To ensure access to effective treatments for patients with opioid use disorder (OUD), the U.S. Senate should pass S.3257 before the end of 2022. S.3257 will amend the Controlled Substances Act (CSA) to lengthen the period of time during which injectable buprenorphine for OUD may be administered to a patient after being delivered to the administering health care practitioner. Specifically, S.3257 will expand the time limit under Section 309A(a)(5) of the CSA from 14 to 60 days.

Why increase access to treatments for individuals with OUD?

In 2020, roughly 2.7 million people in the United States had OUD. From June 2021 through May 2022, more than 103,000 lives were lost to drug poisoning in the U.S. Seventy-five percent of drug poisoning deaths involve opioids, such as heroin and illicit fentanyl. Thus, there is an urgent need to ensure individuals with OUD can access life-saving treatments.

Increasing access to medications for OUD (MOUD) can also help address racial disparities in health outcomes. For instance, one 2021 study found that Black Americans, American Indians, and Alaskan Natives were more likely than white Americans to experience opioid-involved poisonings. Therefore, as a matter of health equity, it is essential to reduce barriers to treatment for individuals with OUD.

Why is it difficult for individuals with OUD to receive injectable buprenorphine treatments?

Currently, under Section 309A(a)(5) of the Controlled Substances Act (CSA), a health care provider is required to administer injectable buprenorphine for OUD to the patient named on the prescription not later than 14 days after the medication was delivered to the provider.

A patient’s ability to receive treatment for OUD can be hindered by scheduling complications; a lack of housing, transportation, or childcare; or co-occurring mental illness. 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.
The 14-day rule results in waste of MOUD treatments.
Under the 14-day rule, 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 his or her provider, the medication must be disposed of, thereby wasting valuable health care resources. The disposal requirement is not based on any patient-health or medication-efficacy concerns because the medication does not expire or become ineffective after the 14th day, it just must be discarded to comply with the 14-day rule.

The 14-day rule is life-threatening for individuals with OUD.
When an individual with OUD is unable to visit their health care provider within 14 days, the medication is disposed of. After this medication disposal, it is unlikely that an insurer would pay for a replacement product, resulting in patients having to either pay out-of-pocket for the treatment or go without it. For many patients, paying out-of-pocket may not be financially feasible, forcing them to forgo a week or month’s supply of buprenorphine for OUD. This situation puts the patient at risk for a recurrence of OUD symptoms, active substance use, poisoning by illicit substance, and death.

How will passing S.3257 and increasing the limit to 60 days help expand access to MOUD treatments?
Increasing the 14-day rule to 60 days will expand access to MOUD treatments by ensuring that patients, providers, pharmacies, and insurers have time to coordinate, as necessary, for the administration of injectable buprenorphine.

What is the current status of the bill?
On June 22, 2022, the 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. However, the Senate has yet to sign a companion bill. Thus, it is essential that the Senate pass S.3257 before the end of 2022. Otherwise, legislative advocacy must begin anew in 2023, while patients’ OUD treatment options remain restricted by the 14-day limit.

How can I get involved?
If you would like to get involved in supporting access to MOUD treatments through expanding the 14-day rule to 60 days, you can:

1. Call your U.S. Senators’ DC offices and tell their staff, “I would like Senator XXX to know that S.3257 must be passed before the end of 2022 to prevent poisonings and deaths of persons with OUD whose buprenorphine injections are rescheduled, and to avoid the waste associated with mandatory product disposal.”

2. Write a letter to the Senate HELP Committee.

3. Contact Aimed Alliance to help organize advocates in favor of passing the legislation: policy@aimedalliance.org

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