

November 22, 2022

The Honorable Jeanne Shaheen
United States Senate
506 Hart Senate Office Bldg.
Washington, DC 20510

Subject: Passage of S. 3257 To Expand the Injectable Buprenorphine Time Limit

Dear Senator Shaheen:

Thank you for introducing S. 3257. This legislation would amend the Controlled Substances Act (CSA) to lengthen the period of time during which injectable buprenorphine for opioid use disorder (OUD) may be administered to a patient after being delivered to the administering practitioner. The undersigned not-for-profit organizations respectfully ask the Senate to pass S. 3257 as soon as possible.¹

S. 3257 would expand the time health care providers can hold injectable buprenorphine for patients with OUD from 14 days to 60 days. Providing a 60-day administration window is necessary to ensure the availability and continuity of individually appropriate treatment for persons who, without treatment, may be at risk of OUD recurrence or progression, drug poisoning, and death.

Nearly three million people in the U.S. live with OUD.² Opioid-involved poisonings killed more than 77,800 Americans in the 12 months preceding June 2022.³ Time is of the essence.

Buprenorphine is a prescription medication approved by the Food and Drug Administration (FDA) to treat OUD.⁴ For successful treatment, buprenorphine needs to be taken consistently.⁵ Buprenorphine is available in daily oral tablets, daily dissolvable films, and monthly injections.⁶ A weekly injectable buprenorphine medication is under development.⁷

Section 309A(a)(5) of the CSA requires that a health care provider administer injectable buprenorphine OUD medication to the patient named on the prescription not later than 14 days

¹ On June 22, 2022, the U.S. House of Representatives passed H.R. 7666 with broad bipartisan support. Section 264 of H.R. 7666 contains a provision expanding the 14-day limit to 60 days.

² <https://www.ncbi.nlm.nih.gov/books/NBK448203/#:~:text=Introduction-.Opioid%20use%20disorder%20and%20opioid%20addiction%20remain%20at%20epidemic%20levels,States%20are%20dependent%20on%20heroin.>

³ <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>

⁴ <https://www.samhsa.gov/medication-assisted-treatment/medications-counseling-related-conditions/buprenorphine>

⁵ <https://nida.nih.gov/publications/research-reports/medications-to-treat-opioid-addiction/how-do-medications-to-treat-opioid-addiction-work#:~:text=It%20has%20been%20used%20successfully,through%20specialized%20opioid%20treatment%20programs.&text=Buprenorphine%20is%20a%20partial%20opioid,strongly%20than%20full%20agonists%20do.>

⁶ <https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2020/12/medications-for-opioid-use-disorder-improve-patient-outcomes>

⁷ <https://www.drugs.com/history/brixadi.html>

after the medication was delivered to the provider.⁸ The purpose of the 14-day limit is to prevent the diversion of the medication to the illicit market.⁹

The 14-day limit is too short considering the coordination required to facilitate injectable buprenorphine prescribing, insurance coverage and payment, delivery and receipt, and appointment scheduling and attendance. Sixty days are necessary to ensure that medication administration may take place at a time when the patient, provider, and medication are available.

The 14-day limit unnecessarily hinders patient access to injectable treatment for OUD. A 2020 Government Accountability Office (GAO) report stated that the number of injectable buprenorphine prescriptions was only one percent of the number of prescriptions for oral buprenorphine.¹⁰ Additionally, “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 the design of these formulations reduce opportunities for diversion due to how they are administered.”¹¹

Finally, the 14-day limit wastes valuable health care resources and places patients’ recovery and lives at risk. For example, if an insured patient is not able to attend a medical appointment on or before the 14th day after the injectable buprenorphine was delivered to her provider, the medication must be disposed of. It is unlikely that an insurer would pay for a replacement product, and it is common for patients not to be able to pay for medications out of pocket. A patient may be forced to go without a week or month’s worth of buprenorphine for OUD. This situation would put the patient at risk for a recurrence of OUD symptoms, active substance use, poisoning by illicit substance, and death.

Expanding the limit under Section 309A(a)(5) of the CSA to 60 days is necessary to enable patients, providers, pharmacies, and insurers to coordinate as necessary for the administration of injectable buprenorphine. Sixty days are necessary to prevent poisonings and deaths of persons with OUD who postpone their injections, and to avoid the waste associated with product disposal. S. 3257 proposes to amend Section 309A(a)(5) by replacing the 14-day limit with a 60-day limit.

For these reasons, we ask that the Senate pass S. 3257 as soon as possible. Once again, thank you for introducing this legislation and for all you do to reduce the prevalence of substance use disorders and drug poisonings.

Sincerely,

Aimed Alliance
Addiction Policy Forum
A mother's addiction journey
American Psychological Association

⁸ <https://www.law.cornell.edu/uscode/text/21/829a>

⁹ <https://www.gao.gov/assets/gao-20-617.pdf>

¹⁰ <https://www.gao.gov/assets/gao-20-617.pdf>

¹¹ <https://www.gao.gov/assets/gao-20-617.pdf>

Association of Nurses in AIDS Care
C4 Recovery Foundation
Center for U.S. Policy
CADCA
Face It Together
Female Opioid Research and Clinical Experts (FORCE)
Global Recovery Initiatives Foundation
HealthyWomen
National Council for Mental Well Being
No More ODs, Inc.
Partnership to End Addiction
Shatterproof
The Kennedy Forum
Treatment Alternatives for Safe Communities (TASC)
WestCare Foundation
Young People in Recovery