



# Buprenorphine Basics

Sarah Blevins, PharmD, BCIDP, AAHIVP

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# Financial Disclosure

❖ Nothing to disclose.

# Evidence-Based Disclosure

- ❖ Just because it's a law, doesn't mean it's evidence based.

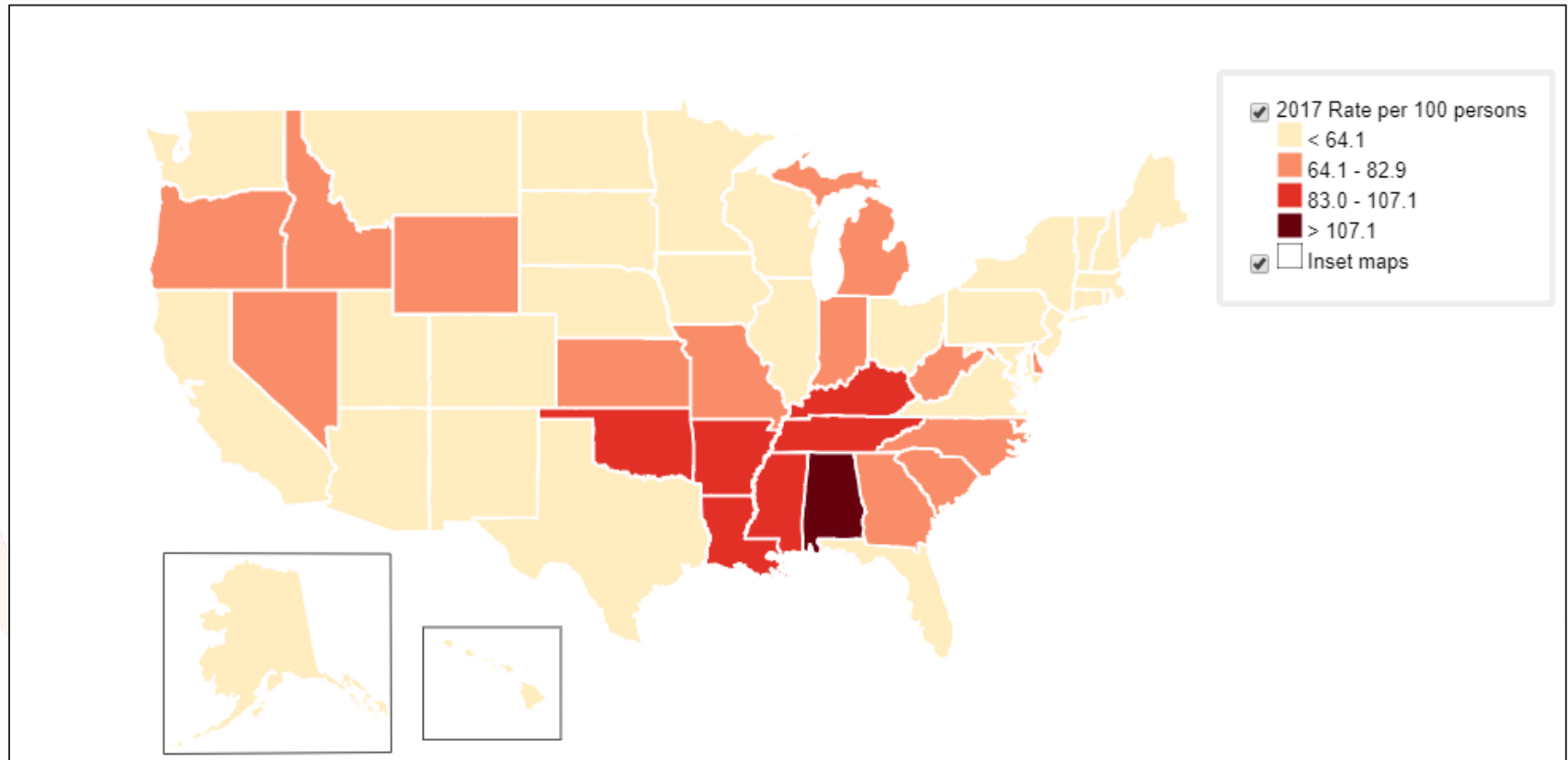
*“One of the great mistakes is to judge policies and programs by their intentions rather than their results.”*

*-Milton Friedman*

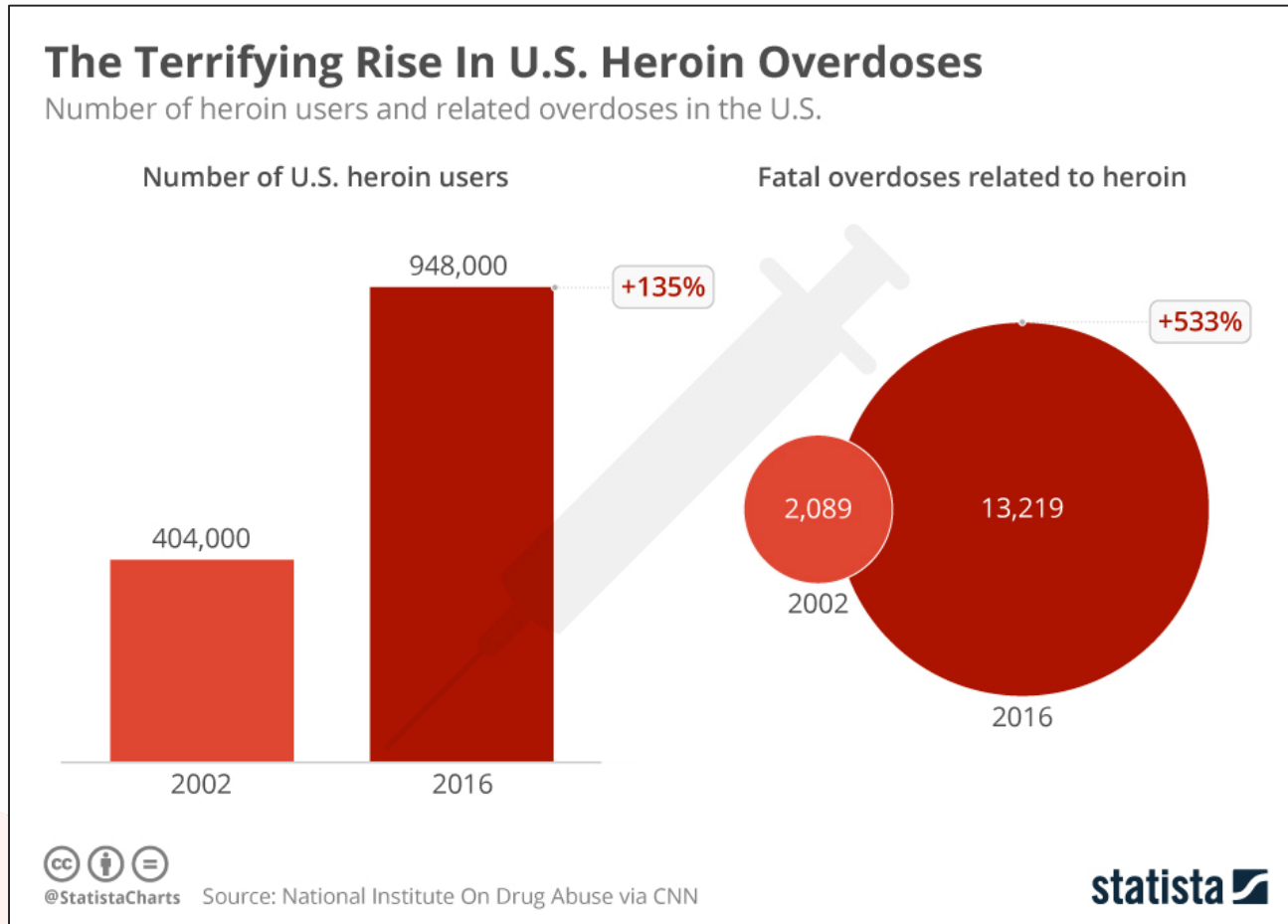
# Objectives

- Review buprenorphine mechanism of action and place in medication assisted treatment
- Discuss federal controlled substance laws
- Review state buprenorphine prescribing regulations

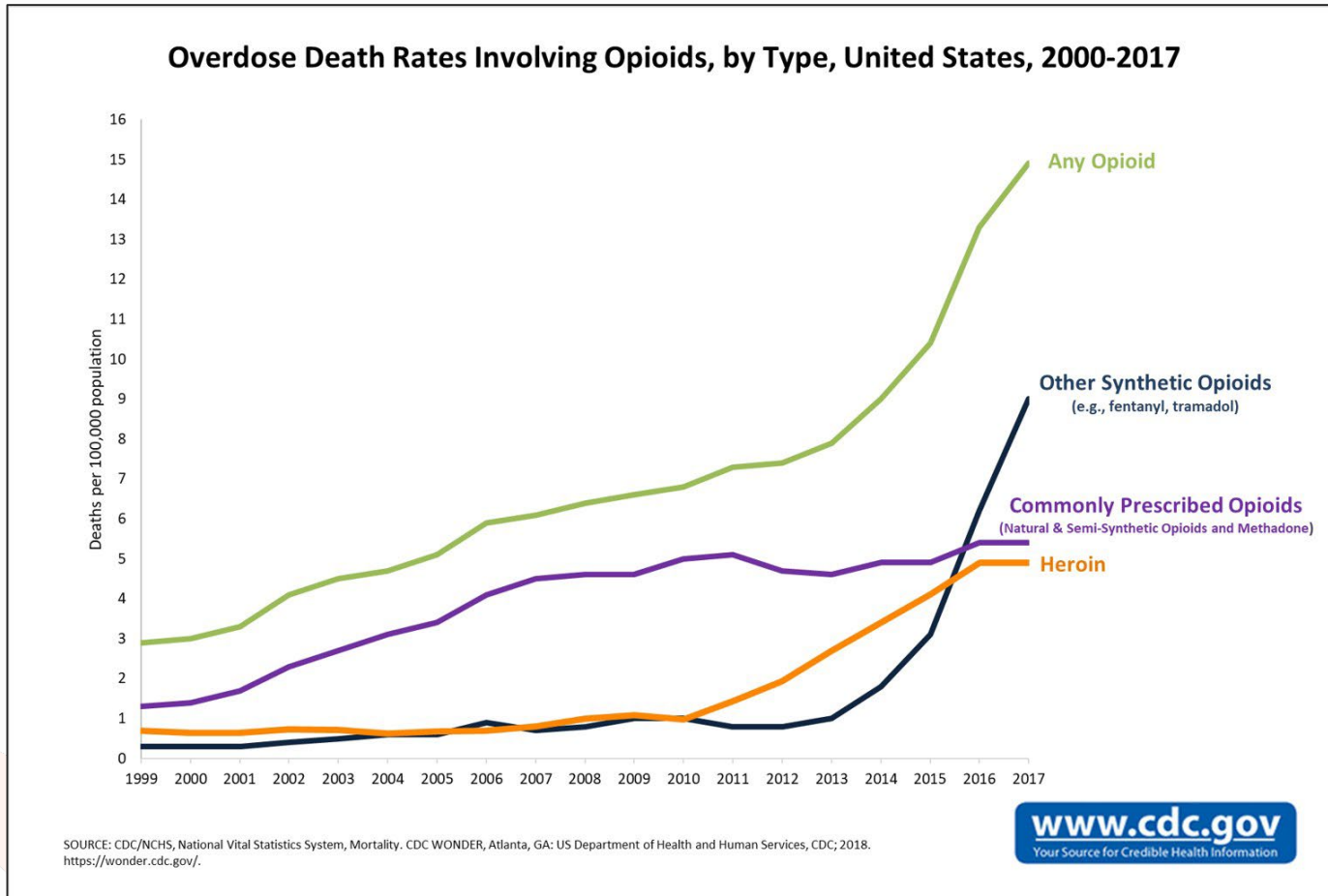
# State Opioid Prescribing Rate, 2017



# Heroin

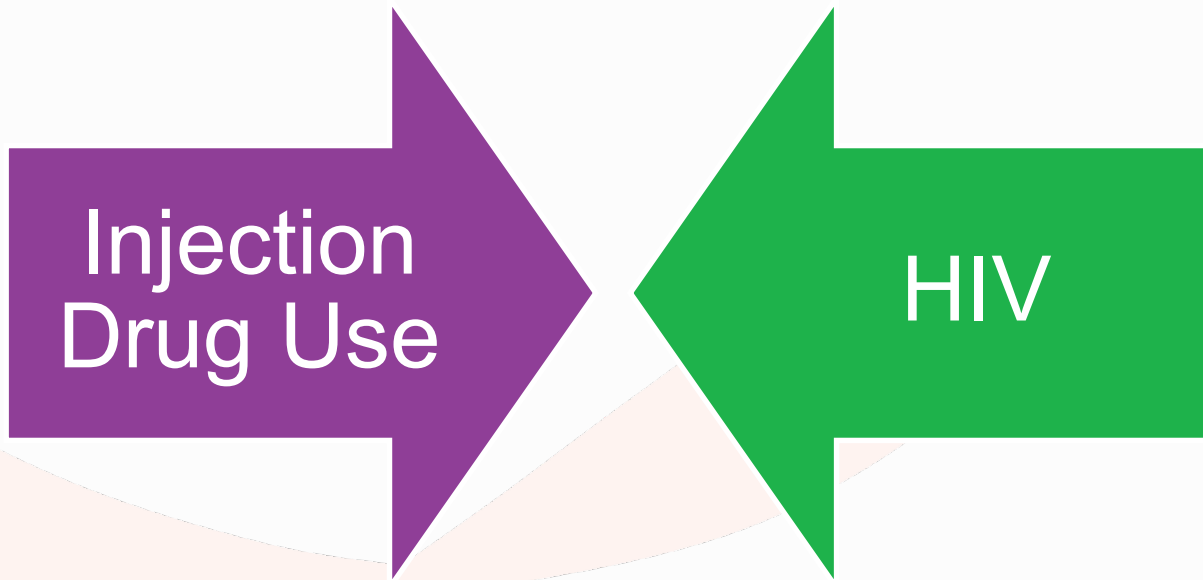


# Overdose Deaths



# HIV and Injection Drug Use

- ❖ In 2017, 1 in 10 new HIV diagnoses were due to:
  - Injection drug use
  - Injection drug use and MSM\*





# What is Buprenorphine?

# Buprenorphine Products

<b>Buprenorphine Only</b>	
Subutex®	Sublingual Tablet
Belbuca®	Sublingual Film
Butrans®	Transdermal Patch
Buprenex®	Injectable solution
Sublocade®	Subcutaneous Injection
Probuphine®	Subcutaneous Implant
<b>Buprenorphine/Naloxone</b>	
Suboxone®/Bunavail®	Sublingual Film
Zubsolv®	Sublingual Tablet

Because a pharmacist is giving this talk. . .

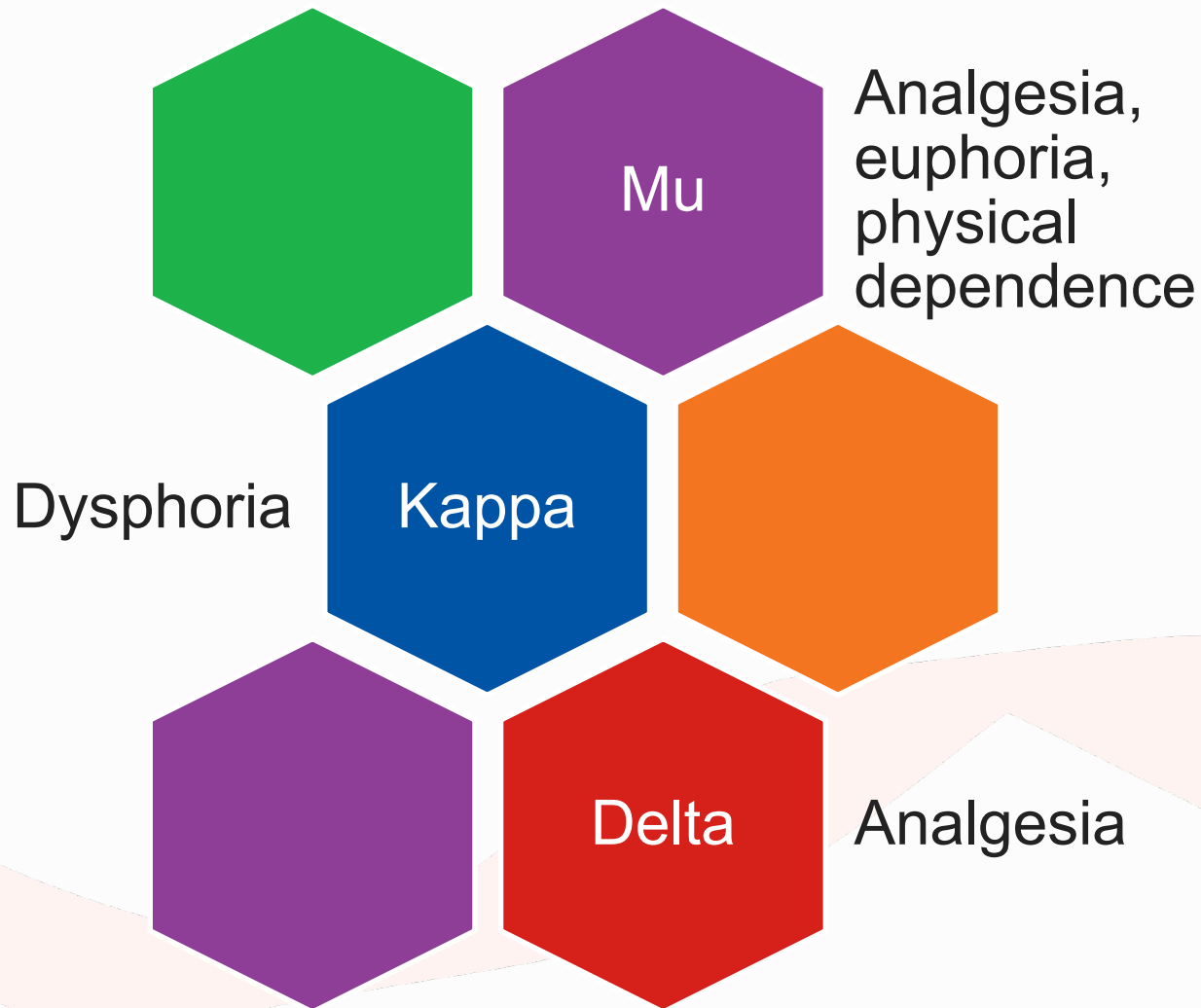


Narcotic

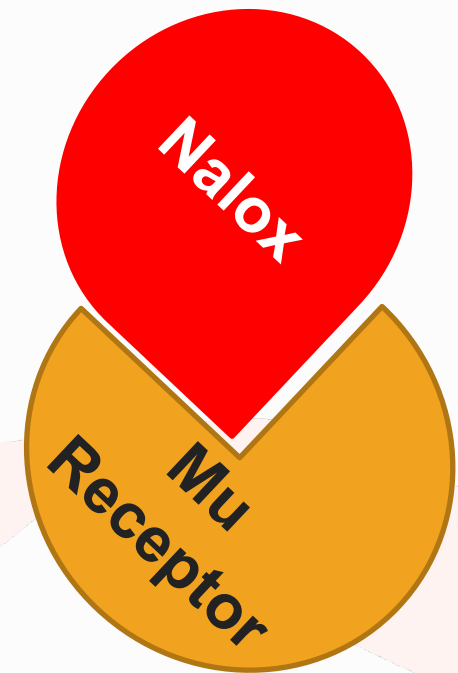
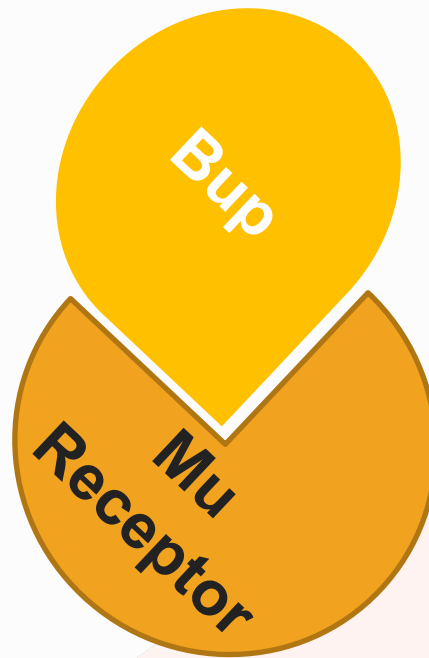
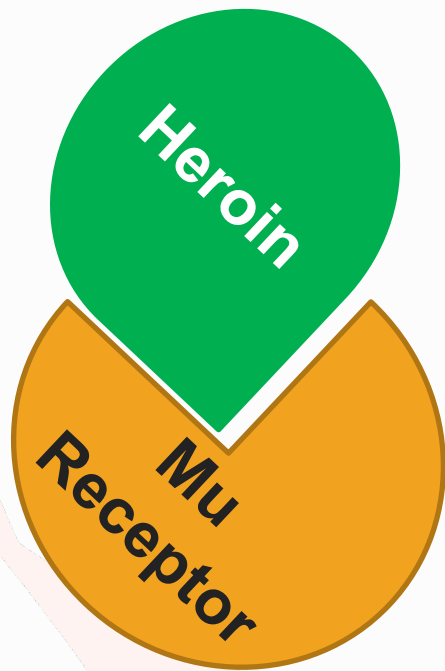
Opioid

Opiate

# Opioid Receptors



# Mu Receptor Binding



# The Basics

Analogue of thebaine

Partial mu receptor agonist

Extremely poor bioavailability

Co-formulated with naloxone

Indication: opioid dependence; acute and chronic pain

# Why Co-formulated with Naloxone?

## Buprenorphine/Naloxone

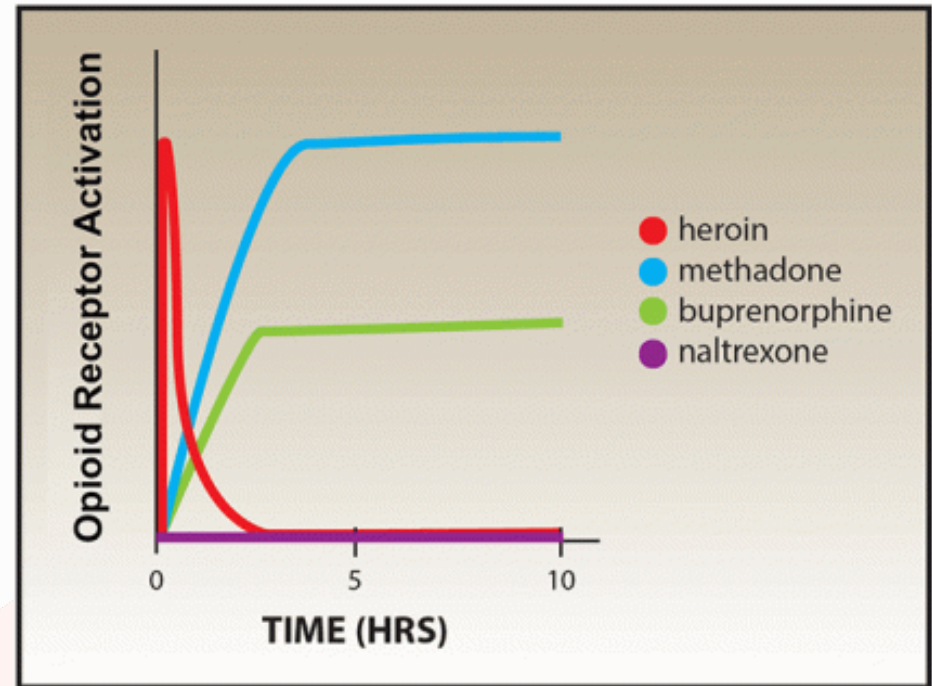
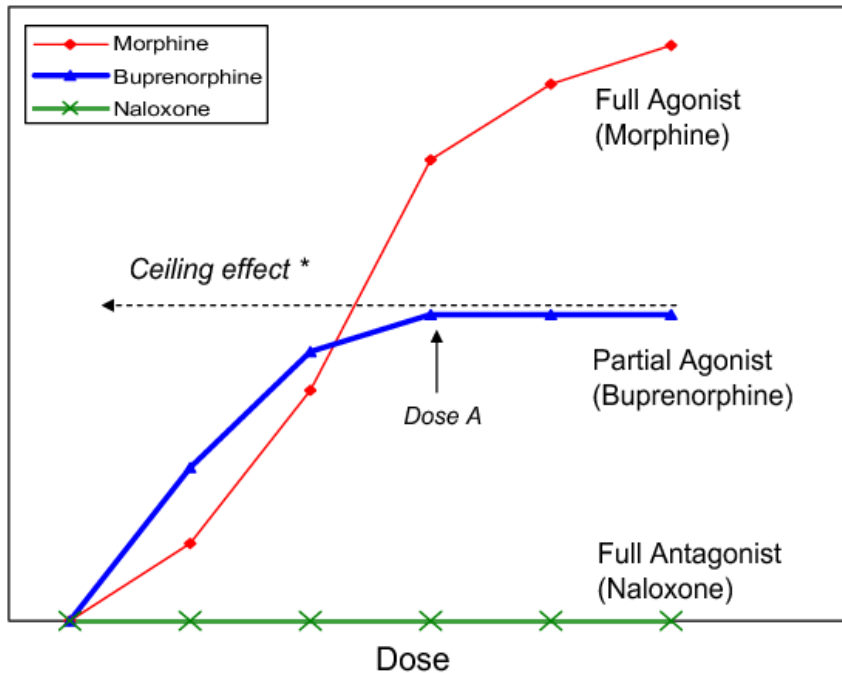


✓ Buprenorphine  
~~Naloxone~~

✓ Buprenorphine  
✓ Naloxone

# Pharmacodynamics

Curve of Morphine and Buprenorphine





# Ling et al. *Addiction* 1998; 93(4):475-486

❖ Buprenorphine vs. Placebo

❖ 16-week study

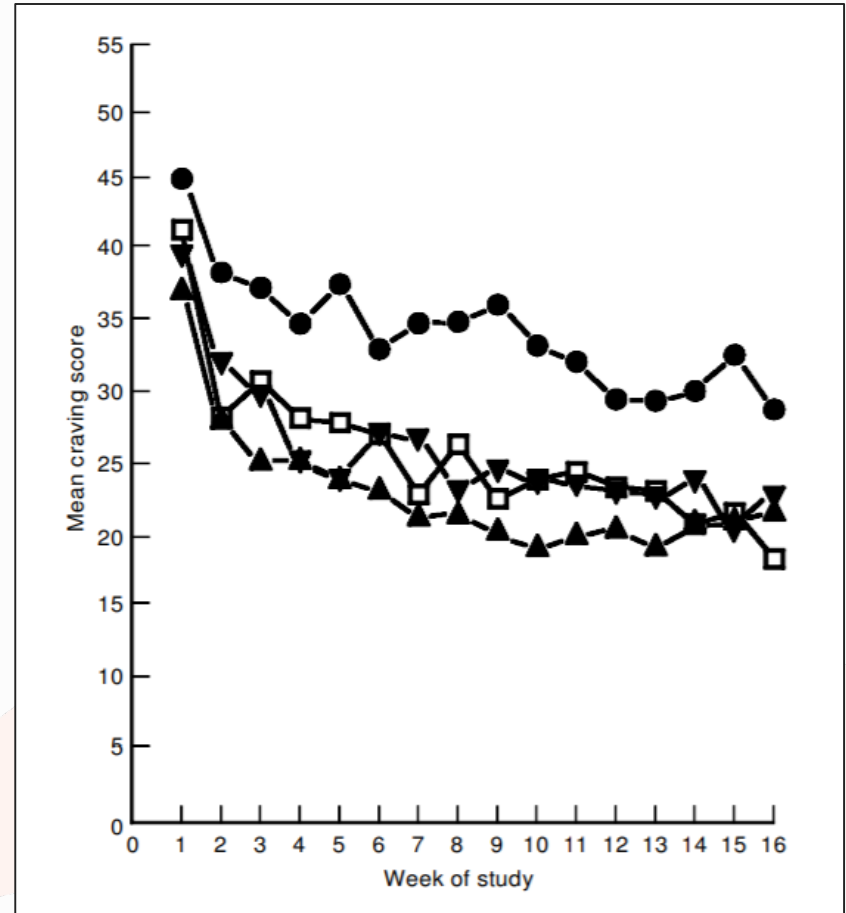
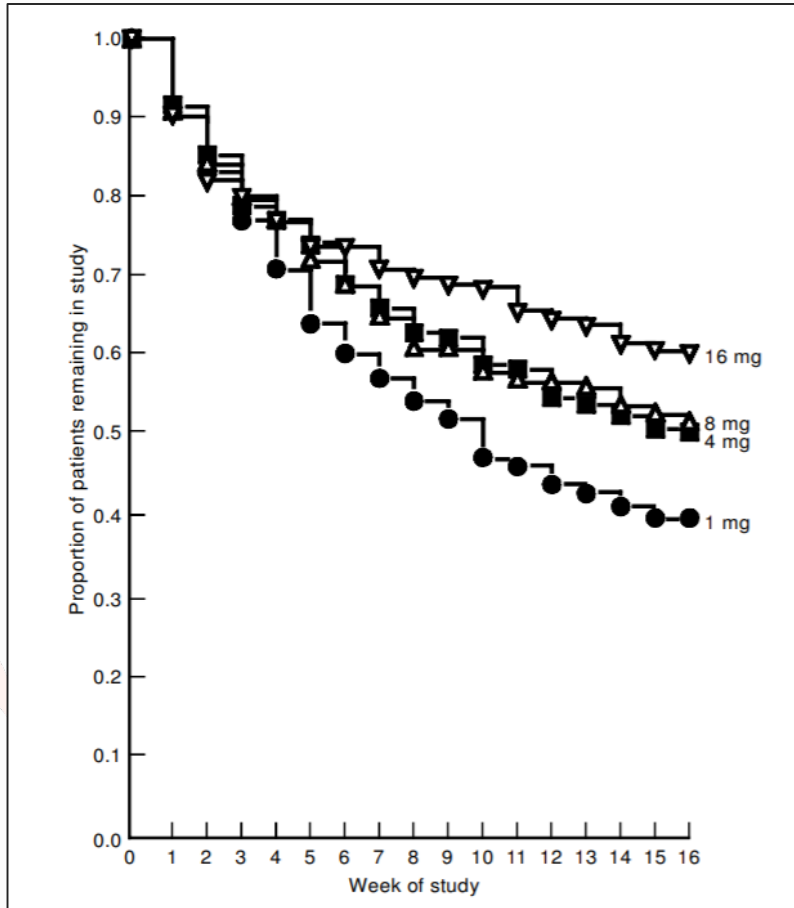
❖ Outcomes:

- Retention in treatment
- Illicit opioid use
- Cravings
- Global ratings

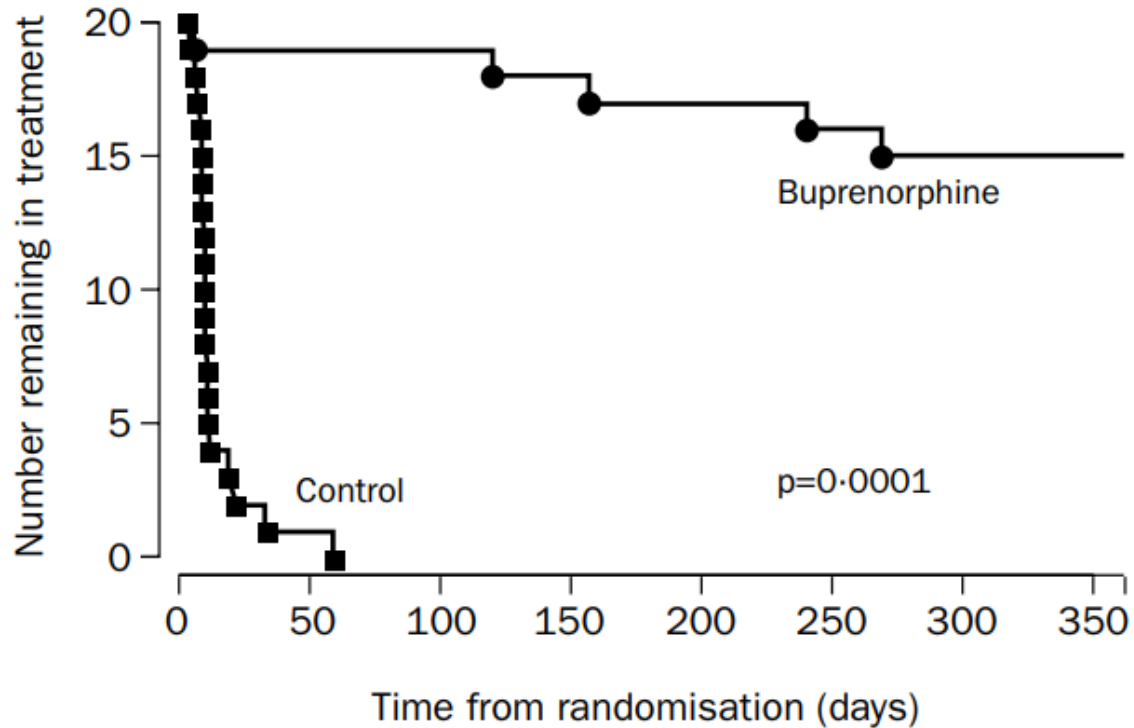
❖ Average Patient:

- White
- High school education
- Unmarried or divorced
- Unemployed for past 3 years
- Tried methadone previously

# Results



# Retention in Treatment



## Number at risk

20	19	18	17	17	16	15	15
20	1	0	0	0	0	0	0

# Trivia Break





# Driving that Train, High on Cocaine . . .



Keep the "reducer" happy

**'METHEDRINE'**  
in **OBESITY**

means help

- For those who eat too much
- For those who are depressed

"Methedrine" dispels abnormal craving for food, subtly elevates the mood.

"Methedrine" brand Methamphetamine Hydrochloride Tablets 5 mg., scored

**BURROUGHS WELLCOME & CO. (U.S.A.) INC., Tuckahoe, New York**

**PARKER'S TONIC**  
THE GREAT HEALTH AND STRENGTH  
RESTORER

Are you weary in Brain and Body  
-AVOID INTOXICANTS AND RELY ON  
**PARKER'S TONIC**

Obtain that  
your health and  
appetite

As most people as  
the usual factors  
the body through  
the system  
with

**BURNETT'S  
COCAINE**

**FOR THE HAIR.**  
CURES DANDRUFF, SOOTHES ALL  
IRRITATION OF THE SCALP, MAKES  
THE HAIR GROW AND GIVES A BEAUTI-  
FUL LUSTRE.

PRICE, 50c. AND \$1.00 PER BOTTLE.

SEND YOUR ADDRESS FOR OUR  
PAMPHLET ON THE  
HAIR.  
ITS CARE AND MANAGEMENT.

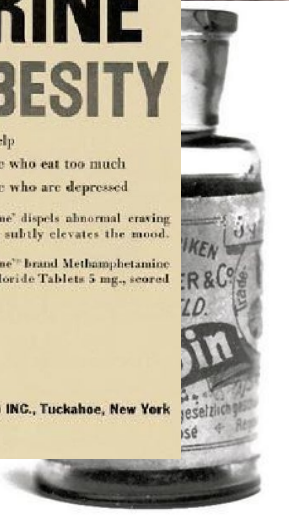
Joseph Burnett Co., Boston.

**COCAINE  
SYRUP & AN**

For Soda Water and o

This "INTELLECTUAL  
DRINK contains the val  
ULANT properties of the  
nuts, and makes not c  
refreshing and invigorat  
the soda water fountain  
ages), but a valuable B  
nervous affections —  
HYSTERIA, MELANCHOLY,  
The peculiar flavor o  
palate; it is dispensed f  
manner as any of the fr

Chemist,  
Sole Proprietor, Atlanta, Ga.



**SLEEPLESS BABY?**  
USE  
**LAUDANUM**

**ALSO AIDES IFF**

- Pain Relief
- Yellow fever
- Cardiac Disease
- Colds
- Dysentery
- Excessive Secretions

# Where are we now?

1906

- Pure Food and Drug Act
- Addictive substances must be included on label

1938

- Food, Drug, and Cosmetic Act
- Focus on safety (i.e., drug shouldn't kill you law)

1964

- Kefauver Harris Amendment
- Focus on safety and efficacy (i.e., drug should work and not kill you law)

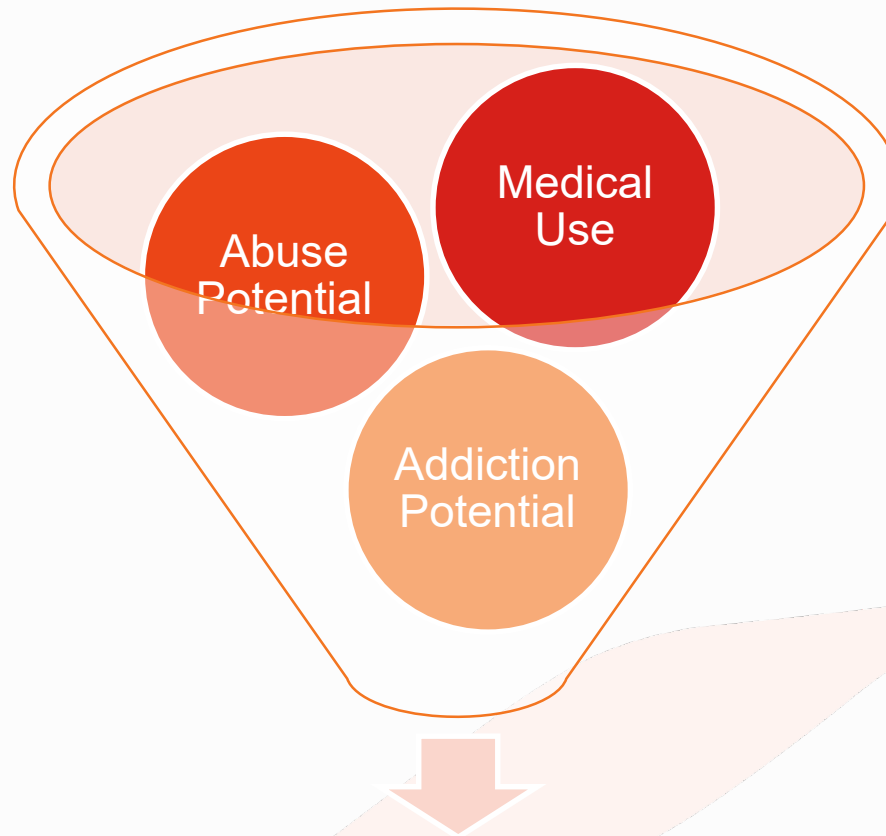
1970

- Controlled Substances Act
- Established the DEA, drug schedules, and international trade regulation

2000

- Drug Addiction Treatment Act
- Allows qualified healthcare providers to treat opioid dependency

# I would like to schedule my drug, please!



**Federal Schedule**

# A Review of (Federal) Schedules

I

- High abuse potential
- No accepted medical use

II

- High abuse potential
- Accepted medical use
- Severe psych and physical dependence

III

- Abuse potential less than II
- Accepted medical use
- Moderate to low physical dependence
- High psych dependence

IV

- Low abuse potential
- Accepted medical use
- Limited psych and physical dependence

V

- Low abuse potential relative to IV
- Accepted medical use
- Limited psych and physical dependence relative to IV



# Name That (Federal) Schedule

Drug	Schedule
Cocaine	II
Peyote	I
Testosterone	III
Codeine	II
Zolpidem	IV
Methamphetamine	II
Buprenorphine	III
Cannabidiol	V
Alprazolam	IV

# Who you gonna call?

Drug Enforcement Agency (DEA)

Cabinet for Health and Family Services (CHFS)

Food and Drug Administration (FDA)

Board of Pharmacy

Board of Medicine

Local, State, Federal Law Enforcement

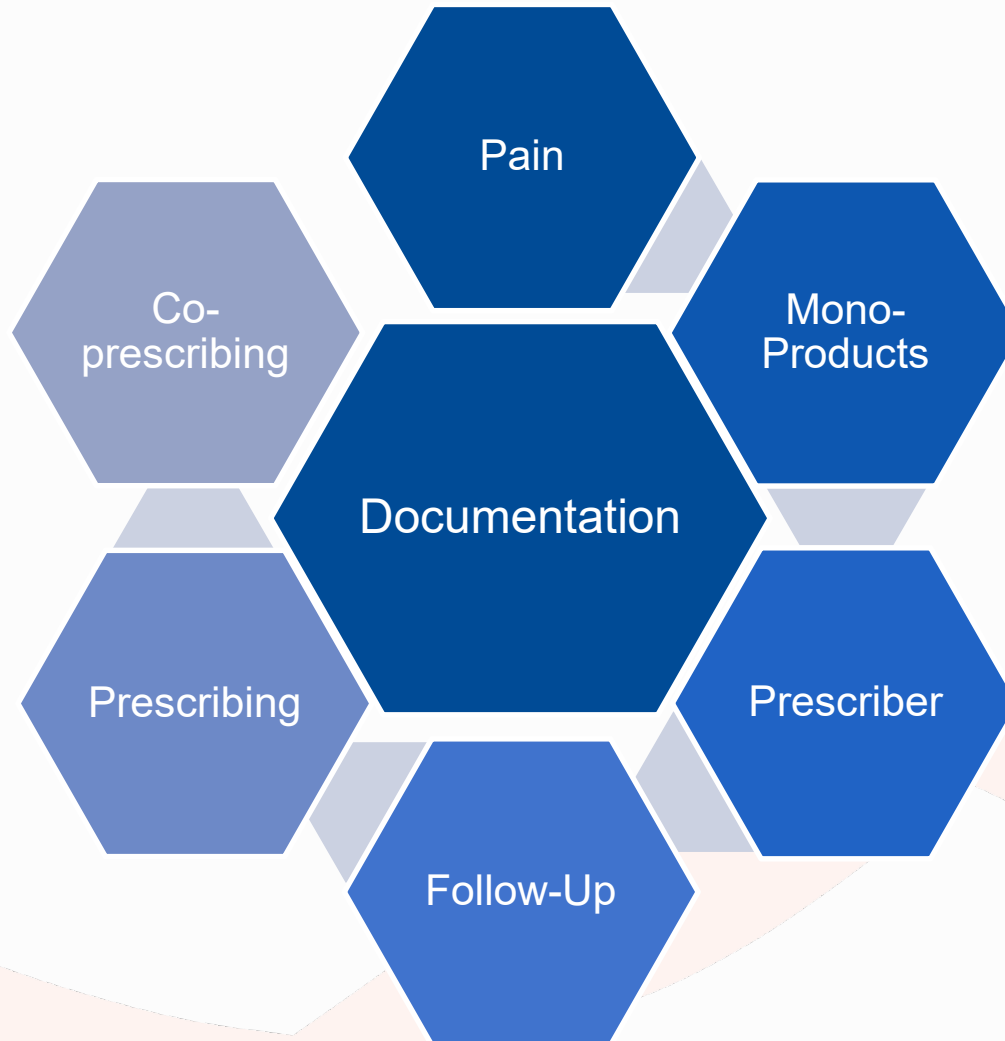
# Drug Addiction Treatment Act

- ❖ Established “waived” DEA license
  - Do not have to register as an opioid treatment program
  - “X” license
- ❖ 30 patients → 100 patients → 275 patients
- ❖ Buprenorphine
- ❖ SUPPORT Act
  - Treat 100 patients in first year
  - Extending prescribing privileges to midlevel practitioners

# Trivia Break



# Buprenorphine Prescribing



# Common Themes

## Consent and Treatment Plan

Thoroughly documented  
HPI

Social  
Support

HIV/HCV  
Testing

Behavioral  
Treatment Plan

Consult  
specialists  
when needed

# Prescriber Requirements

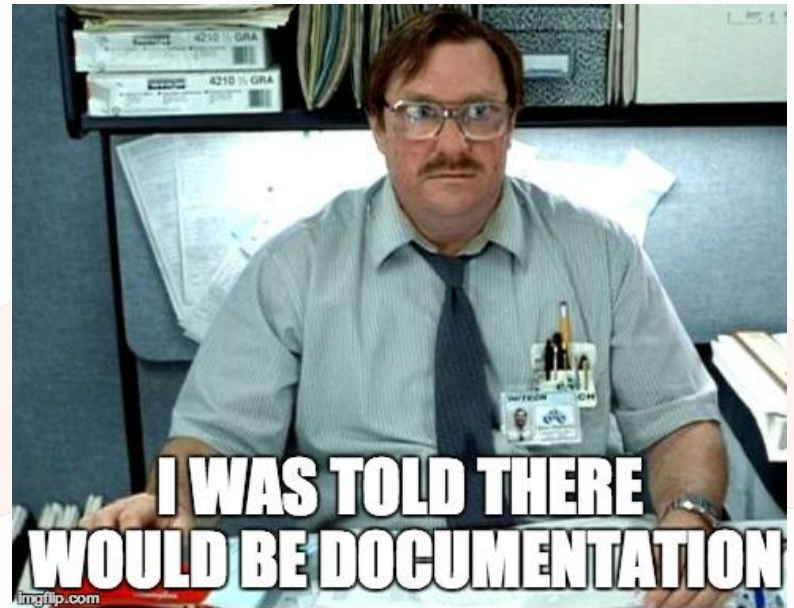
- ❖ DEA license and waiver in good standing
- ❖ Complete a SAMHSA\* certified course
- ❖ <https://www.samhsa.gov/medication-assisted-treatment/training-materials-resources/apply-for-practitioner-waiver>

\*Substance Abuse and Mental Health Services Administration



# Documentation

- ❖ History of Present Illness
- ❖ Substance Abuse History
- ❖ Social and Family History
- ❖ Past Medical History – Psych History
- ❖ Physical Exam
- ❖ Injection Drug Use History
  - HIV Screen
  - Hepatitis Serology
- ❖ CBC, CMP, and Drug Screen





# Initial Documentation

- ❖ Review prior medical records
- ❖ Review prescription drug monitoring report for 12 month period prior
- ❖ Explains risks and benefits of treatment
- ❖ Obtain written informed consent
- ❖ Urine drug screen

# Women of Child Bearing Age

- ❖ Pregnancy test
- ❖ Counseled on risk of neonatal abstinence syndrome
- ❖ Pregnant or Breastfeeding?
  - Coordinate care with OB/GYN

## Is Buprenorphine/Naloxone Unsafe in Pregnancy??

- ❖ Mullins et al. J Addict Med 2019 Sep 17
- ❖ ACOG Committee Opinion No. 711; August 2017

# Urine Drug Screens

- ❖ Drug screen panel should reflect local drug use patterns
- ❖ Qualitative vs. Quantitative
- ❖ Confirm or refute patient's self-report
- ❖ Pair with pill count
- ❖ Help patients succeed

Buprenorphine  
Methadone  
Oxycodone  
THC  
Amphetamines  
Benzodiazepines  
Cocaine  
Other Opioids

# Induction

Recommend in  
office induction

Document why  
if office  
induction is not  
done

Document  
COWS\*

Behavior  
modification  
treatment plan

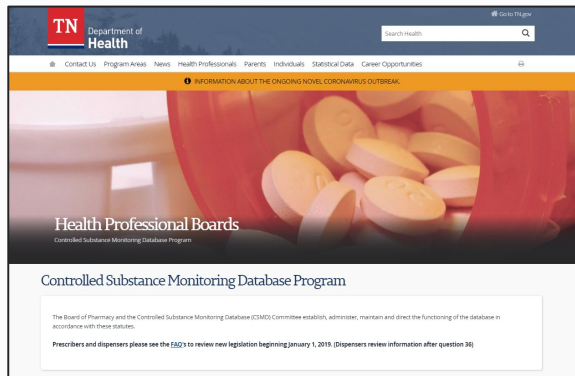
\*Clinical Opiate Withdrawal Scale

# Prescription Drug Monitoring Programs

❖ Check frequently

❖ Helps ensure:

- Patients are filling buprenorphine
- Patients are not filling other controlled substances



# Prescribing

- ❖ Call-in, fax, written, e-scribe
- ❖ Valid for 180 days from issue
- ❖ Can write  $\leq 5$  refills
- ❖ Include DEA X license
- ❖ Sign it



# Just Say No: Co-prescribing

- Stimulants
- Benzodiazepines
- Sedative-hypnotics
- Opioids



# But what if??

My patient REALLY needs it?

- Consult a board certified physician in Addiction Medicine or Psychiatry

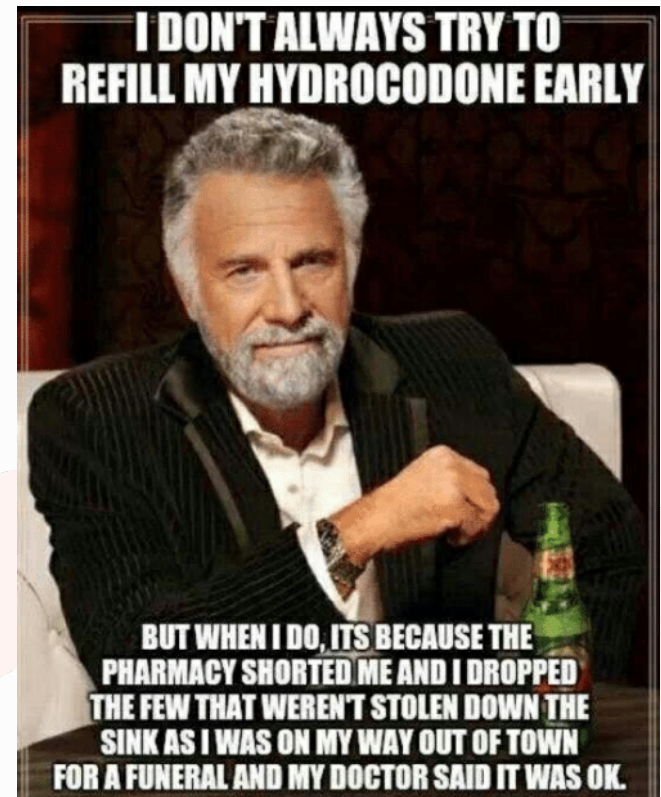
I can't find a psychiatrist or an addiction specialist?

- No more than 30 days
- Extraordinary or acute medical needs



# More What Ifs

- ❖ What if my patient says their buprenorphine was stolen?
  - Have them file a police report
  - Have a plan in place prior to theft



# Buprenorphine for Pain

## ❖ Transdermal or Buccal Film

- Pain severe enough to require around-the-clock, long-term opioid treatment
- Should not be prescribed prn

## ❖ Intravenous or Intramuscular

- Administered in physician's office
- Acute pain severe enough to require opioids

# Resources

- ❖ <https://www.tn.gov/content/dam/tn/health/documents/2018%20Buprenorphine%20Tx%20Guidelines.PDF>
- ❖ <https://www.samhsa.gov/>
- ❖ <https://www.asam.org/>

## Tennessee Nonresidential Buprenorphine Treatment Guidelines *(Summer 2018 Update)*



# Risk Reduction

## ❖ Naloxone

- <https://www.safeproject.us/naloxone-awareness-project/state-rules/>
- Everyone with an opioid prescription or a diagnosed opioid use disorder should have naloxone!

## ❖ HIV Pre-exposure Prophylaxis

- <https://www.hiv.gov/blog/cdc-recommends-prep-for-injection-drug-users>
- <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf>

## ❖ Syringe Exchange/Clean Needles

- <https://www.nasen.org/map/>

# Last Trivia Break

79,596,606

# Questions??