


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


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PainWeek and PainWeekEnd 2019



3/2/19

**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 Office
Washington, District of Columbia

FOR IMMEDIATE RELEASE Wednesday, January 31, 2019

U.S. Attorneys Issue Warnings to Opioid Prescribers

Washington, D.C. – U.S. Attorneys in the District of Columbia issued a warning to opioid prescribers in the District of Columbia, Maryland, Virginia, and West Virginia, to advise them of the consequences of prescribing opioids to patients who are at risk of addiction. The warning letter states that the U.S. Attorneys are aware of the increasing number of opioid-related deaths in the region and are concerned about the potential for addiction. The U.S. Attorneys are urging prescribers to exercise caution when prescribing opioids and to monitor their patients for signs of addiction. The U.S. Attorneys are also urging patients to use opioids responsibly and to avoid sharing their medication with others.

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Department of Justice
U.S. Attorney Office
Washington, District of Columbia

FOR IMMEDIATE RELEASE Wednesday, January 31, 2019

Clearwater Doctor Sentenced To Prison For Health Care Fraud


Washington, D.C. – U.S. Attorney in the District of Columbia announced today that a Clearwater, Florida doctor has been sentenced to 18 months in prison for health care fraud. The doctor, Dr. [Name], was found guilty of submitting false and inflated bills to Medicare and Medicaid. The doctor was also found guilty of conspiracy to commit health care fraud. The doctor was sentenced to 18 months in prison and a \$100,000 fine. The doctor was also ordered to pay restitution to Medicare and Medicaid. The U.S. Attorney is praising the work of the FBI and the U.S. Marshals Service in bringing this case to a successful conclusion. The U.S. Attorney is also praising the work of the Clearwater, Florida office in bringing this case to a successful conclusion.

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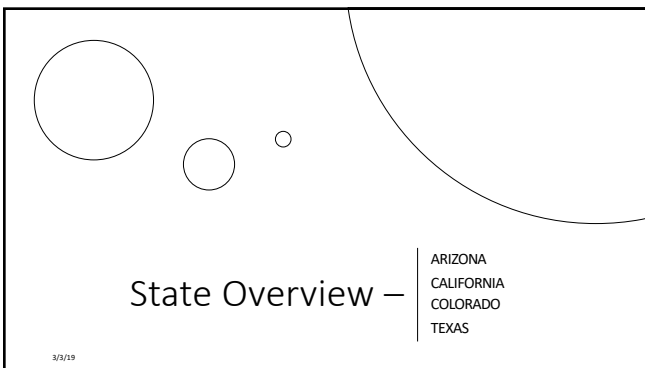
<p>Legitimate Medical Purpose</p> <ul style="list-style-type: none"> • One or more generally recognized medical indication for the use of the controlled substance 	<p>Usual Course of Professional Practice</p> <ul style="list-style-type: none"> • According to licensing and professional standards, including consideration of licensing board material; • Steps of a "Reasonably Prudent" Practitioner 	<p>Reasonable Steps to Prevent Abuse and Diversion</p> <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"
<p>DEA "Standards" for Registrants who Prescribe Controlled Substances 3/3/19</p>		

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

Assess

Reassess, Prudent Care, Coordination of Care

Stratify

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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

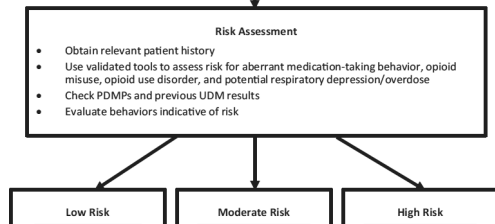
- 8 Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for 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

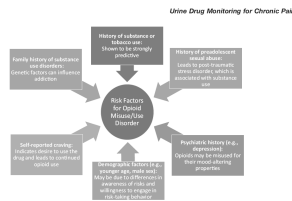
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American Academy of Pain Medicine Says Risk Assessment is . . .



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



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Charles E Argoff, Daniel P Alford, Jeffrey Fudin, Jeremy A Adler, Matthew J Bair, Richard C Dart, Roy Gandolfo, 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/pny288>

Arizona Says Risk Mitigation is . . .

RISK MITIGATION

7. For patients on long-term opioid therapy, discuss and document informed consent which includes the risks of opioid use, nation for diversion, tolerance and dependence, and overdose.

The degree of this discussion will vary with opioid therapy dose, duration, history of previous opioid use, and other risk factors. The discussion should include the risks of opioid use, tolerance and dependence, and overdose. The discussion should also include the risks of diversion, tolerance and dependence, and overdose. The discussion should also include the risks of opioid use, tolerance and dependence, and overdose.

8. Do not use long-term opioid therapy in patients with untreated substance use disorders.

The discussion should include the risks of opioid use, tolerance and dependence, and overdose. The discussion should also include the risks of diversion, tolerance and dependence, and overdose. The discussion should also include the risks of opioid use, tolerance and dependence, and overdose.

9. Avoid concurrent use of opioids and benzodiazepines. If patients are currently prescribed both agents, evaluate tapering or no add therapy for use in both medications.

<https://azdhs.gov/documents/auj-jenices/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 . . .

1. Discuss the risks of opioid use, tolerance and dependence, and overdose. The discussion should include the risks of opioid use, tolerance and dependence, and overdose. The discussion should also include the risks of diversion, tolerance and dependence, and overdose. The discussion should also include the risks of opioid use, tolerance and dependence, and overdose.

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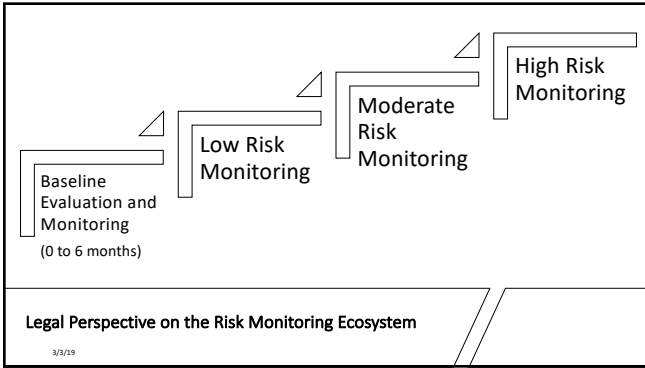
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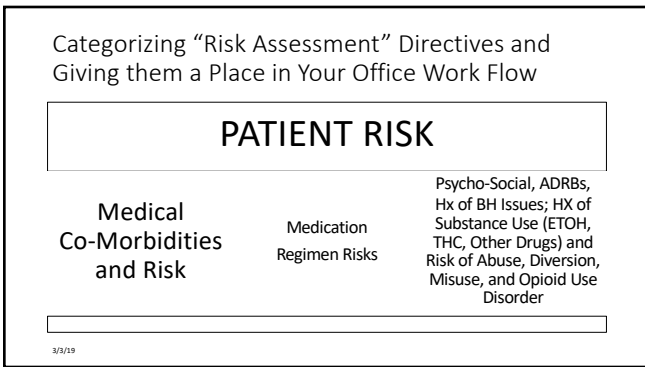
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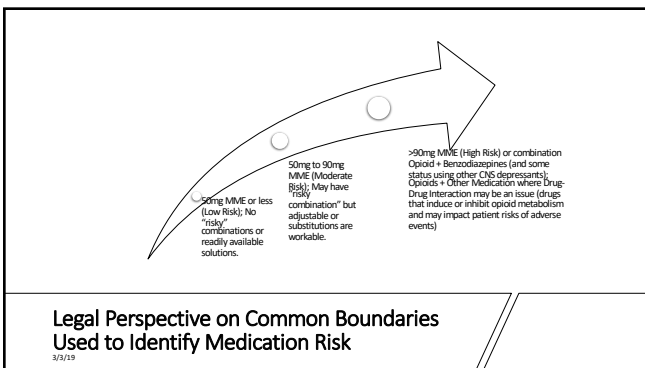
Additional Examples

- 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?

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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 1 minute 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.

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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
Po drugs	4	4
Personal history of substance abuse		
Alcohol	3	3
Illegal drugs	4	4
Po drugs	5	5
Age between 15-45 years	1	1
History of preadolescent sexual abuse	3	0
Psychological disease		
ADD, OCD, bipolar, schizophrenia	2	2
Depression	1	1
Scoring totals		

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/SMA16-474?>

CONSIDER PRESCRIBING NALOXONE ALONG WITH THE PATIENT'S INITIAL OPIOID PRESCRIPTION. Naloxone overprescription limits opioid receptors and is the evidence to assure opioid toxicity. With proper education, patients on long-term opioid therapy and others at risk for overdose may benefit from having a naloxone kit for emergency use, written and needed or prescribed. Check the patient's history of substance abuse. A naloxone kit should be used in the event of a possible or suspected overdose (2).

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

- Taking high doses of opioids for long-term management of chronic mild/moderate or severe pain.
- Prescribed, sharing, or using opioid medication regularly (and that are at risk for inappropriate opioid utilization).
- Discharged from emergency medical care following opioid intoxication or poisoning.
- At high risk for overdose because of a legitimate medical need for analgesia coupled with a non-pediatric or confirmed history of substance abuse, dependence, or nonmedical use of prescription or other opioids.
- On opioid agonist preparations that may increase risk for opioid overdose such as extended-release/long-acting preparations.
- Completing mandatory opioid destruction or diversion programs.

To learn more about our naloxone kits, visit www.samhsa.gov.

OPIOID OVERDOSE

The risk of opioid overdose can be identified through adherence to the following clinical practices, which are supported by a non-scientific level of evidence (2)(4).

ASSESS THE PATIENT. Obtaining a history of the patient's past use of high-potential oral opioid prescription medications with blood alcohol is an essential but step in 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, keep from getting nervous or upset, relax your nerves, make you feel better, etc. like that?"
- "Have you been taking any medications to help you sleep?"
- "Have you been using needles for the opioid?"
- "Have you ever taken a medication to help you with a cough or asthma problem?"
- "Have you ever taken a medication for a nervous attack?"
- "Have you taken a medication to give you more energy or to not sleep on any occasion?"
- "Have you ever been treated for a possible or suspected opioid overdose?"

SAMHSA Opioid Overdose Toolkit

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SAMHSA Medication List

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The screenshot shows the 'Rx Pain Medications' page with a 'My Medications' table. The table has columns for Medication, Formulation, Pain Relief, and Power Red Top. Below the table is a 'NEED HELP?' section with contact information for SAMHSA and CDC.

Resources: Websites

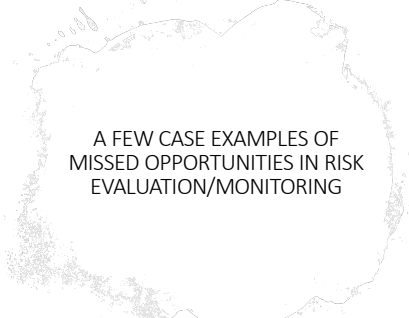
CDC
<http://www.cdc.gov/drugoverdose/prescribing/providers.htm>
 • Provider and patient materials, including prescribing checklists, flyers, and posters

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

DHMH Opioid Website
dhmh.maryland.gov/medicaid-opioid-dur

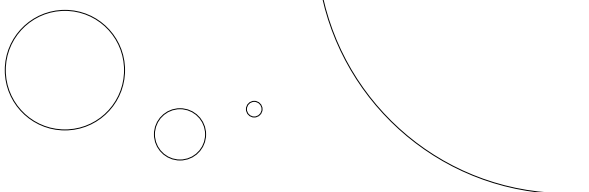


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A FEW CASE EXAMPLES OF
MISSED OPPORTUNITIES IN RISK
EVALUATION/MONITORING

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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

- 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

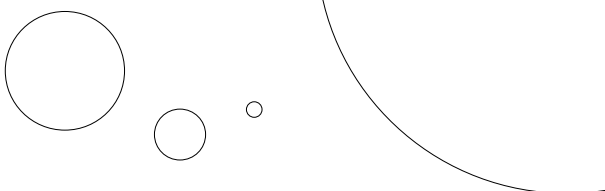
How often does the MD see the patient?

- 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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Naloxone and Minimizing Risk | Quick Reminder

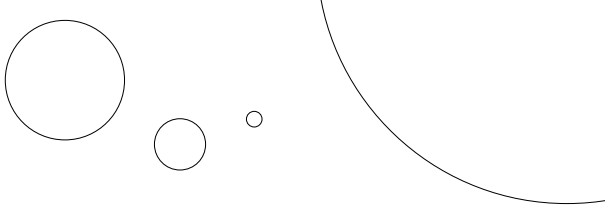
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REMEMBER:

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)



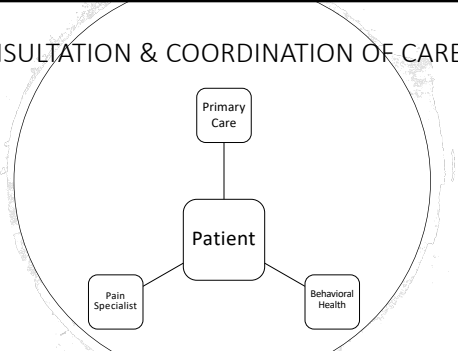
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Coordination of Care
Addressing the Weaknesses




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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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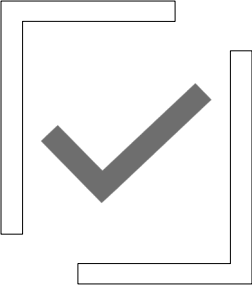
REMINDER

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

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Questions?

- Thank you!
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