December 22, 2020

Mr. Scott Brinks
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

Submitted via regulations.gov

RE: Implementation of the SUPPORT Act of 2018: Dispensing and Administering Controlled Substances for Medication-Assisted Treatment, Docket No. DEA-499

The College of Psychiatric and Neurologic Pharmacists (CPNP) appreciates the opportunity to comment on the Interim Final Rule (IFR) on the implementation of provisions in the Substance Use Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) Act. CPNP urges the DEA to consider the recommendations below that seek to remove obstacles and increase access to medication assisted therapy (MAT) for the multitude of Americans in need of treatment for opioid use disorders.

CPNP is a professional association of nearly 3,000 members who envision a world where all individuals living with mental illness, including those with substance use and neurologic disorders, receive safe, appropriate, and effective treatment. Most members are specialty pharmacists and Board Certified Psychiatric Pharmacists (BCPPs) who specialize in psychiatry, substance use disorder, psychopharmacology, and neurology.

Psychiatric pharmacists graduate with a Doctor of Pharmacy degree, a required six to eight years of higher education, and have more training specific to medication use than any other healthcare professional. Psychiatric pharmacists, a specialty within clinical pharmacy, are primarily board certified and residency-trained mental healthcare practitioners who have specialized training in providing direct patient care and medication management for the complete range of psychiatric and substance use disorders. Psychiatric pharmacists work as treatment team members but also in decision-making and leadership roles in state and federal organizations, academia, and industry.

The need for substance use services, including for opioid use disorders (OUD), is greater than ever and services are not keeping up with demand. Deaths due to drug overdose have increased more than threefold over the past 19 years (from 6.1 deaths per 100,000 people in 1999 to 20.7 deaths per 100,000 people in 2018).[1] One of the most insidious effects of the COVID-19 crisis is its impact on efforts to fight the opioid epidemic. CDC estimates that more than 81,000 drug overdose deaths occurred in the twelve months ending in May 2020.[2]

[1] Centers for Disease Control and Prevention (CDC), National Center for Health Statistics. Multiple Cause of Death 1999-2018 on CDC WONDER Online Database. Accessed at http://wonder.cdc.gov/mcd-icd10.html.
[2] CDC Press Release. Overdose Deaths Accelerating During COVID-19: Expanded Prevention Efforts Needed. 12.17.2020. Accessed at https://www.cdc.gov/media/releases/2020/p1218-overdose-deaths-covid-19.html.

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At the same time patients are facing external stressors that can trigger relapse, the public health emergency has upended existing MAT programs, which were already, in many cases, struggling to meet patient need. To expand access to MAT, CPNP supports the *Mainstreaming Addiction and Treatment Act* to eliminate the DATA waiver requirement to allow buprenorphine to be utilized like other Schedule III drugs. While this is not under the authority of DEA to change, CPNP believes it is important to continue to state publicly that more needs to be done to increase access to substance use treatment and removal of the DATA waiver requirement is an important step. In the absence of Congressional action, CPNP has recommended that the Health and Human Services (HHS) Secretary use the authority granted by the Comprehensive Addiction and Recovery Act (CARA) (P.L. 114-198) to revise the "qualifying other practitioner" requirements to include psychiatric pharmacists as eligible for the DATA waiver. At present, the exclusion of psychiatric pharmacists from X-waiver eligibility has deprived patients of access to MAT at a time when demand for care far outstrips capacity.

Recommendations

1. **Clarify that practitioners who are not DATA-waived can administer buprenorphine pursuant to a lawful prescription by a DATA-waived practitioner**

Under 21 U.S.C. § 829a and 21 CFR part 1306.07(f), (1) a qualifying practitioner (i.e., a DATA-waived practitioner) acting within the scope of DATA 2000 must issue a lawful prescription for an injectable buprenorphine product for Opioid Use Disorders (OUD), and (2) the pharmacy can then deliver the medication to *either* the DATA-waived prescriber or the practitioner who will administer it to the patient. Congress did not expressly require that the latter be a "qualifying practitioner," rather only a "practitioner" who will administer the medication.

There is confusion as to whether non-DATA-waived practitioners and pharmacists can administer an injectable buprenorphine product pursuant to a valid prescription from a DATA-waived practitioner. As such, the current pharmacy practice is to only allow the injectable medication prescribed by the DATA-waived practitioner to be sent to the registered address of the DATA-waived practitioner.

Such clarification is necessary to avoid delays or disruptions in care when a waivered practitioner is unavailable to administer the medication. This change is particularly necessary for expanding treatment to patients who do not have access to a waivered practitioner in their community but can be prescribed the medication via telehealth, including during public health emergencies, and have the medication administered by a practitioner or pharmacist in their community.

CPNP requests that DEA clarify in the final rule that 21 CFR part 1306.07(f) permits practitioners and pharmacists who are not DATA-waived to administer buprenorphine injections pursuant to a valid prescription from a DATA-waived practitioner.

2. **Increase the number of days a practitioner can administer buprenorphine after receipt of the medication from 14 day to 60 days pursuant to authority granted under the SUPPORT Act**

In order to combat the ongoing opioid epidemic, it is vital that all individuals diagnosed with opioid use disorder have the necessary access to important forms of medication for treatment, namely long acting injectable formulations of buprenorphine. The SUPPORT Act's requirement for practitioners to administer injectable buprenorphine to the patient within 14 days of the date the medication is received does not account for delays in shipping from specialty pharmacies and is proving unworkable for providers and patients. Problematically, if an injectable buprenorphine product is not administered within 14 days of receipt, it must be destroyed.

The SUPPORT Act grants the DEA authority to modify the 14-day administration limit however, the IFR retains the 14-day limit. Key to that modification was ensuring that long acting injectable buprenorphine products did not pose a risk of diversion, to be determined by a GAO study. GAO subsequently found a reduced risk of diversion in its August 2020 Report ,[3] which states that "because patients lack control over the administration of injectable and implantable buprenorphine, patients receive consistent treatment exposure and therefore experienced improved health outcomes and reduced opportunities for diversion."

CPNP urges the DEA exercise its authority to extend the time limit in which practitioners must administer the medication to the patient to 60 days.

3. DEA should treat Psychiatric Pharmacists as practitioners who can administer injectable buprenorphine to the extent permitted under state law

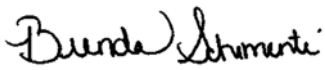
Psychiatric pharmacists also have a deep understanding of MAT that extends beyond that of most other healthcare providers. When included in providing MAT services, psychiatric pharmacists' involvement has been demonstrated to improve patient adherence and success with buprenorphine treatment for OUD; reduce per patient dosing of buprenorphine through improved medication management, monitoring and titration; and reduce overall costs for treating patients with SUDs by relieving providers from services including medication management, counseling, monitoring and follow-ups.[4]

The Controlled Substances Act (CSA) defines "practitioner" as "a physician, . . . pharmacy . . . or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices . . ., to distribute, dispense, . . . administer . . . a controlled substance in the course of professional practice or research.[5]" As such, a pharmacist who is employed by and acting under the authority of a DEA-registered pharmacy, clinic or physician, and authorized by state law to dispense controlled substances, should be considered a "practitioner" under the CSA.

Given that 21 U.S.C. § 829a and the IFR use the term "practitioner," the statutory definition of practitioner should apply to the rule and, therefore, CPNP urges that psychiatric pharmacist be considered a practitioner who can administer injectable buprenorphine pursuant to a valid prescription and as authorized under state law.

CPNP appreciates the opportunity to provide comments on these issues that are critical to increasing access and reducing barriers in access to medication assisted treatment for opioid use disorders. If you have any questions or require any additional information, please do not hesitate to contact me or our Health Policy Consultant, Laura Hanen at laura.hanen@faegredrinker.com or 202-230-5385.

Sincerely



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[3] *Opioid Use Disorder: Treatment with Injectable and Implantable Buprenorphine*, GAO (Aug. 2020). Accessed at https://www.gao.gov/assets/710/708581.pdf.

[4] Goldstone LW, DiPaula BA, Caballero J, Park SH, Price C, Slater MZ. Improving medication-related outcomes for patients with psychiatric and neurologic disorders: value of psychiatric pharmacists as part of the health care team. Mental Health Clinician. 2015;5(1):1-28. Accessed at https://doi.org/10.9740/mhc.2015.01.001.

[5] 21 U.S.C. § 802