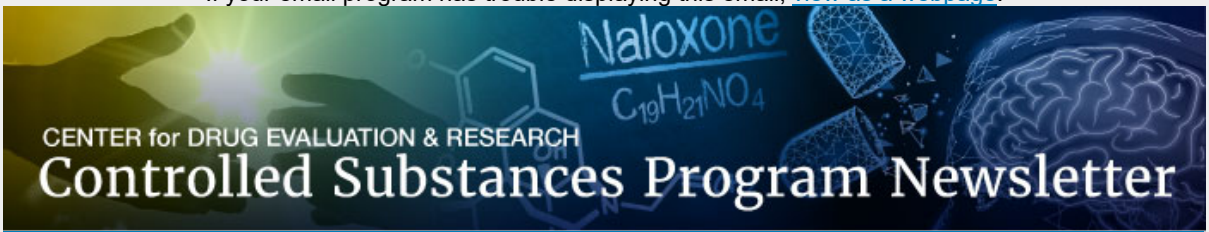


FDA U.S. FOOD & DRUG ADMINISTRATION

A Message from Marta

Dear Colleagues and Friends,

Welcome to the Fall season and the second issue of the Controlled Substances Program Newsletter. We've accomplished so much in the overdose prevention space recently, and I am excited to share all of it with you.

In this issue, you'll read about some of our latest actions in furthering the goals of FDA's Overdose Prevention Framework. These actions include the long-awaited approval of a modification to the Opioid Analgesic Risk Evaluation and Mitigation Strategy (OA REMS)—an effort furthering FDA's goal of increasing available options for safe opioid drug disposal that came to fruition after extensive engagement with various stakeholders, including federal partners. We are proud to announce that beginning March 31, 2025, outpatient pharmacies and other dispensers will be able to provide patients with pre-paid drug mail-

back envelopes when dispensing opioid medications. And our work on disposal continues with our focus on increasing access to additional in-home drug disposal options.

I'm also excited to share that according to Centers for Disease Control and Prevention (CDC) data, in the 12-month period ending in June 2024, predicted overdose deaths declined from 113,154 to 96,801, roughly a 14.5% decrease from the prior year. This significant decrease in overdose deaths serves as testament that the many actions and continuing efforts we've undertaken to increase access to life-saving naloxone and expand buprenorphine access are indeed making a difference and saving lives.

I hope you'll enjoy reading about what we've been up to in continuing our mission to prevent and reduce instances of overdose and overdose deaths. Remember: the overdose crisis is an evolving public health issue, and no one person or agency can conquer it alone. Our biggest strength lies in community.

Most of all, we hope you'll feel empowered to join us in our mission by using the information and resources provided within to continue the work of preventing overdoses in your communities as well.

Until next time…

Marta Sokolowska, PhD
Deputy Center Director for Substance Use and Behavioral Health

What We've Been Up to Lately

- A draft of an FDA grant-funded clinical practice guideline on benzodiazepine tapering was issued by the American Society of Addiction Medicine for public comment. This guideline intends to assist clinicians in helping patients safely taper from their benzodiazepine medication while minimizing withdrawal symptoms.
- FDA partnered with the Reagan-Udall Foundation for the FDA to host a public workshop, Advancing Treatments for Post-Traumatic Stress Disorder (PTSD). The workshop brought together researchers and scientists, drug developers, federal partners, and stakeholders with lived PTSD experience to explore efforts to accelerate treatment development for PTSD, including psychedelic drug development. Materials from this workshop are also listed on Reagan-Udall's website.
- FDA awarded a cooperative agreement grant to Baylor College of Medicine to support the development, implementation, and evaluation of a human abuse potential study (HAP) on the use of botanical kratom. This HAP study follows the completion of a pilot single ascending dose (SAD) study, as part of the agency's ongoing efforts better understand the abuse potential and safety of kratom, a plant indigenous to Southeast Asia.
- FDA awarded a cooperative agreement to the University of Maryland to assess and gain an understanding of the mechanisms of action, ingredients, safety, usability, and capability of commercially available in-home drug disposal systems. Researchers will collect the data using standard pharmaceutical laboratory techniques applied to the in-home systems, various analyses, and participant surveys and interviews.
- Last month, FDA announced approval of a modification to the Opioid Analgesic Risk Evaluation and Mitigation Strategy (OA REMS). With this approval, companies participating in the OA REMS Program have been notified that they will

be required to provide pre-paid drug mail-back envelopes (MBEs) upon request to outpatient pharmacies and other dispensers of opioid analgesics by **March 31, 2025**. Once fully implemented, FDA intends for patients and caregivers to be provided a free, pre-paid drug mail-back envelope by outpatient pharmacies or other dispensers of opioid analgesics that order MBEs from the OA REMS.

Just F.Y.I. (For Your Information)

Safe Use of Prescription Stimulants and Risks of Nonmedical Use

To address continuing concerns of misuse, abuse, and addiction of prescription stimulants, in May 2023, FDA required sponsors of prescription stimulants products to update and standardize their prescribing information to clearly inform patients, caregivers and health care professionals of risks associated with their stimulant medications.

Prescription stimulants can be an important option for treating disorders for which these medicines are indicated—such as binge-eating disorder and narcolepsy. However, nonmedical use, misuse, or even appropriate use can result in certain side effects, such as anxiety, sleep problems, loss of appetite, restlessness, or other serious health problems. To address knowledge gaps, FDA entered an interagency agreement with the Agency for Healthcare Research and Quality to complete evidence-based reports on the diagnosis and management of attention-deficit/hyperactivity disorder (ADHD) in adults. More information about the reports will be made available here.

For additional information or resources, you may want to contact the Substance Abuse and Mental Health Services Administration for questions or concerns about prescription stimulant nonmedical use. Also, be aware of access to care disruptions that can increase risks of injury and overdose as described in the Center for Disease Control and Prevention's Health Alert Network Health Advisory published in June 2024.

Engage With Us

FDA Foundation's Demand Modeling Assessment

Each year, FDA submits an estimate of medical, scientific, and reserve stock needs for Schedule I and II substances to the Drug Enforcement Administration (DEA). In turn, DEA uses these estimates, along with data from other sources, to set an overall quota or limit for these substances, as well as individual quotas for manufacturers of these substances.

To inform potential improvements in the quality of these annual estimates, the Foundation is conducting an analysis on behalf of the FDA to evaluate forecasting techniques used by government agencies, the private sector, and academic researchers to predict demand for controlled substances. If you are interested in learning more about the project or contributing to this analysis, please fill out the linked form to receive updates.

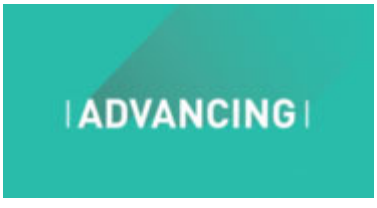
Sign Up for Updates

About Our Work

CDER's Controlled Substances Program is charged with executing activities under FDA's Overdose Prevention Framework, which consists of four overarching priorities that align with the U.S. Department of Health & Human Services' Overdose Prevention Strategy to address the public health emergency as it continues to evolve.

Supporting primary prevention by eliminating unnecessary initial prescription drug exposure and inappropriate prolonged prescribing

Encouraging harm reduction through innovation and education



Advancing development of evidence-based treatments for substance use disorders

Protecting the public from unapproved, diverted, or counterfeit drugs presenting overdose risks

Resources

FDA Overdose Prevention Framework

HHS Overdose Prevention Strategy

Our Partners

CDC CMS CBP DEA IHS HHS NIH SAMHSA VA