BRIEFING:
Constructive Transfer and Compounding Controlled Substance Medications
*April 2024**

**This briefing, originally adopted by APC's Board of Directors in 2010 has been updated to highlight the stance the DEA has recently taken with regard to the constructive transfers of controlled substances to physicians.*

For at least 20 years, the DEA has taken the legal position that the Controlled Substances Act (CSA) prohibits a pharmacist from transferring a patient-specific controlled substance prescription medication 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).

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

The 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 notably conflicts with FDA's interpretation of the FDCA's prescription requirement for 503A pharmacies.

Legal and legislative history shows that this issue has not been fully adjudicated, with previous cases such as *Wedgewood Village Pharmacy v. DEA (2007)* raising questions about the DEA's position on constructive transfer. Congress has also taken note of the issue, with bills introduced (but never passed) aimed at allowing constructive transfers of controlled substances to physicians, though concerns have been raised about potential unintended consequences of those bills.

Efforts to address the issues have included bipartisan legislative initiatives and calls for DEA rulemaking. Following pressure from stakeholders, the DEA issued a letter in 2016 outlining circumstances under which it would consider constructive transfers to prescribing physicians allowable. The DEA reiterated this opinion in a 2018 letter to Janssen Pharmaceuticals related to in-office administration of the

controlled substance esketamine nasal spray Spravato®. *The DEA indicated that it intends to use enforcement discretion if the controlled substance delivered to the prescribing physician is a single dose of medication*. Subsequently, enforcement actions by the DEA have largely ceased.

Pharmacy compounders should keep these requirements in mind when dispensing controlled substance prescriptions that are intended to be administered under the supervision of a practitioner, such as ketamine, or when the patient may "live" at the same location that a prescriber practices (such as a rehab facility).

This ongoing issue highlights the need for continued dialogue and advocacy to reconcile conflicting interpretations and ensure clarity and consistency in regulations governing the transfer of controlled substances to prescribing physicians for safekeeping and administration.

APC strongly recommends consulting a pharmacy attorney before dispensing a controlled substance prescription, in any amount, to anyone other than the ultimate user of the medication.

For reference: DEA Practitioner Manual and The Controlled Substance Act

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The Alliance for Pharmacy Compounding is the voice for pharmacy compounding, representing more than 500 compounding small businesses – including compounding pharmacists and technicians in both 503A and 503B settings – as well as prescribers, educators, researchers, and suppliers.

In traditional compounding, pharmacists create a customized medication, most often from pure ingredients, for an individual patient pursuant to a prescription. Pharmacists' ability to compound medications from pure ingredients is authorized in federal law and for good reason: Manufactured drugs don't come in strengths and dosage forms that are right for everyone, and prescribers need to be able to prescribe customized medications when, in their judgment, a manufactured drug is not the best course of therapy for a human or animal patient.

Every day, APC members play a critical role in patients' lives, preparing essential, custom medications for a range of health conditions, including autism, oncology, dermatology, ophthalmology, pediatrics, women's health, animal health, and others.