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

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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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Department of Justice

U.S. Attorney's Office

Eastern District of Wisconsin

SHARE

FOR IMMEDIATE RELEASE — Tuesday, February 5, 2019

U.S. Attorneys Issue Warnings to Opioid Prescribers

Matthew D. Krueger, United States Attorney for the Eastern District of Wisconsin, and Scott C. Blader, United States Attorney for the Western District of Wisconsin, announced today that their offices, in coordination with federal and state law enforcement agencies, have sent notification letters to numerous medical professionals around Wisconsin cautioning them about their opioid prescribing practices. These letters are part of a broader federal and state effort to reduce the number of people becoming addicted to opioids.

This week, the U.S. Attorneys have sent letters to over 180 physicians, physician assistants, and nurse practitioners advising that a review of their prescribing practices showed that they were prescribing opioids at relatively high levels compared to other prescribers. The letters warn that these prescribing practices may be contributing to the flow of prescription opioids into illegal markets and fueling dangerous addictions. Although the letters acknowledge that the prescriptions may be medically appropriate, the letters remind the practitioners that prescribing opioids without a legitimate medical purpose could subject them to enforcement action, including criminal prosecution. The names of the practitioners will not be released.

The harm caused by opioid over-prescribing and abuse is staggering. Drug overdoses are the leading cause of death for persons under 50 in the United States. In 2014, an average of 78 people died each day of a drug overdose. By 2017, that figure had risen to 114 deaths per day, and to more than 130 deaths per day in 2018. Nearly 70% of the more than 70,200 drug overdose deaths in 2017 involved an opioid. In Wisconsin alone, 916 people died of opioid overdoses in 2017. Opioid-related deaths now exceed automobile deaths in the state.

Of current heroin users, the majority began their descent into addiction by abusing prescription opioids. Whether an opioid addict begins by receiving a prescription from a physician, by sharing pills with a friend, or by exploring the family medicine cabinet, opioid abusers eventually turn to the street drug market. In Wisconsin, opioids prevalent in street drug markets include Oxycodone and Hydrocodone diverted from clinics and pharmacies through fraudulent, reckless, and negligent over-prescribing. Addicts looking to buy prescription opioids from street drug markets increasingly receive counterfeit pills laced with fentanyl and other deadly synthetic opioids—a recent phenomenon that has fueled dramatic increases in overdose deaths.

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Department of Justice

U.S. Attorney's Office

Middle District of Florida

SHARE

FOR IMMEDIATE RELEASE — Wednesday, January 30, 2019

Clearwater Doctor Sentenced To Prison For Health Care Fraud

Tampa, Florida – U.S. District Judge James S. Moody Jr. today sentenced Jayam Krishna Iyer (66, Clearwater) to six months in federal prison for committing health care fraud, ordered Iyer to forfeit over $52,000 in health care fraud proceeds, and order her to pay restitution to the Medicare and Medicaid programs.

In addition, the court ordered Iyer to forfeit her Florida medical license, permanently excluding her from participating in the Medicare and Medicaid programs. And, Iyer agreed to surrender her DEA registration number, which had been used to prescribe controlled substances, and not to reapply for a DEA registration number for at least 20 years.

According to court documents, Iyer owned and operated Creative Medical Center, located on Druid Road East in Clearwater. The center functioned as a pain management clinic; Iyer conducted office visits and wrote prescriptions for controlled substances, including oxycodone, morphine, and fentanyl.

Beginning in July 2011 and continuing through December 2017, Iyer carried out a scheme to defraud Medicare by billing for face-to-face office visits with Medicare and Medicaid patients, when, in fact, certain patients had not gone to Iyer's office and had not been examined by her on the claimed dates. Instead, family members of patients had visited Iyer's office, where she issued prescriptions for Schedule II controlled substances, including oxycodone, to the family members in the patients' names. Iyer thereby violated a Florida law requiring doctors to perform an in-person office visit and examination of each patient before issuing Schedule II controlled substance prescriptions.

Iyer also falsified her electronic medical records, including vital statistics, to make it appear that the actual patients had been present in her office for an office visit, when they had not.

Iyer submitted at least $52,000 in false and fraudulent Medicare and Medicaid claims.

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Legitimate Medical Purpose

- One or more generally recognized medical indication for the use of the controlled substance

Usual Course of Professional Practice

- 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

- 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

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POSITION OF TRUST

Reminder:

Core Responsibilities when Prescribing Controlled Substances

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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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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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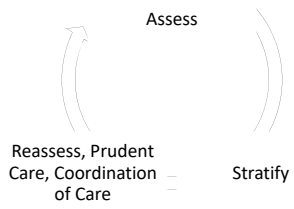
Basic Risk Mitigation Process



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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 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.

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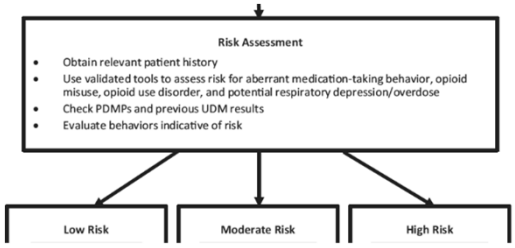
American Academy of Pain Medicine Says Risk Assessment is . . .



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

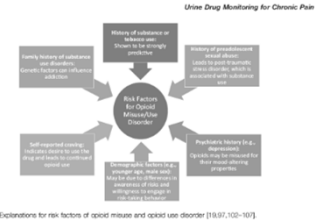

Figure 3 Explanations for risk factors of opioid misuse and opioid use disorder [19,97,102–107].

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/pnx285

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Arizona Says Risk Mitigation is . . .

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 . . .

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Additional Examples

- Washington State
- California
- Tennessee
- Texas
- Florida

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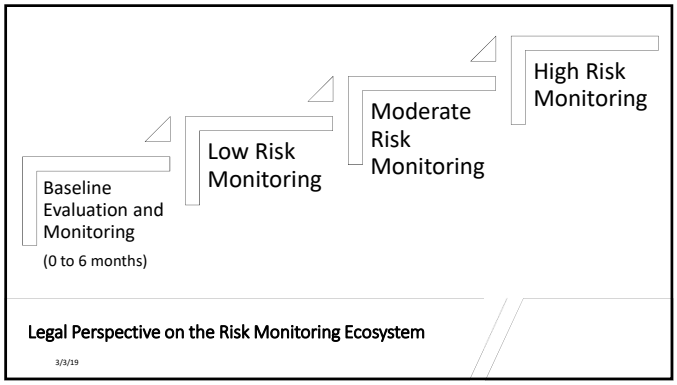

Legal Perspective on the Risk Monitoring Ecosystem

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Categorizing "Risk Assessment" Directives and Giving them a Place in Your Office Work Flow

PATIENT RISK

Medical Co-Morbidities and Risk	Medication Regimen Risks	Psycho-Social, ADRBs, Hx of BH Issues; HX of Substance Use (ETOH, THC, Other Drugs) and Risk of Abuse, Diversion, Misuse, and Opioid Use Disorder

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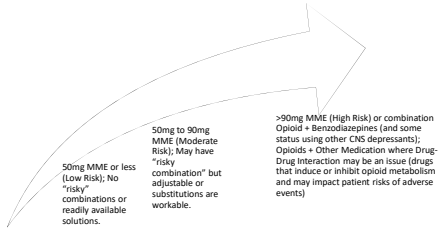

Legal Perspective on Common Boundaries Used to Identify Medication Risk

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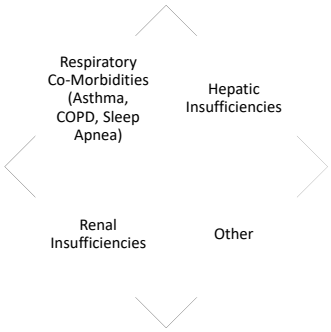
Legal Perspective on Commonly Referenced Medical Co-Morbidities that Enhance Risk of Overdose Event



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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?

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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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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 to 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	1	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 16—45 years	1	1
History of preadolescent sexual abuse	3	0
Psychological disease		
ADD, OCD, bipolar, schizophrenia	2	2
Depression	1	1
Scoring totals		

THE SOAPP FAMILY

Screening and Opioid Assessment for Patients with Pain

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

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

	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 to higher doses of medication to treat your pain?	○	○	○	○	○
3. How often have you felt impaired with your doctors?	○	○	○	○	○
4. How often have you felt that things are just too overwhelming that you can't handle them?	○	○	○	○	○
5. How often is there tension in the home?	○	○	○	○	○
6. How often does you counted pain pills to see how many are remaining?	○	○	○	○	○
7. How often have you been concerned that people will judge you for taking pain medication?	○	○	○	○	○
8. How often do you feel bored?	○	○	○	○	○
9. How often have you taken more pain medication than you were supposed to?	○	○	○	○	○
10. How often have you worried about being left alone?	○	○	○	○	○
11. How often have you felt a craving for medication?	○	○	○	○	○
12. How often have others expressed concern over your use of medication?	○	○	○	○	○

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SAMPLE

A Closer Look at SOAPP-R

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NEW SOAPP-8 and OTHERS

- 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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SOAPP's Sister Tool – COMM

Current Opioid Misuse Measure

Current Opioid Misuse Measure (COMM)™

The Current Opioid Misuse Measure (COMM)™ is a brief patient self-assessment to monitor chronic pain patients on opioid therapy. The COMM™ was developed with guidance from a group of pain and addiction experts and input from pain management clinicians in the field. Experts and providers identified six key issues to determine if patients already on long-term opioid treatment are exhibiting aberrant medication-related behaviors:

- *Signs & Symptoms of Intoxication*
- *Emotional Volatility*
- *Evidence of Poor Response to Medications*
- *Addiction*
- *Healthcare Use Patterns*
- *Problematic Medication Behavior*

The COMM™ will help clinicians identify whether a patient, currently on long-term opioid therapy, may be exhibiting aberrant behaviors associated with misuse of opioid medications. In contrast, the Screener and Opioid Assessment for Patients with Pain (SOAPP®) is intended to predict which patients, being considered for long-term opioid therapy, may exhibit aberrant medications behaviors in the future. Since the COMM™ examines concurrent misuse, it is ideal for helping clinicians monitor patients' aberrant medication-related behaviors over the course of treatment. The COMM™ is:

- A quick and easy to administer patient-self assessment
- 17 items
- Simple to score
- Completed in less than 10 minutes
- Validated with a group of approximately 500 chronic pain patients on opioid therapy
- Ideal for documenting decisions about the level of monitoring planned for a particular patient or justifying referrals to specialty pain clinic.
- The COMM™ is for clinician use only. The tool is not meant for commercial distribution.
- The COMM™ is **NOT** a lie detector. Patients determined to misrepresent themselves will still do so. Other clinical information should be used with COMM™ scores to decide if and when modifications to particular patient's treatment plan is needed.
- It is important to remember that all chronic pain patients deserve treatment of their pain. Providers who are not comfortable treating certain patients should refer those patients to a specialist.

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SOAPP's Sister Tool – COMM

COMM™

[illegible]

Please answer the questions using the following scale:	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
1. [illegible]	○	○	○	○	○
2. [illegible]	○	○	○	○	○
3. [illegible]	○	○	○	○	○
4. [illegible]	○	○	○	○	○
5. [illegible]	○	○	○	○	○
6. [illegible]	○	○	○	○	○

Please answer the questions using the following scale:	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
7. In the past 30 days, how often have you been in an argument?	○	○	○	○	○
8. In the past 30 days, how often have you had trouble controlling your anger (e.g., road rage, screaming, etc.)?	○	○	○	○	○
9. In the past 30 days, how often have you needed to take pain medications belonging to someone else?	○	○	○	○	○
10. In the past 30 days, how often have you been worried about how you're handling your medications?	○	○	○	○	○
11. In the past 30 days, how often have others been worried about how you're handling your medications?	○	○	○	○	○
12. In the past 30 days, how often have you had to make an emergency phone call or show up at the clinic without an appointment?	○	○	○	○	○
13. In the past 30 days, how often have you gotten angry with people?	○	○	○	○	○
14. In the past 30 days, how often have you had to take more of your medication than prescribed?	○	○	○	○	○
15. In the past 30 days, how often have you borrowed pain medication from someone else?	○	○	○	○	○
16. In the past 30 days, how often have you used your pain medicine for symptoms other than for pain (e.g., to help you sleep, improve your mood, or relieve stress)?	○	○	○	○	○

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Sample Tools Focused on Medical and Medication-Related Risks

Read the fine print

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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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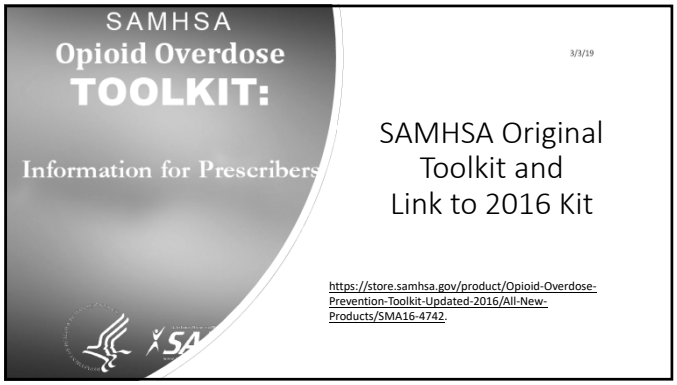

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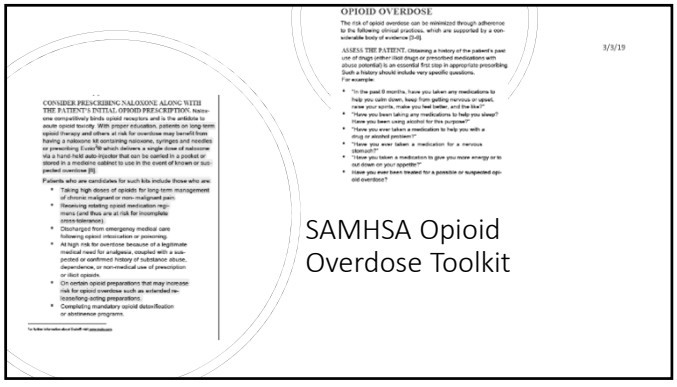
SAMHSA Original Toolkit and Link to 2016 Kit

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



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SAMHSA Opioid Overdose Toolkit

SAMHSA (Substance Abuse and Mental Health Services Administration)

"REDUCE THE RISK"

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Rx Pain Medications

KNOW THE OPTIONS • GET THE FACTS

Prescribing Opioids: Reduce the Risk

The Facts

Reducing Use, Misuse, and Overdose

NEED HELP?

SAMHSA CDC

SAMHSA (Substance Abuse and Mental Health Services Administration)

- Medication and Substance Use Risks
- Dangerous Drug Interactions

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Rx Pain Medications

KNOW THE OPTIONS • GET THE FACTS

Dangerous Drug Interactions

Did you know...

IN CASE OF EMERGENCY

Call 9-1-1 or the National Poison Help number at 1-800-222-1222.

SAMHSA CDC

SAMHSA (Substance Abuse and Mental Health Services Administration)

A simple treatment agreement

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Rx Pain Medications

KNOW THE OPTIONS • GET THE FACTS

Prescription Pain Medication Agreement

I agree to the following:

NEED HELP?

SAMHSA CDC

SAMHSA Medication List

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Rx Pain Medications

KNOW THE OPTIONS • GET THE FACTS

My Medications

NEED HELP?

SAMHSA CDC

Resources: Websites

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

MARYLAND DEPARTMENT OF HEALTH & MENTAL HYGIENE

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

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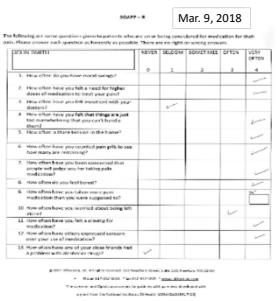
John Smith's Last Risk Assessment Responses Mar. 9, 2018



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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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John Smith's Last UDT Timeline

LAST OV and UDT SAMPLE	LAST UDT REPORT	Patient Overdosed and died	Test Results Reviewed
Mar. 9, 2018	Mar. 12, 2018	Mar. 18, 2018	Mar. 31, 2018

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

Objective 3

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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

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- 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

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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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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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

- SAFE USE
- SAFE STORAGE
- SAFE DISPOSAL
- 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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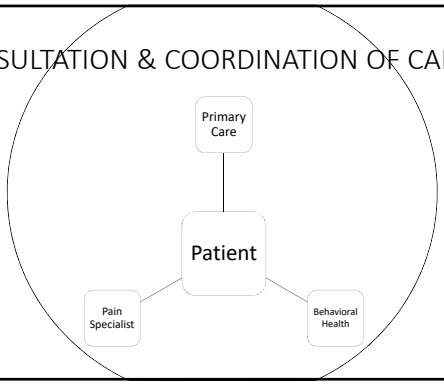
CONSULTATION & COORDINATION OF CARE



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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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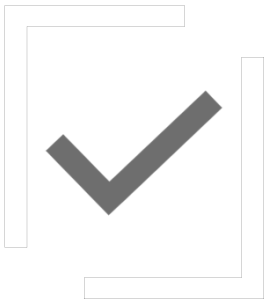
REMINDER

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

3/3/19



Questions?

- Thank you!

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

3/3/19