Regulatory Issues and Medication Assisted Treatment (MAT)

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Note: An updated version of this module is forthcoming pending revision from SAMHSA.
L. F. McNicholas Disclosures

- Dr. McNicholas has no relevant financial relationship(s) with ACCME defined commercial interests to disclose.

The contents of this activity may include discussion of off label or investigative drug uses. The faculty is aware that is their responsibility to disclose this information.
Target Audience

• The overarching goal of PCSS is to make available the most effective medication-assisted treatments to serve patients in a variety of settings, including primary care, psychiatric care, and pain management settings.
Educational Objectives

At the conclusion of this activity participants should be able to:

- Describe the legal differences between an opioid treatment program (OTP) and office-based practice
- Demonstrate if, and when, the prescriber can increase the number of patients to be treated with buprenorphine products
- List which medical professionals may prescribe or dispense buprenorphine products, and under which conditions they may prescribe or dispense
- Explain the needed confidentiality of patient records for patients in substance use treatment
- Demonstrate how to appropriately practice using telemedicine
Outline

• 42 Code of Federal Regulations (CFR), Part 8 – OTP Regulations


• Comprehensive Addiction and Recovery Act (CARA)

• 42 CFR, Part 2 – Confidentiality
Controlled Substances Act

• Controlled Substances Act of 1972 is the overarching legislation covering the appropriate prescribing and dispensing of controlled substances
• It is this legislation that mandates that methadone is only to be used in OTPs, and prior to 2000, it forbid doctors from prescribing opioids to patients suspected or known to have a substance use disorder
• DATA 2000, and later CARA 2016, amended this legislation
Treating Opioid Use Disorder (OUD) with MAT and the Law

- Buprenorphine in Office-Based Practice – DATA 2000 and amendments, CARA
- Naltrexone – no legal restrictions
- Methadone in OTP – 42 CFR, Part 8
- Buprenorphine in OTP – 42 CFR, Part 8

- An amendment to the Controlled Substances Act

- Allows practitioner to prescribe FDA approved narcotic drugs in schedule III, IV, V, or combinations of such drugs, for maintenance or detoxification treatment
• Permits no limitations on the quantities of the drugs that may be provided for unsupervised use, unless the drugs have been subject to adverse determination

• Drugs and practitioner must meet certain requirements
**Practitioner Requirements:**

- “Qualifying physician”
- Has capacity to refer patients for appropriate counseling and ancillary services
- No more than 30 patients (individual practice) for the first year
- May request approval to treat up to 100 patients after the first year
“Qualifying Physician”

- Board certified in Addiction Psychiatry
- Certified in Addiction Medicine by the American Board of Addiction Medicine (ABAM)
- Certified in Addiction Medicine by the American Osteopathic Academy (AOA)
- Investigator in buprenorphine clinical trials leading to FDA approval
- Has completed 8 hours of training provided by one of the following organizations (or others designated by HHS):
  - American Academy of Addiction Psychiatry (AAAP)
  - American Medical Association (AMA)
  - American Osteopathic Academy of Addiction Medicine (AOAAM)
  - American Psychiatric Association (APA)
  - American Society of Addiction Medicine (ASAM)
- Training/experience as determined by state medical licensing board
- Other criteria established by the Secretary of HHS
• Must notify the Secretary of HHS online:
  ▪ His/Her name
  ▪ DEA registration
  ▪ Category for qualification (1 to 7) as noted in previous slide
  ▪ Certify intention to comply with law

Notifications must be submitted online at:
http://buprenorphine.samhsa.gov/forms/select-practitioner-type.php
• **Narcotic Drug:**
  (Narcotic is used here in the legal sense of the Controlled Substances Act: It includes all opioid products as well as other drugs and medications such as cocaine and illegal substances)
  - Approved by the FDA for use in maintenance or detoxification treatment of opioid use disorder
  - Schedule III, IV, or V
  - Drugs or combinations of drugs
  - Buprenorphine is the only drug currently approved (Schedule III)
# Buprenorphine Formulations - DATA 2000

<table>
<thead>
<tr>
<th>Content</th>
<th>Route</th>
<th>Products</th>
<th>Available Doses</th>
<th>Equivalent Dose to 8mg Buprenorphine</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>With Naloxone</strong></td>
<td>Sublingual</td>
<td>Film (suboxone)</td>
<td>2mg Bup/0.5mg Nx 4mg Bup/1mg Nx 8mg Bup/2mg Nx 12mg Bup/3mg Nx</td>
<td>8mg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tablet - Generic</td>
<td>2mg Bup/0.5mg Nx 8mg Bup/2mg Nx</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sublingual</td>
<td>Tablet - (Zubsolv®)</td>
<td>1.4mg Bup / 0.36mg Nx 2.9mg Bup / 0.7mg Nx 5.7mg Bup / 1.4mg Nx 8.6mg Bup / 2.1mg Nx 11.4mg Bup / 2.6mg Nx</td>
<td>5.7 mg</td>
</tr>
<tr>
<td></td>
<td>Buccal</td>
<td>Film (Bunavail®)</td>
<td>2.1mg Bup / 0.3mg Nx 4.2mg Bup / 0.7mg Nx 6.3mg Bup / 1mg Nx</td>
<td>4.2mg</td>
</tr>
<tr>
<td><strong>Mono-product</strong></td>
<td>Sublingual</td>
<td>Tablet - Generic</td>
<td>2mg Bup 8mg Bup</td>
<td>8mg</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Implant</td>
<td>probuphine (Four implants for six-months in one arm)</td>
<td>74.2mg</td>
<td>74.2 mg</td>
</tr>
<tr>
<td></td>
<td>Injection</td>
<td>sublocade (Once-monthly injection)</td>
<td>100mg, 300mg 300mg: First dose 100mg: Steady state dose</td>
<td></td>
</tr>
</tbody>
</table>
Not Approved – DATA 2000

- Methadone
- Buprenorphine immediate release injectable (Buprenex®)
- Sublingual film for pain (Belbuca®)
- Transdermal buprenorphine (Butrans®)
- Tramadol
- Any medication not on the approved list

- DATA 2000 and CARA only apply to scheduled medications.
Use of buprenorphine products in hospital setting:

- If a patient is in the hospital for reasons other than substance use disorder, buprenorphine may be ordered by any provider for medical stabilization for the duration of hospitalization.
- If the patient is not to continue with opioid use disorder (OUD) treatment, the patient should be tapered off buprenorphine appropriately before discharge.
- If the patient is to be continued on OUD treatment after discharge, arrangements for that treatment with an OTP or DATA-waived practitioner MUST be done prior to discharge.
• Use of buprenorphine products in medical emergencies for the treatment of OUD:
  - If a patient is seen for emergency care and wants treatment for OUD, but no OTP or DATA-waived practitioner is available, the emergency practitioner may invoke the “72 Hour Rule” or “3-Day Rule.”
72 Hour Rule or 3-Day Rule

• “3-Day Rule”
  - According to the DEA, 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 or certified as a DATA-waivered practitioner, 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
    - Treatment may not be carried out for more than 72 hours
    - The 72-hour period cannot be renewed or extended
Revised Regulations:
- Physicians may request approval to treat up to 275 patients after one year at 100 patients (as allowed under DATA 2000)
- These physicians must be board certified in addiction psychiatry or addiction medicine or practice in a qualified practice setting
- Annual reporting requirements

Legislation:
- Signed into law 7/22/2016
CARA 2016

• Expands prescribing privileges to nurse practitioners (NPs) and physician assistants (PAs) for five years (until October 1, 2021)

• NPs and PAs must complete 24 hours of training to be eligible for a waiver to prescribe and must be supervised by or work in collaboration with a qualifying physician if required by state law
CARA 2016

- Qualified Practice Setting:
  - Provides 24 hour emergency coverage
  - Provides case management and related services
  - Use health information technology
  - Registered with state prescription monitoring program
  - Accepts third-party payment for some services
• New Standards of Care:
  ▪ Board certified practitioners
  ▪ Access to behavioral health services
  ▪ Follows evidence-based treatment guidelines
  ▪ Individualized treatment plans
  ▪ Diversion control plans
  ▪ Use of state Prescription Drug Monitoring Program
  ▪ Annual reporting requirements
CARA Reporting Requirements

- Average monthly caseload of patients receiving buprenorphine based MAT, per year
- Percentage of active buprenorphine patients that received psychosocial services (either by direct provision, including medical management or referral) in the past year due to:
  - Treatment initiation
  - Change in clinic status
- Percentage of patients who had a Prescription Drug Monitoring Program (PDMP) query in the past month
CARA Reporting Requirements (cont)

• Number of patients at the end of the reporting year who:
  ▪ Have completed an appropriate course of treatment with buprenorphine for the patient to achieve and sustain recovery
  ▪ Are not being seen by the provider due to referral to more OR less intensive level of care
  ▪ No longer desires to continue use of buprenorphine
  ▪ Are no longer receiving buprenorphine for other reasons
42 CFR, Part 8

- Treatment governed by Federal Regulation 42 CFR Part 8
- Accreditation and certification based system of OTPs
  - Oversight – Substance Abuse and Mental Health Services Administration (SAMHSA)/Center for Substance Abuse Treatment (CSAT)/Division of Pharmacologic Therapies (DPT)
  - Oversight to improve treatment not just regulate
  - Tripartite oversight
    - Department of Health and Human Services (DHHS)/SAMHSA (certification)
    - State (licensure / registration)
    - Drug Enforcement Agency (DEA) (registration)
42 CFR, Part 8

- Initial application/provisional certification for 1 year
- Recertification at least every 3 years
- Requires compliance with state statues and regulations
- Apply to SAMHSA for:
  - Addition of new medical units
  - Relocation
- Notify SAMSHA of program changes
  - Program Sponsor
  - Medical Director

Within 3 weeks
• Administrative and organizational structure
• Quality assurance/improvement
• Diversion control plan
• Staff credentials
• Patient admission criteria
• Required services
• Record keeping and patient confidentiality
• Medication dispensing and administration
• Unsupervised use (take-home doses)
• Interim maintenance
• Detoxification
“Short-term detoxification” is defined as < 30 days.
“Long-term detoxification” is defined as 30 – 180 days.
“Maintenance” treatment is defined as:
- “Comprehensive” treatment
  - Medical + “rehabilitative” services
- “Interim” treatment is defined as:
  - Medical services while awaiting referral to “comprehensive” treatment
  - Maximum of 120 days, must refer to comprehensive treatment thereafter.
42 CFR, Part 8 – Admission Criteria

• Qualified personnel using accepted medical criteria, Diagnostic Statistical Manual (DSM) diagnoses the patient with an opioid use disorder including:
  ▪ Current physiological dependence
  ▪ Has been dependent at least 1 year prior to admission
• AND the patient:
  ▪ Voluntarily chooses maintenance treatment
  ▪ Has relevant facts concerning use of opioids clearly and adequately explained
  ▪ Has provided written informed consent to treatment, (standard example form) in Appendix of CSAT Accreditation Guidelines of OTPs
Patient less than 18 years old

- Two documented unsuccessful attempts at short-term detoxification or drug-free treatment within a (12) month period

- Parent or legal guardian consents in writing
Buprenorphine in OTP

• Patients may choose buprenorphine/naloxone in an OTP that offers both methadone and buprenorphine/naloxone.
• The clinic is not restricted in the number of patients receiving buprenorphine, as are office-based under DATA 2000.
• The federal guidelines for methadone take-home doses are not applicable to patients receiving buprenorphine/naloxone, but the labeling must meet OTP and local standards.
Confidentiality

- The law, 42 CFR Part 2, and regulations were written during a time of great concern about the potential use of substance use disorder information against an individual.

- The purpose of 42 CFR Part 2 is to ensure that a patient receiving treatment for a substance use disorder in a Part 2 program is not made more vulnerable than an individual with a substance use disorder who does not seek treatment.
Confidentiality

- The scope of the law
  - Restricts disclosure and use of patient-identifying information, including reporting to PDMPs
  - Patient-identifying information is anything that reveals a person is receiving, has received, or has applied for substance use disorder treatment.
  - Cannot disclose participation in substance use disorder treatment – but can disclose identity under some circumstances
  - Includes current, former, and deceased patients
Confidentiality

• Background on 42 CFR Part 2 applies to federally assisted “alcohol and drug abuse” programs.

• Patient consent must be obtained before sharing information from a program that is subject to 42 CFR Part 2.

• Once this information has been disclosed, no re-disclosure is permitted without the patient’s express consent to re-disclose or unless otherwise permitted under Part 2.
Confidentiality

• A program is considered to be federally assisted if:
  1. It is conducted in whole or in part, whether directly or by contract or otherwise by any department or agency of the United States (but forget this if VA or DoD);

  2. It is being carried out under a license, certification, registration, or other authorization granted by any department or agency of the United States including but not limited to:
    - (i) Participating provider in the Medicare program;
    - (ii) Authorization to conduct maintenance treatment or withdrawal management; or
    - (iii) Registration to dispense a substance under the Controlled Substances Act to the extent the controlled substance is used in the treatment of substance use disorders.
Confidentiality

• Currently, the definition does not apply to general medical facilities, but does apply to general medical/psychiatric practices.

• Added definition: “Treating provider relationship means that, regardless of whether there has been an actual in-person encounter, (a) a patient agrees to be diagnosed, evaluated and/or treated for any condition by an individual or entity and (b) the individual or entity agrees to undertake diagnosis, evaluation and/or treatment of the patient, or consultation with the patient, for any condition.”
Confidentiality

- Limited exceptions for disclosure without consent:
  - Medical emergencies
  - Scientific research
  - Audits and evaluations
    - Medicare, Medicaid, CHiP
  - Child abuse reporting
  - Crimes on program premises or against program personnel
  - Court order (NOT subpoena)
  - Communications with a qualified service organization (QSO) of information needed by the organization to provide services to the program
Confidentiality

• Breach of privacy of information protected by Part 2 can still lead to civil and criminal consequences for patients.
  ▪ Loss of employment, housing, child custody
  ▪ Discrimination by medical professionals and insurers
  ▪ Arrest, prosecution and incarceration

• Modernize the regulations and make them more understandable and less burdensome.
Definition of Telemedicine

- The term "practice of telemedicine" means, for purposes of this subchapter, the practice of medicine in accordance with applicable Federal and State laws by a practitioner (other than a pharmacist) who is at a location remote from the patient and is communicating with the patient, or health care professional who is treating the patient, using a telecommunications system referred to in section 1395m(m) of title 42, which practice—

Definition of Telemedicine

• (A) is being conducted—
  ▪ (i) while the patient is being treated by, and physically located in, a hospital or clinic registered under section 823(f) of this title; and
  ▪ (ii) by a practitioner—
    – (I) acting in the usual course of professional practice;
    – (II) acting in accordance with applicable State law; and
    – (III) registered under section 823(f) of this title in the State in which the patient is located
Telemedicine

- DEA’s statement “Use of Telemedicine while providing MAT” emphasizes that all conditions of the definition of telemedicine must be met, therefore
  - The physician providing telemedicine must be licensed in the state in which the patient is seen.
  - Must have all appropriate state licenses, including, if needed a state DEA license.
  - Should have a practice agreement with the clinic or practice in which the patient is seen.
Telemedicine

• If all the above are met, then the physician does not have to do the initial or follow-up interviews face-to-face.
  - The physician should ensure that the person doing the evaluation is qualified to adequately assess the patient and to determine if the patient needs and qualifies for prescribed buprenorphine.
Summary

- 42 CFR, Part 8, governing OTPs, primarily methadone, is very rigid and restrictive.
- DATA 2000 and CARA 2016 allow for the prescribing of Schedule III, IV and V medications for the treatment of OUD; the medications used under these laws and regulations must be FDA-approved for treating OUD.
- Confidentiality of patients and their records in substance use treatment is more stringent than normal and governed under 42 CFR, Part 2, revised in 2017 (more revision is probable).
- Telemedicine is allowed under the Ryan White Exemption.
References

- SAMHSA MAT info
  - www.samhsa.gov/medication-assisted-treatment

- Federal Guidelines for Opioid Treatment Programs (January 2015)
  - store.samhsa.gov/shin/content//PEP15-FEDGUIDEOTP/PEP15-FEDGUIDEOTP.pdf

- 42 CFR, Part 2
  - www.samhsa.gov/health-information-technology/laws-regulations-guidelines
References

• DATA 2000
  ▪ www.samhsa.gov/programs-campaigns/medication-assisted-treatment/legislation-regulations-guidelines

• CARA 2016
  ▪ www.samhsa.gov/programs-campaigns/medication-assisted-treatment/training-materials-resources/qualify-np-pa-waivers
  ▪ www.samhsa.gov/medication-assisted-treatment/buprenorphine-waiver-management/increase-patient-limits
PCSS Mentor Program

- PCSS Mentor Program is designed to offer general information to clinicians about evidence-based clinical practices in prescribing medications for opioid addiction.
- PCSS mentors are a national network of providers with expertise in addictions, pain, evidence-based treatment including medication-assisted treatment.
- 3-tiered approach allows every mentor/mentee relationship to be unique and catered to the specific needs of the mentee.
- No cost.

For more information visit: pcssNOW.org/mentoring
PCSS Discussion Forum

Have a clinical question?

Ask a Colleague

A simple and direct way to receive an answer related to medication-assisted treatment. Designed to provide a prompt response to simple practice-related questions.

Ask Now
PCSS-MAT is a collaborative effort led by the American Academy of Addiction Psychiatry (AAAP) in partnership with the: Addiction Technology Transfer Center (ATTC); American Academy of Family Physicians (AAFP); American Academy of Neurology (AAN); American Academy of Pain Medicine (AAPM); American Academy of Pediatrics (AAP); American College of Emergency Physicians (ACEP); American College of Physicians (ACP); American Dental Association (ADA); American Medical Association (AMA); American Osteopathic Academy of Addiction Medicine (AOAAM); American Psychiatric Association (APA); American Psychiatric Nurses Association (APNA); American Society of Addiction Medicine (ASAM); American Society for Pain Management Nursing (ASPMN); Association for Medical Education and Research in Substance Abuse (AMERSA); International Nurses Society on Addictions (IntNSA); National Association of Community Health Centers (NACHC); National Association of Drug Court Professionals (NADCP), and the Southeast Consortium for Substance Abuse Training (SECSAT).

For more information: www.pcssNOW.org

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