The U.S. Senate should pass S.3257 before the end of 2022. S.3257 will lengthen the period of time during which injectable buprenorphine for opioid use disorder (OUD) may be administered to a patient.

Public Health Rationale

More than 103,000 lives were lost to drug poisoning in the 12 months ending May 30, 2022. Seventy-five percent of drug poisoning deaths involve opioids, such as heroin and illicit fentanyl. There is an urgent need to ensure individuals with OUD can access life-saving treatments.

Buprenorphine for OUD

Buprenorphine is approved by the Food and Drug Administration to treat OUD. Injectable buprenorphine is administered by a health care practitioner and delivers a steady dose over time.

One person dies of a drug poisoning EVERY FIVE MINUTES.
Regulatory Barrier

Section 309A(a)(5) of the Controlled Substances Act (CSA) requires that a health care provider administer injectable buprenorphine for OUD to the patient not later than 14 days after the pharmacy delivered the medication to the provider.

The 14-day limit is too short considering the coordination required for prescription processing, insurance coverage and payment, delivery and receipt, and appointment scheduling and attendance.

Wasteful

If an insured patient is not able to attend a medical appointment on or before the 14th day, the medication must be disposed of, thereby wasting valuable health care resources.

Life-Threatening

After the medication is disposed of, it is unlikely that an insurer would pay for a replacement product. A patient may be forced to go without buprenorphine. This situation puts the patient at risk for active substance use, poisoning, and death.

Increase the Limit to 60 Days

Sixty days are necessary to enable patients, providers, pharmacies, and insurers to coordinate the administration of injectable buprenorphine. S.3257 will expand the time limit under Section 309A(a)(5) of the CSA from 14 to 60 days.

Urgent Need for Action

On June 22, 2022, the House of Representatives passed H.R. 7666. Section 264 of H.R. 7666 contains a provision expanding the 14-day limit to 60 days. The Senate has not yet acted.

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.

Summary

S.3257 is necessary to prevent poisonings and deaths of persons with OUD whose buprenorphine injections are rescheduled, and to avoid the waste associated with mandatory product disposal.

Senators:

Please pass S.3257 before the end of 2022.