

Congress of the United States
Washington, DC 20510

October 6, 2020

The Honorable Timothy J. Shea
Acting Administrator
U.S. Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

Dear Acting Administrator Shea:

As rates of opioid overdose deaths rise nationwide and the coronavirus disease 2019 (COVID-19) continues to have an outsized impact on opioid use disorder (OUD) patients, we write to again urge the Drug Enforcement Administration (DEA) to finalize “partial fill” regulations.

In 2016, the *Comprehensive Addiction Treatment and Recovery Act* (CARA) was signed into law with bipartisan support.¹ Section 702 of the legislation allows patients to take home only a portion of their opioid prescription and then return to have the remainder filled if their pain continues, thereby affording both patients and doctors greater control over the amount of opiates in their possession and in circulation.² However, the DEA’s current definition of “partial fill” only allows a “partial fill” if the pharmacist does not have enough medication to completely fill a prescription.³ This outdated definition prevents pharmacists from fulfilling the intent of Section 702.

As you may be aware, we have previously written to your agency to request that it update its “partial fill” regulations so that Section 702 can be fully implemented.⁴ While the Department of Health and Human Services (HHS) published its final rule on partial fill,⁵ DEA has failed to issue its proposed rule, despite assurances in recent years that “this proposed rule is a top priority” for the agency.⁶ DEA’s failure to act essentially renders the new HHS rule useless.

¹ Comprehensive Addiction and Recovery Act of 2016, S. 524, <https://www.congress.gov/bill/114th-congress/senate-bill/524/text>.

² Public Law 114-198, Section 702, <https://www.congress.gov/114/plaws/publ198/PLAW-114publ198.pdf>.

³ 21 C.F.R. § 1306.13.

⁴ Office of Senator Elizabeth Warren, Press Release, July 26, 2018, <https://www.warren.senate.gov/oversight/letters/lawmakers-urge-dea-to-update-partial-filling-regulations-for-controlled-substances>.

⁵ Department of Health and Human Services, “HIPAA Administration Simplification Information Bulletin,” January 24, 2020, <https://www.cms.gov/files/document/d0-final-rule-information-bulletin.pdf>.

⁶ Letter from DEA Section Chief Sean R. Mitchell to Senator Elizabeth Warren, April 5, 2018, <https://www.warren.senate.gov/imo/media/doc/2018.7.26%20DEA%20Partial%20Fill%20Regs%20Update%20Letter.pdf>.

The opioid crisis, meanwhile, continues to devastate communities across the country, exacerbated by the large number of opioids currently in circulation. More than 50,000 Americans died in 2019 due to an opioid overdose – with tens of thousands more likely experiencing a non-fatal overdose.⁷ More than 10 million people aged 12 and older reported abusing an opioid in the past year, with over 50 percent of those who abused a prescription pain reliever reporting that they obtained it from a friend or family member, and just 37 percent as a prescription from their doctor.⁸ In 2015, doctors prescribed three times more opioids than they did in 1999, and more than two thirds of patients prescribed opioids reported having large amounts of unused opioids after their procedures.⁹ Additionally, since the initial outbreak of the COVID-19 pandemic, 40 states have reported increases of opioid overdoses.¹⁰

The ready availability of opioids to millions of Americans and the disruption of life-saving treatment during the COVID-19 pandemic have compounded this ongoing national crisis. Defining “partial fill” and fully implementing Section 702 of CARA will reduce the number of prescription opioids in circulation, a crucial step in addressing the opioid crisis that is devastating communities across the country. DEA’s continuing foot-dragging on this issue puts Americans at risk.

Given this urgent need and DEA’s inaction, we respectfully request that you provide a status update, including the date by which DEA expects to finalize and make public the partial fill regulations. We also ask that you provide us a staff-level briefing on this matter no later than October 20, 2020.

We appreciate your attention to this matter.

Sincerely,

Elizabeth Warren
United States Senator

Katherine Clark
Member of Congress

Dianne Feinstein
United States Senator

Steve Stivers
Member of Congress

Shelley Moore Capito
United States Senator

⁷ Centers for Disease Control and Prevention, “Provisional Drug Overdose Death Counts,” <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>

⁸ Center for Behavioral Health Statistics and Quality. (2020). *Results from the 2019 National Survey on Drug Use and Health: Detailed tables*. Rockville, MD: Substance Abuse and Mental Health Services Administration. Retrieved from <https://www.samhsa.gov/data/>.

⁹ National Institutes of Health, “Prescription opioids commonly unused after surgery” a systematic review,” Bicket et al., November 1, 2018, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5701659/>.

¹⁰ American Medical Association, “Issue brief: Reports of increase in opioid-related overdose and other concerns during COVID-19 pandemic,” September 8, 2020, <https://www.ama-assn.org/system/files/2020-09/issue-brief-increases-in-opioid-related-overdose.pdf>.