

Updates/Announcements

May 2023

General Updates

FDA Announces Preliminary Assessment that Certain Naloxone Products Have the Potential to be Safe and Effective for Over-the-Counter Use

The Federal Register notice includes a preliminary assessment that certain naloxone drug products—up to 4 milligrams (mg) nasal spray and up to 2 mg autoinjector for intramuscular (IM) or subcutaneous (SC) use—may be approvable as safe and effective for nonprescription use. This preliminary assessment is intended to facilitate development and approval of nonprescription naloxone products; however, it is not a final determination that certain naloxone drug products are safe and effective for nonprescription use, and it does not mandate an immediately effective switch to nonprescription/over-the-counter (OTC) availability for naloxone.

<https://www.fda.gov/news-events/press-announcements/fda-announces-preliminary-assessment-certain-naloxone-products-have-potential-be-safe-and-effective>

Department of Drug & Alcohol Program (DDAP) Updates

DEA Announces Important Change to Registration Requirement

On December 29, 2022, with the signing of the Consolidated Appropriations Act of 2023 (the Act), Congress eliminated the “DATA- Waiver Program.” To DEA registrants:

- A DATA-Waiver registration is no longer required to treat patients with buprenorphine for opioid use disorder.
- Going forward, all prescriptions for buprenorphine only require a standard DEA registration number. The previously used DATA-Waiver registration numbers are no longer needed for any prescription.
- There are no longer any limits or patient caps on the number of patients a prescriber may treat for opioid use disorder with buprenorphine.
- In Pennsylvania, no current state laws or regulations prohibit practitioners from adopting this change.

Separately, the Act also introduced new training requirements for all prescribers. **These requirements will go into effect on June 21, 2023.** The DEA and SAMHSA are actively working to provide further guidance and DEA will follow up with additional information on these requirements.

- Please contact the Diversion Control Division Policy Section at ODLP@dea.gov for additional guidance.

NEW VIRTUAL Training Available

The Department of Drug & Alcohol Programs (DDAP) is pleased to announce an online training module addressing Xylazine and Overdose Response. Please see the attached flyers for more information.

New Online Module: Xylazine: The New Drug Additive

This online training video, presented by Savage Sisters Recovery, will provide information on national and statewide opioid statistics and updates on current drug supply trends, including critical information on Xylazine. Also included in this module is a demonstration of overdose reversal procedures when the presence of Xylazine is suspected. This training will last approximately 30 minutes and is approved for 30 minutes of PCB Continuing Education Credits.



New Online
Module - Xylazine; T