with the BOP, the DEA and with NM elected officials and will be discussing next steps in our advocacy effort with our legislative committee.