Damoth, Debbie@DCA

From: MONTY GODDARD <montygoddard@msn.com>
Sent: Friday, October 11, 2024 4:37 PM
To: Damoth, Debbie@DCA
Subject: Oct 16th, E & C Committee Mtg - Agenda Item IV
Attachments: DEA & HHS Ltr (Undated but prior to March 8, 2024).pdf; AMA, et al, May 10 letter to DEA, HHS, et al.pdf; Injunctive Relief Thresholds.pdf

Hi Debbie,

I am very pleased to see the impact of the state AGs' nationwide opioid settlement with the three major distributors of controlled substances to pharmacy shelves is this coming week's Oct 16th, E & C Committee meeting Agenda Item IV. I plan to attend "virtually".

I am requesting this email and its three attached PDFs be distributed to the E & C Committee members prior to the meeting.

I wish to "prime" the committee members with solid evidence the settlement is causing real harm to the controlled substance supply chain ahead of the scheduled presentation. I hope they will ask questions of and seek answers of the presenters in the event the presentation does not specifically address these harms in sufficient detail.

The first two PDFs, although focused on the supply of MOUDs (Buprenorphine/Suboxone), clearly substantiate the supply chain harm impacting all controlled substances as a direct result of the aforementioned settlement's "Injunctive Relief".

The third PDF is a portion of the Injunctive Relief's customer(pharmacy/pharmacy chains) specific order "Thresholds" requirements. Thresholds which the distributors must establish and keep secret from their customers.

In conclusion, here is my succinct analysis of the injunction's thresholds impact:

If a pharmacy submits an order, or summation of orders, exceeding the distributor's secret threshold for the pharmacy, the injunction requires the distributor to cease filling all orders for controlled substances to the pharmacy, AND to report the offending order as a suspicious order to the pharmacy's state AG and the DEA.

Only after/if the "suspicious order" is "resolved" can supplies resume to the offending pharmacy.

This nefarious process is why pharmacy's err on the side of caution, in order to not exceed their "threshold", when they have ZERO knowledge of what their "threshold" # is.

This “blind” erring on the side of caution by the pharmacies is what is causing much of the shortages on pharmacy shelves!

Thank you again Debbie.

Respectfully.

Monty Goddard PE MSCE

Dear DEA Registrant,

In 2022, 6.1 million people in the United States had an opioid use disorder (OUD). Among them, only 18.3% received medication-assisted treatment. The removal of the Drug Addiction Treatment Act of 2000 "x-waiver" in December 2022 eliminated a significant barrier to treatment for OUD, dramatically increasing the number of medical professionals who can prescribe buprenorphine from the previously eligible 130,000 prescribers.

The Drug Enforcement Administration (DEA) and the Department of Health and Human Services (HHS) are committed to ensuring safe and ready access to medications for opioid use disorder (MOUD), especially in rural or underserved areas where treatment options have been limited. With the passage of the Consolidated Appropriations Act, 2023,[1] there was an immediate and significant increase in the number of practitioners who can prescribe schedule III MOUD products (e.g., buprenorphine combination products containing buprenorphine and naloxone) for patients with OUD.

As access to treatment increases, it is understood that the use of MOUD products will likely increase at the same time. DEA recognizes that there have been recent increases in demand for certain schedule III MOUD controlled substances as compared to years prior to the Opioid Public Health Emergency, and that there may be a corresponding increase in prescriptions for these medications from medical providers. DEA supports collaboration amongst all DEA registrants to ensure there is an adequate and uninterrupted supply of MOUD products when these products are appropriately prescribed. 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. DEA has posted a guidance document on its portal related to this issue: https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-065)(EO-DEA258)_Q_A_SOR_and_Thresholds_(Final).pdf.

For more information, please visit www.samhsa.gov and/or www.DEAdiversion.usdoj.gov. It is our sincere hope that the remarkable increase in the number of medical professionals who can prescribe this life-saving medication will not only change the lives of individuals with OUD, but will also stem the escalating rate of opioid-related deaths at a population level.

Please join us in this fight to save lives.

Sincerely,

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

[1] Pub. L. No. 117-328, 136 Stat. 4459 (2022).

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

XII. THRESHOLDS

A. Each Injunctive Relief Distributor shall use Thresholds to identify potentially Suspicious Orders of Controlled Substances from Customers.

B. Each Injunctive Relief Distributor's CSMP department shall be responsible for the oversight of the process for establishing and modifying Thresholds. The sales departments of the Injunctive Relief Distributors shall not have the authority to establish or adjust Thresholds for any Customer or participate in any decisions regarding establishment or adjustment of Thresholds.

C. Injunctive Relief Distributors shall not provide Customers specific information about their Thresholds or how their Thresholds are calculated.

1. Threshold Setting

a) Injunctive Relief Distributors shall primarily use model-based thresholds. For certain circumstances, Injunctive Relief Distributors may apply a non-model threshold based on documented customer diligence and analysis.

b) Each Injunctive Relief Distributor shall include in its Annual Threshold Analysis and Assessment Report (as required by Section XVIII.F.3.c) to the Monitor summary statistics regarding the use of non-model thresholds and such information shall be considered by the Monitor as part of its Threshold Setting Process Review in the annual Audit Report.

c) For the purposes of establishing and maintaining Thresholds, each Injunctive Relief Distributor shall take into account the Controlled Substances diversion risk of each drug base code. The diversion risk of each base code should be defined and reassessed annually by the Injunctive Relief Distributor's CSMP Committee and reviewed by the Monitor.

d) Each Injunctive Relief Distributor shall establish Thresholds for new Customers prior to supplying those Customers with Controlled Substances and shall continue to have Thresholds in place at all times for each Customer to which it supplies Controlled Substances.

e) When ordering volume from other distributors becomes readily available from the Clearinghouse, an Injunctive Relief Distributor shall consider including such

information as soon as reasonably practicable in establishing and maintaining Thresholds.

f) Each Injunctive Relief Distributor shall incorporate the following guiding principles in establishing and maintaining Customer Thresholds, except when inapplicable to non-model Thresholds:

(1) Thresholds shall take into account the number of nonControlled Substance dosage units distributed to, dispensed and/or number of prescriptions dispensed by the Customer to assist with the determination of Customer size. As a general matter, smaller customers should have lower Thresholds than larger customers.

(2) For the purposes of establishing and maintaining Thresholds, Injunctive Relief Distributors shall use statistical models that are appropriate to the underlying data.

(3) For the purposes of establishing and maintaining Thresholds, Injunctive Relief Distributors shall take into account a Customer's ordering and/or dispensing history for a specified period of time.

(4) For the purposes of establishing and maintaining Thresholds, Injunctive Relief Distributors shall take into account the ordering history of Customers within similar geographic regions, or, where appropriate for Chain Customers, ordering history within the chain.

(5) If appropriate, Thresholds may take into account the characteristics of Customers with similar business models. (a) A Customer's statement that it employs a particular business model must be verified, to the extent practicable, before that business model is taken into account in establishing and maintaining a Customer's Threshold.

2. Threshold Auditing

a) The Injunctive Relief Distributors shall review their respective Customer Thresholds at least on an annual basis and modify them where appropriate.

b) Each Injunctive Relief Distributor's CSMP department shall annually evaluate its Threshold setting methodology and processes and its CSMP personnel's performance in adhering to those policies.

3. Threshold Changes

a) An Injunctive Relief Distributor may increase or decrease a Customer Threshold as set forth in its CSMP policies and procedures, subject to Sections XII.C.3.b through XII.C.3.e.

b) Prior to approving any Threshold change request by a Customer, each Injunctive Relief Distributor shall conduct due diligence to determine whether an increase to the Threshold is warranted. This due diligence shall include obtaining from the Customer the basis for the Threshold change request, obtaining and reviewing Dispensing Data and/or Pharmacy Customer Data for the previous three (3) months for due diligence purposes, and, as needed, conducting an on-site visit to the Customer. This Threshold change request diligence shall be conducted by the Injunctive Relief Distributor's CSMP personnel.

c) No Injunctive Relief Distributor shall proactively contact a Customer to suggest that the Customer request an increase to any of its Thresholds, to inform the Customer that its Orders-to-date are approaching its Thresholds or to recommend to the Customer the amount of a requested Threshold increase. It shall not be a violation of this paragraph to provide Chain Customer headquarters reporting on one or more individual Chain Customer pharmacy location(s) to support the anti-diversion efforts of the Chain Customer's headquarters staff, and it shall not be a violation of this paragraph for the Injunctive Relief Distributor's CSMP personnel to contact Customers to seek to understand a Customer's ordering patterns.

d) An Injunctive Relief Distributor's Chief Diversion Control Officer may approve criteria for potential adjustments to Customer Thresholds to account for circumstances where the Thresholds produced by the ordinary operation of the statistical models require modification. Such circumstances include adjustments to account for seasonal ordering of certain Controlled Substances that are based on documented diligence and analysis, adjustments made to permit ordering of certain Controlled Substances during a declared national or state emergency (e.g., COVID-19 pandemic), IT errors, and data anomalies causing results that are inconsistent with the design of the statistical models. Each Injunctive Relief Distributor shall include in its Annual Threshold Analysis and Assessment Report (as required by Section XVIII.F.3.c) to the Monitor information regarding the use of this

paragraph and such information shall be considered by the Monitor as part of its Threshold Setting Process Review in the annual Audit Report.

e) Any decision to raise a Customer's Threshold in response to a request by a Customer to adjust its Threshold must be documented in a writing and state the reason(s) for the change. The decision must be consistent with the Injunctive Relief Distributor's CSMP and documented appropriately.