Proper Prescribing of Controlled Substances

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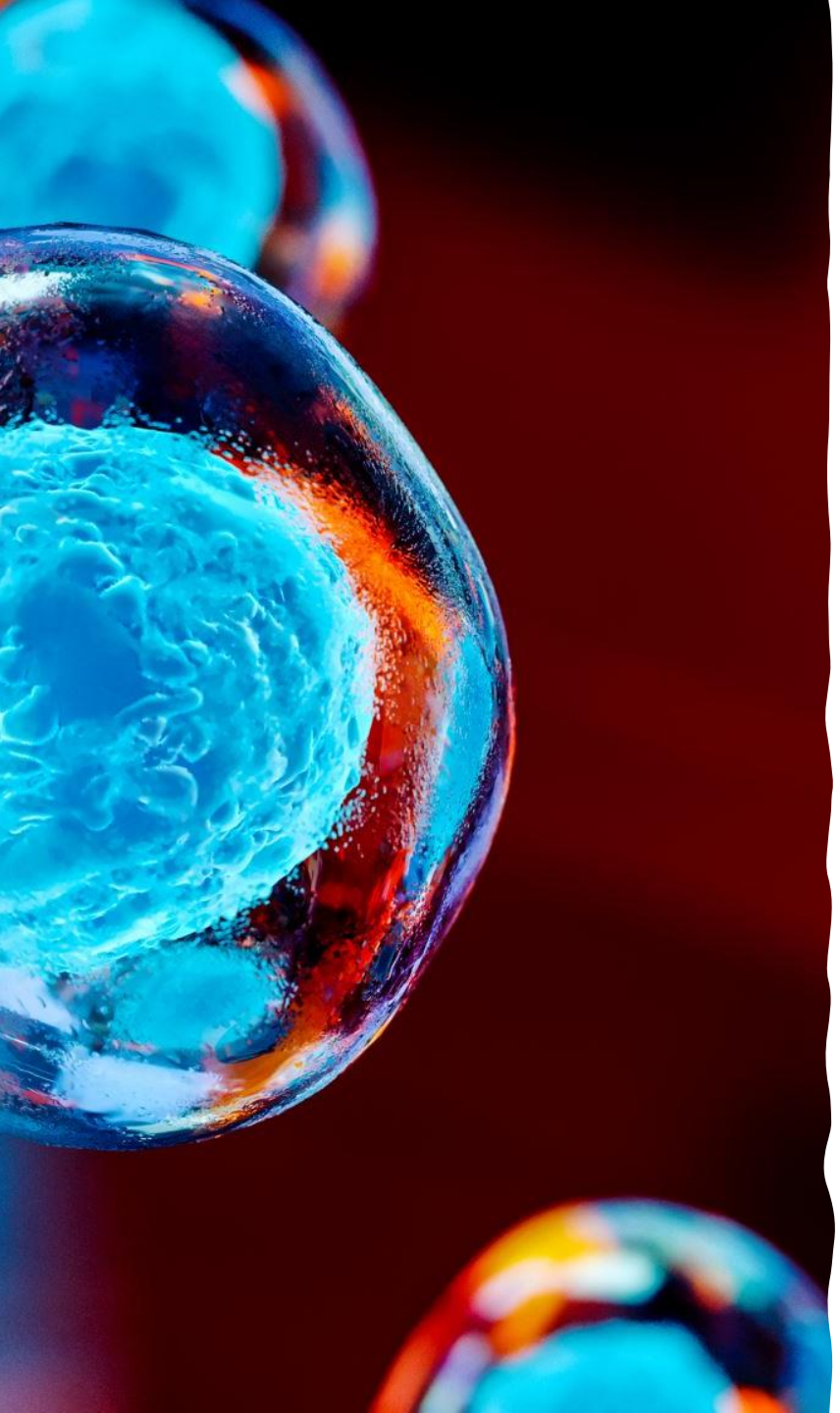


Objectives

1. Learners will understand the concept of prescribing controlled substances.

2. Learners will understand the appropriate use of controlled substances and implement strategies to minimize the risk of misuse, diversion, and overdose of opioids and other controlled substances.

3. Learners will understand the proper prescribing of controlled substances.

4. Learners will become familiar with and implement the CDC guidelines when prescribing opioids for treating and managing chronic pain.

5. Learners will establish clear criteria for initiating, continuing, and discontinuing opioid and controlled substance therapy for chronic pain.

Dealing a Medication

- Physicians are allowed to prescribe addicting substances that have demonstrated medical benefit
- This “allowance” is through a combination of state and federal permissions
- This allowance mandates vigilance and being responsible on the part of the physician

Dealing a Medication

Controlled substances should be prescribed when:

- The benefits outweigh the risk
- There are no safer alternatives available

Can use off label but should do so with extreme caution

With a valid controlled substance agreement

Using Opioids

- Opioids can be useful in certain situations
- The decision to prescribe an opioid is based on the individual's best judgement
- If an opioid (or other controlled substance) is prescribed, then professional judgement should be used

DEA Schedules

Drug schedule	Abuse/dependence potential	Accepted medical use	Need for a prescription	Examples
Schedule I	High	No	Not applicable	Flunitrazepam, LSD, PCP
Schedule II	High	Yes	Yes (un-refillable)	Methadone, cocaine, oxycodone (Percodan®), methylphenidate (Ritalin®) and dextroamphetamine (Dexedrine®)
Schedule III	Low/moderate	Yes	Yes (five refills only)	Anabolic steroids, some barbiturates
Schedule IV	Low	Yes	Yes (five refills only)	Darvon, Talwin, Equanil, Valium and Xanax
Schedule V	May or may not	Yes	No	Over-the-counter medications

Common Categories of Controlled Substances

- Stimulants
- Benzodiazepines
- Opioids
- Barbiturates
- Z hypnotics
- Muscle Relaxers

Using Multiple Controlled Substances

As a general rule, should avoid crossing categories	• Can stack side effects or overcome compensatory systems (i.e. respiratory drive)
As a general rule, should avoid multiple agents in the same class	• Multiple pharmacokinetic profiles can alter the safety analysis
Certain combinations are red flags for monitoring agents:	• Opioid, Xanax, and Soma

Controlled Substance Agreement

- Should be utilized in 100% of patients receiving a controlled substance
- Outlines expectations
- Allows both parties to understand the parameters of the agreement to receive controlled substances

Controlled Substance Agreement Common Elements

- The patient will not obtain controlled substances from any other provider, including emergency departments
- If the patient does obtain a substance from another provider, they will call you immediately
- The patient will obtain prescriptions from one pharmacy only

Controlled Substance Agreement Common Elements

- The patient will not use other addictive or mind-altering substances
  - This may include marijuana
- The patient understands that they may be asked for a urine drug screen at any time
- The patient understands that they may be asked for a pill count at anytime

Controlled Substance Agreement Common Elements

- The patient understands that early refills will not be given for any reason
- The patient understands that any violation of the agreement will result in loss of the right to obtain it
- The patient understands that if they do not violate the agreement then they will receive the medication as long as the physician believes it to be beneficial

Monitoring

Urine Drug Screens

PMP

Pill Counts

Refill timing

Behavior

Drug Testing

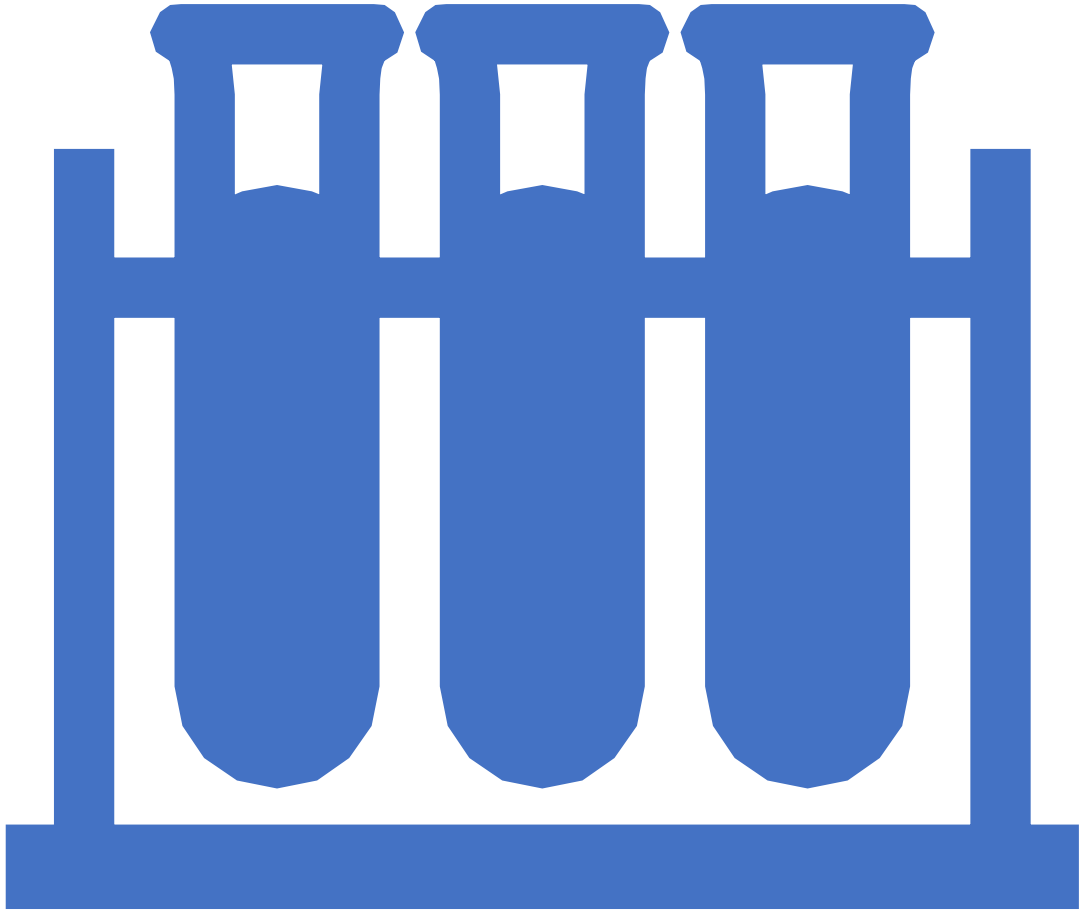
- Screening
  - Immunoassay
  - Lots of false positives
- Mass Spectroscopy
  - Confirmatory
  - Relatively no alternative explanation for a substance to be present

Urine Drug Screens

- Should be done at first visit
- Should be done frequently in the beginning of treatment
- Should be done routinely after
- All patients tested the same

Urine Drug Screens

- Most facilities have a standard set of substances that they test for
- Does not test for all substances
- You should be aware of what your facility/clinic's screen is for



Urine Drug Screens and Opioids

UDS usually tests for “opiates” and not “opioids

Will therefore not test for synthetic opioids

- Fentanyl
- Methadone
- Tramadol

These tests need to be ordered seperately

Urine Drug Screens and Buprenorphine

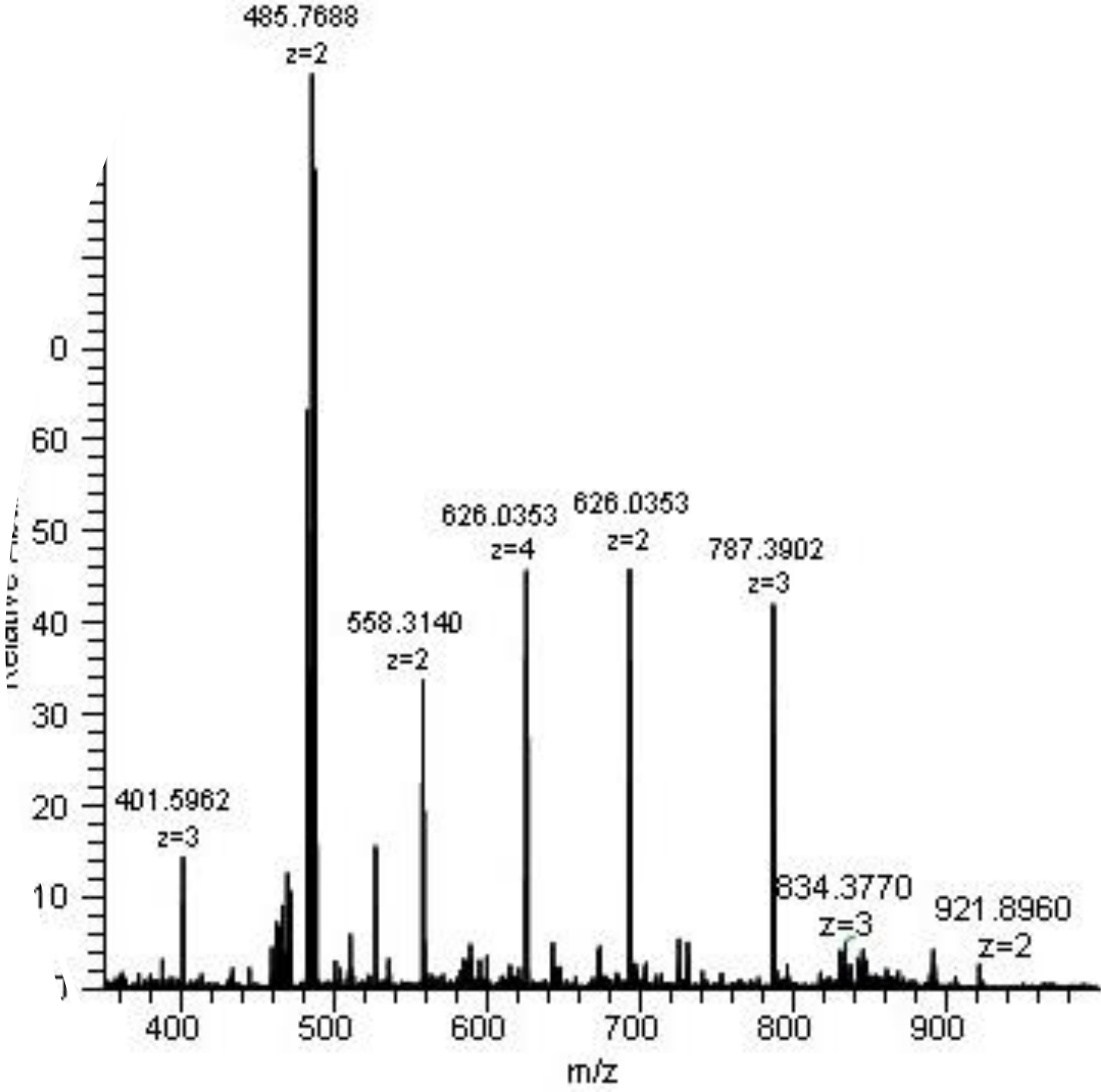
UDS' are an important component of buprenorphine utilization

Usually will test for the metabolite, norbuprenorphine also

If the test is positive for only buprenorphine but absent norbuprenorphine, then diversion may occuring

Mass Spectroscopy

- Confirmatory testing that looks for the chemical signature of a substance
- Can be obtained from urine
- Very expensive
- Should be utilized consistently, albeit sparingly



When to Obtain Confirmatory Testing

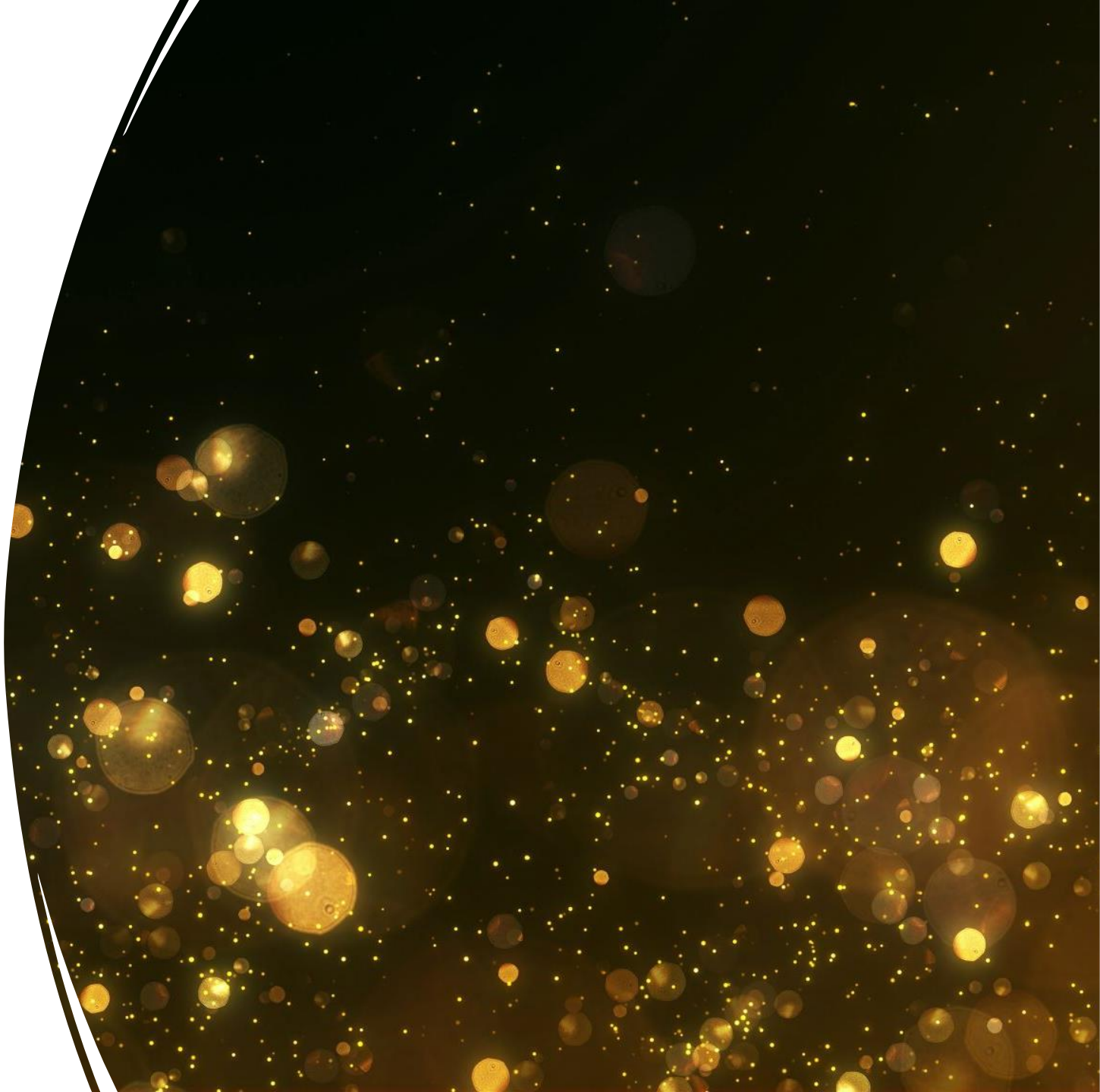
- When the patient refutes the results of the UDS
- When there are serious consequences
- Routinely in order to ensure your process is working as expected

Consequences of Drug Testing Results

- Loss of employment
- Loss of ability to participate in activities (i.e. sports)
- Loss of custody
- Violation of probation/parole
- Driving while Intoxicated

Abnormal Urine Drug Screens

- Inconsistent Positive
  - Positive for something it should not be
- Inconsistent Negative
  - Negative for something it should be positive for



Inconsistent Positive

- Have to acknowledge and have to do something
- Ask yourself how the substance can be contributing to the symptoms
- Are you abiding by the Hippocratic Oath

Inconsistent Positive Options

- More frequent monitoring
- Discontinuation of medication
- Referral to substance treatment

Inconsistent Negative

- Huge Red Flag
- Should consider immediate cessation
- You cannot knowingly contribute to diversion

Prescription Monitoring Program

- Should be checked at every visit
- Adherence to controlled substance contract
- Violations need to be addressed in the chart

Pill Counts

- Can verify adhering to prescription instructions
- Can be done at your office or at a local pharmacy
- Should be random but flexibility is important

Aberrant Behaviors

- Driving the conversation toward controlled substances
- Demanding
  - Certain medications
  - Higher doses
- Refusal to participate in alternative treatment or diagnostics
- History of diversion

Documentation

- Is one of the most important components
- Protects both the patient and the physician
- Is one of the most underperformed areas

Documentation

- HPI
- Social History
- Assessment/Diagnosis
- Treatment Plan

Documentation HPI

- At the first visit, should establish the actual presence of a condition or symptoms that would benefit from the medication
- Should document prior treatment efforts and response
- Should document any past objective evidence
  - Be sure to state what information comes from the patient and what information was viewed by you

Documentation Follow-up

- What is the status of the symptoms listed in the first visit
- What is the status of symptoms associated with the diagnosis
- How exactly has the medication helped, including function
- Has the patient experienced warning signs of addiction:
  - Cravings
  - Withdrawal
  - Tolerance

Documentation Social History

- Have to ask about past history of addiction
    - “What substances have you used before, even once?”
    - “Do you think you have ever been addicted to anything or has a substance ever caused problems in your life?”
    - “Have you ever been to substance treatment or had it recommended to you?”

Documentation Diagnosis

- Should be based on evidence
- Should not be vague
  - i.e. “anxiety” or “low back pain”
- If a mental illness, diagnosis should meet all required DSM criteria

Documentation Treatment Plan

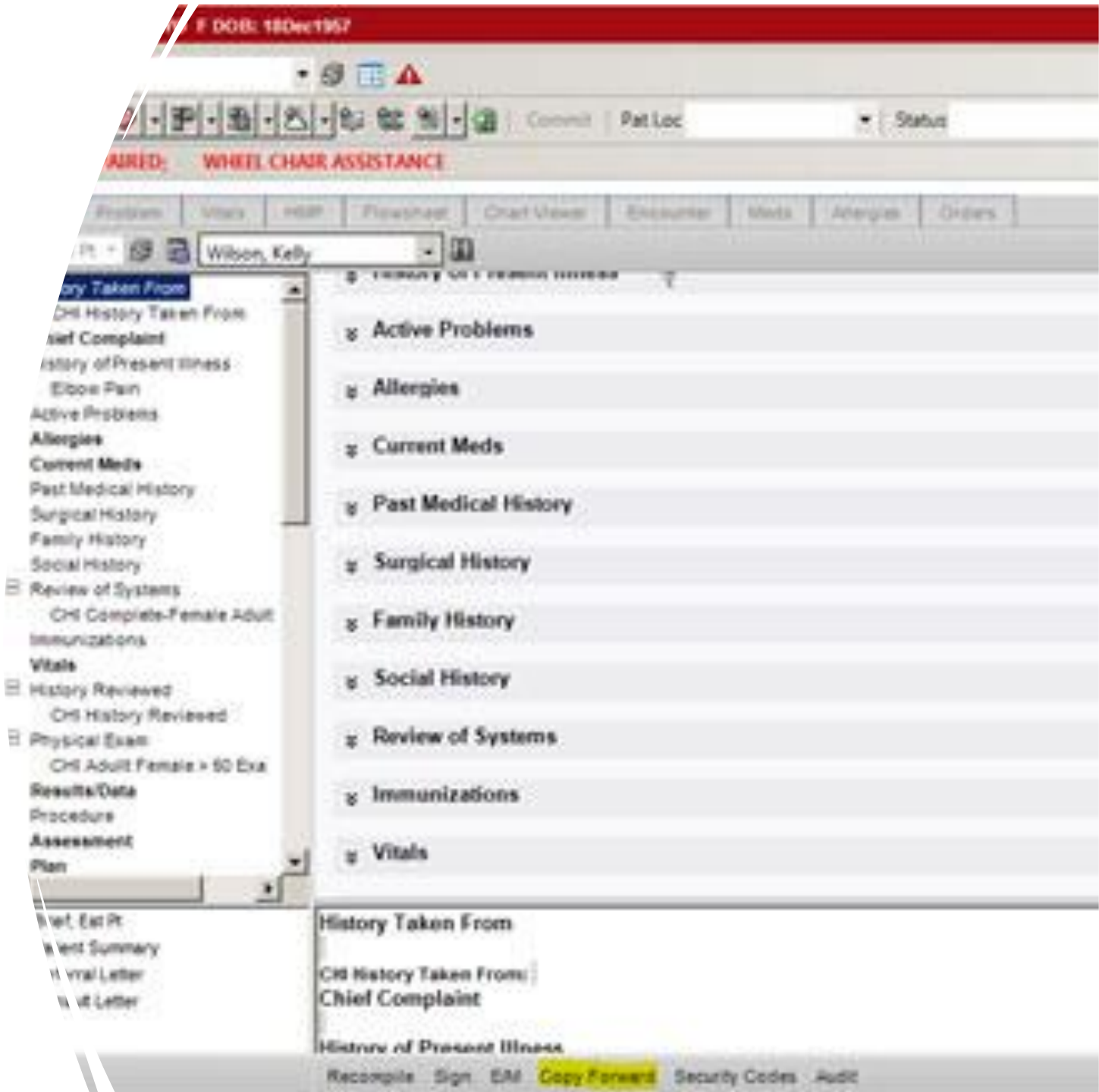
- Should be based on evidence
- Outline the expectations of the medication
  - If they are not met, then what will happen?
- Consider obtaining records to verify diagnosis
- Outline the anticipated length of use of the controlled substance
- Should review monitoring results
  - “UDS reviewed, no abnormal results.”
  - ”PMP reviewed, no unexpected results.”

Common Pitfalls

- Copy forward
- Ignoring abnormal results
  - UDS
  - PMP
- Poor HPI documentation

Copy Forward

- The primary characteristic that I look for in a malpractice/criminal review is that the physician made an individualized assessment at the time of the prescription
- Copying forward the same note month after month calls this into question
- Often simple grammatical mistakes are carried forward demonstrating that the physician was not paying attention



Ignoring Results UDS

- Falsely stating that the UDS was reviewed and there were no abnormal results bluntly demonstrates that the physician either:
  - Was not paying attention
  - Doesn't care about their patient
- Highly correlated with "pill mills"
- Can be very hard to defend, especially with a chronic pattern

Ignoring Results PMP

- As with urine drug screens, ignoring PMP results demonstrates that the physician is not utilizing the required level of vigilance in a high-risk area
- Can also be difficult to defend
- Ignoring both tools can be especially damanging

Poor HPI Documentation

- “Patient states meds are working.”
- “Patient states meds are not working. Will increase dose.”
- “Patient has PTSD. States blood sugars are well controlled.”
  - “Will refill Xanax.”
  - “Will increase Xanax.”

Consequences of Poor Prescribing

- Criminal Charges
- Civil Liability
- Administrative Action

Criminal Charges

- Murder
- Conspiracy
- Violation of Controlled Substances Act
- Many others

Civil Liability

- Malpractice
- While the patient may like the physician, families often don't
- Families will sue if there is a bad outcome
- Standard of Care will be that no reasonable physician would have prescribed such in light of the available information
- Or no reasonable physician would not have obtained more information

Administrative Action

- Loss of DEA license
- Loss of OBNDD license
- Loss of medical license
- Loss of hospital privileges
- Loss of contract with third party payers

What about our colleagues?

- There is an ethical obligation to report dangerous patient care
- May be an affirmative duty in certain situations
- Should report directly to your medical board
    - Administration can be helpful and should be involved but the duty belongs to the licensee, not the health system

When to Report Examples

- When you become aware that a physician is knowingly contributing to diversion
- When you believe the dose poses an imminent threat
- When you believe the physician is not adhering to standard medical practice
    - i.e. no physical exam

2016 CDC Guidelines

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Early Release / Vol. 65
March 15, 2016

CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

2016 CDC Guidelines

1. OPIOIDS ARE NOT FIRST-LINE THERAPY

Non-pharmacologic therapy and **non-opioid pharmacologic therapy** are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with non-pharmacologic therapy and non-opioid pharmacologic therapy, as appropriate.

Alternatives to Opioids

- Physical therapy
- Osteopathic Manipulative Treatment (OMT)
- Acetaminophen
- Ibuprofen

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2. ESTABLISH GOALS FOR PAIN AND FUNCTION

Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.

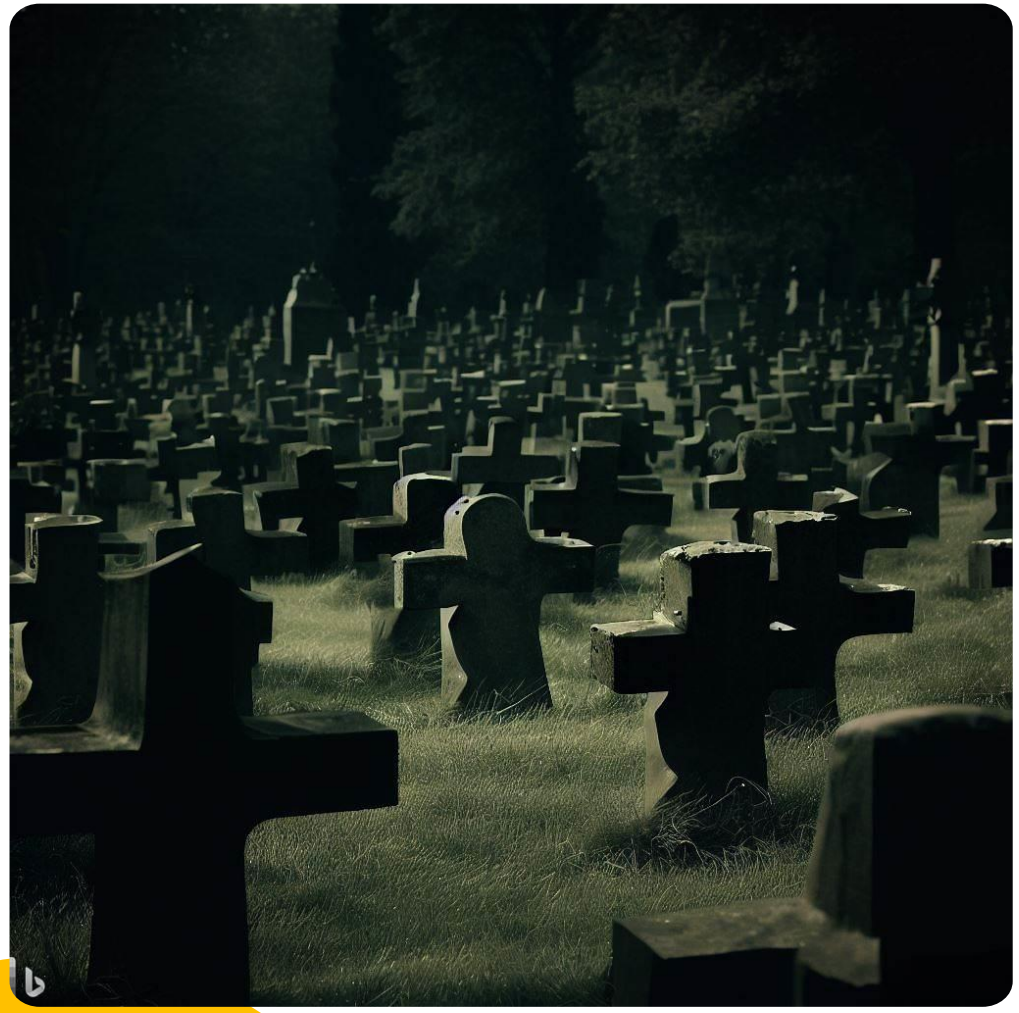
What is your goal of using opioids?

- To have the patient pain free?
  - Is that likely?
- What is the patient able to do because of the medication?
- What evidence do you have that the benefits are worth the risk?

CDC Guidelines

3. DISCUSS RISKS AND BENEFITS

Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy.



Risks

- Death
- Hospitalization
- Increased Pain
- Addiction

Benefits of Opioids for Chronic Pain

- Highly Controversial

Benefits of Opioids for Chronic Pain

Randomized trials have demonstrated that opioid therapy for up to 12–16 weeks is superior to placebo, but have not addressed longer-term use.

The US has conducted an experiment of population-wide treatment of chronic pain with long-term opioid therapy. The benefits have been hard to demonstrate, but the harms are now well demonstrated.

Sullivan MD, Howe CQ. Opioid therapy for chronic pain in the United States: promises and perils. Pain. 2013 Dec;154 Suppl 1(0 1):S94-S100. doi: 10.1016/j.pain.2013.09.009. Epub 2013 Sep 11. PMID: 24036286; PMCID: PMC4204477.

2016 CDC Guidelines

4. USE IMMEDIATE-RELEASE OPIOIDS WHEN STARTING

When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/ long-acting (ER/LA) opioids.

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5. USE THE LOWEST EFFECTIVE DOSE

When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥50 **morphine milligram equivalents (MME)/day**, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day.

MME

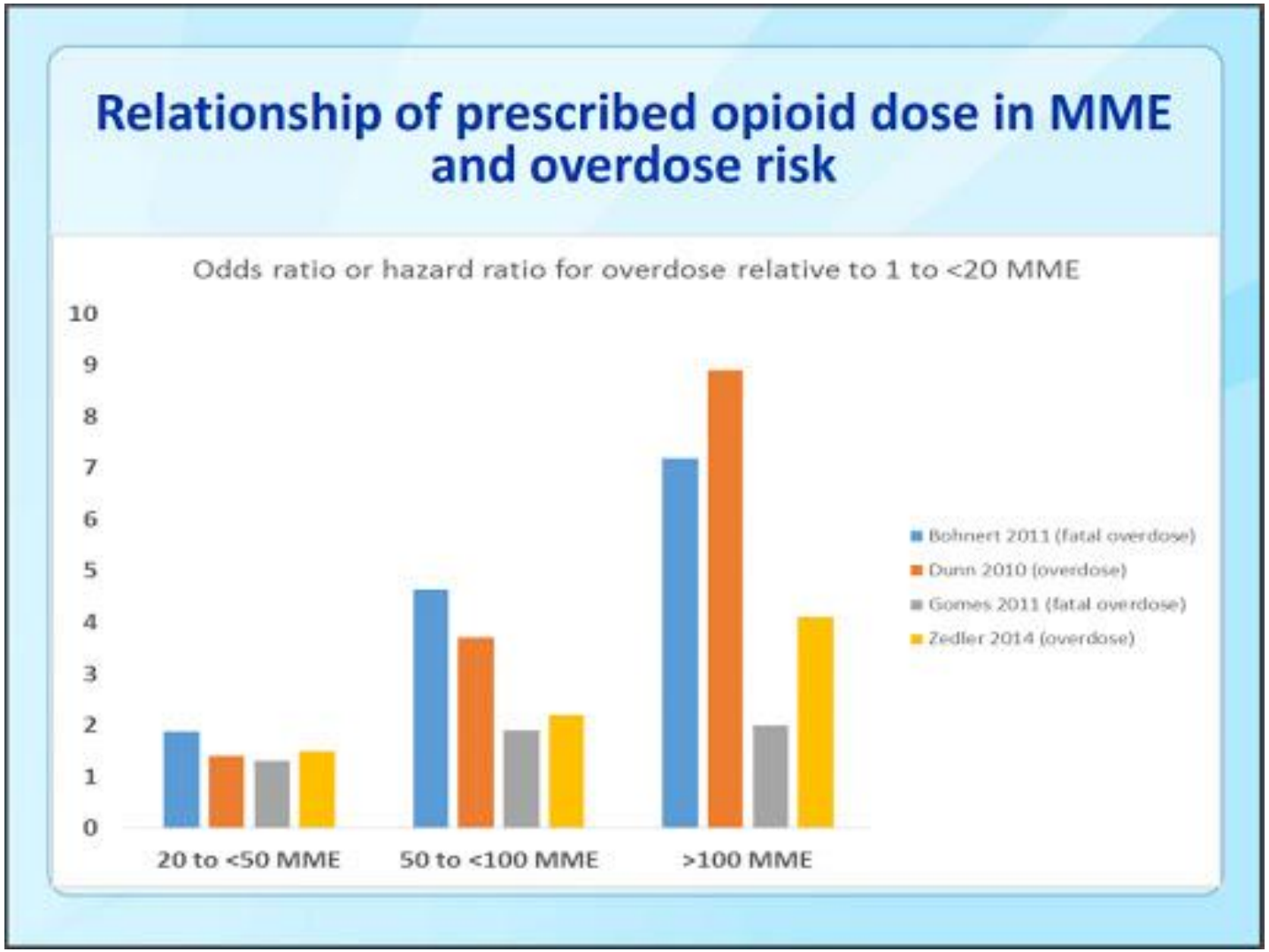
- Convert all opioids to morphine
- Calculate the 24 hour dose

MME Conversion Chart

Calculating morphine milligram equivalents (MME)

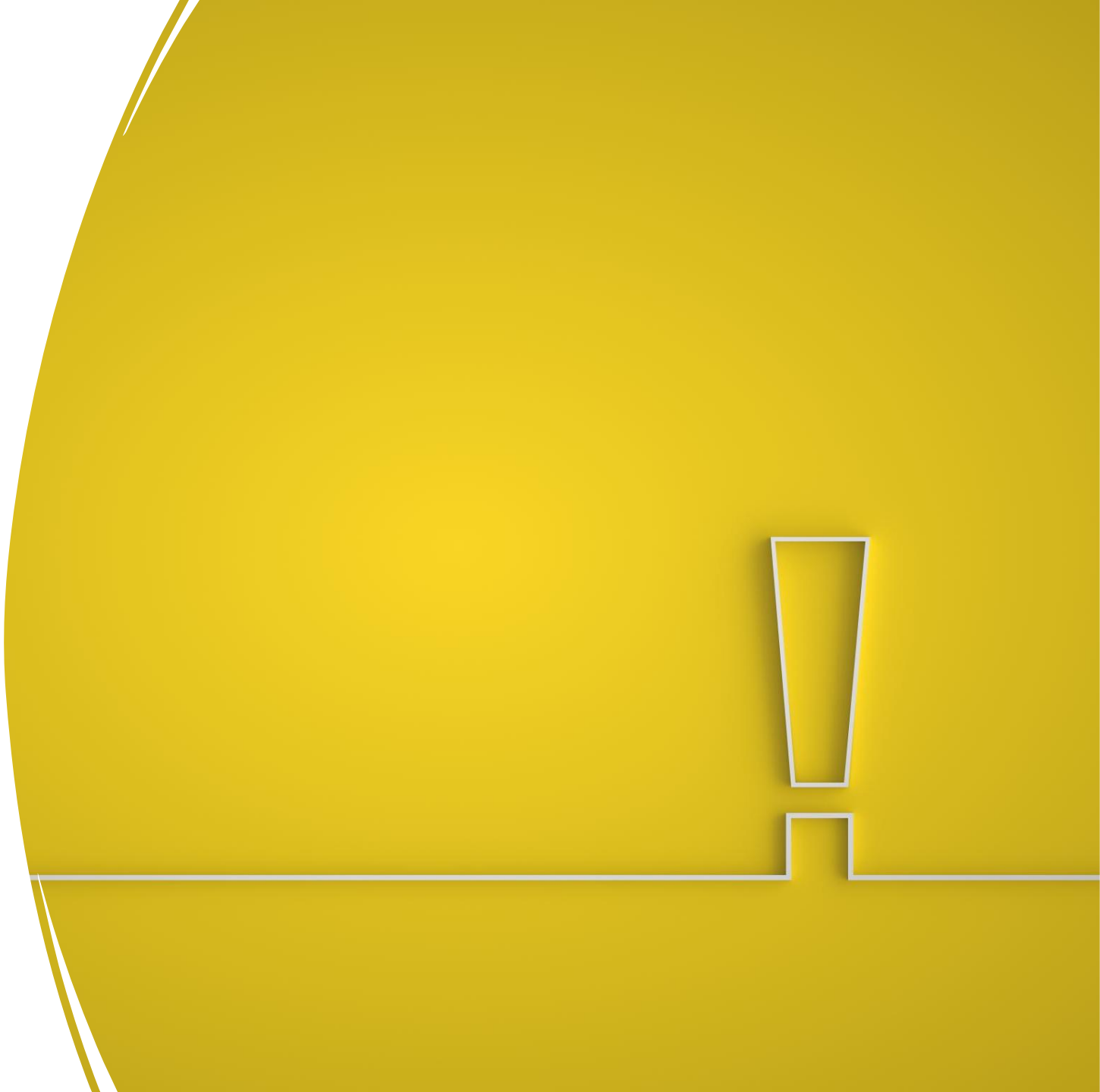
OPIOID (doses in mg/day except where noted)	**CONVERSION FACTOR**
Codeine	0.15
Fentanyl transdermal (in mcg/hr)	2.4
Hydrocodone	1
Hydromorphone	4
Methadone	
1-20 mg/day	4
21-40 mg/day	8
41-60 mg/day	10
≥ 61-80 mg/day	12
Morphine	1
Oxycodone	1.5
Oxymorphone	3

Risk of Overdose by MME



MME in Oklahoma

- There is no legal limit on MME in the State of Oklahoma
- Pharmacies and Insurance companies can limit
- Liability significantly increases if there is a bad outcome



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6. PRESCRIBE SHORT DURATIONS FOR ACUTE PAIN

Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed.

CDC MMWR March 2017

Choice of first prescription	Number (%) of patients	One-year probability of continued use, %	Three-year probability of continued use, %
Long Acting Opioids	6,588 (0.5)	27.3	20.5
Tramadol	120,781 (9.33)	13.7	6.8
Hydrocodone Short Acting	742,112 (57.3)	5.1	2.4
Oxcodone Short Acting	219,224 (16.9)	4.7	2.3
Schedule II Short Acting	14,877 (1.2)	8.9	5.3
Schedule III-IV and Nalbuphine	190,665 (14.7)	5.0	2.2

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7. EVALUATE BENEFITS AND HARMS FREQUENTLY

Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.

Check Ins With the Patient

- Discuss symptomatology
- Discuss the function and benefit of opioids
- Discuss cravings and addiction
- Pill count/UDS

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8. USE STRATEGIES TO MITIGATE RISK

Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use, are present.

Who Needs Narcan?

- Everyone
- Physicians
- Previous overdose
- Concurrent Benzodiazepines

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9. REVIEW PDMP DATA

Clinicians should review the patient's history of controlled substance prescriptions using state **prescription drug monitoring program (PDMP)** data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months.

Oklahoma PMP

- Must be checked at the initial prescription and every 6 months
- Should be checked at every prescription
- When you don’t check it, you are acknowledging that information was readily available that would have changed your decision that you decided not to ask
- Failure to check per statute can result in action:
  - Criminal
  - Civil
  - Administrative

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10. USE URINE DRUG TESTING

When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.

Urine Drug Screens

- Should be done at first visit
- Should be done frequently in the beginning of treatment
- Should be done routinely after
- All patients tested the same

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11. AVOID CONCURRENT OPIOID AND BENZODIAZEPINE

Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.

Are Benzodiazepines Addictive?

- Yes!
- Schedule IV
- True abuse liability is unknown but thought to be very high

Benzodiazepine Statistics

- Between 1996-2013:
  - Prescriptions increased by over 67% (Yale)
  - Overdoses increased by 500%
- Xanax is the #1 prescribed psychiatric medication in the country
  - 50 million prescriptions annually
- Improper use of Xanax results in over 125,000 emergency room visits per year
- Among teenagers, addiction rates to Benzos are higher than opioids

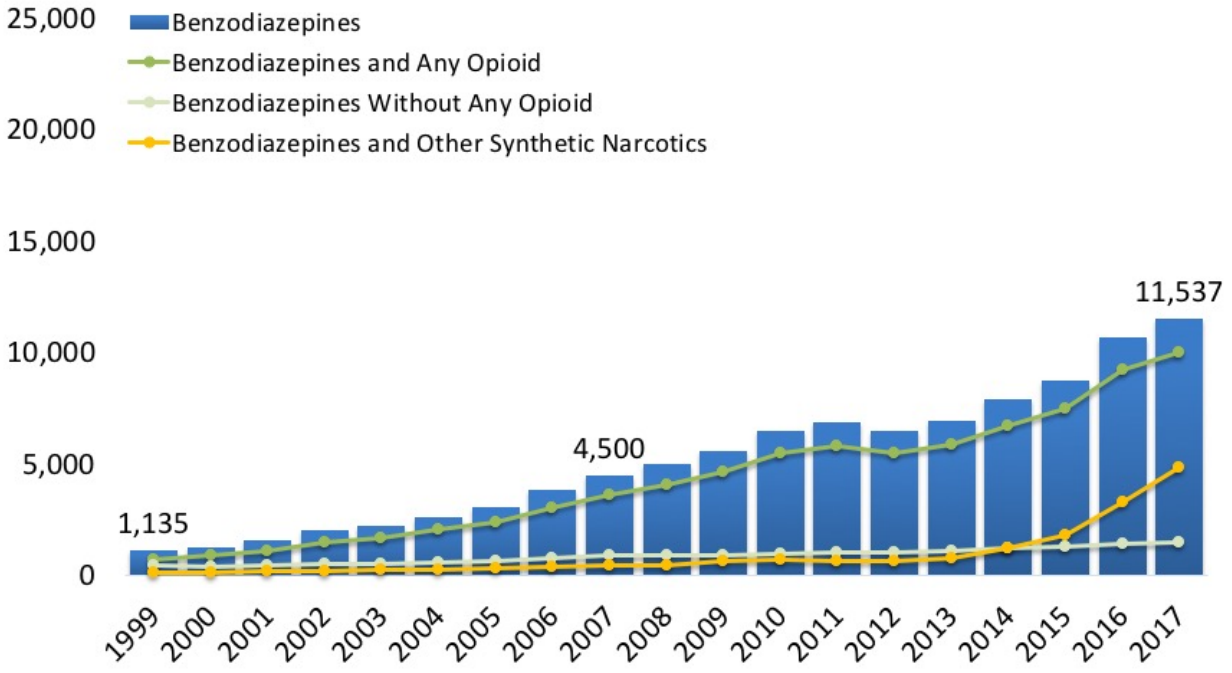
https://drugabuse.com/benzo-epidemic-a-killer-hiding-in-the-shadow-of-opioids/

Trends in Benzodiazepines Prescriptions

- Benzodiazepines prescriptions have increased by 51%
- Visits for benzodiazepines increased from 3.4 to 7.8% of all primary care visits
- Prescription rates did not change among psychiatrists, but instead by primary care

Opioid Overdose Deaths & Benzodiazepines

Figure 8. **National Drug Overdose Deaths Involving Benzodiazepines, by Opioid Involvement,** Number Among All Ages, 1999-2017



Source: : Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2017 on CDC WONDER Online Database, released December, 2018

Beaman's Rules for Benzos

- Don't Use Them
- Not first-line therapy for anxiety (SSRIs)
- Doesn't treat anxiety, masks it
- Highly addictive

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12. OFFER TREATMENT FOR OPIOID USE DISORDER

Clinicians should offer or arrange evidence-based treatment (usually **medication-assisted treatment** with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.

What happens if a patient is addicted to opioids?

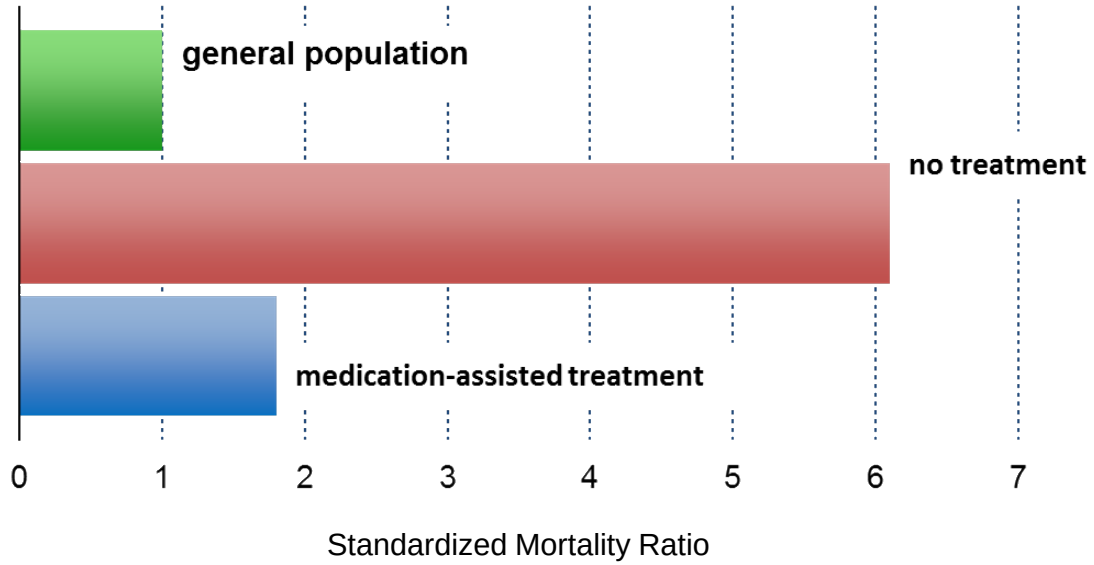
Don’t fire them

Help them obtain treatment for their disease like you would any other illness

Prompt termination could increase liability

Benefits of MAT: Decreased Mortality

Death rates:



Dupouy et al., 2017
Evans et al., 2015
Sordo et al., 2017

PCSS Providers Clinical Support System

The Goal is to Keep People Alive

Conclusion

- Physicians are gatekeepers of proper utilization of high-risk medications
- The use of controlled substances requires vigilance and monitoring
- Documentation is important for patient safety and physician liability

Questions?

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