


**Embrace Changes and Prevent Overdose:  
A Basic Blueprint for Legal Risk Mitigation and Response**

Created and presented by:  
Jennifer Bolen, JD  
PainWeek and PainWeekEnd 2019



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**Disclosures for Jennifer Bolen,  
JD (as of 03/01/2019)**

- Consultant: Paradigm Labs



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**Course Objectives**

Identify

- Identify common trends in legal actions against opioid prescribers.

List and Describe

- List three common weaknesses associated with documentation of risk assessment of patients for chronic opioid therapy, and describe how they can contribute to bad legal outcomes.

Explain

- Explain how to create a risk evaluation action plan and supporting documentation.

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**OBJECTIVE 1:**

Identify common trends in legal actions against opioid prescribers.



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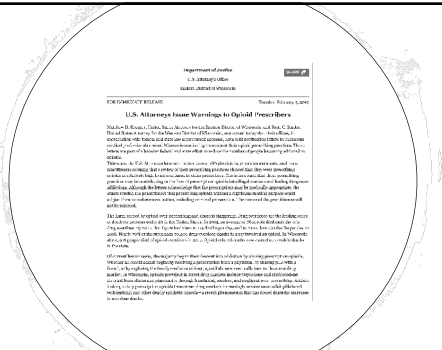
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Department of Justice  
U.S. Attorney Office  
Miami, Florida

**FOR IMMEDIATE RELEASE**

**U.S. Attorneys Issue Warnings to Opioid Prescribers**

Miami, Florida – U.S. Attorneys for the Southern District of Florida, led by U.S. Attorney Thomas J. Breen, today announced that they have issued written warnings to 100 opioid prescribers in Miami-Dade County, Florida, for allegedly prescribing opioids in violation of the Controlled Substances Act. The warnings are part of a broader effort to combat the opioid crisis and protect public health. The warnings state that the prescribers have been found to be prescribing opioids in violation of the Controlled Substances Act, specifically for reasons such as prescribing opioids to patients who are not in pain, prescribing opioids to patients who are already taking opioids, and prescribing opioids to patients who are at risk of addiction. The warnings also state that the prescribers have been found to be prescribing opioids in violation of the Controlled Substances Act, specifically for reasons such as prescribing opioids to patients who are not in pain, prescribing opioids to patients who are already taking opioids, and prescribing opioids to patients who are at risk of addiction. The warnings also state that the prescribers have been found to be prescribing opioids in violation of the Controlled Substances Act, specifically for reasons such as prescribing opioids to patients who are not in pain, prescribing opioids to patients who are already taking opioids, and prescribing opioids to patients who are at risk of addiction.

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Department of Justice  
U.S. Attorney Office  
Tampa, Florida

**FOR IMMEDIATE RELEASE**

**Clearwater Doctor Sentenced to Prison for Health Care Fraud**

Tampa, Florida – U.S. District Judge Andrew S. McEachron today sentenced Dr. James Keith to 18 months in prison for health care fraud. Dr. Keith was found guilty of submitting false claims to Medicare and Medicaid for services that were never provided. The judge also ordered Dr. Keith to pay a \$1 million fine and to be supervised by the Federal Probation Department for 18 months. The judge stated that Dr. Keith's actions were a clear violation of the law and that he deserved a significant sentence. The judge also stated that Dr. Keith's actions were a clear violation of the law and that he deserved a significant sentence. The judge also stated that Dr. Keith's actions were a clear violation of the law and that he deserved a significant sentence.

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<b>Legitimate Medical Purpose</b> <ul style="list-style-type: none"><li>• One or more generally recognized medical indication for the use of the controlled substance</li></ul>	<b>Usual Course of Professional Practice</b> <ul style="list-style-type: none"><li>• According to licensing and professional standards, including consideration of licensing board material;</li><li>• Steps of a "Reasonably Prudent" Practitioner</li></ul>	<b>Reasonable Steps to Prevent Abuse and Diversion</b> <ul style="list-style-type: none"><li>• Proper Risk Evaluation, Stratification, and Monitoring Protocols, including overdose risk evaluation</li><li>• PDMP, UDT, NALOXONE, OPIOID TRIAL, VISIT FREQUENCY</li><li>• Many other "reasonable steps"</li></ul>
<b>DEA "Standards" for Registrants who Prescribe Controlled Substances</b> <small>3/2/19</small>		

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**POSITION OF TRUST**

**Reminder:**  
Core Responsibilities when Prescribing Controlled Substances



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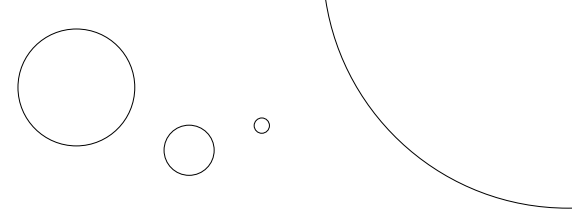
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**State Overview —**

- ARIZONA
- CALIFORNIA
- COLORADO
- TEXAS



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INSERT STATE UPDATES FOR EACH LOCATION

- STATE-SPECIFIC SLIDES WILL BE INSERTED FOLLOWING RESEARCH JUST PRIOR TO THE PRESENTATION.
- THIS KEEPS THE MATERIAL CURRENT FOR ATTENDEES.
- BOLEN WILL UPLOAD USEFUL HANDOUTS AND CITE LINKS.
- ADDENDUM: I REMOVED HEAVY GRAPHICS (PDF CLIPS) FROM THIS SECTION TO REDUCE SIZE OF FILE. NONE REFERENCED ANY COMPANY OR MEDICATION BRAND. ALL LICENSING BOARD RELATED.

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**OBJECTIVE 2:**

List three common weaknesses associated with documentation of risk assessment of patients for chronic opioid therapy, and describe how they can contribute to bad legal outcomes.



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**LEGAL PERSPECTIVE:**

Three common risk mitigation weaknesses – chronic opioid therapy

- 1 • Poor Risk Assessment Process and Follow Through.
- 2 • Untimely Use of Information gathered through Risk Assessment/Evaluation and Patient Encounters.
- 3 • Failure to Coordinate Care with Other Healthcare Providers and Lack of Patient Education Related to Coordination of Care Issues.

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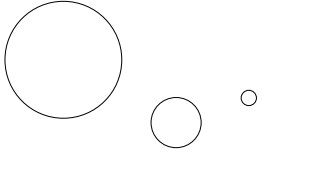
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REALITIES OF RISK ASSESSMENT

A LEGAL PERSPECTIVE ON THE RISK "ECOSYSTEM" AND CHRONIC OPIOID THERAPY

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What does risk assessment and monitoring mean to you?

Audience input

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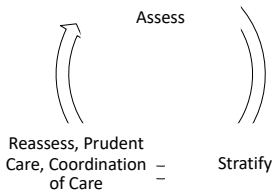
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Basic Risk Mitigation Process



Assess

Stratify

Reassess, Prudent Care, Coordination of Care

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CDC Says Risk Assessment is . . .  
[https://www.cdc.gov/drugoverdose/pdf/Guidelines\\_Factsheet-a.pdf](https://www.cdc.gov/drugoverdose/pdf/Guidelines_Factsheet-a.pdf)

ASSESSING RISK AND ADDRESSING HARMS OF OPIOID USE

- 8 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 patients 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.
- 9 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, changing from every prescription to every 3 months.
- 10 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.
- 11 Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.

CLINICAL REMINDERS

- Evaluate risk factors for opioid-related harms
- Check PDMP for high dosages and prescriptions from other providers
- Use urine drug testing to identify prescribed substances and undisclosed use
- Avoid concurrent benzodiazepine and opioid prescribing
- Arrange treatment for opioid use disorder if needed

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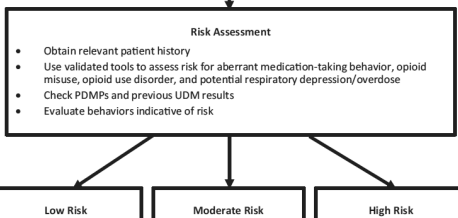
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American Academy of Pain Medicine Says Risk Assessment is . . .



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American Academy of Pain Medicine Says Risk Factors of Opioid Misuse and Opioid Use Disorder Include . . .

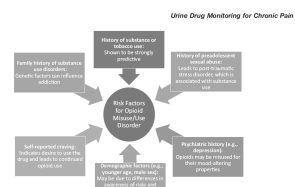


Figure 3 Explanations for risk factors of opioid misuse and opioid use disorder [18(07):100-107].

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Charles E Argoff, Daniel P Alford, Jeffrey Fudin, Jeremy A Adler, Matthew J Bair, Richard C Dart, Roy Gandolfi, Bill H McCarberg, Steven P Stanos, Jeffrey A Gudin, Rosemary C Polomano, Lynn R Webster; Rational Urine Drug Monitoring in Patients Receiving Opioids for Chronic Pain: Consensus Recommendations, *Pain Medicine*, Volume 19, Issue 1, 1 January 2018, Pages 97-117, <https://doi.org/10.1093/pm/pny285>.

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**Legal Perspective on Commonly Referenced Medical Co-Morbidities that Enhance Risk of Overdose Event**

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**Legal Perspective: Commonly Referenced Psycho-Social Factors and Risk**

Behavioral Health History

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Aberrant, Drug Related Behaviors (PDMP-Doctor-shopping, Discharge for self-escalation, other behaviors tied to patient's relationship with prescription drugs and other substances)

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Smoking, Drinking - Personal and First Degree Relative History; Substance Use Disorder, Treatment, Etc.

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Other

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**Quick Sorting of "Risk Assessment" Tools**

- Questions you should ask yourself when you reexamine the "risk assessment" process and tools you use:
  - Which Risk Domain am I Addressing with a Particular Process or Tool?
  - How often do I use the tool? What should I do if I used the tool too often and the patient has given different answers?
  - How will I document that I addressed the same?
  - How will I factor the patient's "risk" under that domain into my overall risk evaluation of him/her?
    - How will I do so without inappropriately labeling the patient?
    - Do I need outside peer support to properly evaluate the patient?
  - How will I structure my "risk levels" –
    - Low, moderate, high?
    - Low and Mod/high?
    - Low and High?
  - How will I establish my treatment plan boundaries for each risk level? How will I keep this information current, so I can see it before each visit or procedure?

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## A Quick Glance at a Couple of Tools Focused on Abuse, Misuse, Diversion, Opioid Use Disorders

Read the fine print

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### Opioid Risk Tool (ORT)

- Background
- What "risk" does it assess?
- How does it "rank" risk?
- How should that factor into the "rest of the story"?

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#### Opioid Risk Tool

**Introduction**

The Opioid Risk Tool (ORT) is a brief, self-report screening tool designed for use with adult patients in primary care settings to assess risk for opioid abuse among individuals prescribed opioids for treatment of chronic pain. Patients categorized as high-risk are at increased likelihood of future abusive drug-related behavior. The ORT can be administered and scored in less than 3 minutes and has been validated in both male and female patients, but not in non-pain populations.

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### BIG HINT . . .

- DO. NOT.
- GIVE THE QUESTIONNAIRE WITH THE SCORING INFORMATION.
- TO. THE. PATIENT.

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#### Opioid Risk Tool

This tool should be administered to patients upon an initial visit prior to beginning opioid therapy for pain management. A score of 3 or lower indicates low risk for future opioid abuse, a score of 4-7 indicates moderate risk for opioid abuse, and a score of 8 or higher indicates a high risk for opioid abuse.

Mark each box that applies	Female	Male
<b>Family history of substance abuse</b>		
Alcohol	2	3
Illegal drugs	2	3
Rx drugs	4	4
<b>Personal history of substance abuse</b>		
Alcohol	3	3
Illegal drugs	4	4
Rx drugs	5	5
<b>Age between 18-45 years</b>	1	1
<b>History of preadolescent sexual abuse</b>	3	0
<b>Psychological disease</b>		
AD/CD, bipolar, schizophrenia	2	2
Depression	1	1
<b>Scoring totals</b>		

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## THE SOAPP FAMILY

Screening and Opioid Assessment  
for Patients with Pain

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**Screening and Opioid Assessment for Patients with Pain-Revised (SOAPP-R)**

The following are some sample questions given to patients who are on or being considered for prescriptions for their pain. Please answer each question as honestly as possible. There are no right or wrong answers.

	Never	Sometimes	Often	Always
1. How often do you have mood swings?				
2. How often have you had a mood swing before when a medication is not your pain?				
3. How often have you had trouble sleeping at night?				
4. How often have you had that feeling like you are overreacting and getting angry or being angry?				
5. How often do you have a change in mood when you are on pain medicine?				
6. How often do you have a change in mood when you are on pain medicine?				
7. How often do you have a change in mood when you are on pain medicine?				
8. How often do you have a change in mood when you are on pain medicine?				
9. How often do you have a change in mood when you are on pain medicine?				
10. How often have you worried about being on pain medicine?				
11. How often have you had a craving for pain medicine?				
12. How often have you had a craving for pain medicine?				

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### A Closer Look at SOAPP-R

Screening and Opioid Assessment for Patients with Pain-Revised (SOAPP-R)

	Never	Sometimes	Often	Always
1. How often do you have mood swings?				
2. How often have you had a mood swing before when a medication is not your pain?				
3. How often have you had trouble sleeping at night?				
4. How often have you had that feeling like you are overreacting and getting angry or being angry?				
5. How often do you have a change in mood when you are on pain medicine?				
6. How often do you have a change in mood when you are on pain medicine?				
7. How often do you have a change in mood when you are on pain medicine?				
8. How often do you have a change in mood when you are on pain medicine?				
9. How often do you have a change in mood when you are on pain medicine?				
10. How often have you worried about being on pain medicine?				
11. How often have you had a craving for pain medicine?				
12. How often have you had a craving for pain medicine?				

	Never	Sometimes	Often	Always
13. How often do you have a change in mood when you are on pain medicine?				
14. How often do you have a change in mood when you are on pain medicine?				
15. How often do you have a change in mood when you are on pain medicine?				
16. How often do you have a change in mood when you are on pain medicine?				
17. How often do you have a change in mood when you are on pain medicine?				
18. How often do you have a change in mood when you are on pain medicine?				
19. How often do you have a change in mood when you are on pain medicine?				
20. How often do you have a change in mood when you are on pain medicine?				
21. How often do you have a change in mood when you are on pain medicine?				
22. How often do you have a change in mood when you are on pain medicine?				

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## NEW SOAPP-8 and OTHERS

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Cannot access SOAPP-8 publicly; Paid access unless other arrangements are made.

Differences between SOAPP-8 and SOAPP-R

Additional Discussion

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General Resources for Tools on Medication and Medical Risks: Evaluation and Monitoring

- CDC
- SAMHSA (focus for purpose of lecture)
- FSMB
- State Licensing Boards
- Local Medical Associations

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SAMHSA Opioid Overdose TOOLKIT: Information for Prescribers

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SAMHSA Original Toolkit and Link to 2016 Kit

<https://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit-Updated-2016/All-New-Products/SMA16-4742>




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**OPPIOID OVERDOSE**

The risk of opioid overdose can be minimized through adherence to the following clinical practices, which are supported by a comprehensive body of evidence (18).

**SAMHSA THE PATIENT:** Check the history of the patient's past use of drugs (other than drugs or prescribed medications with abuse potential) as a medical risk (see appropriate prescribing). Such a history should include very specific questions. For example:

- "In the past 6 months, have you taken any medications to help you calm down, have been getting nervous or upset, or have your spirits, mood, or feelings been better, and the like?"
- "Have you taken any medications to help you sleep?"
- "Have you been using alcohol for this purpose?"
- "Have you ever taken a medication to help you with a drug or alcohol problem?"
- "Have you ever taken a medication for a nervous disorder?"
- "Have you taken a medication to give you more energy or to feel better or your appetite?"
- "Have you ever been treated for a possible or suspected opioid overdose?"

**CONSIDER MEDICATION-RELATED RISK ALONG WITH THE PATIENT'S INTELLECT, OPPIOID PRESCRIPTION, HISTORY, AND CURRENT DRUG USE AND RISK OF OVERDOSE TO OPIOID TOXICITY.** With proper education, patients on long-term opioid therapy and others at risk for overdose may benefit from having a naloxone kit containing naloxone, syringes and needles or pre-filled Sytox<sup>®</sup> which delivers a single dose of naloxone via a hand-held auto-injector that can be carried in a pocket or purse. It is highly valued to use in the event of known or suspected overdose (19).

**Patients who are candidates for such kits include those who are:**

- Taking high doses of opioids for long-term management of chronic pain or non-management pain
- Receiving multiple opioid medications (eg, morphine and fentanyl) and those at risk for incomplete opioid titration
- Discharged from emergency medical care following opioid overdose or poisoning
- At high risk for overdose because of a legitimate medical need for analgesia, coupled with a history of prolonged history of substance abuse, dependence, or non-medical use of prescription or illicit opioids
- On several opioid preparations that may increase risk for opioid overdose such as extended-release or long-acting preparations
- Participating in intensive opioid detoxification or abstinence programs

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SAMHSA Opioid Overdose Toolkit

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## SAMHSA Medication List

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### Resources: Websites

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**CDC**  
<http://www.cdc.gov/drugoverdose/prescribing/providers.htm>  
 • Provider and patient materials, including prescribing checklists, flyers, and posters

**SAMHSA**  
<http://www.samhsa.gov/atod/opioids>

**DHMH Opioid Website**  
[dhmh.maryland.gov/medicaid-opioid-dur](http://dhmh.maryland.gov/medicaid-opioid-dur)



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**A FEW CASE EXAMPLES OF  
MISSED OPPORTUNITIES IN RISK  
EVALUATION/MONITORING**

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### John Smith's Last Risk Assessment Responses Mar. 9, 2018

SOAPP-R

Mar. 9, 2018

John Smith

	NEVER	SOMETIMES	SOMETIMES	OFTEN	VERY OFTEN
	0	1	2	3	4
1. How often do you have mood swings?					
2. How often have you felt a need for higher doses of medication to feel your pain?					
3. How often have you felt dissatisfied with your medication?					
4. How often have you been taking your pain pills more often than you were supposed to?					
5. How often have you been taking your pain pills more often than you were supposed to?					
6. How often have you needed pain pills to have your pain controlled?					
7. How often have you been concerned that people will stop you from taking pain pills?					
8. How often do you feel sad?					
9. How often have you taken more pain medication than you were supposed to?					
10. How often have you worried about being left without medication?					
11. How often have you been taking more pain pills than you were supposed to?					
12. How often have you been taking more pain pills than you were supposed to?					
13. How often have you had any problems or been arrested?					
14. How often have you attended an AA or NA meeting?					
15. How often have you been in an argument that was so out of control that someone got hurt?					
16. How often have you been sexually abused?					
17. How often have others suggested that you have a drug or alcohol problem?					
18. How often have you had to borrow pain medications from your family or friends?					
19. How often have you been treated for an alcohol or drug problem?					

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### John Smith's Last Office Visit 3/9/18



- Complained of anxiety, lack of sleep, pain, and alcohol troubles.
- Concerned about running out of alprazolam because his prescribing physician is not available.
- Total MME is 180mg/day
- Requested Drug Test
- Updated SOAPP-R
- Patient's BP was 88/64
- During visit, provider:
  - Rx FENTANYL, 50mcg Q72 = 120 mg MME
  - Rx Oxycodone, 10mg Q6 hours (40mg) = 60mg MME
  - Rx Alprazolam to keep patient from having seizures; supply covers 7 days (1 tablet BID)

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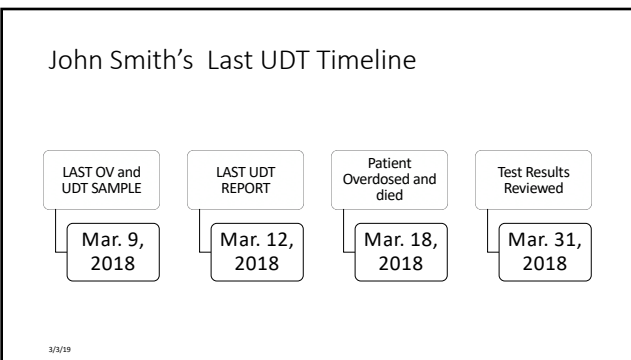
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Explain how to create a risk evaluation action plan and supporting documentation.

Objective 3

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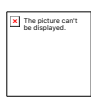
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Key is TIMELY Assessment and Evaluation for use in treatment of patient and Physician Involvement



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**Legal Perspective: Critical Risk Monitoring Considerations**

- Frequency of visit AND Frequency of re-evaluation with MD
- Frequency of PDMP check if state does not require specific frequency
- Frequency of Drug Testing and Nature of Drug Testing Menu
- Type of medications that will be allowed
- Dose and Combination of medications that will be allowed without additional monitoring and provider support, including consults/referrals
- Issuance and Confirmation of Naloxone Prescription
- Exit or Additional Provider Support Strategies

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PHYSICIAN DIRECT INVOLVEMENT IN PATIENT RISK MONITORING

How often does the MD see the patient?

- Initial visit?
- Thereafter?

How often should the MD see the patient?

- Relative to patient risk level?
- Relative to patient progress/lack thereof with Tx plan?
- Both?

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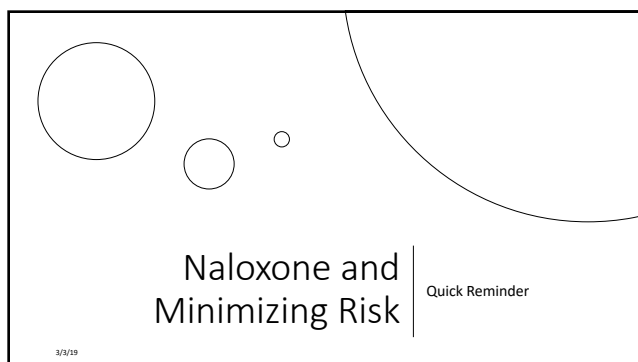
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Naloxone and Minimizing Risk | Quick Reminder

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REMEMBER:

It does not do any good to issue a Naloxone prescription to a high risk patient without making sure they filled it.

Some states may provide a limited immunity here; Most do not.

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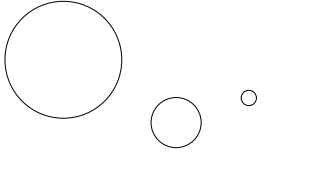
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Education: It's a Process  
and Not a One-Time Thing

Parents and Staff

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**EDUCATE PATIENTS (and HIPAA-Consented Family/Friends) FROM THE START**

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SAFE USE

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SAFE STORAGE

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SAFE DISPOSAL

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NALOXONE



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**Adjust your Written Treatment Agreement**

- Patient's agreement **NOT TO ABUSE ALCOHOL**
  - Test for it
  - Deal with it relative to ongoing opioid therapy (or BZO therapy)
- Patient's agreement **TO NOT USE OTHER MEDICALLY UNAUTHORIZED SUBSTANCES (including THC)**
  - Test for THC
  - Deal with it relative to ongoing opioid therapy (or BZO therapy)



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Coordination of Care  
Addressing the Weaknesses



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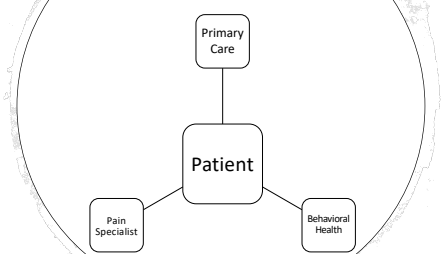
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CONSULTATION & COORDINATION OF CARE



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Addressing Adverse Patient Events in a Timely Fashion

With your staff  
In your practice processes and work flows  
In your documentation practices

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**REMINDER**

**Individualized Patient Care:**

1. Looks backwards and constantly reevaluates the data points

2. And moves forward with the patient's best interests in mind, carefully balancing risks and benefits

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### Questions?

- Thank you!
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