

What is Necessary and Sufficient to Provide Naltrexone or Buprenorphine in Primary Care Settings?

A Project RAMP Resource

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CONFLICT OF INTEREST AND DISCLOSURE

- Dr. Gordon has no fiduciary conflicts of interest
- Some of the material presented herein has been previously published from work at the University of Pittsburgh, University of Utah, and the Veterans Health Administration
- The views expressed in this presentation are Dr. Gordon's and do not necessarily reflect the position or policy of any institution, agency, or government
- Buprenorphine (BUP) = buprenorphine + naloxone unless otherwise stated

TODAY'S OBJECTIVES

1. Understand the current environment to prescribe naltrexone and buprenorphine for opioid use disorder in primary care environments
2. Relate the requirements to prescribe naltrexone and buprenorphine in primary care environments
3. Describe some helpful tools to enable primary care providers to prescribe naltrexone and buprenorphine
4. Examine models of care to prescribe naltrexone buprenorphine in primary care environments

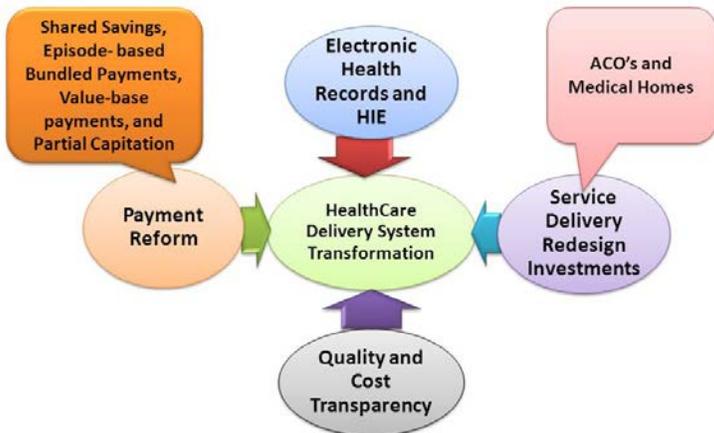
TODAY'S OBJECTIVES (caveats...)

- Today's objectives are easy for naltrexone
 - No real special requirements to prescribe naltrexone in office based settings
 - Although often providers use the requirements to prescribe buprenorphine in office based settings when they prescribe naltrexone
- A majority of necessary and sufficient regulations to provide medication treatment for opioid use disorder is for buprenorphine care
 - While there are many requirements, practices and providers easily achieve them...
 - It is relatively easy...

Changing Primary Care Environment

- Integrated mental health providers
- Active addiction engagement and treatment
 - Pharmacotherapy and non-pharmacotherapy approaches

CMS Tools for Transforming the Delivery System



VA HEALTH CARE | Defining EXCELLENCE in the 21st Century



PACT
PATIENT ALIGNED CARE TEAM

PCMH 6: Measure and Improve Performance

Standard

- Measure performance (preventive/chronic/acute care clinical measures)
- Track utilization measures
- Patient experience survey - identifies vulnerable populations
- Continuous quality Improvement
- Report performance
 - Clinical measures

Meaningful Use Criteria

Report:

- Ambulatory clinical quality measures to CMS/ state
- Immunization data to registries
- Syndromic surveillance data to public health agencies



NCQA
Measuring quality. Improving health care.

Achieving NCQA Recognition as a Patient-Centered Medical Home
RI Statewide Learning Collaborative February 5, 2011

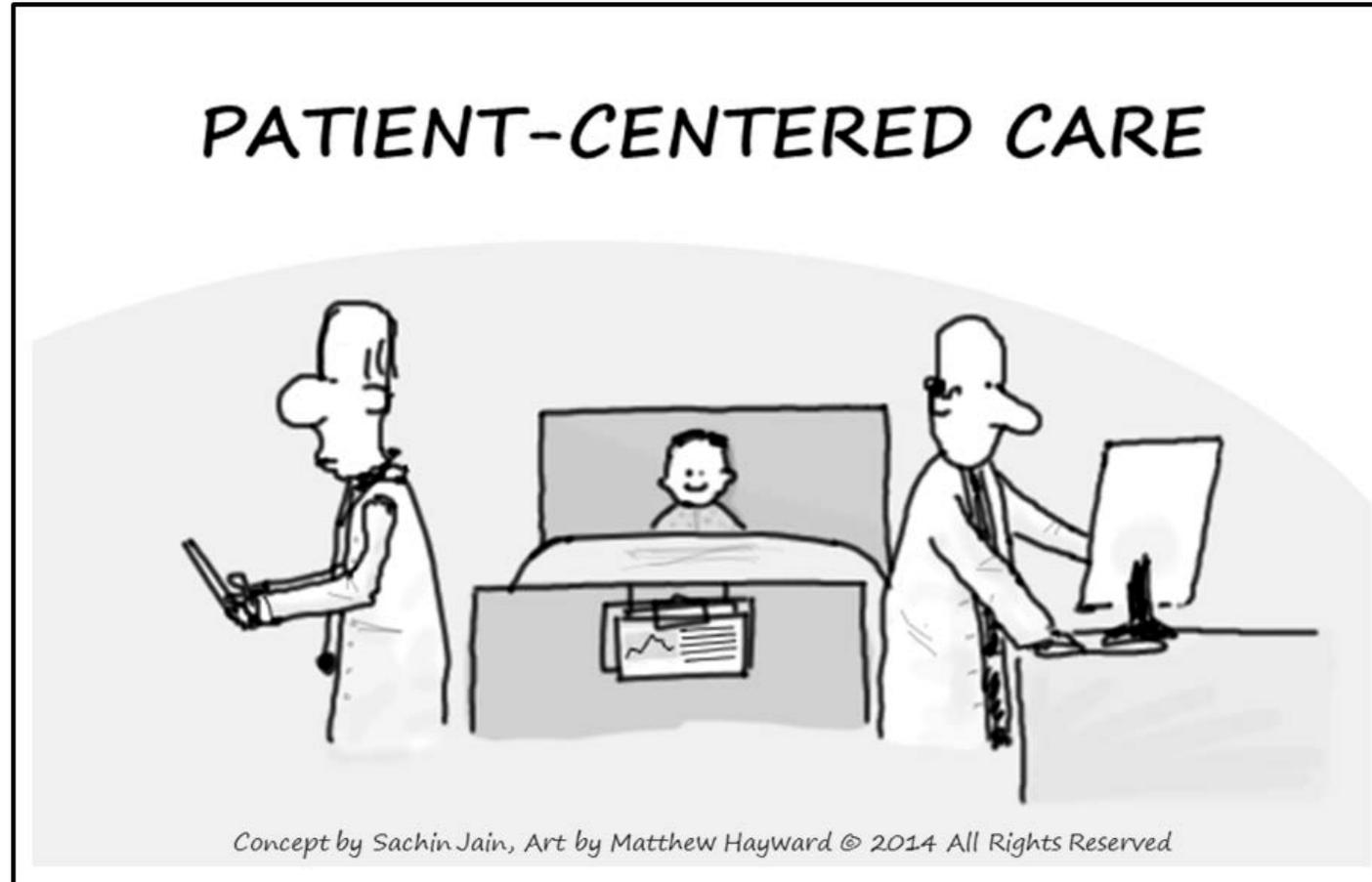
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Primary Care Environment



"Sometimes I think the collaborative process would work better without you."

Primary Care Environment



Addiction Primary Care Approach

- Major push has been to screen for hazardous alcohol use in primary care
- Emerging literature regarding how to screen for drug/prescription drug problems
- Collaborative and integrative health care models
- Push to consider pharmacotherapy for all patients identified as having addictions
- **SBIRT**

S.BI.RT.

(mainly for Hazardous drinking...)

- SCREENING (S)
 - then ASSESSMENT
- BRIEF INTERVENTIONS (BI)
 - or other TREATMENT in the office
- REFERRAL TO TREATMENT (RT)

All primary care practitioners should be doing...

Primary Care Approach: Integrating Addiction Care

- Change the culture
 - Team care and at least interdisciplinary approaches
 - Addiction is important and must be addressed
- Empower all providers to address addiction
 - Active training and retraining of wrap around services
- Physician (and now NP/PA) targets
 - Primary care addiction expertise (ABAM/ASAM)
 - Encourage buprenorphine waived clinicians (58% of waived prescribers actually prescribe)
 - Encourage pharmacotherapy
- Address “vulnerability” in specialized clinics
- Provide easy linkages to addiction and mental health care
- Don’t build a new system of care, do what you do but do it for patients with addiction
 - Don’t need MORE salaried employees or policies or procedures!

Time to step up.

**Can Substance Use
Disorders be Managed
Using the Chronic Care
Model?**

**Review and
Recommendations from a
NIDA Consensus Group**

2016 White House Actions

- Presidential Memorandums
 - **Section 1: Policy**
 - Improved access to medication-assisted treatment (MAT)
 - **Section 3: Improving Access to Medication-Assisted Treatment and Modernizing Benefit Design**
 - Direction to identify any barriers individuals with opioid use disorders would encounter in accessing MAT
- **Expand access to treatment**

<https://www.whitehouse.gov/the-press-office/2016/07/05/obama-administration-takes-more-actions-address-prescription-opioid-and>
<https://www.whitehouse.gov/the-press-office/2015/10/21/presidential-memorandum-addressing-prescription-drug-abuse-and-heroin>

Expanding Access to Treatment

- Department of Health and Human Service (DHHS) through the Substance Abuse Mental Health Service Administration (SAMSHA) issued a final rule on July 6, 2016
- Ensure high-quality care and that aim to minimize the risk of diversion
- Limits based on time of approval to prescribe under DATA2000:
 - Baseline is **30** patients/time
 - *After 1st year*, physicians increase to **100** patients/time
 - *After 1st year approved at 100 patients/time*, physicians can petition to increase to **275** patients/time (with requirements needed).

Drug Abuse Treatment Act (DATA) 2000

- Allowed “Qualified” physicians to treat opioid dependence outside methadone facilities
- DEA issues (free!) to qualifying practitioners a new DEA number to use medication for opioid dependence
- Only buprenorphine or buprenorphine/naloxone is approved for use under DATA 2000
- New 2017!
 - Independently licensed PA/NPs can prescribe
 - 8 hour BUP courses available online for free
 - Extra training required of PA/NPs

Buprenorphine Products

- Buprenorphine IV (1981 approved)
 - Indication: **PAIN**
- Buprenorphine (2002 approved)
 - Indication: **OPIOID USE DISORDER**
 - Tablets available
- Buprenorphine/Naloxone (2002 approved)
 - Indication: Opioid use disorder
 - SL/Buccal Tablets and Film available
- Buprenorphine Patches (2010 approved)
 - Indication: **PAIN**
- Buprenorphine Implants (2016 approved)
 - Indication: **OPIOID USE DISORDER**
- Buprenorphine Depot Injections (2017 approved)
 - Indication: **OPIOID USE DISORDER**
 - (this has yet to be out in the market)



Practitioner Requirements (ONLY 4!)

- To prescribe buprenorphine in office-based settings, the practitioner must:
 1. **be certified by DEA** to prescribe buprenorphine (easy)
 - Practitioner should meet certification requirements
 - Practitioner should have an “X” DEA license
 2. have the **capacity to refer** patients to additional treatment
 3. have the **capacity to perform history and physical** and appropriate **lab tests**
 4. meet any **state requirements for the practice of medicine**

It is important to note that “capacity” does not mean
...“must do” or “must do for all patients”

Physician Requirements

- Must be licensed in the State/Commonwealth
- Must have an individual DEA license
 - Buprenorphine limits (30, 100, 275) include ALL populations for the treatment of opioid use disorder regardless of setting
 - Unless within a licensed drug and alcohol treatment program where the dispensation of buprenorphine occurs under the program license
 - If you have 4 clinic settings that one is prescribing to, then all 4 setting patients count toward your limits
 - You cannot have more than your limits AT ANY ONE TIME – NOT annually
 - Limits are for ACTIVE prescription
 - If you provide a prescription for buprenorphine for 30 days and the patient does not return to you after 31 days, technically, they are no longer active

Physician Requirements: Obtaining Waivers

- The Drug Addiction Treatment Act of 2000 (DATA 2000) allows for physicians to complete an eight hour training to be able to prescribe and dispense sublingual formulations of buprenorphine/naloxone for opioid use disorder (OUD)
- Under DATA 2000, only certain organizations can offer the certification to clinicians

Physician Requirements: Obtaining Waivers

- Subsequently, several organizations (identified DATA2000) are credentialed offer the eight-hour trainings. The three organizations currently conducting the bulk of the waiver trainings:
 - American Academy of Addiction Psychiatry (AAAP)
 - American Osteopathic Academy of Addiction Medicine (AOAAM)
 - American Society of Addiction Medicine (ASAM)
- Trainings can be obtained:
 - 1) in person
 - 2) online
 - 3) partly in-person and partly online.

Physician Requirements: Obtaining Waivers

- Trainings are open to all clinicians
 - you don't need to apply for a waiver to attend
 - Physicians in training (residents) may take the course and apply for their waivers when they receive their individual DEA license
- To obtain a waiver, the clinician must have
 - an individual Drug Enforcement Administration (DEA) license
 - Be a clinician in good standing

Physician Requirements: Obtaining Waivers

- As of 2017, physician assistants (PAs) and nurse practitioners (NPs) can obtain waivers to prescribe sublingual formulations of buprenorphine/naloxone for OUD through the recently enacted Comprehensive Addiction and Recovery Act (CARA) 2016
 - To obtain this waiver, PAs and NPs must complete 24 hours of approved training
- In general, to prescribe buprenorphine, PAs and NPs must
 - have an independent DEA license
 - able to prescribe Schedule III medications in their state.
- Some states may have restrictions on PA/NP prescribing
 - However, they may still attend the training, and when/if they are able to prescribe, the credentialing will allow them to prescribe

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Physician Requirements: Obtaining Waivers

- Some of the trainings are free and others require a fee
- One of the best sources for a schedule of upcoming in-person trainings can be found at
 - www.pcssmat.org/mat-basics/mat-waiver-training (which covers AAAP and AOAAM trainings)
 - www.asam.org/education/liveonline-cme/buprenorphine-course (which covers ASAM trainings)

Training Links:

- AAAP (www.aaap.org) offers its trainings for clinicians through the Providers' Clinical Support System (PCSS) MAT initiative.
www.pcssmat.org/models-of-buprenorphine-induction/
- AOAAM (www.aoaam.org) offers trainings for physicians:
www.aoaam.org/?page=PCSSMAT
- ASAM (www.asam.org) offers trainings for physicians and NPs/PAs at the following link:
www.asam.org/education/live-online-cme/buprenorphine-course

Physician Requirements: Obtaining Waivers

- After obtaining the initial waiver:
 - you can prescribe to 30
 - If you want, after a year, you can then apply to the DEA to prescribe to 100
 - If you want, after a year, you can then apply to the DEA to prescribe to 275
 - There are more reporting requirements when you go to 275

Is an X waiver NEEDED to prescribe buprenorphine for opioid use disorder

- There are special circumstances for providing buprenorphine:
Buprenorphine for conditions other than opioid use disorder (addiction)
 - Neither the [Controlled Substances Act](#), as amended by DATA 2000, nor Drug Enforcement Administration (DEA) regulations [Administering or Dispensing Narcotic Drugs, 21 Code of Federal Regulations \(CFR\) 1306.07](#) impose any limitations on a physician or other authorized hospital staff to maintain or detoxify a person with buprenorphine 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 other than opioid dependency, such as myocardial infarction, 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 waiver is not required** for practitioners in order to administer or dispense buprenorphine or methadone in this circumstance. It is good practice, however, for the admitting physician to consult with the patient's substance misuse treatment provider, when possible, to obtain treatment history.

Is an X waiver NEEDED to prescribe buprenorphine for opioid use disorder

- There are special circumstances for providing buprenorphine: **Buprenorphine in medical emergencies (Three day rule or 72 hour rule)**
 - Under the [Narcotic Addiction Treatment Act – 1974 \(PDF | 437 KB\)](#), all practitioners who use narcotic drugs for treating opiate addiction must obtain a separate registration under 21 U.S.C. Section 823(g)(1) or a [DATA 2000 Waiver](#) under 21 U.S.C. Section 823(g)(2).
 - However, according to 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 waived DATA 2000 physician, 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
 - The intent of regulation [21 Code of Federal Regulations \(CFR\) 1306.07\(b\)](#) is to provide practitioners with flexibility in emergency situations where they 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 or detoxification treatment program.

Is an X waiver NEEDED to prescribe buprenorphine for opioid use disorder

- Technically, you do NOT need an “X waiver” to prescribe buprenorphine for an “off label” use of buprenorphine solely for pain
 - Patients who are prescribed for pain do not technically count on your prescribing limits
- BE CAREFUL in prescribing for pain – it is off label, could cause investigations, and you may be at more liability
- No problem in prescribing for a patient with PAIN AND ADDICTION
 - this occurs all the time
 - Counts on your limits for buprenorphine for opioid use disorder

DEA Audits

- The DEA is charged to conduct audits of physicians who achieve waiver certification under DATA 2000
- These audits are supposed to occur every 2-3 years
- These are NOT “for cause” investigations, but just audits about buprenorphine care
- DEA agents will be looking for:
 - Are you over your patient limit?
 - Are you prescribing to patients with opioid use disorder?
 - Are you checking urine drug screens and providing good quality of care

Physician Necessary Resources

- When preparing for office-based buprenorphine treatment, practitioners should have the necessary resources in place:
 1. Referral resources
 2. Capacity to get laboratory and urine test results
 3. Coverage
 - Can be a problem for some clinicians
 - Covering non-X-waivered providers can “manage” patients, but not prescribe
 4. Security and storage procedures for medications

KEY CLINICAL QUESTION

A nurse practitioner is interested in starting to prescribe buprenorphine.

Is this possible?

Advanced Practice Nurses: Increasing Access to Opioid Treatment by Expanding the Pool of Qualified Buprenorphine Prescribers

Matthew Tierney, MS, PMHNP-BC,^{1,2} Deborah S. Finnell, DNS, PMHNP-BC, CARN-AP, FAAN,³
Madeline A. Naegle, PhD, CNS-PMH, BC, FAAN,⁴ Colleen LaBelle, BSN, RN-BC, CARN,⁵
and Adam J. Gordon, MD, MPH^{6,7}

YES!



BUT MUST BE ABLE TO DO IN INDIVIDUAL STATES BASED ON PA/NP LICENSING

KEY CLINICAL QUESTION

As a physician employed by the Federal Government (Federal Qualified Health Centers, Veterans Administration, Indian Health Service, Federal Department of Corrections, etc.) practicing in a Federal Government installation, am I eligible for a DATA 2000 waiver?

(Many of these providers have institutional DEAs, not personal DEA licenses)

YES!

- MDs employed by an agency of the Federal Government are eligible for DATA 2000 waivers
- In order to be eligible for a waiver under DATA 2000, a physician must have a valid, *individually assigned DEA* registration number
 - (in addition to a license to practice medicine and the credentialing/training discussed elsewhere)
- A physician who is directly employed by the Federal Government may obtain a DEA number, *free of charge*, without being licensed in the state where the Federal facility is located

KEY CLINICAL QUESTION

A practitioner is interested in starting a buprenorphine “clinic”

Are affiliated staff (e.g., nurses, social workers, psychologists) necessary or required to implement this care?

NO

(But they can be extremely useful...)

Models of Care

- Buprenorphine can be prescribed in:

1. Office-based settings (Primary care, specialty clinics)

2. Drug and alcohol treatment settings

- Other addiction treatment programs
- Methadone programs

3. ER and URGENT CARE settings

4. Inpatient settings

- There are requirements and models for care in each setting

Models of Care

- Physician Directed Model
 - Physician does it all
- Nurse Care Management Model
 - (Massachusetts model or Boston University Model)
 - Nurse does everything but prescribe
- Co-located Model
 - Addiction/Bup prescriber expertise is embedded along side provider
 - Perhaps one member of the clinic team gets all the patients
- Referral Model
 - Prescribers refer (and receive) patients from another clinic/program/hub
- Pharmacy Model
 - Imbedded pharmacists do everything but prescribe.

Models of Care

- Recent Federal Practitioner papers (2005 and 2009) describes several federal models of care and have been used to model non-VA office based practices
 - Geppert CMA, Toney GB, Siracusano D, Thorius M. Outpatient Buprenorphine Treatment for Opioid Dependence. Fed Pract. 2005;22(7): 9-40.
 - Gordon AJ, Geppert CMA, Saxon A, Cotton A, Bondurant T, Krumm M, Acquaviva MP, Trafton J. Models for implementing buprenorphine treatment in the VHA. Fed Pract. 2009;26(5):48-57.

Models for Implementing Buprenorphine Treatment in the VHA

Adam J. Gordon, MD, MPH, Cynthia M.A. Geppert, MD, PhD, MPH, Andrew Saxon, MD, Ann Cotton, PsyD, Timothy Bondurant, MD, Margaret Krumm, BA, Mary Pat Acquaviva, PA, and Jodie Trafton, PhD

Models of Care: Office-Based Settings

- Buprenorphine treatment for opioid dependence can be provided in office-based settings similar to treatments for *all other medical and mental health disorders*
- Barriers to initiate or provide buprenorphine care occur when providers in office-based settings attempt to make these environments “feel” like formal substance abuse treatment program environments
 - **These environments are different!**
 - **It hard to replicate an addiction treatment environment**
 - **“Keep it simple” and “grow from experience”**

Office-Based Care

- This is **EASY**
- The settings....
 - Primary care
 - Outpatient psychiatry
 - HIV, GI, and ID clinics....
 - *Any other outpatient clinic*
- No requirements except:
 1. Waivered clinicians
 2. Provider requirements under DATA 2000
 3. Insurance requirements

Yes, that is **all you need** to start...!

KEY CLINICAL QUESTION

A physician in an outpatient psychiatric outpatient clinic is interested in starting to prescribe buprenorphine

Are *protocols* to prescribe or *program rules* regarding buprenorphine care necessary?

NO

(only physician requirements for DATA 2000 and practice requirements)

What is buprenorphine care in this regard?

- **Regular** care
- Provided by **regular** providers
- In **regular** environments

- Don't try to be a drug and alcohol treatment program or an addiction specialist ...

... there is no need to be

Some general guidances regarding care regardless of setting

- In general, the practitioner should:
 - Have consent for medical treatment
 - Complete and document a recent history and physical exam
 - Diagnose and document opioid use disorder
 - Provide and document a treatment plan
 - Offer, provide, and document periodic re-evaluations
 - Revise treatments according to patient progress
 - Keep good medical records and document

Some helpful provider clinical tools for buprenorphine care

- Initial contact phone questionnaire
- DSM-IV criteria with worksheet form
- Clinical Opioid Withdrawal Scale (COWS)
- History and physical form
- Family guide to buprenorphine maintenance treatment
- Patient treatment planning questions
- Patient information about buprenorphine
- Patient responsibilities and agreement form
 - Educational document through imed consent process

Over time many providers will not use these...

Working with Office Staff

- It is important to **EDUCATE** the staff regarding opioid treatment
- Important points that should be addressed are:
 - Treating patients with substance abuse disorder
 - Role and importance of medication in treatment of opioid dependence
 - Maintenance of patient confidentiality
 - Treatment philosophy
 - Means of providing medication
 - Role of non-pharmacological treatments



Likely the **MOST** important part of implementation...

Clinical Staff Considerations

- Frontline clinical staff **can manage** most of the day-to-day issues with buprenorphine care
 - There are models of care where the nurse (nurse care manager) is the main provider
- For example:
 - Manage induction/stabilization
 - Follow up visits
 - Urine screens, monitor labs, call backs
 - Ongoing education
 - Co-manage with medical psychiatric services
 - Prescriptions/pharmacy
 - Tracking of patients and outcomes

Role of the covering physician

- Be realistic – 24 hour coverage, 7 days per week is not sustainable
- Covering physician should have knowledge and experience using buprenorphine and know the office policies and procedures
- **Waiver only needed** if physician will be **prescribing** buprenorphine

Where to obtain provider and patient material

- There are many websites that have downloadable material for patients and physicians regarding buprenorphine care
- Sites especially worthwhile to examine:
 - www.pcssmat.org (many webinars!)
 - www.buprenorphine.samhsa.gov (all the logistics)
 - www.buppractice.com
 - Organizations mentioned earlier

A simple model of providing Buprenorphine care in Primary Care



DISCUSSION

