

Congress of the United States
Washington, DC 20510

December 21, 2017

Acting Administrator Robert Patterson
United States Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

Dear Acting Administrator Patterson:

We are writing to urge you to swiftly update Drug Enforcement Administration (DEA) regulations and guidance related to the partial filling of Schedule II controlled substances. Updated regulations and guidance will give prescribers and pharmacists additional clarity about the new provisions of federal law and other steps that may be taken to better address the nation's opioid crisis.

The opioid crisis continues to have devastating effects across this country. More than 33,000 Americans died from opioid-related drug overdoses in 2015, and prescription painkillers continue to be a major contributor to the epidemic.¹ According to the Centers for Disease Control and Prevention (CDC), while opioid prescriptions have decreased in recent years, the rate of prescribing was still three times higher in 2015 compared to 1999.² During the same period from 1999 to 2015, opioid-related overdose deaths quadrupled.³

Large amounts of unused medications are a key contributor to this crisis. A recent report found that between 67% and 92% of patients who underwent orthopedic, thoracic, obstetric, or general surgical procedures reported they had unused opioids remaining after the procedures.⁴ In most cases, these unused prescription drugs are left in the medicine cabinet, and can be easily misused by the patient or diverted to friends and family.⁵ According to the Substance Abuse and Mental Health Services Administration, over 70 percent of people who misuse prescription painkillers got them from a friend, relative, or doctor.⁶ The DEA's National Prescription Drug Take Back days are a useful tool for safely disposing of unused and unwanted prescription drugs – but they aren't enough. Often, people don't utilize these safe disposal practices and medications continue to sit in the cabinet.

¹ "Opioid Overdose," *Centers for Disease Control and Prevention* (online at: <https://www.cdc.gov/drugoverdose/index.html>). Accessed Dec. 15, 2017.

² "Opioid Prescribing," *CDC Vital Signs* (July 2017) (online at: <https://www.cdc.gov/vitalsigns/pdf/2017-07-vitalsigns.pdf>).

³ "Understanding the Epidemic," *Centers for Disease Control and Prevention* (online at: <https://www.cdc.gov/drugoverdose/epidemic/index.html>). Accessed Dec. 14, 2017.

⁴ Bicket, Long, and Pronovost, "Prescription Opioid Analgesics Commonly Unused After Surgery," *JAMA Surgery* (November 2017) (online at: <https://jamanetwork.com/journals/jamasurgery/article-abstract/2644905>).

⁵ Lewis, Cucciare, and Trafton, "What do patients do with unused opioid medications?" *The Clinical Journal of Pain* (August 2014) (online at: <https://www.ncbi.nlm.nih.gov/pubmed/24281287>).

⁶ Lipari and Hughes, "How people obtain the prescription pain relievers they misuse," *SAMHSA* (January 12, 2017) (online at: https://www.samhsa.gov/data/sites/default/files/report_2686/ShortReport-2686.html).

Congress has taken important steps to address the significant role that unused prescription drugs have played in the opioid epidemic, including by enacting bipartisan legislation introduced by Senators Warren and Capito, and Representatives Clark and Stivers, to reduce the amount of unused opioid medications in circulation. This legislation, incorporated as Section 702 of the *Comprehensive Addiction and Recovery Act (CARA)*, amended the *Controlled Substances Act* to enable patients or physicians to request a “partial fill” of any Schedule II medication, including prescription opioids like OxyContin and Vicodin.⁷

Partial fill enables a patient to request only a few days’ worth of their prescription be filled, and leaves them the option to return to the pharmacy for the remainder of their prescription if they still require additional pain treatment. The partial fill legislation empowers patients to have conversations with their health providers and pharmacists about how many prescription opioids they feel comfortable having in their home, and to go home from the pharmacy with an amount appropriate for them – while still having the option to return for the rest.

The *Comprehensive Addiction and Recovery Act* became law in July 2016 and explicitly authorizes the partial filling of Schedule II controlled substances, unless prohibited by state law.⁸ However, a number of states, medical organizations, and pharmacies have expressed concerns about the lack of action by the DEA to update its partial-fill regulations to align with current law. DEA regulations, issued in 2010, only address “partial fill” in limited circumstances for pharmacists and Long Term Care Facilities. For instance, DEA regulations state: “The partial filling of a prescription for a controlled substance listed in Schedule II is permissible if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription... no further quantity may be supplied beyond 72 hours without a new prescription.”⁹

These outdated DEA regulations, which include a different definition of “partial filling” from the definition provided in CARA, have led to significant confusion on the part of pharmacists and prescribers. These health care providers are critical partners in the fight against the opioid epidemic but are reluctant to move forward with implementation of the law or to proactively implement programs to partially fill initial opioid prescriptions until the DEA updates its regulations. In response to recent letters from Senators Warren and Capito inquiring about their implementation of partial fill authorities, the American Pharmacists Association (APhA), the American Association of Colleges of Pharmacy (AACP), and the National Association of Chain Drug Stores (NACDS) indicated that many of their members have expressed significant confusion regarding outdated DEA regulations, and that the outdated definition of “partial filling” is contradictory to the current law.

For instance, APhA wrote that they are “aware of significant confusion regarding partial fills because DEA has yet to update their regulations or clarify their position regarding partial

⁷ Comprehensive Addiction and Recovery Act of 2016, S. 524, 114th Cong. § 702 (2016) (online at: <https://www.congress.gov/114/plaws/publ198/PLAW-114publ198.pdf>).

⁸ Controlled Substances Act, 21 U.S.C. § 829 (online at: <https://www.deadiversion.usdoj.gov/21cfr/21usc/829.htm>).

⁹ 21 C.F.R. § 1306.13 (online at: https://www.deadiversion.usdoj.gov/21cfr/cfr/1306/1306_13.htm).

fills.”¹⁰ According to AACP, “Pharmacy is a highly regulated profession and while state regulations are typically reasonably easy to interpret, it is sometimes much more difficult to understand the DEA position on controlled substances and their management.”¹¹ According to the NACDS, “pharmacies are concerned about potential DEA enforcement action for partially filling controlled substance prescriptions.”¹²

Medical member organizations are also ready and willing to inform their members about partial fill policies, but are awaiting clear federal guidance before they disseminate additional information. APhA, the Association of American Medical Colleges (AAMC), and the American Dental Association (ADA) have all indicated that they would be able to disseminate more information about partial fill policies once the DEA has updated its regulations. APhA said, “when DEA updates their regulations or issues additional clarification regarding partial fills, APhA will use its opioid resource center and other communication tools to increase members’ awareness of federal changes.”¹³ AAMC expressed similar sentiments, writing, “as the Drug Enforcement Administration (DEA) begins to implement the law, we will have the opportunity to share this information as appropriate through our various membership newsletters, webinars, or other communications.”¹⁴ The ADA said they “plan to alert [their] members and share practical resources to help them comply once the final regulations are published.”¹⁵

Updating these regulations and providing clarity on the DEA’s implementation of the law will help give providers a powerful tool for implementing recent CDC opioid prescribing guidelines, which recommend prescribing “only the number of days that the pain is expected to be severe enough to require opioids.” For acute pain, the CDC observes that an opioid prescription of “three days or less is often enough; more than seven days is rarely needed.”¹⁶ A recent study of over 215,000 individuals showed that for patients dealing with different medical procedures, the optimal length of an opioid prescription varied. The study concluded that “the optimal length of opioid prescriptions lies between... 4 to 9 days for general surgery procedures, 4 to 13 days for women’s health procedures, and 6 to 15 days for musculoskeletal procedures.”¹⁷ The definition of “partial filling” provided in CARA enables patients to take home a limited number of pills, only for the expected duration of the pain severe enough to require opioids, and return to the pharmacy to pick up more of their prescription if acute pain persists.

Encouraging prescribers and pharmacists to embrace partial fill policies for their patients will help to reduce the number of opioids that could be misused in homes across the country. We urge you to move swiftly to resolve the current discrepancy between outdated regulatory definitions of “partial fill” and changes to federal law made by Section 702 of the

¹⁰ APhA letter to Senators Warren and Capito (September 29, 2017).

¹¹ AACP letter to Senators Warren and Capito (September 21, 2017).

¹² NACDS letter to Senators Warren and Capito (September 27, 2017).

¹³ APhA letter to Senators Warren and Capito (September 29, 2017).

¹⁴ AAMC letter to Senators Warren and Capito (October 4, 2017).

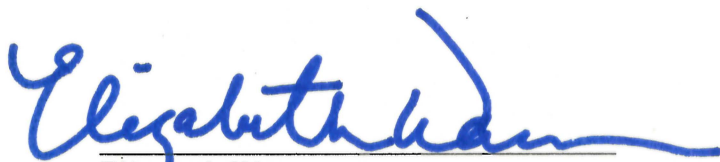
¹⁵ ADA letter to Senators Warren and Capito (September 28, 2017).

¹⁶ “Opioid Prescribing,” CDC Vital Signs (July 2017) (online at: <https://www.cdc.gov/vitalsigns/pdf/2017-07-vitalsigns.pdf>).

¹⁷ Scully, Schoenfeld, and Jiang, “Defining Optimal Length of Opioid Pain Medication Prescription After Common Surgical Procedures,” *JAMA Surgery* (September 27, 2017) (online at: <https://jamanetwork.com/journals/jamasurgery/article-abstract/2654949?redirect=true>).

Comprehensive Addiction and Recovery Act by issuing regulations to implement this provision. We urge you to use these regulations and guidance to provide clarification for prescribers and pharmacists working to implement programs to partially fill opioid prescriptions. Thank you for your immediate attention to the issuance of the partial fill regulations and guidance.

Sincerely,



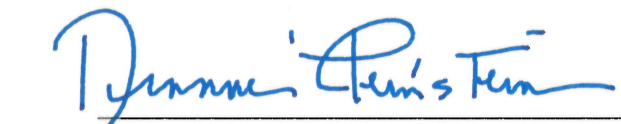
Elizabeth Warren
United States Senator



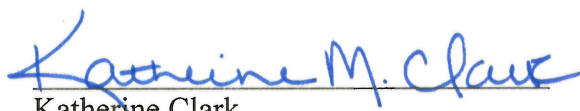
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United States Senator




Chuck Grassley
United States Senator



Dianne Feinstein
United States Senator



Katherine M. Clark
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