



Alliance for
Pharmacy
Compounding

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Alliance releases ketamine compounding best practices

April 15, 2024 (Alexandria, Virginia) – The Alliance for Pharmacy Compounding (APC) has issued [Best Practices for Preparing and Dispensing Compounded Ketamine by Pharmacies](#), a document aimed at guiding compounding pharmacies in preparing compounded ketamine drugs with care and utmost compliance with federal and state laws and regulations.

“These best practices flow from APC’s mission to elevate the practice of pharmacy compounding,” said APC Board Chair Joseph P. Navarra, RPh, owner of Town Total Compounding in Woodbury, NY. “They’ll guide pharmacists in practicing with the highest integrity, all in the interest of ensuring patients get the compounded medications they need and that those medications are of highest quality.”

The ketamine best practices are geared toward traditional state-licensed compounding pharmacies – also known as 503A pharmacies in the U.S. Food, Drug & Cosmetic Act – which may only dispense drugs upon receipt of a prescription, written by a legitimate prescriber, for a specific patient.

“Compounded ketamine therapy presents a viable alternative for patients grappling with conditions resistant to FDA-approved treatments,” said APC’s Chief Advocacy Officer Tenille Davis, PharmD. “Prescribers are following the latest scientific evidence and are writing prescriptions for compounded ketamine when they judge it is the best treatment for a specific patient.”

“Pharmacists recognize that ketamine is a controlled substance medication with risks of addiction, abuse, and diversion. Diligence is essential to ensure the responsible use and safeguard against misuse of these therapeutic options,” says the APC best practices document.

APC Board Vice President Gina Besteman, PharmD, of Women’s International Pharmacy in Madison, Wisc., who chaired the work group that proposed the document, sees it as a compliance checklist that pharmacy team members should use as an ongoing reference. “Most of these best practices are just good common sense. What we’ve tried to do is collect and organize them in a way that can help compounding pharmacies think carefully about what they’re doing when they prepare ketamine for a patient pursuant to a prescription.”

The ketamine best practices document makes clear APC’s stance on compounding the drug: “The Alliance for Pharmacy Compounding supports the responsible compounding and dispensing of ketamine products by pharmacies pursuant to a prescription,” it reads. The document covers:

- Pharmacist Legal Obligations
- Diversion Concerns
- Dosing Limits
- Dosage Forms
- Documentation
- Patient Education

- Constructive Transfer
- Ketamine Onboarding Checklist for 503B Sourcing

With the ketamine best practices, APC also released an updated [Statement on Constructive Transfer of Compounded Controlled Substance Drugs](#). The statement was first adopted by the organization in 2010.

Constructive transfer refers to U.S. Drug Enforcement Agency regulations stipulating to whom a pharmacy can and cannot dispense – or “transfer” – a patient-specific controlled substance drug.

The new revisions provide pharmacy compounders with an updated briefing, highlighting the DEA's recent limited enforcement actions regarding the constructive transfer of controlled substances to physicians. The statement also reiterates the position the DEA has taken regarding pharmacists and their obligations outlined in the federal Controlled Substances Act.

“The provided information aims to support pharmacists in making informed decisions regarding the delivery of controlled substances to prescribers for in-office administration, including certain dosage forms of ketamine,” said APC's Davis.

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.