Written Comments Received

#2 Monty Goddard PE MSCE

From: MONTY GODDARD <montygoddard@msn.com>
Sent: Tuesday, February 4, 2025 7:53 AM
To: Damoth, Debbie@DCA <Debbie.Damoth@dca.ca.gov>
Subject: Feb 6th Brd of Pharm Mtg - Agenda Item X

Hi Debbie,

I look forward to this week's Board of Pharmacy meeting's Agenda Item X: *Addressing the Crisis, Improving Addiction Medicine Access at Pharmacies* presentation by ASAM's President Dr. Brian Hurley, et al.

I am requesting this email and its two attached PDFs be distributed to the Board of Pharmacy members prior to the meeting.

I wish to "prime" the board members with relevant information related to the shortage of MOUDs. Specifically, this shortage is not unique to MOUDS. All controlled substances have been similarly impacted by the iniquitous draconian *Injunctive Relief* provisions of the state AGs' nationwide opioid settlement with the three major distributors of controlled substances to pharmacy shelves.

I want to provide to the board members evidence that remediation efforts to date, by not only ASAM, and the AMA, APA, AShP, but also the DEA and HHS have excluded any mention of all other similarly impacted controlled substances. The first attached PDF, is a May 10, 2024, joint letter from; ASAM, AMA, APA, and AShP. Although focused on the supply of MOUDs, it clearly substantiates the supply chain harm impacting all controlled substances is a direct result of the aforementioned settlement's "*Injunctive Relief*".

This May 10th letter, which should have been addressed to the state AGs focuses solely on MOUDS, therefore discriminating against the large population of patients who are unable to fill their just as legitimate prescriptions for other similarly impacted controlled substances. This addressing issue, and the letter's obvious discrimination has been pointed out via separate correspondence to ASAM, AMA, APA, and AShP. A respectful request that these organizations expand their "ask" to include all impacted controlled substances was made.

The second attached PDF is this correspondence, a letter from the National Campaign to Protect People in Pain. It was both emailed by its signatory, Richard Lawhern, PhD,

and USPS mailed, certified/receipt requested, by me on June 28, 2024, to the presidents of these four organizations, Dr. Hurley included.

Despite my having received signed receipts proving the letter was delivered to all four recipients admin staff, AND despite repeated subsequent follow-up, no response has been received.

The upcoming presentation (Agenda Item X) would be an opportune time for Board members to engage on this **critical question:** Should efforts be made to help only one group of patients or should the Board support efforts to assist all patient populations in receiving their legitimately prescribed controlled substances?

Thank you again Debbie.

Respectfully.
Monty Goddard PE MSCE

May 10, 2024

The Honorable Anne Milgram
Administrator
Drug Enforcement Administration
U.S. Department of Justice
8701 Morrissette 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

[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

June 28, 2024

President Bruce A. Scott, MD
American Medical Association
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President Alex C. Varkey, PharmD
American Pharmacists Association
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Washington DC, 20037

President Brian Hurley, MD
American Society of Addiction Medicine
11400 Rockville Pike, Suite 200
Rockville MD, 20852

President Leigh A. Briscoe-Dwyer, PharmD
American Society of Health System Pharmacists
4500 East-West Highway, Suite 900
Bethesda, MD 20814

RE: Your joint letter of May 10, 2024

Dear President Scott, President Varkey, President Hurley, President Briscoe-Dwyer:

We have read your May 10, 2024, letter to the Drug Enforcement Administration, the U.S. Department of Health and Human Services, the White House Office of National Drug Control Policy, and the Substance Abuse and Mental Health Services Administration. We are grateful that your letter acknowledges the harm being done to the supply chain by "thresholds" on pharmacy orders of controlled substances, but we have two issues of concern. First, none of your letter's addressees have direct control of the implementation of these "thresholds", and second is the letter's focus on medications for opioid use disorder (MOUDs) to the exclusion of all other similarly impacted controlled substances.

These harmful "thresholds" were implemented by the three major distributors of all controlled substances, AmerisourceBergen (now Cencora), McKesson, and Cardinal Health, in compliance with their nationwide opioid settlement with the settling state Attorneys General (AGs). No question, the *Injunctive Relief/Exhibit P* of this settlement has caused great harm to the legitimate supply of all controlled substances from the manufacturers to pharmacy shelves. Relief from this *Injunctive Relief*, including but not limited to the offending "thresholds" must come from the responsible state AG's.

Your letter correctly states this sad truth: ***"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."

Every word in **bold** above is just as true for many more millions of truly innocent patients unable to fill their just as legitimate prescriptions for other controlled substances. Why exclude all non-MOUD medications in your request for threshold relief? Patients suffering from pain and mental health issues are just as entitled to their legitimately prescribed controlled FDA approved medications.

One example of the harm to innocent pain patients of the state AG's settlement's *Injunctive Relief* is documented by Kaiser Permanente's (KP/TPMG) physician group's ill-advised reaction to it; across the board forced tapers of pain patients' medications. Patients were first warned of this now implemented action with these words in a *NCAL Pharmacy Operations and Services* letter dated, January 23, 2023:

"*Kaiser Permanente prescribers and pharmacists are reviewing opioid treatment plans and prescriptions in response to …* ***a legal settlement between wholesalers and the government***." *… Because of nationwide changes in supplies, prescribing and dispensing controlled substances affecting both KP and non-KP pharmacies,* ***some pharmacies may run out of certain medications****."*

When a senior Kaiser patient with documented severe pain conditions was put on a protocol to force taper her, she pleaded with her Kaiser physician to stand up for her. When her physician said she would lose her job if she spoke up, the patient put in a formal complaint through Kaiser's grievance process. The Kaiser response was that their pharmaceutical companies (their Distributor) would stop providing their medications if they did not comply with the "guidelines." The "guidelines" were later verified to be the *Injunctive Relief* of the state AGs' National Opioid Settlement. Quoting from Kaiser's January 14, 2023, response, a letter from the Assistant Chief of Adult and Family Medicine, Kaiser Vacaville, "*These protocols in part are in place and rigid due to pressure pharmaceutical companies not providing meds to pharmacies who are not complying with these guidelines. So it is not just federal regulations that are dictating decisions made by TPMG*".

Additionally, there has been considerable media coverage about the harmful impact to the supply of a myriad of controlled substances, not just MOUDs, due to the state AGs' nationwide settlement with the three major distributors of controlled substances. The attachment to this letter is a sampling of this reporting.

Please expand your very appropriate "ask" to include all controlled substances and resend your letter to include all the signatories (or the current office holders) of the AG's settlement with the distributors. Doing so will ensure you receive a response from the individuals responsible for the *Injunctive Relief*. Expanding your very appropriate "ask" to include all controlled substances will deliver the message that you are fighting for all vulnerable patients without discrimination or bias.

Thank you for your engagement on this critical issue. We look forward to reading your revised, more inclusive, and readdressed letter.

Sincerely,

Richard A Lawhern PhD, Patient Advocate

for the Speakers Bureau, National Campaign to Protect People In Pain
Publications: http://www.face-facts.org/Lawhern/
Facebook: http://www.facebook.com/red.lawhern/
Personal Website: http://www.lawhern.org

Attachment: ***Media Reports of AGs' Settlement's Harm***