LANCASTER COUNTY JOINING FORCES
Coordinating efforts to reduce deaths from opioids and heroin

Updates/Announcements
May 2023

General Updates

SAMHSA is Alerting Providers and Grantees About the Risk of Xylazine

SAMHSA is alerting providers and grantees about the risks of xylazine in this Dear Colleague letter. Xylazine is increasingly being found in the illicit drug supply, often in combination with opioids like fentanyl. Xylazine can cause circulatory changes that lead to painful lesions, necrosis, and even limb loss. Xylazine is especially risky because it is not detected in routine toxicology tests, so people who use drugs may be exposed without knowing. When a provider suspects exposure, SAMHSA recommends managing patients accordingly and alerting the local public health department.

SAMHSA's goal with this alert is to provide information about the consequences of xylazine exposure, what practitioners can do to mitigate harm, and how SAMHSA is responding to this emerging public health challenge. SAMHSA thanks grantees and providers for their vital role in carrying out this life-saving work.Read the full Dear Colleague Letter

HHS Launches New Website to Help People Find Support for Issues with Mental Health, Drugs, or Alcohol

As part of continuing efforts by the Biden-Harris Administration to increase access to mental health and substance use resources, the U.S. Department of Health and Human Services (HHS) launched FindSupport.gov, a new user-friendly website, designed for the general public, to help people identify available resources, explore unbiased information about various treatment options, and learn how to reach out to get the support they need for issues related to mental health, drugs, or alcohol.

See the full press release.

DEA, SAMHSA Extend COVID-19 Telemedicine Flexibilities for Prescribing Controlled Medications

On May 9th, 2023, ahead of the expiration of the COVID-19 Public Health Emergency (PHE), the Drug Enforcement Administration (DEA) and the Substance Abuse and Mental Health Services Administration (SAMHSA) issued the "Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications" – a temporary rule that extends telemedicine flexibilities adopted during the COVID-19 public health emergency (PHE).

The temporary rule will take effect on May 11, 2023, and extends the full set of telemedicine flexibilities adopted during the COVID-19 public health emergency for six months – through November 11, 2023. For any practitioner-patient telemedicine relationships that have been or will be established up to November 11, 2023, the full set of telemedicine flexibilities regarding prescription of controlled medications established during the COVID-19 PHE will be extended for one year – through November 11, 2024.

See the full announcement

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.
- DEA Announces Important Change to Registration Requirement

Revised Methadone Take-Home Flexibilities Extension Guidance

- **Background:** Under the federal COVID-19 public health emergency (PHE), which is due to end on May 11, 2023, SAMHSA is currently allowing up to 28 days of take-home medications for patients on stable dosages, as deemed appropriate by their physician. In November 2021, SAMHSA announced that the methadone take-home flexibilities will be extended for one year after the end of the PHE. The Department of Drug and Alcohol Programs (DDAP) submitted our written concurrence with this exemption in February 2022. Furthermore, SAMHSA issued a notice of proposed rulemaking in December 2022 that proposes modifying regulations related to methadone take-home supply up to 28 days, among other changes.

- **Update:** SAMHSA has issued updated guidance on the extension of methadone take-home flexibilities: https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines/methadone-guidance

- This revised guidance will be effective upon the expiration of the PHE, and will remain in effect for one year after the end of the PHE, or until the final regulations are published, whichever occurs sooner. DDAP submitted our written concurrence with this exemption on April 20, 2023. The written concurrence is our agreement with SAMSHA that opioid treatment programs in Pennsylvania may continue to exercise these flexibilities during this time period.

- If you have any further questions, please contact the Bureau of Program Licensure at (717) 783-8675 or RA-licensuredivision@pa.gov.

New NASTAD Resource: Wound Care & Medical Triage for People Who Use Drugs and the Programs That Serve Them

The NASTAD DUH team is excited to announce a new resource, *Wound Care and Medical Triage for People Who Use Drugs*. This comprehensive guide provides information and recommendations regarding general health, safer use practices, common viral, fungal, parasitic, and other injection-related infections, overdose and overamp, tapering, withdrawal, medications for opioid use disorder, and seeking medical care. This resource was developed through the CDC-funded National Harm Reduction Technical Assistance Center in collaboration with project consultant Kacey Byczek.

Wound Care & Medical Triage for People Who Use Drugs and the Programs That Serve Them is intended to be used by people who use drugs and the community-based organizations, grassroots programs, health departments, and other harm reduction service providers that work with people who use drugs. This guide is formatted to be easily viewed electronically and printed both in its entirety and in sections.

Please share this resource widely with your networks, and reach out to Drug User Health team or Billy Golden with any questions or suggestions.

Regulatory Suspensions and End of the COVID-19 Public Health Emergecy

As the Department of Drug and Alcohol Programs (DDAP) shared in an email on February 3, the COVID-19 public health emergency (PHE) expired, May 11, 2023.

Under Act 30 of 2022, DDAP's regulatory suspensions that are "related to federal exemptions granted under the federal public health emergency declaration" were extended until "the last day federal exemptions granted under the federal public health emergency declaration are authorized." In other words, Act 30 aligned the timing for DDAP's regulatory suspensions with the deadline for flexibilities granted by the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Drug Enforcement Administration (DEA) – not with the deadline of the PHE itself.

Below is a description of each currently-suspended regulation, how these flexibilities are being extended, and efforts to make these changes permanent at the federal level.

Methadone take-home supply

Current regulatory suspension: Under the federal PHE, SAMHSA is currently allowing up to 28 days of take-home medications for patients on stable dosages, as deemed appropriate by their physician. DDAP's regulation at 28 Pa. Code § 715.16(e) (prohibiting narcotic treatment programs [NTPs] from permitting a patient to receive more than a 2-week take-home supply) is currently suspended under Act 30.

Expiration of the PHE: SAMHSA issued a notice of proposed rulemaking in December 2022 that proposed modifying regulations related to methadone take-home supply up to 28 days, among other changes. In April 2023, SAMHSA issued updated guidance on the extension of methadone take-home flexibilities. This revised guidance will be effective upon the expiration of the PHE and will ***remain in effect for one year after the end of the PHE, or until the final regulations are published, whichever occurs sooner.*** DDAP submitted our written concurrence with this exemption on April 20, 2023. The written concurrence is our agreement with SAMSHA that NTPs in Pennsylvania may continue to exercise these flexibilities during this time period.

Buprenorphine telehealth – for NTPs

Current regulatory suspension: Under the federal PHE, SAMHSA and the DEA are currently allowing initial evaluations for a patient who will be treated with buprenorphine to be completed via telehealth. DDAP has two related regulations that are currently suspended under Act 30:

- 28 Pa. Code § 715.9(a)(4): requires NTPs to make a face-to-face determination before admission to treatment, for those clients who will receive medication to treat opioid use disorder (OUD).
- 28 Pa. Code § 715.6(d): requires NTPs to have narcotic treatment physician services onsite.

Expiration of the PHE: SAMHSA issued a notice of proposed rulemaking in December 2022 that proposed the use of telehealth in initiating buprenorphine, among other changes. In June 2022, SAMHSA announced to State Opioid Treatment Authorities that ***flexibilities around telehealth***

evaluations before buprenorphine treatment at NTPs, specifically, will be extended for one year after the end of the PHE (now May 11, 2024). SAMHSA reaffirmed this extension on May 10, 2023, and DDAP submitted our written concurrence on the same day that NTPs in Pennsylvania may continue to exercise these flexibilities during this time period.

Buprenorphine telehealth – for office-based providers

Current regulatory suspension: Under the federal PHE, the DEA is currently allowing initial evaluations for a patient who will be treated with buprenorphine to be completed via telehealth. The Pennsylvania Department of State's (DOS') regulation at 49 Pa. Code § 16.92(b)(1) (requiring an initial physical examination of a patient prior to prescribing buprenorphine for the treatment of OUD) is currently suspended under Act 30.

Expiration of the PHE: On May 9, 2023, DEA released a temporary rule to extend COVID-19 telemedicine flexibilities for controlled substance prescriptions for 6 months. Current flexibilities are in place until November 11, 2023. DOS has indicated that their regulation at 49 Pa. Code § 16.92(b)(1) will remain suspended accordingly. ***Clinicians may treat new patients with buprenorphine following a telehealth evaluation through November 11, 2023. For any practitioner-patient relationship established on or before November 11, 2023, a one-year grace period will continue through November 11, 2024.*** This grace period not only allows clinicians the ability to continue their established telemedicine relationships with patients under the flexibilities that were in place under the COVID-19 PHE but also allows clinicians a period of time to prepare patients for upcoming changes in federal regulations. In the meantime, DEA is continuing to carefully evaluate comments received on its proposed rulemaking to make a form of this flexibility permanent.

SAMHSA and DEA have made clear that support for these flexibilities have been overwhelmingly positive, decreased stigma associated with OUD, and enhanced care for patients. DDAP has also recognized the benefits to theses flexibilities and looks forward to seeing them made permanent in forthcoming regulatory updates.

Resources:

- Methadone Take-Home Flexibilities Extension Guidance
- SAMHSA Proposed Rulemaking: Medications for the Treatment of Opioid Use Disorder
- DEA Guidance to Qualifying Practitioners
- The Physical Evaluation of Patients Who Will Be Treated With Buprenorphine at Opioid Treatment Programs
- DEA Proposed Rulemaking: Expansion of Induction of Buprenorphine via Telemedicine Encounter
- Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Substances

If you have any further questions, please contact the Bureau of Program Licensure at (717) 783-8675 or RA-licensuredivision@pa.gov.