The Intersection of DEA, Opioids and MAT

Dennis Wichern
DEA Special Agent (Ret.)
PDC LLC

Who I Am

• Retired DEA Special Agent in Charge - Chicago.
• 30 years of experience.
• Worked through the Indiana “pill mill” crisis during 2005 through 2014.
• Have been partnering with medical community/prescribers for last 10 years through controlled substance compliance programs.
• Developer of CME prescription drug compliance programs focusing on hospitals, pharmacies, OTP's, MAT, pain, prescriber safeguards and training programs.
• I am not an attorney.
• Zero medical training.
Disclosure Statement

- This is not a promotional talk for any pharmaceutical company.
- I will not discuss off-label/investigative use of any commercial product.

Presentation Outline

- DEA Background & Authority
- HHS/SAMHSA MAT Requirements
- Recent Federal Legislation
- Case Studies & Red Flags
- Other Updates & DEA Resources
- MAT Practice Safeguards
- Q & A
DEA’s Primary Focus & Background

• Cartels, Gangs, and Criminal Organizations Trafficking Heroin, Fentanyl, Cocaine and Methamphetamine
• Not MAT Providers or OTP’s
• However, DEA has oversight of pharmaceutical controlled substances (CS’s)
• And is required by law to review those that use CS’s daily

DEA’s Role with Medical Providers & Hospitals

DEA’s authority under the CSA is not equivalent to that of a State medical board. DEA does not regulate the general practice of medicine.

The responsibility for educating and training physicians so that they make sound medical decisions in treating pain (or any other ailment) lies primarily with medical schools, post-graduate training facilities, State accrediting bodies, and other organizations with medical expertise.

DEA’s authority is limited to controlled substances only.

DEA’s Role with Controlled Substances

DEA’s statutory responsibility under the Controlled Substance Act (CSA) is twofold:

1) prevent diversion and abuse of drugs
2) ensure an adequate and uninterrupted supply is available to meet the country’s legitimate medical, scientific, and research needs.

DEA has no medical doctors on staff and must hire one to define standard of care if needed.

https://www.deadiversion.usdoj.gov/prog_dscrpt/index.html

Controlled Substances Act of 1970
21 USC

Legal foundation of federal government’s authority for controlled substances and listed chemicals.

Under the CSA, Congress established a "closed system" of distribution to prevent the diversion of controlled substances.

All persons who lawfully handle controlled substances must be registered with DEA or exempt from registration.

Ultimate users (patients) are not required to register with DEA to possess controlled substances.

The regulations are approximately 50 years old and subject to interpretation.
The Intersection of DEA, Opioids, and MAT

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THE CSA'S CLOSED SYSTEM
EVERYONE IS REGISTERED
RECORDKEEPING FOR ALL CONTROLLED SUBSTANCES

Reverse Distributor
Record Keeping & Security Requirements

All Registered
Recordkeeping for all CS's

Manufacturer
Record Keeping & Security Requirements

Distributor
Record Keeping & Security Requirements

Practitioner
Record Keeping & Security Requirements

Foreign Manufacturer
Record Keeping & Security Requirements

Patient

Prescription Drug Consulting LLC DEA Compliance & Training Experts

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DEA DIVERSION CONTROL PROGRAM
Includes

Cyclic Investigations

Record Keeping Requirements

Established Schedules

Security Requirements

Registration

Established Quotas

ARCOS

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HHS/SAMHSA Authority

vs

DEA Authority

Medically Assisted Treatment (MAT) of Opioid Use Disorder (OUD) Authorities

**HHS/SAMHSA**
- Medical practice
- The medications used
- ASAM partnership

**DEA**
- Security of the drugs
- Recordkeeping requirements
- Runs independently
DATA Waived & Office Based Opioid Treatment (OBOT)

Drug Abuse Treatment Act (DATA) of 2000


Provider Licensing

1. State Medical License
2. State Controlled Substance Registration
3. Federal Controlled Substance Registration (DEA) $888 fee for three years.
4. X-Number (DEA & HHS) License to treat substance users. Must have license from SAMHSA. No additional fee.

5. All federal licenses contingent on state licenses
The Intersection of DEA, Opioids, and MAT

### Obtaining a DATA Waiver

1. Provider takes 8 hour MAT training class from SAMHSA
   - NPs and PAs take 24 hour class
   - SAMHSA verifies provider requirements & notifies DEA

2. DEA assigns a special identification number in addition to a provider regular DEA number (X number)

3. Year 1: up to 30 patients
   - Year 2: up to 100 patients
   - Year 2: Can go to 275 patients if or earlier?

4. New 30 patient cap without training (6/26/2021)
   - What file NO with SAMHSA

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**DEA Compliance & Training Experts**
MAT Training

https://www.samhsa.gov/medication-assisted-treatment/become-buprenorphine-waivered-practitioner

275 Patient Requirements

Two Options
1) By holding additional credentialing; or
2) By practicing in a qualified practice setting

- "Board certification in addiction medicine or addiction psychiatry by the American Board of Addiction Medicine or the American Board of Medical Specialties, or certification by the American Board of Addiction Medicine or the American Society of Addiction Medicine."

- "Qualified Practice Setting"
  1) Provides professional coverage for patient medical emergencies during hours when the practice is closed.
  2) Provides access to case management services for patients, including referral and follow-up services for programs that provide or financially support medical, behavioral, social, housing, employment, educational, or other related services.
  3) Uses health information technology if it is already required in the practice setting.
  4) Is registered for their state prescription drug monitoring program where operational and in accordance with federal and state law.
  5) Accepts third-party payment for some services, though not necessarily for buprenorphine-related services and not necessarily all third-party payers.


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Medications to Treat Opioid Addiction

- **Methadone**
  - NTP’s/OTP’s/Methadone Clinics
  - Can also be prescribed for pain & three day rule

- **Naltrexone**
  - not a CS

- **Buprenorphine**
  - DATA Waived

Common Forms of Buprenorphine

- Suboxone
- Subutex
- Zubsolv
- Sublocade
- Probuphine
- Generics

https://www.samhsa.gov/medication-assisted-treatment/become-buprenorphine-waivered-practitioner
Opiate Treatment Programs (OTPs)
Methadone Clinics
Narcotic Treatment Programs (NTPs)

- Established in 1972
- Public/private
- Dispense liquid methadone for addiction & bup
- Also provide counseling
- Highly regulated

Inside a Opioid Treatment Program
OTP Take Home Doses

Methadone Take-Home Flexibilities Extension Guidance

On March 16, 2020, SAMHSA issued an exemption to Opioid Treatment Programs (OTPs) whereby a state could request “a blanket exception for all stable patients in an OTP to receive 28 days of Take-Home doses of the patient’s medication for opioid use disorder.” States could also “request up to 14 days of Take-Home medication for those patients who are less stable but who the OTP believes can safely handle this level of Take-Home medication.” Almost two years since this exemption was granted, states, OTPs, and other stakeholders report that it has resulted in increased treatment engagement, improved patient satisfaction with care, and few incidents of misuse or medication diversion. There is sufficient evidence to conclude that this exemption has enhanced and encouraged use of OTP services.

https://www.samhsa.gov/medication-assisted-treatment/statutes-regulations-guidelines/methadone-guidance

OTP Mobile Methadone Component

Letter to OTP Directors, SOTAs and State Directors on Mobile Component (PDF | 216 KB)

Information regarding the authorization for Opioid Treatment Programs (OTPs) to add a “mobile component” to their existing registration. This is an opportunity to expand access to medications for treatment of Opioid Use Disorders (OUD), especially in remote or underserved areas.

https://www.samhsa.gov/medication-assisted-treatment/statutes-regulations-guidelines#mobile
**OTP Compliance Officers**

240-276-2700
or email [DPT@samhsa.hhs.gov](mailto:DPT@samhsa.hhs.gov).

“SAMHSA’s OTP Compliance Officers also provide OTPs with ongoing guidance and support and will review and make a decision regarding unsupervised or take-home use.”

https://www.samhsa.gov/medication-assisted-treatment/about-dpt/otp-compliance-officers

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**OTP Licensing**

1. State Approval
2. SAMHSA Approval
3. DEA license/registration (last step)

DEA’s only authority is the security and the recordkeeping for controlled substances – methadone and buprenorphine.
Differences Between DATA - Waived/OBOT/MAT Practice & Opioid Treatment Program

**DATA Waived/OBOT**
- SAMHSA approved
- Patient limits
- Cannot prescribe or dispense methadone
- Allowed to prescribe and dispense buprenorphine
- Counselors onsite not required
- Flexible guidelines

**OTP Treatment Programs**
- Federal, state & SAMHSA approved
- No patient limits
- Allowed to dispense liquid methadone
- Allowed to dispense buprenorphine
- Counselors onsite
- Fairly rigid guidelines

Nationwide Numbers
1,889,057 - MD's, DO's, NP's & PA's (9/1/2022)

**120,288 DATA/OBOT's**
(9/1/2022)

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<tr>
<td>Practitioner-DW/30</td>
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<tr>
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<td>16,417</td>
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<tr>
<td>Practitioner-DW/275</td>
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<td>Nurse Practitioner-DW/30</td>
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<td>Physician Assistant-DW/100</td>
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<td>Nurse Practitioner - DW/275</td>
<td>2,242</td>
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<tr>
<td>Physician Assistant-DW/275</td>
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**1,956 OTP's**
(9/1/2022)

https://dpt2.samhsa.gov/treatment/
2016 CARA Highlights & FAQ’s

Comprehensive Addiction and Recovery Act (CARA)

• In effect since July 22, 2016
• Qualifying physicians can treat up to 30, 100 or 275 patients (Board Certification for those treating 275)
• Qualifying NP’s and PA’s can treat up to 30 or 100 – forever.
• Revised SAMHSA guidelines TIP 63 published February 15, 2018.
• When in doubt – email SAMHSA.
• About 6% of total are waived.

Data Waived Physicians as of 9/2021 - SAMHSA

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<tr>
<th>Patient Limit</th>
<th>Waived Physicians</th>
<th>Percentage</th>
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<td>30 patient</td>
<td>85,191</td>
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<tr>
<td>100 patient</td>
<td>26,266</td>
<td>(22%)</td>
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<tr>
<td>275 patient</td>
<td>8,821</td>
<td>(7%)</td>
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<tr>
<td>Total</td>
<td>120,288</td>
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Who Decides the MAT Patient Caps?

CARA Highlights
Final Rule - 42 CFR Part 8

- “The final rule also includes requirements to ensure that patients receive the full array of services that comprise evidence-based MAT and minimize the risk that the medications provided for treatment are misused or diverted.”
- “HHS has changed the highest patient limit from 200 to 275.”
- “With respect to the comments suggesting that no limit apply to patients treated with new formulations, HHS does not believe that raising the limit beyond that specified in this rule is warranted at this time.”

CARA Highlights
Final Rule - 42 CFR Part 8

- “HHS received comments stating that the proposed rule does not address the many reasons why providers are not prescribing MAT to the fullest extent of their current waivers, including concerns about public and private insurer reimbursement for the additional reporting, documentation, and counseling as well as concerns about on-site DEA inspections.”


DEA MAT Support

December 2019

September 2020 with AMA

https://www.deadiversion.usdoj.gov/pubs/docs/mat.htm
CARA Highlights
Final Rule - 42 CFR Part 8

• “Under the final rule, practitioners authorized to treat up to 275 patients will be required to meet infrastructure requirements that exceed those required for practitioners who have a waiver to treat 100 or fewer patients. HHS proposed additional criteria and responsibilities for practitioners to be able to treat up to the higher patient limit with the specific aims of ensuring quality of care and minimizing diversion.”

• “HHS has determined that increasing the patient limit to 275 balances the pressing need to expand access to MAT with the desire to ensure the provision of high-quality, evidence-based MAT while limiting the risk of diversion.”


CARA Highlights
Final Rule - 42 CFR Part 8

• “Given the significant responsibility associated with prescribing buprenorphine, HHS believes that practitioners should be board certified or practicing in a qualified practice setting to safely and appropriately provide this treatment to up to 275 patients.”

• “HHS believes that in order to ensure quality care, providing behavioral health support services is a key component to delivering effective MAT and encourages all practitioners prescribing covered medications to ensure that their patients receive it. The selection of behavioral health support services is a clinical decision to be made between the practitioner and the patient.”

Anecdotal Information
on Why Data Waived Physicians Do Not Use Their X Numbers

It is estimated that about half of those certified do not treat drug users.

- Do not like nor want patient base
- Small practice providers lack counseling support and expertise
- Some do not believe in replacing one opioid for another opioid
- Addiction treatment is difficult and time consuming
- Success rate is poor, expect 7 to 8 relapses or higher

MAT Guidelines

HHS/SAMHSA Guidelines

ASAM Guidelines

HHS/SAMHSA Guidelines

[Links to relevant guidelines are provided.]
The Intersection of DEA, Opioids, and MAT

Requirements of a OBOT Provider per 2021 Guidelines

- The law requires buprenorphine prescribers to be able to refer patients taking OUD medication to counseling and ancillary services. Buprenorphine prescribers may meet this requirement by keeping a list of referrals or by providing counseling themselves. Section 4-5, page 217


Requirements of a OBOT Provider per 2021 Guidelines

“Office-Based Induction Providers can perform office-based induction by ordering and storing induction doses in the office or by prescribing medication and instructing patients to bring it to the office on the day of induction.” Section 3-60, page 146


Presented by: Dennis Wichern
The Intersection of DEA, Opioids, and MAT

2021 SAMHSA Guidelines
(Multiple Forms in Appendix)

- Appendix
  - Diversion Plan 5-29
  - Bup Office Policy 5-45
  - Treatment Agreement 5-50


Emergency Narcotic Addiction Treatment “The Three Day Rule”
21CFR1306.07(b)

“An exception to the registration requirement, known as the “three day rule” (Title 21, Code of Federal Regulations, Part 1306.07(b)), allows a practitioner who is not separately registered as a narcotic treatment program, to administer (but not prescribe) narcotic drugs to a patient for the purpose of relieving acute withdrawal symptoms while arranging for the patient’s referral for treatment, under the following conditions:

- Not more than one day’s medication may be administered or given to a patient at one time
- This treatment may not be carried out for more than 72 hours and;
- This 72-hour period cannot be renewed or extended

The intent of 21 CFR 1306.07(b) is to provide practitioner flexibility in emergency situations where he may be confronted with a patient undergoing withdrawal. In such emergencies, it is impractical to require practitioners to obtain a separate registration. The 72-hour exception offers an opioid dependent individual relief from experiencing acute withdrawal symptoms, while the physician arranges placement in a maintenance/detoxification treatment program. This provision was established to augment, not to circumvent the separate registration requirement.”
https://www.deadiversion.usdoj.gov/pubs/advisories/emerg_treat.htm
What About DEA MAT Inspections?

Data 2000 Regulations

“Under the authority of the Controlled Substances Act (21 U.S.C. 822 (f)), DEA is authorized to conduct periodic on-site inspections of all registrants. DWPs are also subject to on-site inspections to ensure compliance with the DATA and its implementing regulations.”

https://www.deadiversion.usdoj.gov/pubs/docs/dwp_buprenorphine.htm
The History of DEA MAT Inspections

- Federal law back in 1970’s gave DEA authority to inspect those registered to maintain drugs on a routine basis. DEA routinely inspects all drug manufacturers, wholesalers & distributors.
- Federal law requires security and extensive recordkeeping for all controlled drugs.
- Most OBOTs failed to keep accurate records of their buprenorphine due to lack of knowledge.
- Most if not all inspections lead to benign “Letter of Admonition” to keep better records in future.
- DEA has changed OBOT visits to once every 15 years as of 2016.
- **Best Practice:** Prescribe for induction and never maintain drugs if possible in office setting. Never worry about DEA and records again.

What are the criteria when DEA completes a audit on a MAT Provider?

**DEA’s Authority is Limited to Controlled Substances Only.**
- DEA’s focus during an audit will be on the controlled substance records – bup on hand.
- DEA will also check patient limits 30, 100 or 275.
- Most recordkeeping violations result in only a letter of admonition.

**Prescriber Advice & Counsel**
- If possible, don’t maintain any CS’s/bup at office and write only prescriptions.
- **DEA cannot find a violation if you don’t maintains any CS’s/bup.**
- If you maintain CS’s/bup keep good records that are all in one place. Think checkbook register.
**Required Records – Controlled Substances**

**CFR Part 1304**

- POA’s for II’s – not needed for buprenorphine (III)
- Initial Inventory
- Biennial Inventory
- Closing Inventory
- Receiving Records, 222’s or invoices – 2 year federal retention
- Distribution Records
- Theft and Loss – DEA Form 106 Report to LE
- Drug Destruction – DEA Form 41 – Reverse Distributors – Return to Manufacturer
- Prescriptions vs Dispensing (*Must keep dispensing records*)

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**The DEA Audit Process**

- Two diversion investigators or more
- Two to four hour process
- Starts with a DEA form 82 “Notice of Inspection”
- You have right to refuse
- Administrative search warrant option
- Records need to be “readily retrievable”
The DEA Audit Form

<table>
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<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Names &amp; Strength of Drugs</td>
<td>Initial Inventory as _______</td>
<td>Total Purchased (same time frame)</td>
<td>Total Accountable For (2 +3)</td>
<td>Closing Inventory as of</td>
<td>Total Dispensed</td>
<td>Total Can Account For (5+6)</td>
<td>Difference Over Short = (7-4)</td>
<td>Percentage Difference (8/4 x100)</td>
</tr>
</tbody>
</table>

Providers Who Maintain Office Buprenorphine (bup) for Induction Must Keep the Following Records

- Maintain all bup purchase invoices for two years.
- Conduct a bup inventory audit every two years.
- Maintain a bup dispensing log comprised of patient name, date, amount of bup used and providers initials.
- Keep bup secured in locked cabinet.
- Think checkbook register!
The DEA NTP Manual

June 2022


I Want to Know More
MAT Providers by Zip Code

https://www.samhsa.gov/medication-assisted-treatment/practitioner-program-data/treatment-practitioner-locator

OTP’s by State

https://dpt2.samhsa.gov/treatment/
**Behavioral Health Treatment Services Locator by Zip Code**

[Image: Behavioral Health Treatment Services Locator]

[Link: https://findtreatment.samhsa.gov/]

**SAMHSA MAT Main Page**

[Image: SAMHSA MAT Main Page]

[Link: https://www.samhsa.gov/medication-assisted-treatment]
**SAMHSA MAT Help**

“Individual practitioners interested in applying for a buprenorphine waiver, or who currently have a buprenorphine waiver and have questions, should contact CSAT’s Buprenorphine Helpdesk at 1-866-BUP-CSAT (1-866-287-2728) or by email at infobuprenorphine@samhsa.hhs.gov”

https://www.samhsa.gov/medication-assisted-treatment/about-dpt/otp-compliance-officers

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**DEA DATA Waived Main Page**

https://www.deadiversion.usdoj.gov/pubs/docs/index.html
Most Commonly Abused Pharmaceutical Drugs

Prescription Drug Consulting LLC  
DEA Compliance & Training Experts

91% of all evidence from 273 participating labs from 49 states
https://www.nflis.deadiversion.usdoj.gov
Top Seized Opioids Analgesics

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<tr>
<th>Narcotic Analgesics</th>
<th>Number</th>
<th>Percent</th>
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</thead>
<tbody>
<tr>
<td>Fentanyl</td>
<td>117,945</td>
<td>58.91%</td>
</tr>
<tr>
<td>Diphenoxylate</td>
<td>17,817</td>
<td>8.59%</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>17,818</td>
<td>8.57%</td>
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<tr>
<td>Tramadol</td>
<td>12,366</td>
<td>6.08%</td>
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<tr>
<td>AWRP7</td>
<td>11,877</td>
<td>5.57%</td>
</tr>
<tr>
<td>Hydrocodone</td>
<td>8,460</td>
<td>4.06%</td>
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<tr>
<td>Acetylsalicylic acid</td>
<td>8,077</td>
<td>3.83%</td>
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<tr>
<td>Morphine</td>
<td>7,000</td>
<td>3.35%</td>
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<tr>
<td>Methadone</td>
<td>1,596</td>
<td>0.75%</td>
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<tr>
<td>Codeine</td>
<td>1,413</td>
<td>0.67%</td>
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<tr>
<td>Carfentanil</td>
<td>1,394</td>
<td>0.66%</td>
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<tr>
<td>Hydromorphone</td>
<td>1,079</td>
<td>0.50%</td>
</tr>
<tr>
<td>Valerol-fentanyl</td>
<td>515</td>
<td>0.26%</td>
</tr>
<tr>
<td>Phenethyll-A-MHP</td>
<td>459</td>
<td>0.22%</td>
</tr>
<tr>
<td>Oxycodein</td>
<td>305</td>
<td>0.15%</td>
</tr>
<tr>
<td>Other narcotic analgesics</td>
<td>2,223</td>
<td>1.02%</td>
</tr>
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</table>

Total Narcotic Analgesics Reports: 198,694
Total Drug Reports: 3,201,511

https://www.nflis.deadiversion.usdoj.gov/publicationsRedesign.xhtml

Top Three Benzodiazepines Submitted to Crime Laboratories

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<tr>
<th>Benzodiazepines</th>
<th>Percent</th>
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<tr>
<td>Alprazolam (Xanax)</td>
<td>47%</td>
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<tr>
<td>Clonazepam (Klonopin)</td>
<td>14%</td>
</tr>
<tr>
<td>Diazepam (Valium)</td>
<td>5%</td>
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Walk Me Through Some MAT Case Studies

Types of Investigations & Examples

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<th>Examples</th>
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<td>Administrative</td>
<td>Provider self-abuse</td>
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<tr>
<td>Civil</td>
<td>Recordkeeping violations</td>
</tr>
<tr>
<td></td>
<td>- Manufacturers</td>
</tr>
<tr>
<td></td>
<td>- Dispensers</td>
</tr>
<tr>
<td></td>
<td>- Handlers of CS's</td>
</tr>
<tr>
<td></td>
<td>- Significant fines possible</td>
</tr>
<tr>
<td>Criminal</td>
<td>Pill Mills, Billing fraud &amp; other</td>
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Presented by: Dennis Wichern
Federal Law – Definition of a Legitimate Prescription
Title 21 Code of Federal Regulations (CFR) 1306.04

Section 1306.04 Purpose of issue of prescription.
(a) 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. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

Section 1306.05 Manner of issuance of prescriptions.
(a) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner.

Source: www.deadiversion.usdoj.gov/21cfr/ch/1306/1306_04.htm
www.deadiversion.usdoj.gov/21cfr/ch/1306/1306_05.htm
MAT Civil Fine Only #1
Boston, MA August 8, 2018
(Might have been charged criminally for fraud in other district?)

- Dr. Hung K. Do and his addiction treatment clinic, H.K.D. Treatment Options, have agreed to pay $23,000 to settle claims of improper billing of medical services under the Controlled Substances Act and the False Claims Act. Dr. Vasumathi Brown, a physician employed by H.K.D., has agreed to pay a $12,500 civil penalty for issuing invalid prescriptions for controlled substances under the Controlled Substances Act.

- It is alleged that, at Dr. Do’s direction, Dr. Brown signed hundreds of blank prescriptions for use by unsupervised non-physician staff while Dr. Brown was on vacation in December 2016. Ultimately, unsupervised non-physician staff issued over 600 prescriptions for controlled substances using the pre-signed blank prescriptions. It is further alleged that Dr. Do subsequently billed Medicare improperly for services related to the prescriptions that non-physician staff provided in Dr. Brown’s absence, and that Dr. Do falsely reported to Medicare that Dr. Brown supervised those services.


MAT Civil Fine #2
Syracuse, NY June 8, 2017

“Physician Accepted Payment in Marijuana at Appointments Where Controlled Substances Were Prescribed – Agreed to $50,000 Civil Judgment

The government alleged that, over an approximately year and a half time period, Dr. Blake issued twenty-three Suboxone prescriptions to a patient and was paid by the patient in small quantities of marijuana for at least twelve of the corresponding medical appointments. Dr. Blake admitted to being paid in marijuana but asserted that it was fewer than twelve times. The government also alleged that Dr. Blake created a medical record in only four of the twenty-three visits.

The CSA and its implementing regulations make it unlawful for a physician registered with the Drug Enforcement Administration (DEA) to dispense a controlled substance unless the prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of her professional practice. Violations of this requirement create civil penalty exposure of up to $25,000 per violation.”

MAT Criminal Charges #1
Albany, NY July 19, 2018

“Adrian Morris, age 61, a Clifton Park, New York, psychiatrist specializing in addiction recovery, was arrested today and charged with distributing controlled substances outside the course of professional practice and for no legitimate medical purpose.

According to a criminal complaint, Morris dispensed Xanax, Adderall, and Suboxone to patients for no legitimate medical purpose, and to at least one patient in exchange for sex. In addition to writing unjustified prescriptions to patients, Morris also wrote prescriptions for individuals he never treated.”


MAT Criminal Charges #2
Former Suboxone Clinic Doctor Sentenced for Illegal Prescribing and Health Care Fraud
October 16, 2019

“Bummer and other doctors at Redirections would routinely pre-sign blank prescriptions for buprenorphine, which is a scheduled controlled substance under federal law.

The pre-signed prescriptions were then given to other medically-unlicensed employees at Redirections who completed the prescription and provided it to the patients in exchange for cash. On numerous occasions, the doctors were not physically present at Redirections and did not exam their patients when prescriptions bearing their names were issued.

Because the prescriptions were illegally issued, Medicare and Medicaid were defrauded when Redirections’ patients used their insurance to fill the prescriptions.

Common OBOT MAT Problem Areas & Red Flags

• Non-provider owner/manager
• Non-provider owner/manager has access to blank prescriptions/pre-signed prescriptions
• No insurance accepted (cash only)
• Irregular business hours
• Patient visits lasting just a few minutes
• Complaints from patients, pharmacies, and from other providers
Common OTP Problem Areas

• Overall poor recordkeeping
• Failing to conduct biennial inventory
• Not securing medication in safe
• Not testing alarm system on a regular basis
What About Urine Drug Screens?

(No federal law on UDSs)

Do You have a policy or contract in place?

Positive Screens
• Using MAT – good thing
• Using other drugs – expected and for how long?
• Terminate?
• Expect relapses
• How often and how many?
• Methadone in screen?
  – VA
  – NTP/OTP
  – Importance of PMP use
• Other?
• Importance of following guidelines

Negative Screens
• Not good
• Indicates diversion?
• Terminate patient?
Buprenorphine Diversion

NPR Maryland Article

• Maryland effective July 1, 2016 stopped allowing Suboxone strips under Medicaid but allowing tablet forms.

• “State officials say the change was made to stop the illicit flow of the drug into jails and prisons. “Those Suboxone strips were diverted and smuggled into jails and later were sold or traded in criminal activity that was happening in jails,” says Shannon McMahon, deputy secretary of Maryland’s Department of Health and Mental Hygiene. "The numbers were frankly staggering, the amount of diversion that was happening in the jails.”

https://www.npr.org/sections/health-shots/2016/07/19/486419277/maryland-switches-opioid-treatments-and-some-patients-cry-foul
Buprenorphine Diversion/Smuggling

Columbus, Ohio Dispatch 2017

“Behind prison walls in Ohio, inmates regularly are abusing an opioid normally used to wean people off drugs. Inmates, many of whom are in prison on drug charges in the first place, are sneaking in Suboxone, which is legally prescribed to treat people recovering from heroin addiction. The drug is vying to become the most common contraband drug brought into state prisons — neck-and-neck with marijuana. Prison officials say a strip of Suboxone the size of a postage stamp, which melts on the tongue, goes for about $100 or more in a lucrative prison black market. The Suboxone strips are similar to small mouthwash strips but contain a slow-acting opioid.”

Emergence of State MAT Laws

- West Virginia 2016
- Kentucky 2017
- Tennessee 2017
- Ohio 2017
  - Most new state laws deter cash businesses, must be owned or lead by MD, must be licensed & registered with state, and will be inspected by state authorities. New regs/laws similar to methadone clinic oversight requirements

What else should I know?
Telemedicine - 21 USC 802 (54)

- **Ryan Haight Act - Federal**
  - Background
  - Allows for telemedicine after an in-person evaluation
  - Provider must be licensed in states which it occurs
  - Patient must be in the physical presence of a doctor sitting in medical office
  - New exception regulation by DEA forthcoming

- Risk mitigation
- Evolving medicine & law
- Risk increases with CS's
- Equal state & fed?
- Ensure oversight & guideline adherence
- Stay current

What is Kratom?

- Leaves from a southeast Asia tree
- Used to self-treat pain, anxiety and depression,
- Smoked or put in tea
- Stimulant at low doses
- Sedative at higher doses
- DEA action - 2016
- FDA advisories
  - 2017 – 36 deaths
  - 2018 – 44 deaths
  - 2019 – 91 deaths
- Illegal in states of AL, AR, IN, VT & WI
Dea Press Release
August 26, 2019
Hemp CBD is not a Controlled Substance

“This notice also announces that, as the result of a recent amendment to federal law, certain forms of cannabis no longer require DEA registration to grow or manufacture. The Agriculture Improvement Act of 2018, which was signed into law on Dec. 20, 2018, changed the definition of marijuana to exclude “hemp”—plant material that contains 0.3 percent or less delta-9 THC on a dry weight basis. Accordingly, hemp, including hemp plants and cannabidiol (CBD) preparations at or below the 0.3 percent delta-9 THC threshold, is not a controlled substance, and a DEA registration is not required to grow or research it.”


Law Enforcement & Treatment Partnerships

Develop “A Way Out” Program with Law Enforcement & Treatment Providers?

• “A Way Out” is a Law Enforcement Assisted Diversion pilot program, designed to fast-track users to treatment programs and services. This program is available 24 hours a day, 7 days a week at participating police departments and ensures no criminal charges will be sought for those that may be in possession of narcotics or paraphernalia, as long as assistance is sought out by the prospective program participant.

• Also known as a “Angel Program” or Police Assisted Addiction & Recovery Initiative (PAARI)

• http://awayoultc.org/
• http://paariusa.org/
Wrap it Up

Specific MAT Prescriber Protection & Safeguards

- Follow a general and accepted MAT guideline
- Ensure a counseling referral & component
- Practice due diligence
- No one expects you to be perfect all the time
- Use your PDMP
- Conduct UDS’s
- **Prescribe only for induction in office/out patient setting**
Specific OTP Protection & Safeguards

• Maintain impeccable records.
• Assign one person in each office as the DEA poc.
• Conduct an inventory at least annually if not sooner.
• Keep medication receiving personnel lists accurate and up to date.

DEA FAQ’s
SAMHSA MAT Help

**DATA/OBOT/Buprenorphine**

“Individual practitioners interested in applying for a buprenorphine waiver, or who currently have a buprenorphine waiver and have questions, should contact CSAT’s Buprenorphine Helpdesk at 1-866-BUP-CSAT (1-866-287-2728) or by email at infobuprenorphine@samhsa.hhs.gov”

[https://www.samhsa.gov/medication-assisted-treatment/about-dpt/otp-compliance-officers](https://www.samhsa.gov/medication-assisted-treatment/about-dpt/otp-compliance-officers)

**Opioid Treatment Program**

240-276-2700
or email DPT@samhsa.hhs.gov.

“SAMHSA’s OTP Compliance Officers also provide OTPs with ongoing guidance and support and will review and make a decision regarding unsupervised or take-home use.”

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**Why is Marijuana Still a Schedule I Drug?**

The federal Controlled Substance Act (CSA) was implemented in 1970 and has changed little over the years.

The FDA pursuant to federal law makes determinations as to what is medicine and has for over 50 years. Its scientific assessment team determines the safety and efficacy of drugs intended for human consumption.

The FDA has not approved marijuana as a medicine. (Marinol & Epidolex approved)

DEA places drugs into a Schedule (I through V) according to its accepted medical use and potential for abuse in consultation with the FDA pursuant to CSA. 

Research: Over 350 researchers have been approved to study marijuana and DEA has never turned a researcher approved by the HHS (first step). DEA oversees security requirements.

Why Are So Many People Incarcerated For Drug Possession?
(2012 Data from President Obama’s Whitehouse Website)

**State**

For Federal prisoners, who represent 13 percent of the total prison population, about half (51 percent) had a drug offense as the most serious offense in 2009. And Federal data show that the vast majority (99.8 percent) of Federal prisoners sentenced for drug offenses were incarcerated for drug trafficking.


**Federal**

![Drug Possession Offenders in State Prisons](image)

Why Are There Not More Drug Diversion Programs?

**3,800 Drug Courts and Counting**

There are over 3,800 drug court programs operating within the United States.

Every state – as well as some federal districts – contain at least one drug court program. Since their inception in 1989, drug courts programs have expanded from serving just adults, to include juvenile drug treatment courts, DUI/DWI courts, family treatment courts, mental health courts, veterans treatment courts, tribal healing to wellness courts, and others.

https://ndcrc.org/what-are-drug-courts/
https://www.drugpolicyfacts.org/node/3831
Questions

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