



April 21, 2020

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

Submitted via regulations.gov

RE: Registration Requirements for Narcotic Treatment Programs With Mobile Components Proposed Rule, Docket No. DEA-459

On behalf of College of Psychiatric and Neurologic Pharmacists (CPNP), I am writing to express our support for the Drug Enforcement Administration's (DEA) proposed rule revising the existing regulations for narcotic treatment programs (NTPs) to allow a mobile component associated with the registered program to be considered a coincident activity. These revisions will allow NTPs to provide treatment services for opioid use disorder (OUD) to patients who may not have been able to access these services otherwise.

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, as a specialty within clinical pharmacy, are residency-trained and board certified mental healthcare practitioners who have specialized training in providing direct patient care and treatment for psychiatric disorders including OUD and other substance use disorders (SUDs). As such, psychiatric pharmacists are medication experts that can play a significant role as part of an integrated care team to ensure proper use of medication assisted treatment (MAT) for those dealing with OUDs.

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

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from services including medication management, counseling, monitoring and follow-ups.¹

The Opioid Epidemic and the Need for NTPs

Rates of opioid misuse remain high throughout the country – as do overdoses and overdose deaths – and individuals seeking care for OUD should be able to quickly and safely access treatment.

Approximately 10.3 million people in 2018 had misused opioids in the past year. An estimated 2 million people had an OUD which included 1.7 million people with a prescription pain reliever use disorder and 0.5 million people with a heroin use disorder. However, less than 20% of those with an OUD received treatment at a specialty facility.² Opioids were involved in approximately 70% (46,802) of drug overdose deaths during 2018.³ Action must be taken to save and enhance lives by closing the treatment gap and providing care to the millions of Americans with OUD.

Benefits of Mobile Components for NTPs

NTPs dispense narcotic drugs in schedules II-V at a remote location for the purpose of maintenance or detoxification treatment. The proposed rule would help eliminate the treatment gap by allowing NTPs to use a conveyance, or mobile unit, without having to obtain a separate registration with the DEA. This would allow more individuals to access treatment in a convenient manner.

Under current regulations, an NTP would have to build a brick and mortar facility to treat patients in an underserved area and the proposed rule notes the significant capital and operating expenses associated with doing so. Operating a mobile unit is less expensive for the NTP and allows for greater geographic coverage and treatment availability. Importantly, the proposed rule does not change the requirements for the types of personnel that are authorized to dispense controlled substances. Many NTPs already operate mobile units and these revisions will allow more flexibility, therefore allowing even more NTPs to provide treatment via mobile units.

This proposed rule will be especially beneficial for patients in rural and underserved areas and individuals for whom traveling long distances from their homes may be inadvisable or impossible, such as the elderly or individuals with chronic medical or mental health conditions. This change has already proven to be helpful for incarcerated individuals and correctional facilities who may be having logistic difficulties arranging transport for individuals to an NTP. With the revisions, NTPs may be able to bring their mobile unit to a correctional facility providing treatment for a vulnerable population.

Security, Recordkeeping, Reporting, and Inventory Requirements for Mobile Components

The rule requires NTPs to secure controlled substances in a locked safe that is bolted or cemented to the conveyance. The safe must have an electronic alarm system tied into a 24 hour service. The safe must be emptied each day and secured at the registered location.

¹ 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. *Ment Health Clin* [Internet]. 2015;5(1):1-28. DOI: 10.9740/mhc.2015.01.001.

² Substance Abuse and Mental Health Services Administration. (2019). Key substance use and mental health indicators in the United States: Results from the 2018 National Survey on Drug Use and Health (HHS Publication No. PEP19-5068, NSDUH Series H-54). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from <https://www.samhsa.gov/data/>

³ Wilson N, Kariisa M, Seth P, Smith H IV, Davis NL. Drug and Opioid-Involved Overdose Deaths — United States, 2017–2018. *MMWR Morb Mortal Wkly Rep* 2020;69:290–297. DOI: <http://dx.doi.org/10.15585/mmwr.mm6911a4>external icon

In terms of recordkeeping, DEA proposes that the records generated during the operations of a mobile component of an NTP shall be maintained at the location of the registered NTP in a manner that meets all applicable security and confidentiality requirements, and must be readily retrievable. In terms of reporting, DEA is proposing that an NTP or its mobile component may also use an automated/computerized data processing system for the storage and retrieval of the program's dispensing records that is approved by the DEA. The system must maintain the same information as required in paper records; have an off-site back-up; have the capability of producing a daily hard copy printout of the program's dispensing records, which is then initialed appropriately by each person who dispensed medication to the program's patients; can produce summary reports; and maintain records for two years or longer depending on the state requirement. We laud the DEA for evolving to an electronic record keeping system from a paper one.

Conclusion

CPNP appreciates the opportunity to provide comments on the proposed rule. We agree with the DEA that this rule would make maintenance and detoxification treatments more widely available, which would be a net benefit to society.

CPNP appreciates the opportunity to provide comments on this issue. 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

A handwritten signature in black ink, appearing to read "Brenda Schimenti".

Brenda K. Schimenti

Executive Director

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