





March 27, 2023

Dear Colleague:

As the Substance Abuse and Mental Health Services Administration's (SAMHSA) partners in treating substance use disorders, SAMHSA is grateful for the work that you do in helping to mitigate the impact of the overdose crisis. As part of this, SAMHSA wishes to alert providers and grantees to the risks of xylazine. Xylazine is a non-opioid agent increasingly being found in combination with opioids such as fentanyl. Xylazine, which has not been approved by the FDA for use in humans, can cause severe circulatory changes with devastating effects on human tissue leading to painful open lesions, necrosis, and potentially limb loss. Practitioners must be aware of risks posed by xylazine and prepare to manage patients accordingly. 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.

Xylazine is known as "tranq" or "tranq dope" in the illicit drug market. Xylazine can cause drowsiness, lethargy, and in rare instances, apnea and death. While xylazine is not an opioid, it is dangerous because it can depress breathing, blood pressure, heart rate and body temperature to critical levels. Additionally, people who inject drugs containing xylazine can develop severe skin wounds and patches of dead and rotting tissue that easily become infected and, if left untreated, may lead to amputation. These wounds can develop in areas of the body away from the injection site and may become life-threatening.

Particularly alarming is the finding that routine toxicology tests do not test for xylazine. It may therefore be under-detected and under-accounted for in overdose cases and other life-threatening events. As xylazine is not an opioid, naloxone does not reverse the effects of xylazine. Severe withdrawal symptoms may develop from xylazine, which are, by themselves, unlikely to be managed by medications for opioid use disorder (MOUD) (i.e., methadone, buprenorphine, or naltrexone). Therefore, xylazine presents new potential public health challenges associated with possible withdrawal signs and symptoms.

When a patient presents with a possible exposure, practitioners should provide routine care for opioid intoxication, particularly the administration of naloxone, as indicated. Providers should consider xylazine exposure if patients are not responding to naloxone or when there are signs or symptoms of xylazine exposure (e.g., severe necrotic skin ulcerations). Any individual who is suspected of misusing substances containing xylazine, whether intentionally or not, should receive counseling about the dangers of this substance, and extensive advice on harm reduction. Because xylazine is most often a contaminant with opioids, such as fentanyl, the individual

should also be offered access to MOUD referrals and treatment as they can reduce opioid overdose risk. While testing remains limited at the current time, local health departments may have partnerships with toxicology laboratories that can identify xylazine in drug or biologic samples. Please contact your state and local health department for more information.

Along with the Department of Health and Human Services partners, SAMHSA encourages health care professionals and patients to report adverse events resulting from possible xylazine exposure to their local health department, poison center or the American Association of Poison Control Centers at 1-800-222-1222. FDA's MedWatch Adverse Event reporting may be completed online at www.fda.gov/medwatch.

Informing providers of emerging threats is critical to SAMHSA's mission. SAMHSA's recent activities demonstrate an ability to adapt to these new developments while maintaining unwavering commitment to promoting the nation's health. SAMHSA announced funding opportunities totaling about \$73.5 million for five grant programs, including Medication—Assisted Treatment — Prescription Drug and Opioid Addiction, that address substance misuse and use disorders on multiple fronts. This funding is aligned with the Biden-Harris Administration's efforts to address our nation's overdose crisis and with State Opioid Response grants providing treatment and prevention efforts.

As part of the overdose prevention strategy, SAMHSA has proposed an <u>update to 42 CFR Part 8</u> to make treatment more accessible. Proposed changes include removing stigmatizing language from the rule and making permanent the pandemic flexibilities that allow for take home doses of methadone and the use of telehealth in initiating buprenorphine in opioid treatment programs. In addition, SAMHSA has collaborated with partners to expand access to buprenorphine by implementing the Mainstreaming Addiction Treatment Act, included as Section 1262 of the Consolidated Appropriations Act, 2023, signed into law by President Biden at the end of December 2022. Pursuant to this Act, any practitioner (where state law allows), with a valid license to practice medicine and a Drug Enforcement Administration registration, may now prescribe buprenorphine without having to obtain a special waiver (commonly called "the X-Waiver"). SAMHSA believes these actions will be critical in reducing exposure to illicit or illicitly manufactured fentanyl drug supplies that may be contaminated with xylazine.

SAMHSA thanks you for your partnership in protecting the nation's health in the face of emerging challenges. We look forward to continued partnership in improving outcomes for the millions of people whose lives are afflicted by substance use disorders.

Sincerely,

/Miriam E. Delphin-Rittmon/

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