

May 10, 2024

The Honorable Anne Milgram
Administrator
Drug Enforcement Administration
U.S. Department of Justice
8701 Morrisette Drive
Springfield, VA 22152

The Honorable Admiral Rachel Levine, MD
Assistant Secretary for Health
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Rahul Gupta, MD
Director
White House Office of National Drug Control Policy
1800 G Street, NW
Washington, DC 20503

The Honorable Miriam Delphin-Rittmon, PhD
Assistant Secretary for Mental Health and
Substance Use
Substance Abuse and Mental Health Services
Administration
5600 Fishers Lane
Rockville, MD 20857

RE: Suspicious Order Reporting Requirements for Buprenorphine Products Approved for Opioid Use Disorder

Dear Administrator Milgram, Assistant Secretary Levine, Assistant Secretary Delphin-Rittmon, Director Gupta:

We write to collectively thank the U.S. Drug Enforcement Administration (DEA) and the U.S. Department of Health and Human Services, for their recent clarifications about the Controlled Substances Act (CSA) and treatment for patients with medications for opioid use disorder (MOUD). Along with the Office of National Drug Control Policy, we also greatly appreciate your collective support for increasing access to MOUD—the gold standard for treating patients with opioid use disorder (OUD). One new barrier, however, that needs your urgent attention is the use of thresholds imposed by distributors that are having a negative effect on patients’ access to MOUD—buprenorphine, in particular. We have received multiple reports from physicians and pharmacy colleagues that distributors are delaying or suspending orders of MOUD because of the national opioid settlement agreement.

DEA said last year that “Neither the CSA nor DEA regulations establish quantitative thresholds or limits on the amounts of controlled substances, including MOUD, that DEA registrants may order or dispense, nor do they require registrants to set such thresholds or limits.”¹ Further, we strongly support their recent statement that “Distributors should carefully examine quantitative thresholds they have established to ensure that individuals with OUD who need buprenorphine are able to access it without undue delay.”²

¹ “DEA-Registered Manufacturer and Distributor Established Controlled Substance Quantitative Thresholds and the Requirement to Report Suspicious Orders.” Drug Enforcement Administration Diversion Control Division Guidance Document. January 20, 2023. Available at [https://www.deadiversion.usdoj.gov/GDP/\(DEA-DC-065\)\(EO-DEA258\) Q A SOR and Thresholds \(Final\).pdf](https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-065)(EO-DEA258) Q A SOR and Thresholds (Final).pdf)

² “Dear Registrant Letter.” Anne M. Milgram Administrator, Drug Enforcement Administration Department of Justice. Rachel L. Levine, M.D. ADM, USPHS Assistant Secretary for Health Department of Health and Human. Miriam E. Delphin-Rittmon, Ph.D. Assistant Secretary for Mental Health and Substance Use Department of Health and Human Services. Received March 9, 2024. Available at https://www.deadiversion.usdoj.gov/pubs/docs/Dear_Registrant_MOUD.pdf

However, our organizations are deeply concerned about reports from our members that patients with an OUD have struggled to have prescriptions for buprenorphine products dispensed at pharmacies. It is beyond comprehension that at a time when we all have worked so hard to remove barriers to MOUD that this threshold barrier would rear up and put patients' lives in jeopardy. Two prevailing themes are clear:

- Pharmacies have not increased orders for MOUD because of fears by distributors and pharmacies of exceeding thresholds, which would trigger suspicious order reports (SOR) and subject the pharmacy and distributor to increased DEA scrutiny.
- As a result of the scrutiny and subsequent challenges with pharmacies obtaining sufficient stock of buprenorphine products, patients continue to face delays and denials of MOUD—frustrating the nation's pharmacists and physicians and exacerbating the nation's overdose and death toll.

We hope your recent guidance will help, but we believe additional action is needed. We urge the Administration to build on your actions to increase patients' access to MOUD by issuing guidance concerning enforcement of SOR requirements with respect to buprenorphine products approved by the Food and Drug Administration (FDA) for the treatment of OUD. While we do not have any specific knowledge of exactly how manufacturers and distributors use buprenorphine and other MOUD in their algorithms to identify potential SOR thresholds as required by the opioid litigation settlements, overinclusion is classic risk mitigation. Many manufacturers, distributors and pharmacies also are under pressure to limit MOUD as a result of the national opioid litigation settlement agreements, which lists buprenorphine as a drug of concern. **Administration clarity that no action will be taken by the federal government against any party solely for not including buprenorphine products approved by FDA for OUD in SOR threshold reporting will hopefully provide sufficient breathing room for manufacturers and distributors to remove it from their algorithms, SOR requirements and threshold limits—helping patients at increased risk of harm avoid unnecessary and painful withdrawal, overdose and death.**

As background, the Preventing Drug Diversion Act became law as Section 3292 of the SUPPORT for Patients and Communities Act in 2018 and required that DEA registrants design and operate systems to identify and notify DEA of suspicious orders. The primary intent of this legislation was to address the large quantities of opioid analgesics being supplied to certain pharmacies and the inability of the DEA to track such activity without cooperation from those in the supply chain. There has been a 50 percent decrease in opioid analgesic prescriptions in the past decade, but only a marginal increase in buprenorphine prescriptions. Yet, there continues to be staggering numbers of opioid-related overdose and death, now mostly from illicitly manufactured fentanyl. **Non-enforcement of SOR requirements for buprenorphine products approved by the FDA for OUD will increase access to buprenorphine for the treatment of OUD—a central tenet of the SUPPORT Act and desperately needed to save lives at this point in the nation's overdose and death epidemic.** Non-enforcement of SOR requirements for buprenorphine products approved by the FDA will increase access, reduce stigma, and save lives.

We further highlight that DEA proposed the Suspicious Orders of Controlled Substances rules on November 2, 2020, which were open for comment for 60 days until January 4, 2021. DEA then reopened the comment period for an additional 30 days from February 25, 2021, until March 29, 2021. As of today, the rule has yet to be finalized. In addition to concerns around the short timeframe for comments, those submitted by pharmacies and distributors raised concerns that DEA lacked specificity in its definition of a suspicious order as well as inadequately addressing the burden associated with the proposed systems of identifying and reporting the information.³ Buprenorphine is a well-documented, clinically effective

³ See public comments from the National Community Pharmacists Association (NCPA), the American Society of Health Systems Pharmacists (ASHP), the National Association of Chain Drug Stores (NACDS), the Healthcare Distribution Alliance (HDA), and the Independent Pharmacy Cooperative (ICP)

treatment for OUD, and there must be patient access to this treatment in order to fight the ongoing illicitly manufactured fentanyl-driven overdose and death epidemic. We do not condone buprenorphine diversion, but we also emphasize that buprenorphine diversion mainly occurs because individuals with an OUD cannot readily access treatment. **As long as buprenorphine products approved by the FDA for OUD remain prevalent in SOR reporting requirements and the opioid litigation settlement agreements, access to these buprenorphine products will remain a struggle across the country.**

The undersigned organizations have been advocating for greater access to MOUD by removing a wide variety of barriers to MOUD. However, if a patient seeking treatment finds a physician or other health care professional that they trust who is accessible to them and obtains a prescription for buprenorphine but is then unable to obtain the prescription from their pharmacy, our efforts to expand access to treatment are effectively negated. This is why **we urge clear guidance that explicitly states that suspicious order reporting requirements will not be enforced against buprenorphine approved by the FDA for OUD until further notice.**

The CSA already requires that “a prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.”⁴ Nonenforcement of SOR reporting requirements for buprenorphine products approved by the FDA for OUD will let us do our jobs and serve many more patients with lifesaving MOUD. The intent of the law is to combat illegitimate practices and prevent OUD, not inadvertently stand in the way of patients who need access to MOUD. We look forward to your immediate attention to this matter.

Thank you for your consideration of our recommendations to remove barriers to care for patients with substance use disorders. If you have any questions, or if we can be of assistance, please contact Margaret Garikes, AMA’s Vice President of Federal Affairs, at margaret.garikes@ama-assn.org.

Sincerely,

American Medical Association
American Pharmacists Association
American Society of Addiction Medicine
American Society of Health-System Pharmacists

⁴ 21 CFR 1306.04 See, <https://www.ecfr.gov/current/title-21/chapter-II/part-1306/subject-group-ECFR1eb5bb3a23fddd0/section-1306.04>