

## Matthew J. Strait

April 30, 2024

#### **Disclaimer**



The contents of this document do not have the force and effect of law and are not meant to bind the public or DEA in any way.

This document is intended only to provide clarity to the public regarding existing requirements under the law or agency policies.

I have no financial relationship to disclose.

### Copyright Disclaimer

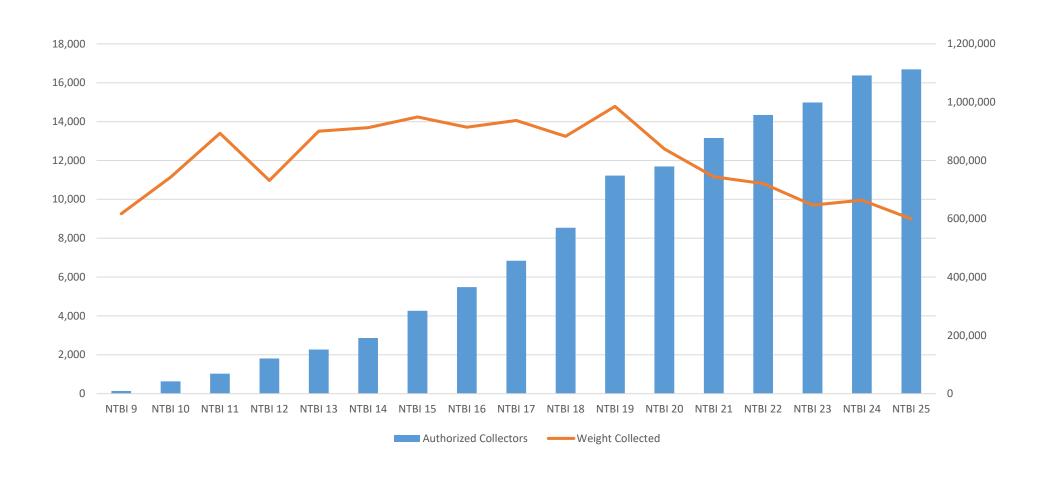


The presentation is for educational purposes.

Materials, images, or sounds authored or created by parties other than DEA may be subject to copyright and are used herein in accordance with the fair use provision of Title 17 United States Code Section 107. DEA's use of these materials does not authorize persons outside of DEA further distribute of use copyrighted materials.

#### WEIGHTS AND AUTHORIZED COLLECTORS BY NTBI EVENT





#### **EVERY DAY IS TAKE BACK DAY**



Dispose of unneeded medication.

√ Clean them out.

√ Take them back.

✓ All year long.







# Mission of the Diversion Control Division

To prevent, detect, and investigate the diversion of controlled pharmaceuticals and listed chemicals from legitimate sources while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs.

#### MEDICATION FOR OPIOID USE DISORDER (MOUD) ISSUES





Consolidated Appropriations Act of 2023: the MAT and MATE Acts



**SORS** and buprenorphine guidance

- "DEA-Registered Manufacturer and Distributor Established Controlled Substance Quantitative Thresholds and the Requirement to Report Suspicious Orders"
- "Prescribing Buprenorphine under the Mainstreaming Addiction Treatment Act (the MAT Act) for Opioid Use Disorder (OUD)"



HHS (SAMHSA) rule: "Medications for the Treatment of Opioid Use Disorder" (89 FR 7528, published 2/2/24)



**HHS/SAMHSA/DEA** joint letter on MOUD

#### DEA/HHS/SAMHSA JOINT MOUD LETTER





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'S GUIDANCE DOCUMENT PORTAL





U.S. DEPARTMENT OF JUSTICE \* DRUG ENFORCEMENT ADMINISTRATION

#### **DIVERSION CONTROL DIVISION**

#### **Guidance Document Portal**

Guidance Document Information

Executive Order 13891 requires agencies to put their guidance documents on easily searchable websites so individuals are able to access them, and Department of Justice policy prohibits using guidance as a substitute for regulation. Guidance may not be used to impose new requirements on persons outside the Executive Branch except as expressly authorized by law or expressly incorporated into a contract, grant, or cooperative agreement. See <u>JM 1-19.000</u>.

Guidance documents are not binding and lack the force and effect of law, unless expressly authorized by statute or expressly incorporated into a contract, grant, or cooperative agreement. Consistent with Executive Order 13891 and the Office of Management and Budget implementing memoranda, the Department will not cite, use, or rely on any guidance not so authorized or incorporated that is not accessible through this guidance portal, except to establish historical facts. To the extent any guidance document sets out voluntary standards (e.g., recommended practices), compliance with those standards is voluntary, and noncompliance will not result in enforcement action. Guidance documents may be rescinded or modified in the Department's complete discretion, consistent with applicable laws.

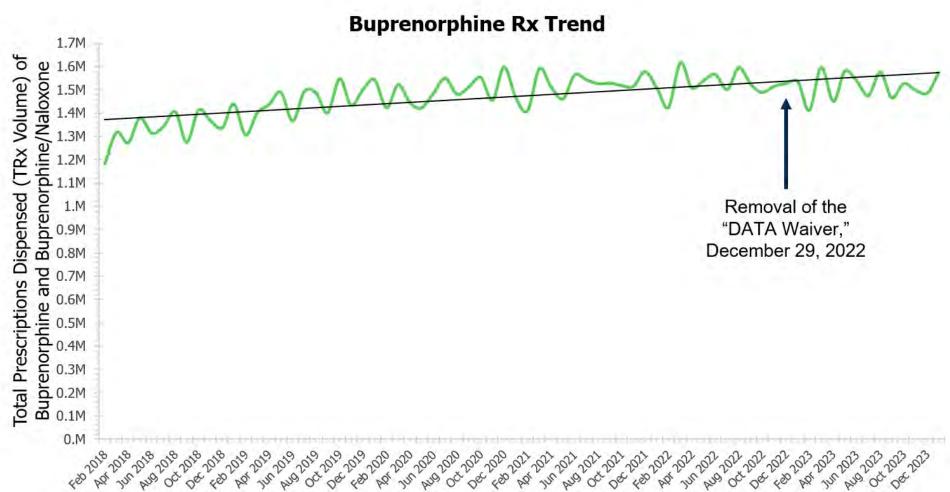
Furthermore, guidance documents may not represent the Department's authoritative or official position and generally are not intended to receive judicial deference. A guidance document may be considered the Department's authoritative or official position only if it is issued in a form understood to reflect the Department's authoritative policy, and only if it emanates from those Department officials whose actions in the relevant context may be said to reflect the considered views of the Department as a whole. See <a href="Question 25 of OMB">Question 25 of OMB</a> <a href="Memorandum M-20-02">Memorandum M-20-02</a>, <a href="Guidance Implementing Executive Order 13891">Guidance Implementing Executive Order 13891</a> (October 31, 2019).

Effective February 28, 2020, these documents can also be viewed and commented on at the United States Department of Justice Guidance Portal, the link to which will be posted soon.

https://apps.deadiversion.usdoj.gov/guidance/#no-back-button

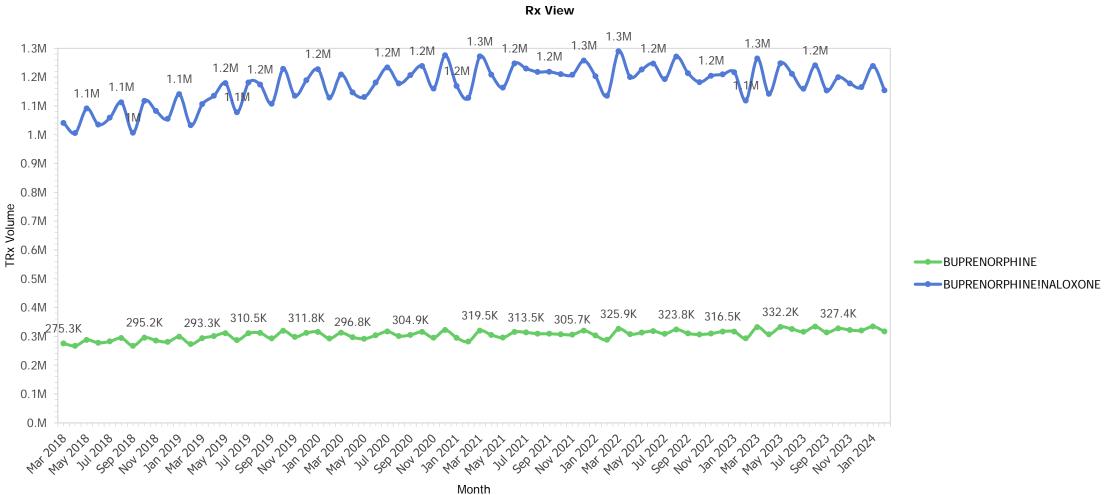
#### **ALL BUPRENORPHINE PRESCRIPTIONS**





## BUPRENORPHINE PRESCRIPTIONS DISPENSED: SINGLE ENTITY AND COMBINATION PRODUCTS





# BUPRENORPHINE SALES TO PHARMACIES (IN KG): ALL PRODUCTS





