

Congress of the United States
Washington, DC 20510

July 26, 2018

Acting Administrator Uttam Dhillon
United States Drug Enforcement Administration
8701 Morrisette Drive
Springfield, VA 22152

Dear Acting Administrator Dhillon:

We write today to urge you to take prompt action to update outdated regulations on the “partial filling” of certain controlled substances.

Section 702 of the 2016 *Comprehensive Addiction and Recovery Act* (CARA) explicitly authorized the partial filling of Schedule II controlled substances, unless prohibited by state law.¹ This provision amended the Controlled Substance Act to allow patients to take home a portion of their opioid prescription and return to the pharmacy to fill the remainder of the same prescription if their pain persists. This provision incorporated language from the *Reducing Unused Medications Act*, which was introduced to address outdated Drug Enforcement Administration (DEA) regulations on partial fill.

Since CARA was signed into law in July 2016, we have continued to hear concerns from stakeholders about the lack of DEA action to update its partial fill regulations to align with existing law. In December 2017, we wrote to former DEA Acting Administrator Patterson with these concerns, requesting that the DEA swiftly update its regulations related to the partial filling of Schedule II controlled substances to provide clarification for prescribers and pharmacists working to implement programs to partially fill opioid prescriptions as outlined in CARA.² In April 2018, DEA confirmed that they were “working on drafting a proposed rule that will both implement Section 702 of CARA and harmonize those statutory requirements with existing regulations involving the partial filling of schedule II controlled substances” and that “this proposed rule is a top priority for the DEA.”³ However, nearly two years after CARA’s enactment, DEA has still not presented a proposed rule.

Pharmacists and prescribers have repeatedly expressed their concern that DEA’s lack of action on this issue poses a barrier to their complete implementation of the partial filling authority established in CARA. In 2016, an estimated 42,000 individuals died from opioid overdoses in the U.S, and it is likely that hundreds of thousands more experienced a nonfatal overdose.⁴ The misuse and diversion of unused opioid medications are a key contributor to this

¹ Comprehensive Addiction and Recovery Act of 2016, S.524, Sec. 702, <https://www.congress.gov/114/plaws/publ198/PLAW-114publ198.pdf>.

² Letter from Senators Elizabeth Warren, Shelley Moore Capito, Chuck Grassley and Dianne Feinstein and Representatives Katherine Clark and Steve Stivers to DEA Acting Administrator Robert Patterson, December 21, 2017, https://www.warren.senate.gov/files/documents/2017_2_21%20DEA%20Partial%20Fill%20Letter.pdf.

³ Letter from DEA Section Chief Sean R. Mitchell to Senator Elizabeth Warren, April 5, 2018.

⁴ Centers for Disease Control and Prevention, “Data Overview,” <https://www.cdc.gov/drugoverdose/data/index.html>; Association of State and Territorial Health Officials, “Opioid-

crisis, with over 70 percent of people who misuse prescription painkillers getting them from a friend, relative, or doctor.⁵ While opioid prescriptions have decreased in recent years, the rate of prescribing in 2015 was still three times higher than in 1999.⁶

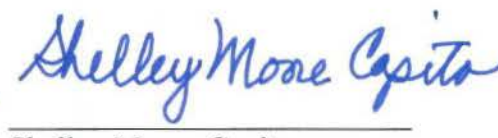
Section 702 of CARA will help reduce the number of opioids that could be misused in homes across the country. However, this can only be fully implemented once DEA takes the necessary steps to amend its outdated guidance. While CARA amended the statutory definition of “partial filling,” DEA regulations currently only address “partial filling” in the limited circumstance when a pharmacist does not have enough medication on hand to fill a full prescription.⁷ This discrepancy between federal law and DEA regulations has created confusion and concern on the part of prescribers and pharmacists that they may be violating DEA regulations if they partially fill a Schedule II prescription.

As states, health care providers, health insurance plans, and pharmacies work to lower unnecessary opioid prescriptions and find alternative and appropriate ways to address pain, we must use every tool in our toolbox to assist them. Once again, we urge you to move swiftly to resolve the current discrepancy between outdated regulatory definitions of “partial filling” and changes to federal law made by Section 702 of CARA by issuing regulations to implement this provision.

Sincerely,



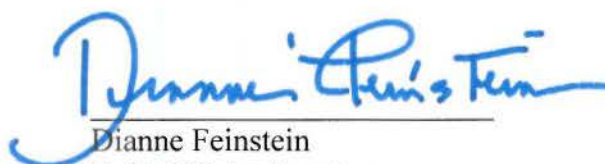
Elizabeth Warren
United States Senator



Shelley Moore Capito
United States Senator



Chuck Grassley
United States Senator



Dianne Feinstein
United States Senator



Katherine Clark
Member of Congress



Steve Stivers
Member of Congress

related Overdoses as a Reportable Condition,” November 16, 2017, <http://www.astho.org/StatePublicHealth/Opioid-related-Overdoses-as-a-Reportable-Condition/11-16-17/>.

⁵ Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality, “How people obtain the prescription pain relievers they misuse,” January 12, 2017, https://www.samhsa.gov/data/sites/default/files/report_2686/ShortReport-2686.html.

⁶ Centers for Disease Control and Prevention, National Center for Injury Prevention and Control, “CDC Vital signs: Opioid Prescribing,” July 2017, <https://www.cdc.gov/vitalsigns/pdf/2017-07-vitalsigns.pdf>.

⁷ 21 C.F.R. § 1306.13