


**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



3/3/19

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

- Consultant: Paradigm Labs



3/3/19

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.



3/3/19

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. Brinkman, have issued a warning to opioid prescribers in the Miami area regarding their prescribing practices. The warning letter states that prescribers who continue to prescribe opioids to patients who are not in pain, or who are at high risk of addiction, may be subject to criminal and civil penalties. The letter also states that prescribers who fail to monitor their patients' pain and addiction risk, or who fail to take appropriate steps to address these risks, may be subject to criminal and civil penalties. The letter also states that prescribers who fail to take appropriate steps to address these risks, may be subject to criminal and civil penalties.

3/3/19

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

FOR IMMEDIATE RELEASE

Clearwater Doctor Sentenced to Prison For Health Care Fraud


Tempa, Florida – U.S. District Judge in Miami County, Florida, sentenced Dr. John J. Smith to 18 months in prison for health care fraud. The doctor was sentenced to 18 months in prison for health care fraud, which includes submitting false bills to Medicare and Medicaid. The doctor was also sentenced to 18 months in prison for health care fraud, which includes submitting false bills to Medicare and Medicaid. The doctor was also sentenced to 18 months in prison for health care fraud, which includes submitting false bills to Medicare and Medicaid.

3/3/19

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

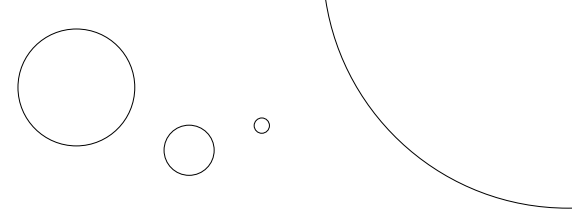
POSITION OF TRUST

Reminder:
Core Responsibilities when Prescribing Controlled Substances



State Overview —

- ARIZONA
- CALIFORNIA
- COLORADO
- TEXAS



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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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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Basic Risk Mitigation Process

Assess

Stratify

Reassess, Prudent Care, Coordination of Care

3/2/19

CDC Says Risk Assessment is . . .
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.

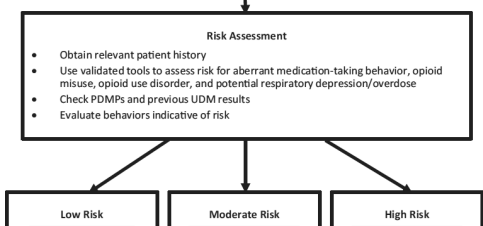
11 Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.

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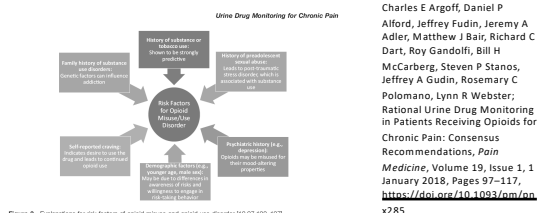
CLINICAL REMINDERS

- 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

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



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



Arizona Says Risk Mitigation is . . .

RISK MITIGATION

For patients on long-term opioid therapy, a healthcare provider must ensure that the risks of pain relief, addiction, and overdose are outweighed by the benefits of pain relief.

The Agency of the Arizona Board of Health Services (ABHS) has issued a new risk mitigation strategy for long-term opioid therapy. The strategy is intended to help healthcare providers (HCPs) and patients make informed decisions about long-term opioid therapy. The strategy is based on the following principles:

- 1. HCPs should only prescribe long-term opioid therapy to patients who have a clear diagnosis of a chronic pain condition and who have failed to respond to non-opioid pain management strategies.
- 2. HCPs should use the lowest effective dose of opioid medication and should avoid prescribing opioids to patients who are at high risk for addiction, overdose, or death.
- 3. HCPs should monitor patients on long-term opioid therapy for signs of addiction, overdose, or death and should provide appropriate interventions if needed.
- 4. HCPs should educate patients on the risks and benefits of long-term opioid therapy and should encourage patients to participate in shared decision-making.

For more information, please visit the ABHS website at <https://azdhs.gov/documents/audiences/clinicians/clinical-guidelines/recommendations/prescribing-guidelines/az-opioid-prescribing-guidelines.pdf>.

<https://azdhs.gov/documents/audiences/clinicians/clinical-guidelines/recommendations/prescribing-guidelines/az-opioid-prescribing-guidelines.pdf> Page

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ARIZONA Says Risk Mitigation in the Inherited Patient is . . .

ARIZONA Says Risk Mitigation in the Inherited Patient is . . .

The Arizona Board of Health Services (ABHS) has issued a new risk mitigation strategy for long-term opioid therapy in inherited patients. The strategy is based on the following principles:

- 1. HCPs should only prescribe long-term opioid therapy to inherited patients who have a clear diagnosis of a chronic pain condition and who have failed to respond to non-opioid pain management strategies.
- 2. HCPs should use the lowest effective dose of opioid medication and should avoid prescribing opioids to inherited patients who are at high risk for addiction, overdose, or death.
- 3. HCPs should monitor inherited patients on long-term opioid therapy for signs of addiction, overdose, or death and should provide appropriate interventions if needed.
- 4. HCPs should educate inherited patients on the risks and benefits of long-term opioid therapy and should encourage them to participate in shared decision-making.

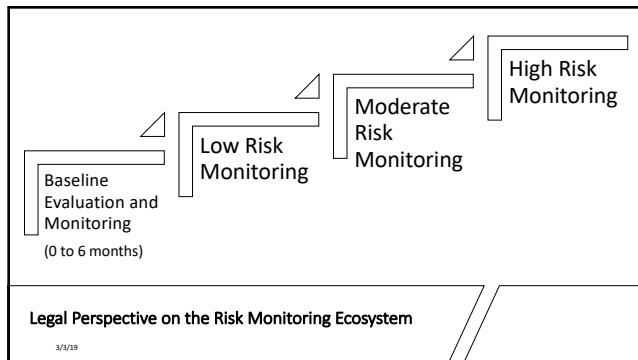
For more information, please visit the ABHS website at <https://azdhs.gov/documents/audiences/clinicians/clinical-guidelines/recommendations/prescribing-guidelines/az-opioid-prescribing-guidelines.pdf>.

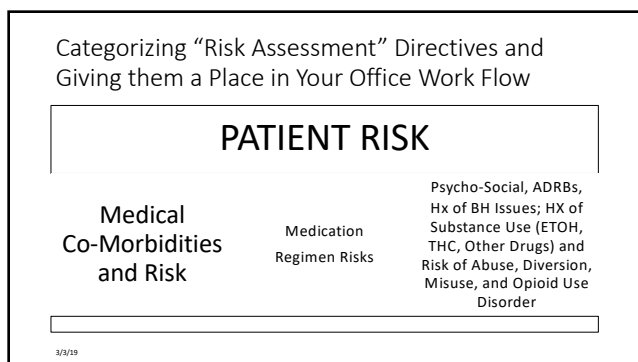
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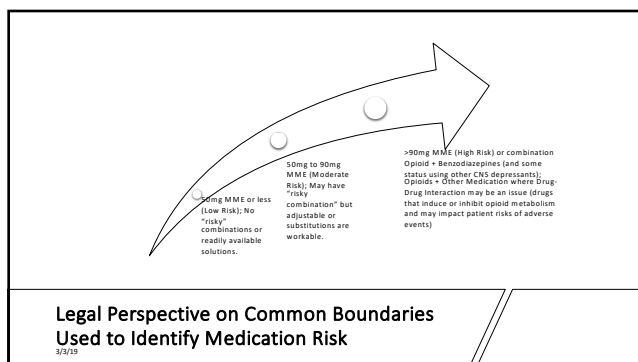
Additional Examples

- Washington State
- California
- Tennessee
- Texas
- Florida

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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

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

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

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?

3/3/19



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

Read the fine print

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.

BIG HINT . . .

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

3/3/19

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
Family history of substance abuse		
Alcohol	2	3
Illegal drugs	2	3
Rx drugs	4	4
Personal history of substance abuse		
Alcohol	3	3
Illegal drugs	4	4
Rx drugs	5	5
Age between 18-45 years	1	1
History of preadolescent sexual abuse	3	0
Psychological disease		
AD/CD, bipolar, schizophrenia	2	2
Depression	1	1
Scoring totals		

THE SOAPP FAMILY

Screening and Opioid Assessment
for Patients with Pain

3/3/19

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

The following are some sample questions for 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	Very Often
1. How often do you have mood swings?				
2. How often have you had a mood swing before others are aware of it?				
3. How often have you had problems with your attention?				
4. How often have you had trouble staying on top of your thinking and judgment?				
5. How often do you have trouble concentrating?				
6. How often do you have trouble getting things done that you are trying to do?				
7. How often do you have trouble getting things done that you are trying to do?				
8. How often do you have trouble getting things done that you are trying to do?				
9. How often do you have trouble getting things done that you are trying to do?				
10. How often do you have trouble getting things done that you are trying to do?				
11. How often do you have trouble getting things done that you are trying to do?				
12. How often do you have trouble getting things done that you are trying to do?				

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A Closer Look at SOAPP-R

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

	Never	Sometimes	Often	Very Often
1. How often do you have mood swings?				
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	Never	Sometimes	Often	Very Often
13. How often do you have trouble getting things done that you are trying to do?				
14. How often do you have trouble getting things done that you are trying to do?				
15. How often do you have trouble getting things done that you are trying to do?				
16. How often do you have trouble getting things done that you are trying to do?				
17. How often do you have trouble getting things done that you are trying to do?				
18. How often do you have trouble getting things done that you are trying to do?				
19. How often do you have trouble getting things done that you are trying to do?				
20. How often do you have trouble getting things done that you are trying to do?				

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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

SOAPP's Sister Tool – COMM

Current Opioid Misuse
Measure

3/3/19

Current Opioid Misuse Measure (COMM)SM

The Current Opioid Misuse Measure (COMM)SM is a brief patient self-assessment to identify current pain concerns or opioid therapy. The COMMSM was developed with guidance from a group of pain and addiction specialists and is a patient management tool to help identify and address current pain and medication-related concerns. Patients are asked to 'flag' any specific concerns and whether they are medication-related.

The COMMSM will be available monthly through patient self-assessment tool that allows patients, the physician and other members of the patient care team to have an ongoing conversation about their pain concerns and opioid therapy. The COMMSM is available to patients who are currently on opioid therapy and are being followed by the provider. The COMMSM is a patient self-assessment tool that allows patients to flag their concerns and whether they are medication-related.

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SOAPP's Sister Tool – COMM

COMM
This tool is intended to be used by patients to assess their current pain concerns and whether they are medication-related. The COMMSM is available to patients who are currently on opioid therapy and are being followed by the provider. The COMMSM is a patient self-assessment tool that allows patients to flag their concerns and whether they are medication-related.

Please answer the questions using the following scale:

Answer	Never	Seldom	Sometimes	Often	Always
1. How often do you have pain that is not relieved by your medication?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. How often do you have pain that is worse than you can tolerate?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. How often do you have pain that interferes with your daily activities?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. How often do you have pain that interferes with your sleep?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. How often do you have pain that interferes with your ability to work?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. How often do you have pain that interferes with your ability to enjoy life?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. How often do you have pain that interferes with your ability to do your job?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8. How often do you have pain that interferes with your ability to take care of your family?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9. How often do you have pain that interferes with your ability to take care of your household?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Sample Tools Focused on Medical and Medication-Related Risks

3/3/19

Read the fine print

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

3/7/19

SAMHSA

Opioid Overdose

TOOLKIT:

Information for Prescribers

3/7/19

SAMHSA Original Toolkit and Link to 2016 Kit

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

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 (16).

ASSESS THE PATIENT—Obtain a history of the patient's past use of single (after first drug) or prescribed medications with abuse potential, as well as a mental health and substance use history. 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 energy 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 get going in the morning?"
- "Have you ever been treated for a possible or suspected opioid overdose?"

3/7/19

SAMHSA Opioid Overdose Toolkit

SAMHSA
(Substance Abuse
and Mental
Health Services
Administration)

"REDUCE THE RISK"

3/3/19

SAMHSA
(Substance Abuse and
Mental Health Services
Administration)

- Medication and Substance Use Risks
- Dangerous Drug Interactions

3/3/19

SAMHSA
(Substance Abuse
and Mental
Health Services
Administration)

A simple treatment agreement

3/3/19

This block contains two documents. On the left is the cover of the 'SAMHSA Medication List' dated 3/3/19. On the right is a form titled 'Rx Pain Medications' with the slogan 'KNOW THE OPTIONS • GET THE FACTS'. The form includes a 'My Medications' section with a table for tracking prescriptions. The table has columns for Medication, How much?, How often?, Reason?, and Prescribed by. Below the table is a 'NEED HELP?' section with contact information for SAMHSA and CDC.

This slide is titled 'Resources: Websites' and lists three resources: CDC (<http://www.cdc.gov/drugoverdose/prescribing/providers.htm>), SAMHSA (<http://www.samhsa.gov/atod/opioids>), and the DHMH Opioid Website (dhmh.maryland.gov/medicaid-opioid-dur). The slide also features the Maryland Department of Health & Mental Hygiene logo and the date 3/3/19.

This slide features a large, circular graphic made of small dots. Inside the circle, the text reads 'A FEW CASE EXAMPLES OF MISSED OPPORTUNITIES IN RISK EVALUATION/MONITORING'. The date 3/3/19 is visible in the bottom right corner.

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


SOAPP-R

John Smith

	NEVER	Seldom	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 any pain relief?					
3. How often have you felt depressed or sad?					
4. How often have you been thinking about suicide or harming yourself?					
5. How often have you been taking any pain medicine more often than you were supposed to?					
6. How often have you received pain pills to use when you were not in pain?					
7. How often have you been in contact with people who use drugs to help them feel better?					
8. How often have you had trouble sleeping?					
9. How often have you taken more pain medicine than you were supposed to?					
10. How often have you worried about being left alone?					
11. How often have you had a change in your thinking?					
12. How often have you been in contact with people who use drugs to help them feel better?					
13. How often have you had trouble sleeping?					
14. How often have others told you that you had a bad temper?					
15. How often have you felt consumed by the need to get pain medication?					
16. How often have you run out of pain medication early?					
17. How often have others kept you from getting what you desired?					
18. How often, in your lifetime, have you had legal problems or been arrested?					
19. How often have you attended an AA or NA meeting?					
20. How often have you been in an argument that was so out of control that someone got hurt?					
21. How often have you been sexually abused?					
22. How often have others suggested that you have a drug or alcohol problem?					
23. How often have you had to borrow pain medications from your family or friends?					
24. How often have you been treated for an alcohol or drug problem?					

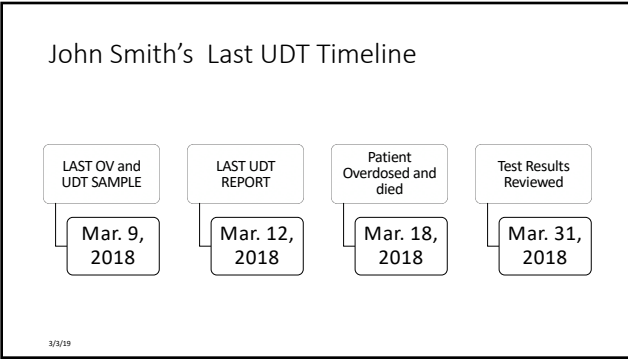
3/9/19

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)

3/9/19





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

Objective 3

3/2/19

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



3/2/19

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

3/2/19

PHYSICIAN DIRECT INVOLVEMENT IN PATIENT RISK MONITORING

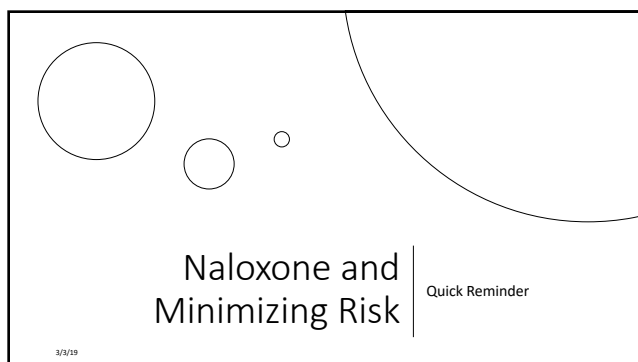
How often does the MD see the patient?

- 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?

3/2/19



Naloxone and Minimizing Risk | Quick Reminder

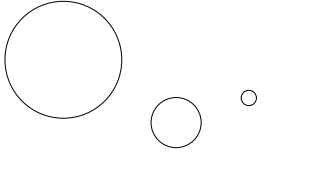
3/2/19

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.

3/2/19



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

Parents and Staff

3/3/19


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

SAFE USE

SAFE STORAGE

SAFE DISPOSAL


NALOXONE



3/3/19

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)



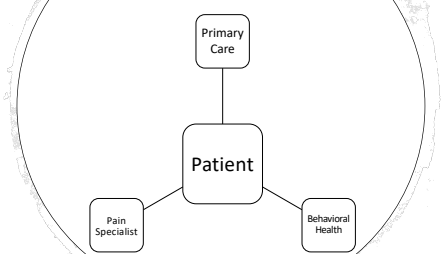
3/3/19

Coordination of Care
Addressing the Weaknesses




3/3/19

CONSULTATION & COORDINATION OF CARE



3/3/19



Addressing Adverse Patient Events in a Timely Fashion

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

3/3/19

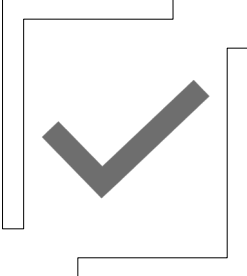
REMINDER

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

3/3/19



Questions?

- Thank you!
- **Jennifer Bolen, JD**
- 865-755-2369
- jbolen@legalsideofpain.com

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