What You Need to Know about Buprenorphine Treatment for Opioid Use Disorder

Is buprenorphine certification right for your practice?

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Faculty Disclosure

- **Dr. Podesta:** Consultant—Kaleo, Pear Therapeutics, JayMac Pharmaceuticals; Speakers Bureau—Alkermes, Orexo, US WorldMeds.

Disclosure

- The faculty have been informed of their responsibility to disclose to the audience if they will be discussing off-label or investigational use(s) of drugs, products, and/or devices (any use not approved by the US Food and Drug Administration).
- Applicable CME staff have no relationships to disclose relating to the subject matter of this activity.
- This activity has been independently reviewed for balance.
- Brand names are included in this presentation for participant clarification purposes only. No product promotion should be inferred.

Learning Objectives

- Discuss the scope of the problem of opioid use disorder (OUD)
- Describe the mechanism and efficacy of OUD treatment, especially buprenorphine
- Review the basic requirements and recommendations for prescribing buprenorphine for OUD

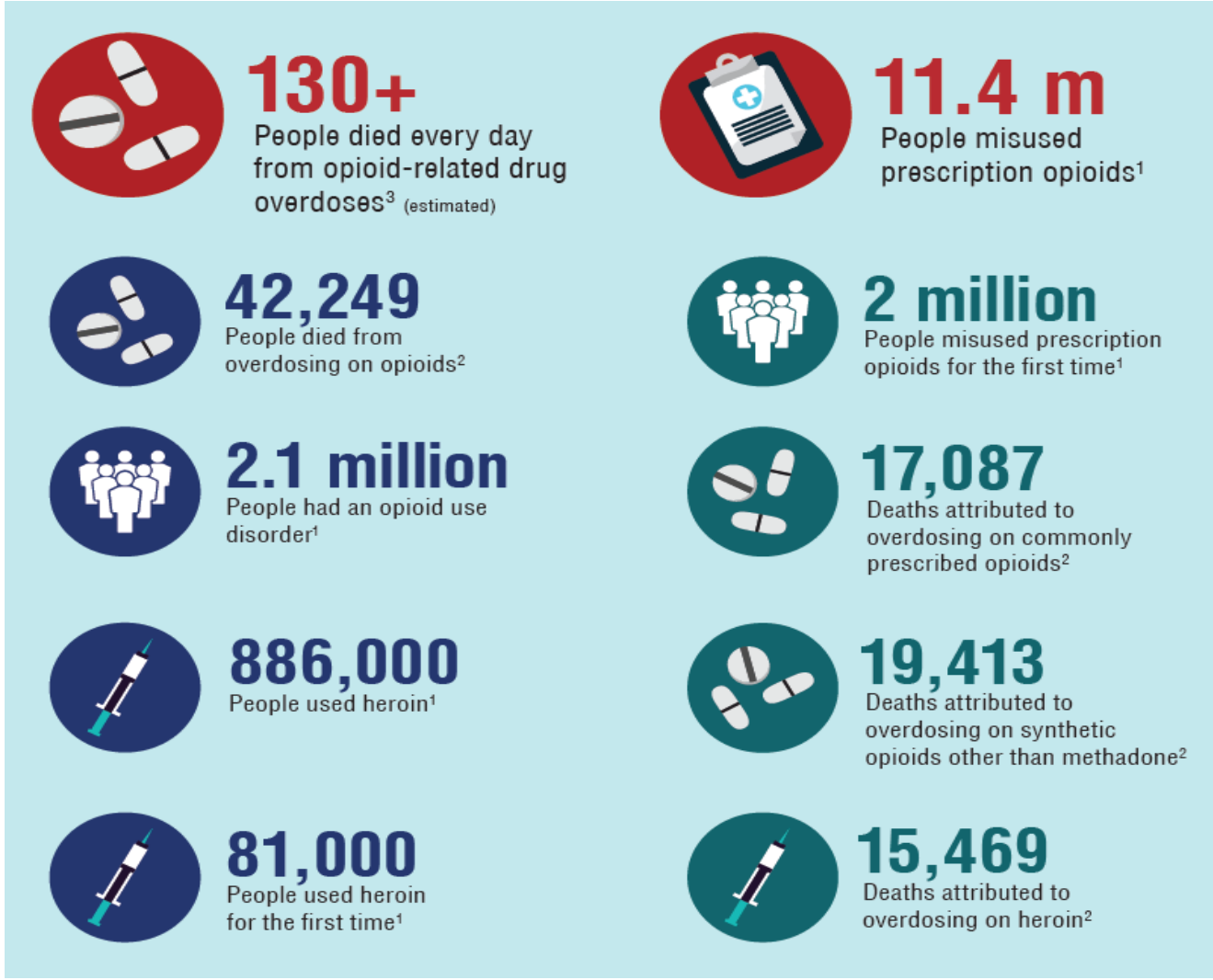
Introduction:
The Scope of the Opioid Epidemic

"The national opioid epidemic is one of the most important public health challenges facing the United States today. This crisis has resulted in death, disability, and increased infectious and other comorbid diseases."

Gold M, et al. The drug epidemic of early initiation, frequent use, and a polydrug reality.
***Clinical Psychiatry News*. October 10, 2018.**

The Opioid Epidemic by the Numbers

2016 and 2017 Data



www.hhs.gov/opioids/sites/default/files/2018-09/opioids-infographic.pdf. Accessed August 12, 2019.

Mixing of drugs was found in half of prescription opioid related deaths (most frequent: benzodiazepines, heroin, cocaine, and alcohol)

Barriers to Treatment

- Stigma (judgement, dirty/clean, language)
- Shame
- Access to care
  - 60% of rural counties in the United States don't have an X# waivered prescriber
  - > 50% of DEA waivered physicians are not prescribing buprenorphine
    - Time, subspecialty back up, complicated, difficult
- Public education, knowledge
- In 2015, only 19.6% of adults (18+) that met criteria for SUD (*DSM-5*) received treatment at a specialty facility (inpatient/outpatient/hospital/mental health care)

DEA = US Drug Enforcement Administration; SUD = substance use disorder.

Jones HE, et al. *Addiction*. 2012;107 Suppl 1:28-35. Sharma A, et al. *Curr Psychiatry Rep*. 2017;19(6):35. Substance Abuse and Mental Health Services Administration. (2018). Key substance use and mental health indicators in the United States: Results from the 2017 National Survey on Drug Use and Health (HHS Publication No. SMA 18-5068, NSDUH Series H-53). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Crawford C. Overcoming Barriers to Opioid Treatment Takes Center Stage. August 11, 2017. www.aafp.org/news/health-of-the-public/20170811opioidsstudy.html. Accessed August 12, 2019.

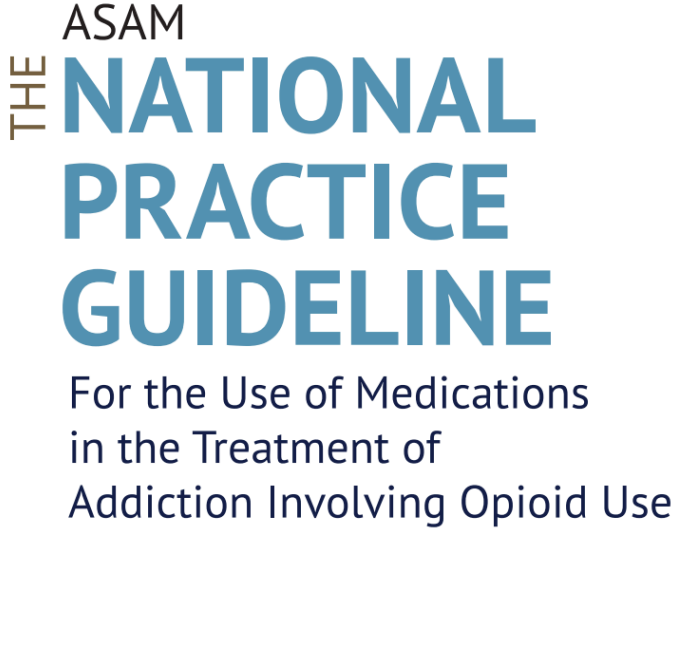
Barriers to Treatment (cont'd)

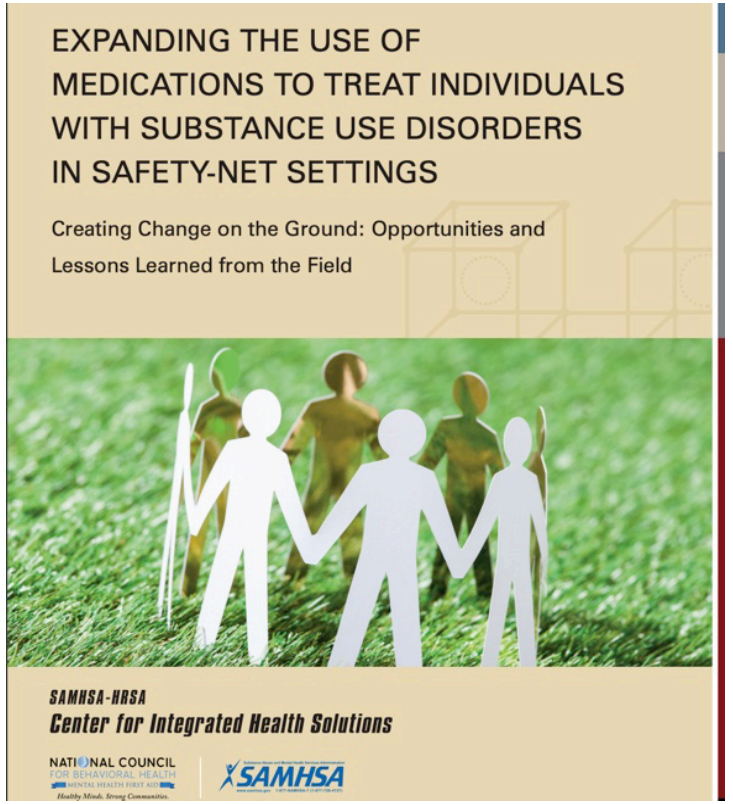
- Detoxification is not treatment
- 2.1 million (United States) with opioid use disorders
- 17.5% receiving treatment
  - Small percentage of those are receiving pharmacotherapy
- Low rate of treatment follow-through after detoxification
- 40% to 60% relapse after treatment (rehabilitation)
- Good outcomes are contingent on adequate treatment length

So what do we do?

Pharmacotherapy for Opioid Use Disorder

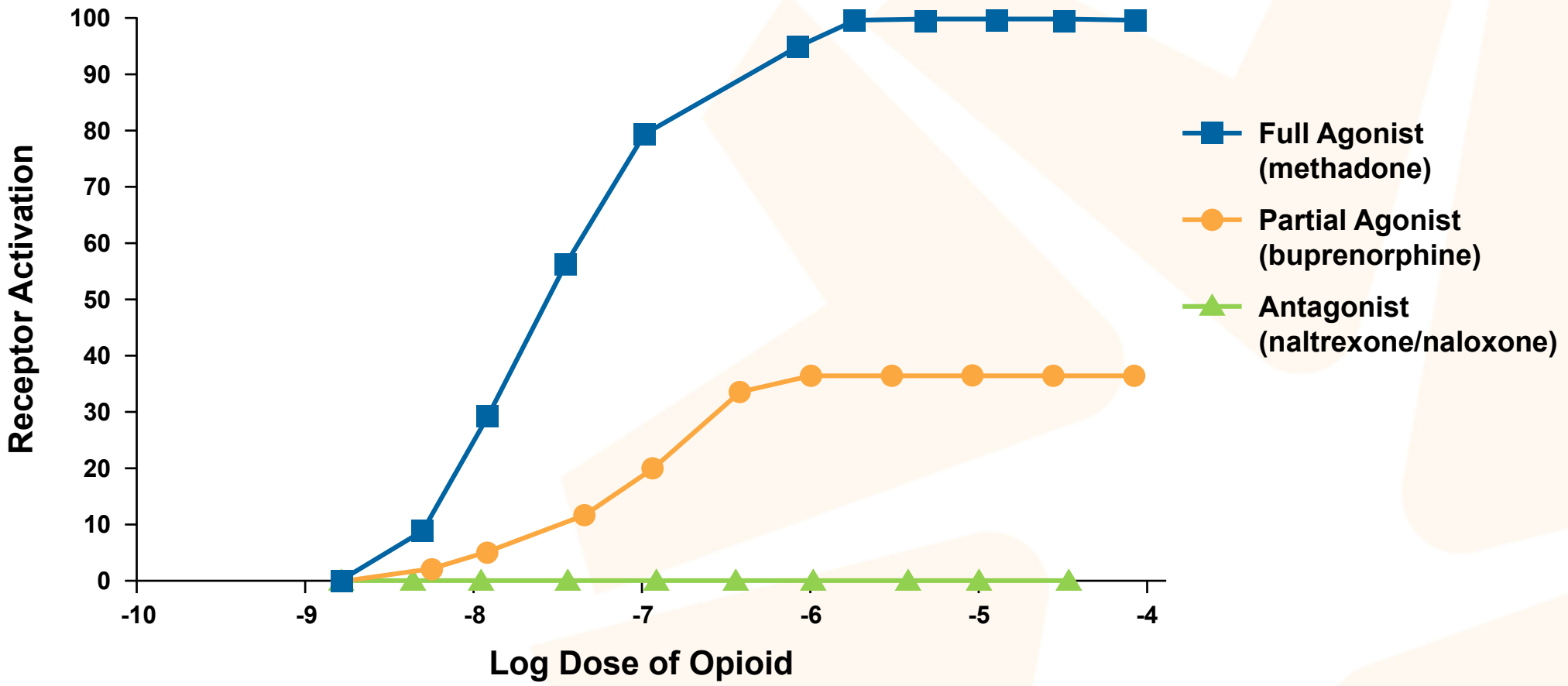
Medication-Assisted Treatment = MAT





Current Guideline Recommendations

3 “MATs” for Opioid Use Disorder



Center for Substance Abuse Treatment. Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction. Rockville (MD): Substance Abuse and Mental Health Services Administration (US); 2004. (Treatment Improvement Protocol (TIP) Series, No. 40.)

Current Guideline Recommendations

- OUD is a chronic disease
- OUD medications (methadone, buprenorphine, naltrexone) reduce illicit opioid use, retain people in treatment, reduce risk of overdose better than placebo or no medications
- OUD MAT are safe and effective, when used appropriately
- OUD MAT can be taken short- or long-term
- Patients taking MAT are considered to be in recovery
- Pharmacotherapy should be considered for all patients with OUD
- Patients should be advised where and how to get MAT
- Doses and schedules must be individualized
- Many patients benefit from counseling as part of their treatment

- We are in an OUD epidemic with significant mortality and morbidity. MAT is safe, effective, and reduces illicit opioid use; retains people in treatment; reduces risk of overdose; and better than placebo or no medications

Substance Abuse and Mental Health Services Administration. TIP 63: Medications for Opioid Use Disorder. February 2018. https://store.samhsa.gov/product/TIP-63-Medications-for-Opioid-Use-Disorder-Full-Document-Including-Executive-Summary-and-Parts-1-5-/SMA18-5063FULLDOC. Accessed August 12, 2019.

Barriers to Opioid Use Disorder *Treatment with Buprenorphine*

- 5% of physicians have waiver to prescribe buprenorphine
- A study in Washington State showed that only 28% of newly waivered prescribers were actually prescribing
- 60% of rural areas do not have a waivered physician

Barriers

- Complicated patients
- Lack of mental health and supportive services
- Low reimbursement
- Untrained support staff
- Extra oversight by DEA (DATA Waiver 2000)

DATA = Drug Addiction Treatment Act.

Center for Behavioral Health Statistics and Quality. (2016). Key substance use and mental health indicators in the United States: Results from the 2015 National Survey on Drug Use and Health (HHS Publication No. SMA 16-4984, NSDUH Series H-51). Hutchinson E, et al. *Ann Fam Med*. 2014;12(2):128-133.

Drug Addiction Treatment Act (DATA) of 2000

- Harrison Narcotics Tax Act of 1914 restricted the use of opioids to pain treatment and outlawed their use for addiction management
- The Controlled Substances Act of 1970 and the Narcotic Addict Treatment Act of 1974 allowed dispensation of specific opioids from federally waived clinics (methadone)
- DATA 2000 authorized practitioners to prescribe specific opioids (buprenorphine) with a new waiver

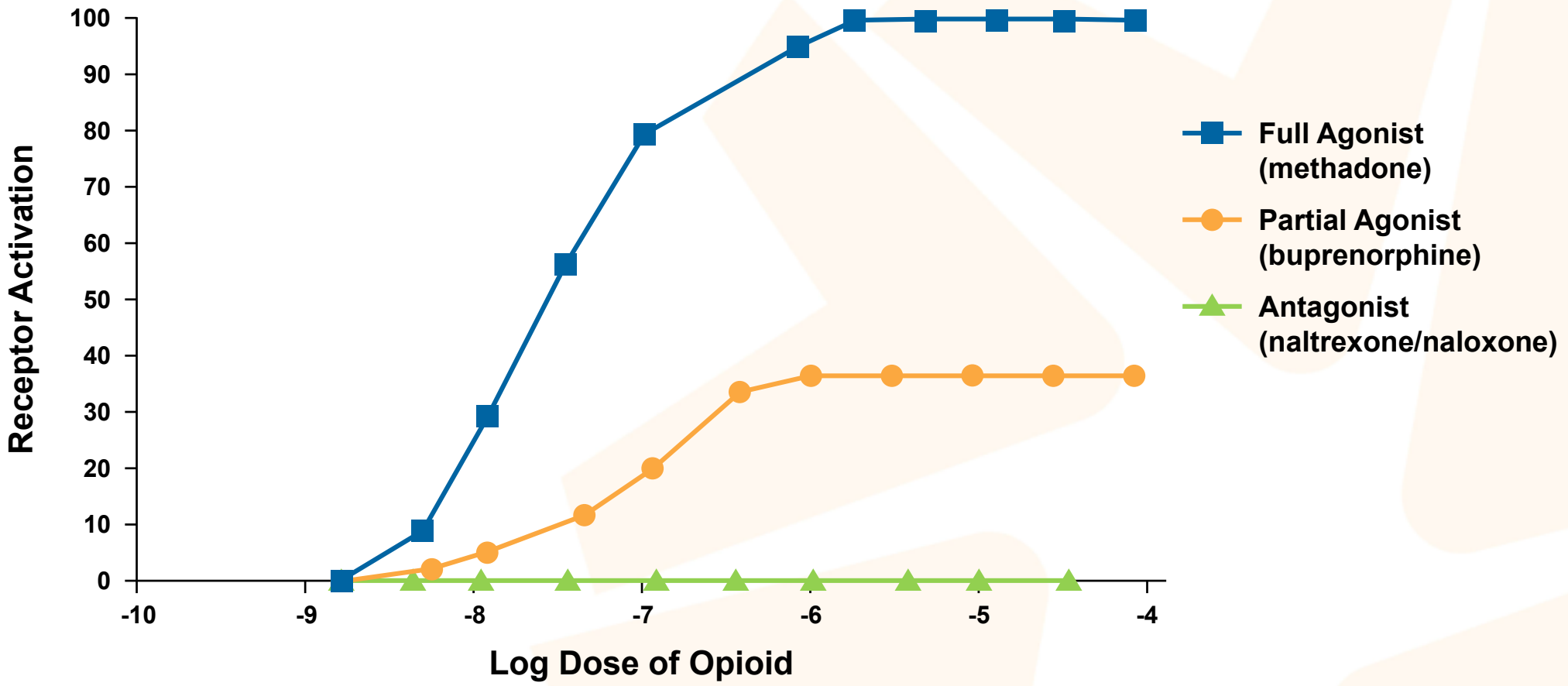
Practitioner Requirements

- Qualifying Physician (MD certified in Addiction Medicine by ASAM or AOA or 8-hour training)
- Must certify capacity to refer patients for counseling and ancillary services
- < 30 patients for individual physicians; up to 100 patients (now 275) with special waiver post-Year 1
- Physicians must register with SAMHSA and DEA

ASAM = American Society of Addiction Medicine; AOA = American Osteopathic Association; SAMHSA = Substance Abuse and Mental Health Services Administration.

Velander JR. *Ochsner J*. 2018;18(1):23-29.

3 “MATs” for Opioid Use Disorder



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Comparison/Qualities of the 3 Treatments for Opioid Use Disorder

	Methadone	Buprenorphine	Naltrexone
FDA Approved	1947	2002	OUD 1984, AUD 1994
Action at the μ-Opioid Receptor	Full agonist	Partial agonist	Antagonist
Administration	Once daily dosing – pill, sublingual tablet, liquid, DISKET®	Daily sublingual film, sublingual tablet, buccal film, 6-month subdermal implant, or extended-release injection	Daily oral medication or monthly intramuscular injection
Setting	Provided at certified OTP settings	Sublingual film, sublingual tablet, or buccal film can be initially provided in a physician's office then as a take-home medication. The 6-month subdermal implant and extended-release injection require HCP administration.	Daily oral can be provided as take-home medication. Monthly injection requires HCP administration.
DEA Schedule	Schedule II controlled substance	Schedule III controlled substance	Not scheduled
Requires Detoxification	No	No	Yes

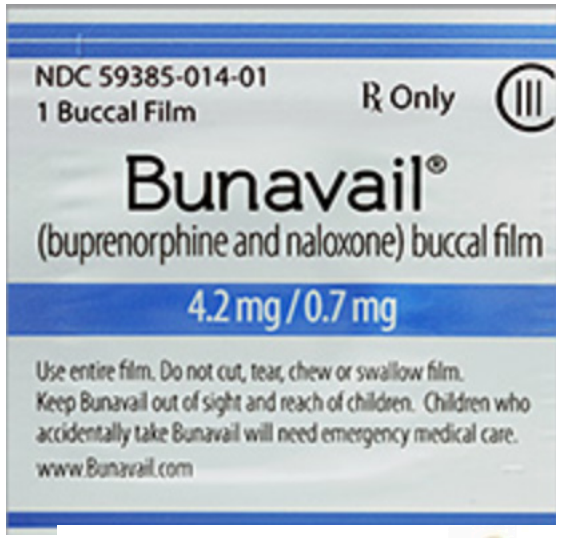
Kosten TR, et al. *Sci Pract Perspect*. 2002;1(1):13-20. US Food and Drug Administration. Drugs@FDA: FDA Approved Drug Products. www.accessdata.fda.gov/scripts/cder/daf/.

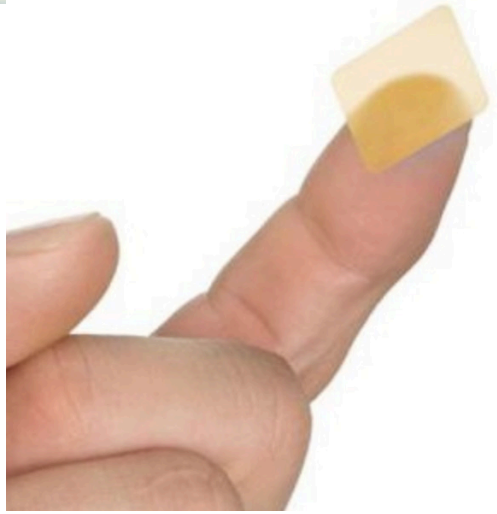
Buprenorphine

- Average daily dose 8–24 mg (equivalent to standard buprenorphine dose, varies based on formulation)
- Mandatory certification from DEA
- Street value – low/medium (often used to bridge to treatment)
- Exhibits ceiling effect on respiratory depression with increasing doses in opioid-experienced individuals
  - (not true for opioid-naive persons; buprenorphine can cause adverse events or deaths if ingested by those without opioid tolerance)
- Buprenorphine is safer in overdose than other opioids
- Buprenorphine/naloxone formulation is advised to be used for treatment of opioid dependence (naloxone diminishes risk of diversion to injection; precipitates withdrawal)

US Food and Drug Administration. Drugs@FDA: FDA Approved Drug Products. www.accessdata.fda.gov/scripts/cder/daf/index.cfm.

Buprenorphine/Naloxone Products





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Considerations for Individualized Selection of Pharmacotherapy

- Appropriateness for patient needs
- Patient preference
- Access to treatment
- Risk of diversion

- Naltrexone, buprenorphine, and methadone are all effective, and should be chosen based on patient preference, lack of contraindications, and access to treatment (proximity and cost)

Implementing Buprenorphine into Your Practice

Starting Buprenorphine Treatment

- Confirm that the patient requesting buprenorphine treatment has OUD
- History/previous treatment records if available
- Physical signs and symptoms: Withdrawal (COWS, SOWS), track marks, abscesses
- UDS(+) for opioids, if (-) history of use and high risk of relapse (recent release/discharge jail, hospital, detoxification, residential treatment)
- In early OUD treatment, more accountability – consider short prescriptions, ≥ 1 week, until patient stabilizes

COWS = Clinical Opiate Withdrawal Scale; SOWS = Subjective Opiate Withdrawal Scale; UDS = urine drug screen.

Substance Abuse and Mental Health Services Administration Providers Clinical Support System. Buprenorphine training. Updated 2018.

American Society of Addiction Medicine. The ASAM National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use. 2015. www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf. Accessed August 12, 2019.

Starting Buprenorphine Treatment

- Document, document, document
  - For patient care
  - In anticipation of DEA site visit
  - For insurance
  - Legal risk mitigation
- Patients sign
  - Informed consent
  - Treatment agreement (not “contract”)

American Society of Addiction Medicine. The ASAM National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use. 2015. www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf. Accessed August 12, 2019.

Prescription Monitoring Program

- Check your state PDMP before initiating treatment, and then regularly during
  - Some states now require PMP checked before prescribing any controlled
  - ASAM recommendations (some states adopted)
    - When used for the treatment of addiction, methadone, and buprenorphine should be explicitly excluded from legislation, regulations, state medical board guidelines, and payer policies that attempt to reduce opioid overdose-related mortality by limiting MME. Higher MME of these medications are necessary and clinically indicated for the effective treatment of addiction involving opioid
    - State medical boards should not use MME conversions of methadone or buprenorphine dosages used in addiction treatment as the basis for investigations or disciplinary actions against prescribers

MME = morphine milligram equivalent; PMP = Prescription Monitoring Program.

Substance Abuse and Mental Health Services Administration Providers Clinical Support System. Buprenorphine training. Updated 2018. American Society of Addiction Medicine. Public Policy Statement on Morphine Equivalent Units/Morphine Milligram Equivalents. October 2016. www.asam.org/docs/default-source/public-policy-statements/2016-statement-on-morphine-equivalent-units-morphine-milligram-equivalents.pdf?sfvrsn=3bc177c2_6. Accessed August 12, 2019. American Society of Addiction Medicine. The ASAM National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use. 2015. www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf. Accessed August 12, 2019.

Buprenorphine Maintenance

- Once a patient is started on buprenorphine
  - Regularly check PMP
  - Regular medication counts (empty/full)
  - Confirm counseling / peer support attendance
  - Regularly and randomly perform UDS
    - Point of care – cups/dips
    - GC/MS – send out

GC/MS = gas chromatography/mass spectrometry.

Substance Abuse and Mental Health Services Administration Providers Clinical Support System. Buprenorphine training. Updated 2018.

American Society of Addiction Medicine. The ASAM National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use. 2015. www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf. Accessed August 12, 2019.

For Patients on Buprenorphine Maintenance

- Patients with OUD should receive psychosocial treatment in addition to MAT
- Lifestyle change is not addressed with giving medication alone
- Aberrant behaviors must be addressed with psychosocial treatment and peer support
- **Tools to increase accountability should be offered**
  - Supportive medication monitoring
  - Individual or group counseling
  - Facilitated 12 Step
  - Mutual support groups
  - 12 Step, Alcoholics Anonymous (AA), Narcotics Anonymous (NA), LifeRing, Refuge Recovery, Self-Management and Recovery Training (SMART)
- Prescribers are required to attest that they can refer patients to addiction counseling and other nonpharmacologic treatment (during waiver training and with DEA site visit)

Substance Abuse and Mental Health Services Administration Providers Clinical Support System. Buprenorphine training. Updated 2018.

American Society of Addiction Medicine. The ASAM National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use. 2015. www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf. Accessed August 12, 2019.

For Patients on Buprenorphine Maintenance (cont'd)

- Document, document, document
- Prescribe only FDA-approved medications for office-based treatment of OUD
  - Buprenorphine/naloxone film, buprenorphine/naloxone tablets, buprenorphine mono-product, buprenorphine long-acting injectable, buprenorphine implant
  - Do NOT prescribe buprenorphine products that are FDA-indicated for pain, not OUD (Buprenex, Belbuca®, Butrans®), buprenorphine nasal spray (was not FDA-approved)

Substance Abuse and Mental Health Services Administration Providers Clinical Support System. Buprenorphine training. Updated 2018.

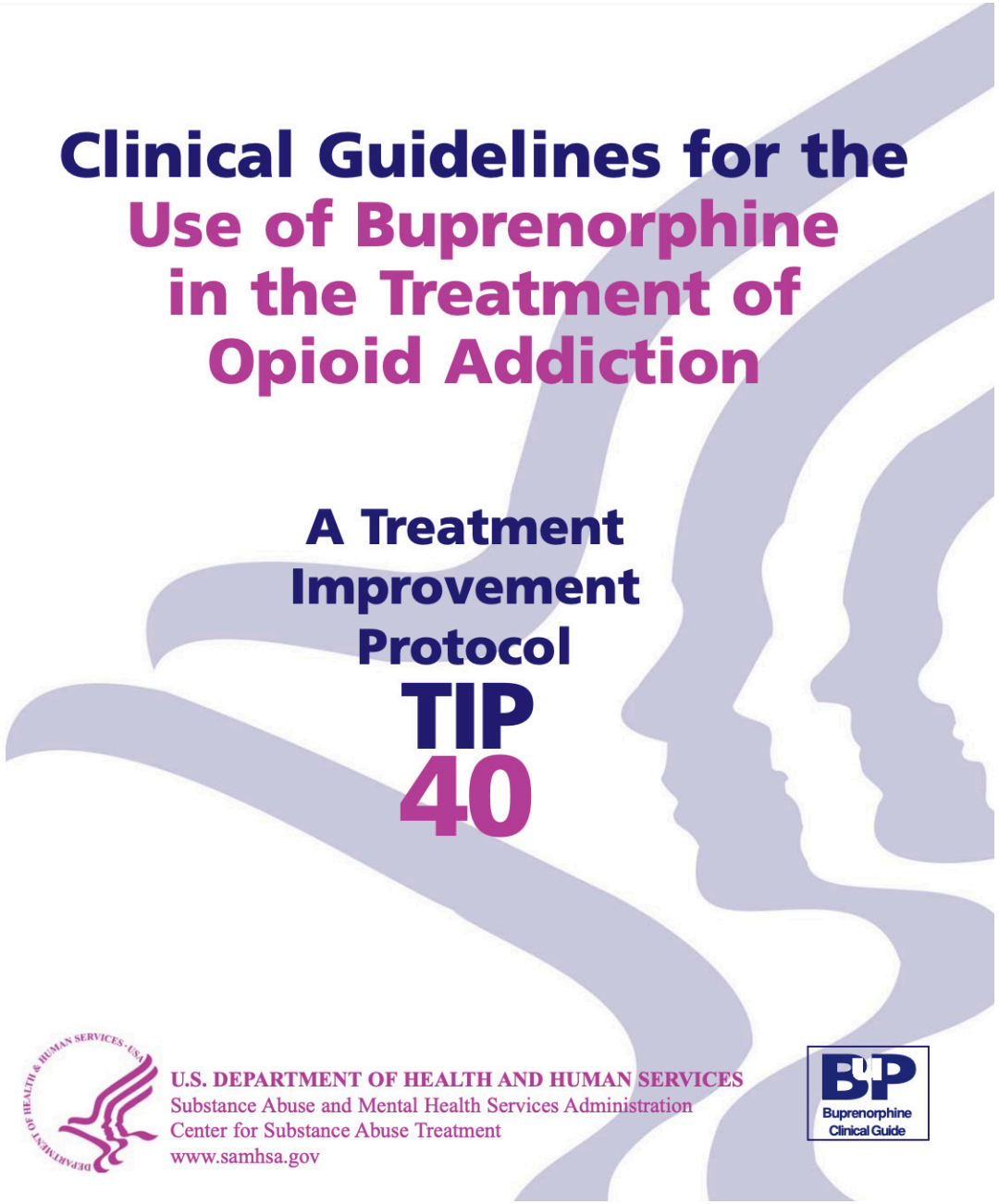
American Society of Addiction Medicine. The ASAM National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use. 2015. www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf. Accessed August 12, 2019.

If you're going to fly the plane …

- Buprenorphine is a partial opioid
- Patients develop dependence to buprenorphine (not tolerance, so dose increase is not merited)
- Withdrawal will occur if patient stops buprenorphine abruptly
- Not all patients need to remain on buprenorphine, many would benefit better from an antagonist
- Stopping buprenorphine can be challenging
- There are protocols available to transition from buprenorphine to naltrexone

Get Started

- Obtain the waiver to offer buprenorphine/naloxone treatment to your opioid-dependent patients
- Make sure all staff understand the confidentiality issues in treating SUDs
- 8-hour waiver training for physicians
- 24-hour waiver training for NPs
  - American Society of Addiction Medicine
  - American Academy of Addiction Psychiatry
  - Substance Abuse and Mental Health Services Administration Providers Clinical Support System



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Concerns

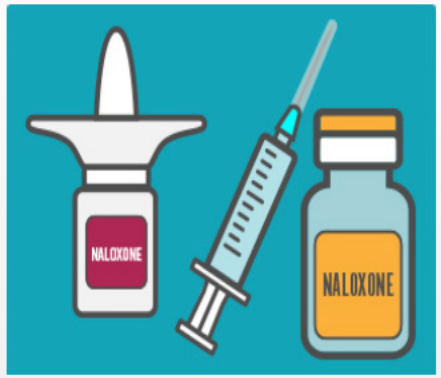
- Diversion
- Polysubstance use
- Transitioning to other levels of care (not “firing”)
- Staff support
- Comprehensive treatment for addiction
- Confusing opioid dependence with opioid addiction/OUD

Movement to “X” the X Number

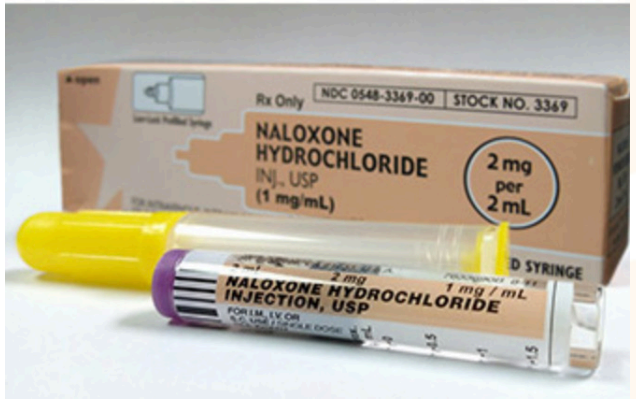
- Mainstreaming Addiction Treatment Act
- 18 states, many physicians, Congress – pushing expansion of substance use treatment
- Removing the DATA waiver
- Deregulate buprenorphine prescribing
- “…removes unnecessary obstacles and really expands the access we’ve created to provide for treatment on demand.” —Rep. Paul Tonko (D-NY)

Facher L. Nearly all doctors can freely prescribe opioids. Now a new movement aims to vastly deregulate an addiction treatment. April 30, 2019. www.statnews.com/2019/04/30/loosen-restrictions-on-prescribing-buprenorphine-addiction-treatment/. Accessed August 7, 2019.

Naloxone



[Surgeon General Public Health Advisory on Naloxone](#) (April 2018)



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How to Become a Waivered Practitioner

- MDs and DOs: 8 hours of training
- NPs and PAs: 24 hours of training

- Both pathways are available from
  - American Society of Addiction Medicine
    www.asam.org/education/live-online-cme/waiver-training
  - American Academy of Addiction Psychiatry
    www.aaap.org/clinicians/education-training/mat-waiver-training/
  - Substance Abuse and Mental Health Services Administration Providers Clinical Support System
    https://pcssnow.org/education-training/

Once Waivered …

- **Year 1**: 30 patients at any given time
- **Year 2**: 100 patients at any given time
- **Year 3**: May apply for 275 patients if
  - – You hold an additional credential (ABAM, ABPM, AAAP)

  OR
  - – You practice in a qualified setting
    - Registered with state
    - Accept third party payment
    - Use HIT
    - Access to case management
    - Night coverage

Why did I go into addiction medicine?

- Genetics/epigenetics
- Forensic psychiatry
- Patients are so interesting
- I’m good at it; patients respond very well to me
- Patients get WELL and recover
- When well, patients are intensely grateful

Why You May Consider Getting Your X# to Treat Opioid Use Disorder

- We have a desperate need for providers
- We need well trained psychiatrists to treat OUD
  - Bio-psycho-social
  - Family
  - Systems
  - Medical
  - Team care
  - Prevention and health promotion
  - Genetics and epigenetics
  - Health policy
  - Forensics and criminal justice
  - Medical ethics

Why You May Consider Getting Your X# to Treat Opioid Use Disorder (cont'd)

- The patients are from all walks of life, interesting, inspiring, and extremely grateful
- Patients get WELL
- Recovery is beautiful for patients and families; being the provider of it can replenish the practitioner