January 10, 2023

Anne Milgram
Administrator
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

Scott A. Brinks
Section Chief, Diversion Control Division
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

RE: Separate Treatment of Buprenorphine in Suspicious Order Regulations

Dear Administrator Milgram and Section Chief Brinks:

We commend US Drug Enforcement Administration (DEA) for its continued commitment to expanding access to medications for opioid use disorder (MOUD).[1] We write to raise an emerging barrier to MOUD that DEA can and should address expeditiously to have immediate impact on continued access to care.

We are the American Pharmacists Association (APhA), the National Alliance of State Pharmacy Associations (NASPA), National Association of Boards of Pharmacy (NABP), and the National Community Pharmacists Association (NCPA). Together, our organizations represent state and territorial boards of pharmacy, state pharmacy associations, independent pharmacy owners, and practicing pharmacists across the country.

As you know, 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 intent of this legislation was to address the large quantities of opioids being supplied to certain pharmacies and the inability of the DEA to track such activity without cooperation from those in the supply chain. 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.

[1] https://www.dea.gov/press-releases/2022/03/23/deas-commitment-expanding-access-medication-assisted-treatment

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.[2]

This lack of specificity and transparency has caused confusion regarding the suspicious order regulations and has resulted in distributors interpreting the proposed rules to the extreme and overzealously identifying what may be deemed a suspicious order, including orders for buprenorphine, which can be used for treatment of OUD. This is extremely concerning as pharmacies have been unable to obtain sufficient quantities of buprenorphine and other controlled substances which impacts patient access, including for legitimately prescribed buprenorphine. Our organizations have heard reports of pharmacies reserving their buprenorphine stock for regular customers and/ or not stocking because of variable supply.

Buprenorphine is a well-documented, clinically effective treatment for OUD and there must be patient access to this treatment in order to fight the ongoing opioid epidemic. In fact, the undersigned organizations have been advocating for greater access to MOUD by increasing the number of prescribers who can offer this safe and effective treatment and otherwise reduce barriers to access. However, if a patient seeking treatment finds a clinician that they trust who is accessible to them and obtains a prescription for MOUD, but is then unable to obtain buprenorphine from their pharmacy, our efforts to expand access to treatment are effectively negated.

For these reasons, **we urge DEA to expeditiously provide guidance to distributors and pharmacies that explicitly states that suspicious order reporting requirements should not apply to buprenorphine for OUD**. The intent of the law was to combat the opioid epidemic, not inadvertently stand in the way of addressing those in treatment.

We look forward to your immediate attention to this matter. We are available to assist and discuss further at your convenience; please do not hesitate to reach out to any of the undersigned organizations (Heather Boyd Hboyd@aphanet.org, Josh Bolin jbolin@nabp.pharmacy, Allie Jo Shipman ajshipman@naspa.us, or Hannah Fish hannah.fish@ncpa.org).

Sincerely,

American Pharmacists Association
National Association of Boards of Pharmacy
National Alliance of State Pharmacy Associations
National Community Pharmacists Association

[2] 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)