

Treating OUD with MAT in the ED: Legal & Regulatory Considerations – the Quick & Easy Guide

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STR-TA
Consortium
State Targeted Response
Technical Assistance



STR-TA Initiative

Working with communities to address the opioid crisis.

- ✧ SAMHSA's State Targeted Response Technical Assistance (STR-TA) Consortium assists STR grantees and other organizations, by providing the resources and technical assistance needed to address the opioid crisis.
- ✧ Technical assistance is available to support the evidence-based prevention, treatment, and recovery of opioid use disorders.

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Working with communities to address the opioid crisis.

- ✧ The STR-TA Consortium provides local expertise to communities and organizations to help address the opioid public health crisis.
- ✧ The STR-TA Consortium accepts requests for education and training resources.
- ✧ Each state/territory has a designated team, led by a regional Technology Transfer Specialist (TTS) who coordinates the implementation of evidence-based practices.

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Contact the STR-TA Consortium

✧ To ask questions or submit a technical assistance request:

- Visit www.getSTR-TA.org
- Email str-ta@aaap.org
- Call 401-270-5900

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MAT in the ED: Legal & Regulatory Considerations – Learning Objectives

Learning objectives

Provide the Emergency Physician with a knowledge of:

- ✧ Buprenorphine Prescribing Rules:
 - “72 hour rule”
 - DEA License "X-waiver"
- ✧ Confidentiality Regulations - 42 CFR Part 2
 - Why methadone treatment doesn't show up on the PDMP
- ✧ DEA Compliance – Prescribing and Dispensing/Administering
- ✧ Key Clinical Documentation and Record Keeping



Qs: What is the “DATA 2000 DEA X-waiver”?

**Aren't There Rules About Using Bupe In
The ED?**

What is the “72 Hour Rule”?



DATA 2000/ X-Waiver

- ✧ “DATA 2000”? “X-waiver”? What does this refer to?
- ✧ “Drug Addiction Treatment Act of 2000”
 - (went into effect in 2002)
- ✧ Provided a “waiver” to treat opioid addiction outside of a traditional opioid treatment program (e.g. a “methadone clinic”) – to **PRESCRIBE buprenorphine**.
 - Interesting, there is no special license/certification required to work as a provider in a methadone clinic.
- ✧ Applies to “schedule III, IV and V medications with FDA approval to treat addiction...”

(psst... Buprenorphine is the only one!)



DATA 2000/ X-Waiver

- ✧ Requirements to get an “X-waiver”:
 - Active state medical license
 - (As of 2017, PAs and APRNs may also apply)
 - Valid individual DEA license
 - Eight-hour course for MD/DOs
 - PAs/APRNs require 24 hours
 - Patient limits apply to patients treated “at any one time”
 - A rolling limit of current prescriptions
 - 30 patients in the first year
 - May increase to 100 pts in year two
 - Then may increase to 275 in year three



DATA 2000/ X-Waiver

- ✧ Again, the “X-waiver” permits the provider to PRESCRIBE bupe:
- ✧ “for the treatment of opioid use disorder, including *maintenance, detoxification ... and relapse prevention*”
- ✧ Assuming, that “the practitioner has the capacity to provide directly, by referral, [or in other manner] appropriate counseling and other appropriate ancillary services.”
 - As an ED provider, referring a patient to an addiction treatment program is sufficient.
 - An ED provider is not required to be able to ensure that a patient follows up with such a program.



“Three Day Rule”

HOWEVER, In the outpatient/ED setting, per the DEA:

Any DEA-licensed practitioner in a DEA registered facility may **administer** (but not prescribe) bupe to a patient to treat withdrawal symptoms ‘while arranging for the patient’s referral for treatment’:

- ✧ “Not more than one day’s medication may be administered or given to a patient at a time.”
- ✧ “Treatment may not be carried out for more than 72 hours.”
- ✧ “The 72-hour period cannot be renewed or extended.”



“Three Day Rule” – the highlights

- ✧ Again, **per the DEA, ANY** licensed provider (MD, DO, PA, APRN) may **administer** a daily dose of bupe to an ED patient for up to 3 days in a row.
 - A DEA X-waiver license is **NOT** required.
 - Every ED is a “DEA Registered Facility” – so no special license or permit is required of the hospital.
- ✧ Does not have to be the same provider all 3 days.
- ✧ The “dose” (in milligrams of bupe) is NOT specified.
 - During a single ED visit, there is no limit on the milligrams of bupe which can be administered (“bupe loading” is possible)



“Three Day Rule” – the highlights

- ✧ The route of administration is NOT specified.
 - Thus, depot injections of long acting subcutaneous or intramuscular formulations of bupe are not excluded.
- ✧ Patients are NOT dispensed a 3-day supply
- ✧ However, An “X-waiver” is required to prescribe any buprenorphine (for the treatment of OUD).
 - Prescribing even a single dose (to be filled at a pharmacy) -- requires an X-waiver.



No limit for admitted patients!

- ✧ If admitting the patient from the ED, NO limit on days of administration:
- ✧ NO “limitations on a physician or other authorized hospital staff to maintain or detoxify a person with bupe as an incidental adjunct to medical or surgical conditions other than opioid dependency.”
- ✧ “A patient with an opioid dependency who is admitted to a hospital for a primary medical problem ... [e.g. acute MI] ... may be administered opioid agonist medications such as methadone and buprenorphine to prevent opioid withdrawal that would complicate the primary medical problem.”
- A DATA 2000 X-waiver is NOT required.



“Three Day Rule” – Referral to Clinic?

- ✧ *Is it **necessary** to be able to refer a patient to an opioid addiction treatment clinic, to administer bupe in the ED for withdrawal or MAT?*
- ✧ Officially, it is required ...
- ✧ The DEA cares about **DIVERSION** of prescribed, or dispensed, bupe.
- ✧ The DEA is far, far less concerned about medications ordered and administered in hospitals.



U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION
DIVERSION CONTROL DIVISION



Back to the DATA 2000/ X-Waiver

- ✧ So, if an ED provider, isn't required to have an X-waiver to be able to administer bupe in the ED ...
 - **Why should an ED doc get an X-waiver?**
- ✧ ED providers should get “X-waivers” to:
 - Learn more about Opioid Use Disorder, AND ...
 - When ED docs prescribe bupe from the ED:
 - Patients don't need to return to the ED daily (“three day rule”) to get a dose of bupe, waiting to get into a clinic.
 - Patients who receive bupe are less likely to return to the same ED within 30 days for a drug-related visit
 - Berg ML, Idrees U, Ding R, et al. Evaluation of the use of buprenorphine for opioid withdrawal in an emergency department. Drug Alcohol Depend. 2007 Jan 12;86(2-3):239-44
 - Patients are twice as likely at 30 days to be in treatment!!
 - D'Onofrio G, O'Connor PG, Pantalon MV, et al, JAMA. 2015 Apr 28;313(16):1636-44



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AAAP American Academy of
Addiction Psychiatry

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Qs: Are there special privacy rules for treating addiction?

What is “42 CFR Part 2”?

Why can't I tell from the PDMP that a patient is in methadone treatment?



Federal Health Privacy Laws

- ✧ **HIPAA:** Health Insurance Portability and Accountability Act of 1996
 - Minimum safeguards to protect privacy of protected health information (PHI)
- ✧ “Confidentiality of Alcohol and Drug Abuse Patient Records, Title 42 Code of Federal Regulations (CFR) Part 2” -- **“42 CFR Part 2”**
 - Promulgated in 1975, updated in 1987, further revisions anticipated
 - Governs confidentiality of alcohol and drug treatment and prevention information
 - Extra protections because of the potential for SUD information to be used against an individual
 - Loss of employment, housing, child custody
 - Discrimination (health professionals, insurers)
 - Criminal consequences
- ✧ **Think of 42 CFR Part 2 as “HIPAA Plus”**



Who is covered by 42 CFR Part 2?

- Applies to federally assisted drug/alcohol treatment and prevention “programs”
- **“Program”** not clearly defined but is interpreted as the following:
 1. Standalone individual or entity whose...
 2. Specific unit within a general medical facility whose...
 3. Individual within a general medical facility whose...

... primary function and identity is to provide drug/alcohol diagnosis, treatment, or referral for treatment



Who is covered by 42 CFR Part 2?

An individual or entity that holds itself out as providing and provides OUD diagnosis, treatment, or referral for treatment

– i.e., The primary role is to provide these OUD services

42 CRF Part 2 **does NOT apply** to general medical facilities

✧ E.g., Hospital, **Emergency Department**, Primary Care

42 CRF Part 2 **DOES apply** to alcohol/drug programs within them

✧ E.g., Inpatient detox unit or outpatient OUD clinic within a medical center

✧ E.g., Addiction specialist working in a primary care practice



Code of Federal Regulations

(CFR) 42 C.F.R. Part 2

- 42 C.F.R. Part 2:
 - **Must obtain signed patient consent** before disclosing information to any third party
 - Including records of prescriptions to pharmacy
 - Disclosure includes any communication (oral, written, or electronic) identifying someone as having an alcohol/drug problem or being a patient in an alcohol/drug program (past or current)
- Additional information at:
 - <https://www.samhsa.gov/about-us/who-we-are/laws-regulations/confidentiality-regulations-faqs>
- An Example Consent Form can be found in TIP-40:
https://www.ncbi.nlm.nih.gov/books/NBK64245/pdf/Bookshelf_NBK64245.pdf



Some Exceptions to Disclosure Rules

- ✧ Internal communications (within the program)
- ✧ Qualified service organization agreement
- ✧ Crimes on premises or against personnel
- ✧ **Medical emergencies**
- ✧ Mandated reports
- ✧ IRB approved research
- ✧ Audit and evaluation
- ✧ Court orders

**Confer with your legal department if uncertain



Consequences of Violating 42 CFR Part 2

- ✧ Criminal penalty
- ✧ Loss of SUD treatment program license or certification
- ✧ Patients may take legal action



Why should ED Docs care about 42 CFR?

- ✧ More difficult to get records from an Opioid Addiction Treatment Clinic/Facility for patients in the ED/hospital:
 - Clinic Staff are trained to vigorously protect patients' privacy.
 - Addiction clinics always expect a signed Release of Information (ROI) form.
 - If a patient can't give consent (e.g. the patient is intubated), an addiction clinic will expect documentation of the emergent medical condition and the reason the patient can't give consent.
 - Will expect in writing before giving any verbal information.
 - Most addiction clinics aren't open after hours, but are expected to have an "after hours" phone number for emergencies.
- ✧ Addiction Clinics also expect an ROI from the patient before requesting ED records.
 - Build getting a signed ROI of the ED record (before the patient leaves the ED), part of your standard "warm hand-off" process.



Why isn't Methadone treatment listed on PDMP reports?

- ✧ If a patient receives treatment in a methadone program (also known as an “OTP” – for “Opioid Treatment Program”), that information is NOT reported to state prescription data monitoring programs (PDMPs).
 - Protected by 42 CFR Part 2.
 - No medication is “prescribed”
 - No prescription – no report to the state board of pharmacy.
 - Methadone programs only “administer” and “dispense” methadone (and in some programs, buprenorphine as well).
 - Methadone clinics report daily to the “State Opioid Treatment Authority” (the “SOTA”) in each state.
 - Some patients are aware of this, and may still seek prescriptions of opioids for either personal use, or to divert.
- ✧ EXCEPTION: Methadone *prescribed* for pain (rarely a good idea), will show up on the PDMP.



Qs: Any special documentation requirements?

Any special documentation tips?



ED Documentation Tips:

- ✧ If prescribing buprenorphine, put the diagnosis of “moderate” or “severe opioid use disorder” on the chart:
 - This diagnosis is usually easily supported by a well-documented ED chart, particularly if patients present with:
 - Opioid Overdose
 - Opioid withdrawal
 - Heroin use
 - History of smoking, snorting, or injecting opioids.
 - An abscess or other infectious complication from injecting opioids.
 - Should be documented when prescribing buprenorphine for the treatment of opioid use disorder
 - If done in the ED this can expedite referral process for many outpatient treatment providers!
 - See next page of DSM-5 criteria for OUD – most patients in the ED with OUD complications easily meet the criteria.



TABLE 1

Summarized DSM-5 diagnostic categories and criteria for opioid use disorder

Category	Criteria
Impaired control	<ul style="list-style-type: none">• Opioids used in larger amounts or for longer than intended• Unsuccessful efforts or desire to cut back or control opioid use• Excessive amount of time spent obtaining, using, or recovering from opioids• Craving to use opioids
Social impairment	<ul style="list-style-type: none">• Failure to fulfill major role obligations at work, school, or home as a result of recurrent opioid use• Persistent or recurrent social or interpersonal problems that are exacerbated by opioids or continued use of opioids despite these problems• Reduced or given up important social, occupational, or recreational activities because of opioid use
Risky use	<ul style="list-style-type: none">• Opioid use in physically hazardous situations• Continued opioid use despite knowledge of persistent physical or psychological problem that is likely caused by opioid use
Pharmacological properties	<ul style="list-style-type: none">• Tolerance as demonstrated by increased amounts of opioids needed to achieve desired effect; diminished effect with continued use of the same amount• Withdrawal as demonstrated by symptoms of opioid withdrawal syndrome; opioids taken to relieve or avoid withdrawal



DEPENDENCE ≠ ADDICTION

ED Documentation Tips:

✧ Documentation of patient education:

- ✧ How to properly take bupe (always and only sublingual)
- ✧ Safe storage
- ✧ Build into the discharge instructions

✧ Plan for referral:

- ✧ Know your local treatment options, and build the macro into the discharge instructions.
- ✧ Partner with administration to develop a hand-off process (use ED social workers, care coordinators, etc.)



Clinical Documentation

– Risk Assessment and Management

- Screening:
 - Increased risk of suicide
 - Assess self-harm or suicidal thoughts, actions, or planning
- Management:
 - Self-Harm/Suicidal: Crisis Services; 911; ED; hospitalization
 - Risk of Harm to Others: Duty to Warn; Protective Services, 911
 - **Overdose Risk: Overdose education and naloxone kit**
- Document clinical decision process of risk assessment and safety planning.



Addiction Clinic Documentation Goals

Elements	Details
General	Open-ended
Symptoms	General, Psychiatric, SUD-specific
Diagnosis	Mild, Moderate, Severe
Medications	Rationale for type of MAT and formulation (pill vs. film) Adherence, Effectiveness/Side-effects Upcoming changes (doses, formulations, refills)
Substance Use	Self-reported use, Cravings, Triggers, Supports/Skills
Lab Results	Current and past test results Upcoming changes (frequency/schedule of testing)
Safety Planning	Suicidal ideation, Risk of harm to others, Overdose risk
Goals of Treatment	Set shared agenda and support collaboration

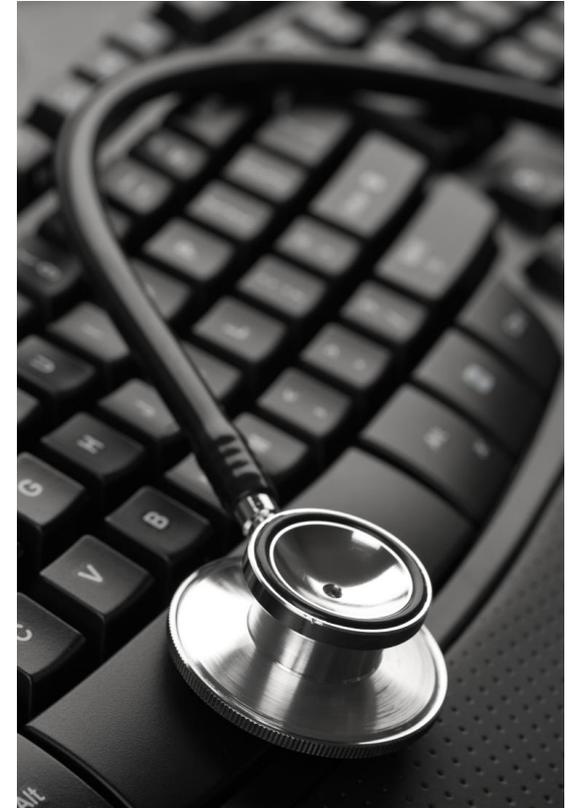
Try to incorporate some of the above, as applicable, in the ED Chart.



Medical Record Keeping

Storage of Records:

- Must keep available according to state and federal requirements
- Can be kept at a central location (but must notify DEA)
- Must be kept in a double-locked, secure place when not in use
- Note: [Electronic Medical Records meet these criteria](#)



Qs: Anything to know about DEA Compliance?

– Prescribing and Dispensing/Administering?



Drug Enforcement Agency (DEA)

- ✧ Authorized by the Controlled Substances Act 21 U.S.C. 822 (f) 880 and 21 CFR 1316.03:
 - Conduct periodic inspections to ensure prescribers and programs comply with:
 - Patient limits that they are waived to treat (30/100/275)
 - Rarely an issue for EM Providers.
 - Record Keeping and Security
 - Other requirement of the Controlled Substances Act
 - All should be easy for EM providers with an EMR.
 - Inspections are low-key and not intended to be punitive.
 - Easiest if the hospital EMR can produce a report of an individual doc's bupe prescribing.



Buprenorphine Prescription Requirements: 21 CFR

- ✧ Basic rules for writing prescription for bupe for the ED:
 - Full identifying information for the patient, including name and address
 - Medication name, strength, dosage form, and quantity
 - Directions for use
 - Dated and signed on the day they are issued
 - All of the above should be simple with any EMR.
- DEA number and DATA 2000 identification number (which begins with the prefix X) – **must be on the script!!**
 - **Review with your EMR administrator** – may not be easy to automate.
- A hospital ED can only provide a “take home” pack of bupe if the ordering ED provider has an X-waiver.
 - **Another reason for ED docs to get X-waivers!**



Office/ED-Based Buprenorphine Storage and Dispensation

- Bupe dispensing/administration is a legal practice under DATA 2000
- Must provide medication security and storage
- Must maintain the following records for 2 years (longer in some states):
 - Inventories of bupe received and amounts dispensed
 - Reports of theft or loss
 - Destruction of controlled drugs
 - Records of dispensing

These records should be covered by your hospital pharmacy and electronic medical record in the ED/hospital based setting

-- But this is another reason that many clinics only perform bupe induction by prescription (as opposed to witnessed “in-office induction”)



Thank you!

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