



December 29, 2020

Timothy J. Shea, Acting Administrator
Drug Enforcement Administration (DEA)
U.S. Department of Justice (DOJ)
8701 Morrissette Drive
Springfield, VA 22152

For electronic submission via [regulations.gov](https://www.regulations.gov)

Re: **RIN 1117-AB55 Docket No. DEA-499**, SUPPORT Act Interim Final Rule

Dear Mr. Shea:

The Center for U.S. Policy (CUSP) would like to provide its feedback on the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018 (SUPPORT Act) Interim Final Rule published on November 2, 2020 and effective on October 30, 2020.

CUSP is a nonpartisan, not-for-profit research and education organization. We are dedicated to advancing innovative solutions to some of our nation's most pressing challenges, including the substance misuse and drug poisoning epidemic. CUSP is home to the Finding the 'ME' in Treatment initiative, which promotes individualized treatment for persons with substance use disorders.

CUSP is generally supportive of the Interim Final Rule. We respectfully request that the DOJ take three specific actions related to the following sections of the SUPPORT Act:

Section 829a: Administering Practitioner Without a DATA 2000 Waiver

Under CUSP's reading of both Section 829a of the SUPPORT Act and the Interim Final Rule, a pharmacy may deliver an implantable or injectable controlled medication prescribed by a practitioner with a DATA 2000 waiver to a DEA-registered practitioner for maintenance or detoxification treatment. The DEA-registered practitioner is not required to possess a DATA 2000 waiver.

Nevertheless, pharmacies and practitioners remain fearful that they will be subjected to DOJ criminal or administrative enforcement action if they practice in accordance with this interpretation of Section 829a.

Under 5 U.S.C. §553(c), after an agency considers public comments on a rule, the agency shall incorporate in the rule a concise general statement of its basis and purpose. We ask that the DOJ include in its statement of the basis and purpose of the Interim Final Rule an express acknowledgment that the SUPPORT Act permits a DEA-registered practitioner who does not hold a DATA 2000 waiver to receive delivery of and administer an implantable or injectable

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controlled medication prescribed by a practitioner with a DATA 2000 waiver for maintenance or detoxification treatment.

Section 829a(a)(3): Pharmacist as Administering Practitioner

Under CUSP's reading of both Section 829a(a)(3) of the SUPPORT Act and the Interim Final Rule, a pharmacy may deliver an implantable or injectable controlled medication prescribed by a practitioner with a DATA 2000 waiver to a DEA-registered pharmacist for maintenance or detoxification treatment. The DEA-registered pharmacist must be authorized to implant or inject controlled medications in the state in which the medication administration takes place.

Nevertheless, pharmacies and pharmacists remain fearful that they will be subjected to DOJ criminal or administrative enforcement action if they practice in accordance with this interpretation of Section 829a(a)(3).

Under 5 U.S.C. §553(c), after an agency considers public comments on a rule, the agency shall incorporate in the rule a concise general statement of its basis and purpose. We ask that the DOJ include in its statement of the basis and purpose of the Interim Final Rule an express acknowledgment that the SUPPORT Act permits a pharmacist authorized under state law to implant or inject controlled medications to administer in such state an implantable or injectable controlled medication prescribed by a practitioner with a DATA 2000 waiver for maintenance or detoxification treatment.

Section 829a(a)(5): Time Limit

A practitioner who receives delivery of an implantable or injectable controlled medication prescribed to a patient for maintenance or detoxification treatment should be given *more than* 14 days after delivery to administer such medication.

The 14-day time limit set forth in the SUPPORT Act and the Interim Final Rule fails to account for scheduling changes, missed office visits, and delays caused by health insurers. It will result in the waste of valuable medications, unnecessary increases in health care costs, and most importantly, an inability for individuals with substance use disorders to access individualized treatments that are not readily susceptible to post-dispensing diversion.

Under Section 829a(b)(2) of the SUPPORT Act, the Attorney General, in coordination with the Secretary of Health and Human Services, may modify the number of days described in subsection (a)(5). CUSP asks that the Attorney General modify the time limit.

Specifically, CUSP requests that a practitioner who receives delivery of an implantable or injectable controlled medication prescribed to a patient for maintenance or detoxification treatment be given 60 days after delivery to administer such medication.

In conclusion, CUSP asks that the DOJ take the following actions:

1. State in plain language that a DEA-registered practitioner who does not hold a DATA 2000 waiver may receive delivery of and administer an implantable or injectable controlled medication prescribed by a practitioner with a DATA 2000 waiver for maintenance or detoxification treatment;
2. State in plain language that a pharmacist authorized under state law to implant or inject controlled medications may administer in such state an implantable or injectable controlled medication prescribed by a practitioner with a DATA 2000 waiver for maintenance or detoxification treatment; and
3. Modify the time limit so that a practitioner who receives delivery of an implantable or injectable controlled medication prescribed to a patient for maintenance or detoxification treatment has 60 days after delivery to administer such medication.

Please contact us if you have questions or would like clarifications. Thank you.

Sincerely,



Michael C. Barnes
Chairman