Advocacy Briefing: S.3257 Facilitating Access to Medication for Opioid Use Disorder

EXECUTIVE SUMMARY

I. Introduction

On November 2, 2022, Aimed Alliance hosted a legislative briefing on facilitating access to medications for opioid use disorders ("MOUD"). Aimed Alliance is a non-profit health policy organization that seeks to protect and enhance the rights of healthcare consumers and providers. The objective of this legislative briefing was to educate patient and professional advocacy groups on the current state of drug poisoning in the United States, and the need for the United States Senate to pass S.3257 to expand the "14-day limit" to 60-days to ensure patients with opioid use disorder (OUD) can access their treatments.

The legislative briefing featured presentations from Dr. Stacey Sigmon, Associate Professor Medicine at the University of Vermont College of Medicine; Christophe McCann, MPA, Legislative Director for Congresswoman Madeleine Dean; K. Shiek Pal, Esq., Senior Counsel to US Senator Jeanne Shaheen; and Michael Barnes, Esq., Counsel to Aimed Alliance.

II. The State of Opioid Use Disorder in the United States

The legislative briefing started with Dr. Sigmon discussing the current state of opioid-involved poisonings and OUD. An individual can develop an OUD when their opioid use causes significant impairment and distress.[1] Dr. Sigmon explained that opioid misuse and dependence have reached epidemic proportions in the United States and continue to pose a threat to national public health and safety. Opioid poisonings have increased since 2017 as a result of both synthetic opioids being introduced in the US and the COVID-19 pandemic. In addition to placing the lives of individuals at risk, OUD and fatal opioid poisonings are estimated to cost the health care system $1.02 trillion.[2]

Fortunately, there are treatments to treat OUD. Dr. Sigmon explained that treatments for OUD are efficacious and reduce morbidity, mortality, and the spread of infectious diseases. Further, she explained that while opioid antagonist treatments such as methadone and buprenorphine can be effective, patients with OUD can experience difficulties in treatment compliance with these therapeutics. While both methadone and buprenorphine are MOUDs, each medication has unique benefits and access barriers.

Methadone is a full opioid antagonist that prevents withdrawal, reduces cravings for opioids, and blocks the effects of exogenous opioids. Methadone is typically administered in a liquid form orally. However, methadone can only be administered at licensed opioid treatment programs (OTPs, also known as methadone clinics), which are highly regulated by the federal

[1] Center for Disease Control, *Opioid Use Disorder*, https://www.cdc.gov/dotw/opioid-use-disorder/index.html#:~:text=Opioid%20use%20disorder%20(OUD)%20occurs,or%20home%2C%20among%20other%20criteria.

[2] Curtis Florence, Feijun Luo, Ketra Rice, *The economic burden of opioid use disorder and fatal opioid overdose in the United States, 2017* (Oct. 2020), https://pubmed.ncbi.nlm.nih.gov/33121867/.

government. Additionally, some individuals are unwilling to enter OTPs due to stigma, concerns regarding confidentiality, and convenience. Many OTPs are also not adequately funded, resulting in a lack of clinic capacity to treat patients with OUD.[3]

Buprenorphine is a partial opioid agonist that suppresses euphoria and sedating effects of OUD. Unlike methadone, buprenorphine is often administered through a daily sublingual tablet or film. Buprenorphine also has a longer duration of action and can remain effective for more than 24 hours without requiring a second dose. Buprenorphine can also be prescribed or administered at a medical office (other than an OTP).

III. Legal Framework Limiting Access to MOUD Treatments

After Dr. Sigmon's presentation, Counsel to Aimed Alliance, Michael Barnes, discussed the regulatory framework surrounding access to MOUD. Mr. Barnes explained access to opioid medications for OUD is heavily restricted by federal law. While the risks of opioid medications for OUD being misused are no greater than those associated with other opioids, the stigma against MOUD has effectively been codified into law. Each type of MOUD treatment is subject to a different regulatory and prescription requirement. For instance, methadone can only be dispensed directly to the patient at federally registered and heavily regulated OTPs, whereas buprenorphine can be prescribed in office by a licensed health care professional with a DATA 2000 "X-waiver." Further, naltrexone, lofexidine, and naloxone (a medication for poisoning reversals) are only available by prescription. Thus, the various treatments for OUD, withdrawal, and poisoning reversals are subject to different regulations.

Federal regulation further impairs access to buprenorphine for patients with OUD. Under the current regulation, injectable buprenorphine that is dispensed to practitioners for administration to patients must be administered on or before the 14th day after delivery of the treatment to the practitioner. If the patient is unable to receive their medication within that 14-day period, the medication must be disposed of.

Fourteen days is insufficient time to coordinate schedules and actions of the patient, prescribers, pharmacies and insurers. Additionally, the 14-day limit creates the potential for unnecessary medical waste; risks of insurance denial; and patients experiencing OUD worsening, potential for drug poisoning, or death. When a medication is disposed of, the patient may not have access to treatment that month, as their health plan may refuse to cover a bridge supply to cover the period between drug disposal and the next month's prescription. Thus, the 14-day limit should be expanded to 60 days to ensure patients can access their OUD treatments and avoid unnecessary medical waste.

Mr. Barnes explained that the current justification for the 14-day limit is to prevent medication diversion (for purposes of misuse). However, a recent 2020 Government Accountability Office report stated, "all of the provider groups GAO spoke with said that diversion of injectable . . . buprenorphine is unlikely, and representatives from three of the six provider groups said that . . . these formulations reduce opportunities for diversion due to how

[3] Bernstein & Bennet, 2013; Gryczynski et al., 2009; Peles et al., 2012, 2013; Peterson et al., 2010.

they are administered." [4] As such, based on the provider experiences established in the GAO report, diversion is not an appropriate justification for a 14-day limit on patient access to injectable buprenorphine. Mr. Barnes also shared that, while the Drug Enforcement Agency has authority to expand the 14-day limit to 60-days, it has consistently refused to do so. As such, patients with OUD need Congress to take action to expand access to MOUD.

IV. Increasing Access to MOUD

Following Mr. Barnes's presentation establishing the legal landscape of MOUD, Mr. Christopher McCann, Legislative Director for Representative Madeleine Dean, discussed the passage of Section 264 of House Bill 7666, which would expand the 14-day limit to 60 days. Mr. McCann explained that Representative Dean was personally interested in supporting this legislation, as her son has been in recovery from OUD for 10 years; thus, she understood the importance of expanding access to these treatments. Mr. McCann also shared that, throughout the bill passage process, it was essential to establish bipartisan support for the legislation and explain why 14 days are insufficient to organize treatment administration.

Subsequently, Mr. Shiek Pal, Senior Counsel to US Senator Jeanne Shaheen, stated that the Senate could potentially pass S.3257 before the end of the year to expand access to MOUD. Mr. Pal explained that the legislation is currently in the HELP Committee, but that the Committee needed to hear from patients, providers, and advocacy organization on the urgency for this legislation to pass.

V. Action Plan

Recognizing the need to swiftly engage an alliance of organizations interested in expanding access to MOUD, Aimed Alliance agreed to lead the advocacy efforts to support the passage of S.3257. Therefore, Aimed Alliance explained it would be circulating a sign-on letter for groups that would like to support the legislation; drafting a fact sheet on the need for expanding the 14-day limit to 60 days; and providing social media resources to garner support for this legislation.

If your organization would like to be included in these efforts to pass S.3257 before the end of the year, please email policy@aimedalliance.org.

[4] Government Accountability Office, *Opioid Use Disorder: Treatment with Injectable and Implantable Buprenorphine,* (Aug. 2020), https://www.gao.gov/assets/gao-20-617.pdf.