Alliance for Pharmacy Compounding

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September 11, 2024

Anne Milgram
Administrator
Drug Enforcement Administration
600-700 Army Navy Drive
Arlington, VA 22202

Re: “Constructive Transfer” or Delivery of Controlled Substances: DEA Guidance

Dear Administrator Milgram:

On behalf of the Alliance for Pharmacy Compounding (APC), I am writing to express our strong support for the Drug Enforcement Administration's (DEA) efforts to finalize and publish the highly anticipated guidance document that addresses the dispensing and delivery of controlled substances.

APC is the voice for pharmacy compounding, representing more than 600 compounding pharmacies and facilities, including compounding pharmacists and technicians in both FDCA Section 503A and 503B settings, as well as prescribers, educators, researchers, and suppliers.

For over fifty years, the DEA has successfully enforced the central mandate of the Controlled Substances Act (CSA) to maintain a closed chain of distribution for those controlled substance drug products with a potential for abuse and diversion. We understand and applaud the DEA’s hard-fought mission to enforce the CSA, along with DEA regulations, which aim to minimize the potential for diversion and abuse while ensuring that controlled substances are dispensed and delivered to patients for legitimate medical purposes. However, the statutory language enacted in 1970 did not anticipate advances in medical technology and clinical therapies, which, in some cases, has created obstacles to ensuring needed patient access and successful medical outcomes.

One significant issue that has persisted is the requirement that controlled substances can only be dispensed and delivered to the “ultimate user,” per definitions found at 21 U.S.C. sections 802(10) and 802(27). According to the CSA, the dispensing and delivery of controlled substances are limited to the patient or a member of the patient’s household. This strict interpretation of the CSA prohibits any alternative dispensing or delivery of critically needed medicines, such as directly to the practitioner’s office for administration to the patient, thereby

reducing the risk of diversion. Some examples where delivery to the practitioner's office of needed controlled substance medications would in fact *decrease* the risk of diversion include compounded controlled substances used in intrathecal pain pumps for treatment of intractable pain and high dose sublingual ketamine used to treat major depressive disorder.

In 2016, the DEA issued a guidance letter stating that delivery or dispensing to a practitioner's office for administration to the patient was not explicitly prohibited by the CSA or DEA regulations. This guidance led to an ubiquitous industry practice where pharmacies delivered controlled substance medications to practitioner's offices in certain cases. We understand that delivery of these needed medications to practitioners' offices for administration to patients did not increase the potential for controlled substance diversion and abuse. However, the subsequent enactment of the SUPPORT Act in 2018 and the issuance of Executive Order 13891 in 2019 complicated the application of this guidance. With the revocation of this Executive Order by President Biden in 2021, the 2016 guidance letter is no longer accessible.

Recently, the DEA issued a letter indicating that, with the exception of the SUPPORT Act's narrow statutory exemption, all controlled substances must be dispensed or delivered to the patient or a member of their household. This interpretation prohibits delivery to locations like a DEA-registered practitioner's office or a nurse working as an agent of the practitioner in the field.

We commend the DEA for what we understand its intention to issue new guidance allowing the dispensing or delivery of controlled substances to a practitioner's office if the patient and practitioner execute a power of attorney (POA). This POA would authorize the practitioner to receive the medication on the patient's behalf for administration in the practitioner's office. This much-needed guidance will remove significant barriers to patient access and ensure the safe delivery of life-sustaining medications to patients that depend on them.

We eagerly await the issuance of this guidance and applaud the DEA's efforts to expand access to alternative pain therapies while maintaining the integrity of the controlled substance distribution system. We hope this is the first step towards further collaboration between the DEA and the industry to offer guidance to industry addressing this critically important patient access issue, and reduce obstacles to needed patient care.

Thank you for your attention to this important matter.

Sincerely,

Scott Brunner, CAE
Chief Executive Officer
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