Laws, Rules, and Regulations Affecting Implementation of MAT Programs

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Speaker Introduction/Disclosures

- Wesley Geminn
  - Chief Pharmacist and State Opioid Treatment Authority, division of clinical leadership; TDMHSAS
  - No relevant disclosures
Objectives

By the end of this presentation, the learner should be able to:

- Compare and contrast the general legal principles between the 3 versions of MAT for OUD
- Recognize recent trends of buprenorphine use in Tennessee
- Discuss the Tennessee Nonresidential Buprenorphine Treatment Guidelines
- Discuss the current laws, rules and regulations relevant to buprenorphine
Types of Treatment Available

- Inpatient
- Residential
- Outpatient
- MAT
21 CFR 1306.07

(a) A practitioner may administer or dispense directly (but not prescribe) a narcotic drug listed in any schedule to a narcotic dependent person for the purpose of maintenance or detoxification treatment if the practitioner meets both of the following conditions:

- (1) The practitioner is separately registered with DEA as a narcotic treatment program.
- (2) The practitioner is in compliance with DEA regulations regarding treatment qualifications, security, records, and unsupervised use of the drugs pursuant to the Act.

(b) Nothing in this section shall prohibit a physician who is not specifically registered to conduct a narcotic treatment program from administering (but not prescribing) narcotic drugs to a person for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment. Not more than one day's medication may be administered to the person or for the person's use at one time. Such emergency treatment may be carried out for not more than three days and may not be renewed or extended.
(c) This section is not intended to impose any limitations on a physician or authorized hospital staff to administer or dispense narcotic drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction, or to administer or dispense narcotic drugs to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts.

(d) A practitioner may administer or dispense (including prescribe) any Schedule III, IV, or V narcotic drug approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment to a narcotic dependent person if the practitioner complies with the requirements of §1301.28 of this chapter.
MAT - Methadone

- The most highly regulated version of MAT

- Can only be used for addiction in a federally-qualified opioid treatment program (OTP)

- Federal laws (42 CFR Part 2) prohibit OTPs from reporting methadone dispensing to a state’s prescription monitoring programs (CSMD in TN)
In Tennessee, any OTP that plans on using methadone will need a Certificate of Need from the Health Services Development Agency.

- Through application, ensures that services allowed to open in areas where they’re needed.
- Expensive - $5.75 per $1000 of estimated project cost. No less than $15,000 and no more than $95,000.

All OTPs must be accredited by a SAMHSA-approved accrediting body (Joint Commission, CARF, some State Departments).

All prospective OTPs must also apply to SAMHSA for a provisional OTP certificate with application to accrediting body.

All OTPs must have a special “Narcotic Treatment Program” registration from the DEA.
Question

How Many OTPs are in Tennessee?

A. 5
B. 13
C. 67
D. 74
MAT - Methadone

- There are currently 13 licensed OTPs in TN
MAT - Buprenorphine

- First drug for office-based opioid treatment (OBOT) under DATA 2000 regulations (Allows prescriber to prescribe CIII-CV substances approved for addiction)

- Obtain DATA waiver, waiver ID is same as DEA # but begins with an “X”

- Max of 30 patients/waiver for 100 after year

- Effective Mid-August 2016, up to 275 after having the 100 patient waiver for one year
  - Must be board-certified or work in a qualified practice setting
MAT - Buprenorphine

- Form of MAT with the most rapidly changing laws and regulations in Tennessee

- This year, we saw several changes passed by the legislature that changes several relevant statutes and directs the promulgation of new rules surrounding OBOTs and OBOTs with dispensing authorization (OBOT Plus).

- Summaries of newly passed legislation can be found on the TDMHSAS website at https://www.tn.gov/behavioral-health
Currently Available Buprenorphine Guidelines

• Tennessee Nonresidential Buprenorphine Treatment Guidelines
  – Applies to any buprenorphine provider in a non-residential setting
  – Adopted by medical and pharmacy boards as policy for standard of care
  – Summer 2018 revised edition currently available

• SAMHSA’s TIP 63: Medications for Opioid Use Disorder
  – Broad guidelines for the use of methadone, buprenorphine, and naltrexone
Currently Available Buprenorphine Guidelines

(Continued)

- ASAM National practice Guideline For the Use of Medications in the Treatment of Addiction Involving Opioid Use
  - Summarizes evidence-based treatment opioid use disorder using medications

- TDMHSAS Emergency Department Buprenorphine Protocol
  - Provides direction on using protocols for treating opioid use disorder in the emergency room
Current Buprenorphine Regulations

• Minimum requirements for nonresidential office-based opiate treatment facilities (OBOTs)
  – Only applies to OBOTs licensed by TDMHSAS
  – Not all buprenorphine prescribers will need a license

• Minimum requirements for nonresidential office-based opiate treatment facilities with dispensing authorization (OBOT Plus)
  – Only applies to OBOTs fully licensed by TDMHSAS and in good standing for at least one year

• DEA’s Practitioner Manual
  – Summarizes requirements under the Controlled Substances Act
  – Applies to all prescribers of controlled substances
What is an OBOT?

- “Suboxone” / Buprenorphine Clinic
- Stand alone clinics, treatment resources, individual physical locations occupied as the professional practice of a prescriber or prescribers licensed pursuant to Title 63, or other entities prescribing products containing buprenorphine, or products containing any other controlled substance designed to treat opiate addiction by preventing symptoms of withdrawal, to **25 percent or more of its patients “or” to 150 or more patients**
How do we regulate OBOTs?

- Admissions / Discharge
- Patient Record
- Individualized Treatment Plan
- Phases of Treatment
- Special Populations
- Counseling
- Medication Management
- Drug Screens
- Detoxification and Medically Supervised Withdrawal
- Diversion Control Plan
- Reporting Requirements
- Patient Rights
- Community Relations
- Staffing Requirements
Individualized Treatment Plan (ITP)

- Must be developed within 30 days of admission in accordance with peer reviewed medication-assisted treatment guidelines developed by nationally recognized organizations.
- Should be reviewed at least every 6 months and discussion held with the patient about their desire to remain in treatment.
- All patients shall receive a medical evaluation at least annually and be documented in the patient chart.
- Shall ensure a comprehensive range of rehabilitative services are available if a patient expresses a need.
- If the patient experiences a relapse, the ITP shall document evidence of intensified services provided.
Phases of Treatment

• Most current phase of treatment must be clearly documented in the patient’s chart.

1. **Induction or stabilization phase**
   • Weekly office visits, appropriate counseling twice a month, observed drug screen at least weekly for a minimum of 3 weeks, and receive case management services weekly

2. **Maintenance phase for less than one (1) year**
   • Every 2 – 4 week office visits, appropriate counseling at least monthly, random observed drug screen at least 8 times annually, case management at least monthly

3. **Maintenance phase for one (1) year or more**
   • At least every 2 month office visits, counseling at least monthly, random drug screens at least 4 times annually, be offered case management at least every 2 months
Medication Management

• “The proper initial dose, medication type, and dosage form shall be based on the clinical judgement of the program physician who has examined the patient and ... in consultation with the patient.”
  • A dose >16mg per day is considered a high dose and 24mg per day is considered a max dose
  • Any dose >24mg per day must have written approval from the State Opioid Treatment Authority (SOTA)
• Must keep a copy of all written prescriptions in the patient’s medical chart
• Prescriber-initiated and led tapering discussions

• Co-prescribing benzodiazepines
  • > 2mg of clonazepam or its equivalent is considered “high dose therapy”
  • Continued high dose therapy must be managed by a physician board certified in addiction medicine, or fellowship trained in addiction psychiatry, or through documented consultation with a physician board certified in addiction medicine or fellowship trained in addiction psychiatry
What is an OBOT Plus?

- An OBOT Plus is a fully licensed OBOT that has authority to physician-dispense buprenorphine

- Public Chapter 978

- But why do OBOTs even need dispensing authority???
How do we regulate OBOT Plus?

All the requirements of the OBOTs with the addition of:

- Medication Storage
- Recordkeeping
- Reporting
- Labeling and Packaging of Buprenorphine Products
- Inventory
- Prerequisites to Issuing Prescriptions or Dispensing Medications
- Central Registry
What Exactly are the Guidelines and Who Do They Guide?

- Intended to be a guide for any provider who wants to provide medication-assisted treatment with buprenorphine for Opioid Use Disorder (OUD)
- Applies to any buprenorphine provider in a non-residential setting
- Adopted by medical and pharmacy boards as policy for standard of care
- Summer 2018 revised edition currently available
- Guidelines reflect the rules

Divided into 3 sections and appendices

1. Prior to Treatment
2. Initiating Treatment
3. Ongoing Treatment
Prior to Treatment

- Assessment and Diagnosis
- Patient Selection
- Consent to Release Information
- Consent to Treatment
- Required Elements for Consent to Treatment Regarding Pregnancy and NAS Prevention
- Requirements for Benzodiazepine Co-prescribing

https://www.tn.gov/content/dam/tn/mentalhealth/documents/FINAL%20Buprenorphine%20Treatment%20Guidelines-Summer%202018.PDF
Initiating Treatment

- Indications for Buprenorphine Without Naloxone
  - Mono-product restrictions
- Selecting a Therapy
- General Dosing Guidelines
- Patient Management
Ongoing Treatment

- Maintenance Treatment
- Monitoring Parameters
- Tapering Treatment
- Relapse Indicators
Naltrexone
Question

Which of the following regarding Naltrexone is correct?

A. The patient must be free from opioids for at least 7 days

B. Must be prescribed from a registered Opioid Treatment Program

C. Only available as an oral tablet

D. Is available without a prescription
MAT - Naltrexone

- Easiest form of MAT to implement

- Tablets approved to treat alcoholism in 1995 and monthly injection (Vivitrol) was approved in 2010 for alcohol and opioid use disorder
  - Blocks euphoric effect of alcohol and opioids.
  - May prevent a misstep from becoming a relapse

- Precipitate withdrawal unless abstinent from opioids for at least 7 days, or 10 days for long acting opioids, like methadone

- It is not a controlled substance and does not need any additional state or federal certifications or licenses, only the authority to prescribe prescription drugs
Naloxone

Role and Usage

- Naloxone is an opioid receptor antagonist that can reverse the life-threatening effects of opioid overdose.
- Naloxone has been used as a “rescue drug” to treat life-threatening effects of opioid overdose by emergency medical personnel, law enforcement, active bystanders, family members, and friends.
- Naloxone availability in the community is one of several approaches to reduce opioid-related deaths.
- Naloxone is not a treatment for addiction, it saves a life.
Naloxone

• Not a controlled substance and may be prescribed by any provider with prescriptive authority

• Many pharmacies have either a standing order or a collaborative pharmacy practice agreement to be able to initiate a prescription for naloxone at the pharmacy

• Naloxone should be considered for anyone who is at risk, or in a position to assist someone is at risk, of experiencing a life-threatening overdose
Now It’s Your Turn to Ask Questions!

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