



Jennifer Bolen, JD

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

Disclosures

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Objectives – Embrace Changes and Prevent Overdose

1

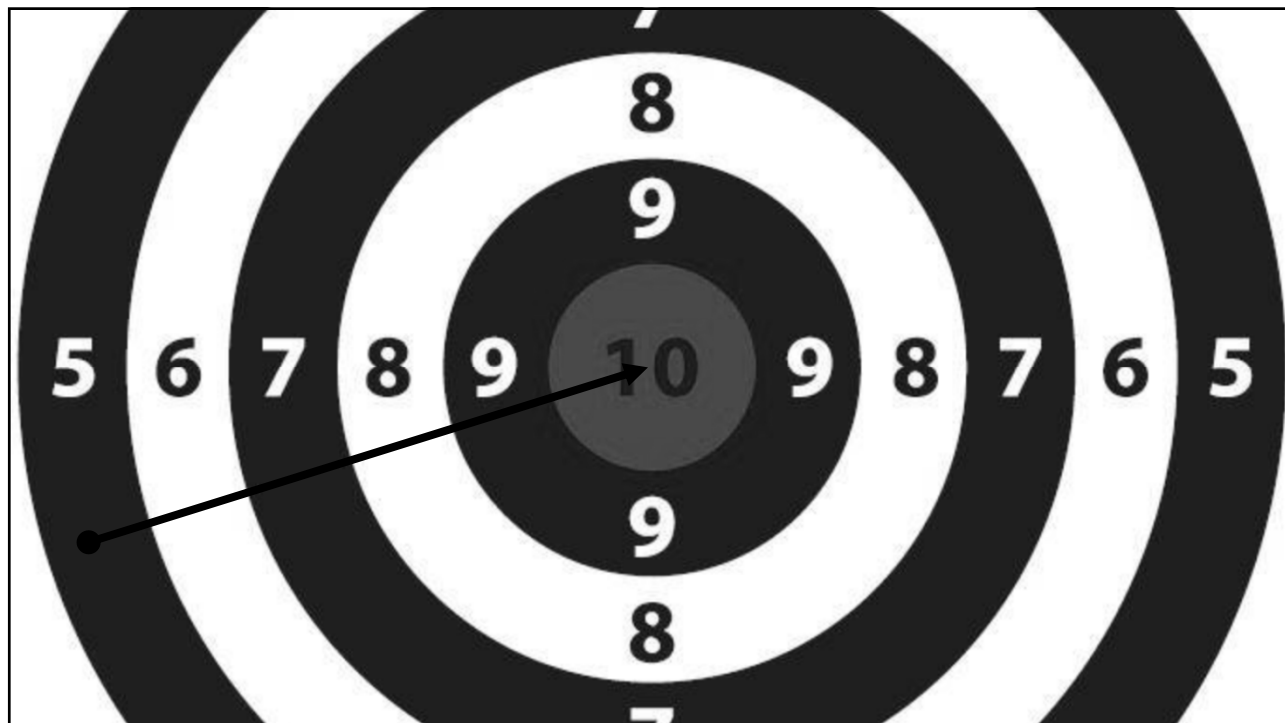
Identify common theories of liability raised in cases charging physicians with inappropriate prescribing resulting in the death of a patient.

2

List basic elements of a risk mitigation and response protocol for the physician's use with his/her office staff and patients.

3

Discuss future risk mitigation areas tied to overdose events (fatal and nonfatal) and establish a framework the clinician can use to stay informed of licensing board requirements.



Why are we still talking
about Risk Mitigation in
Opioid Prescribing?

1. There are STILL bad players in every profession.
2. There are STILL those who do not pay attention to changing standards of care and professional licensing board requirements.
3. There WILL ALWAYS be those who put money before people.
4. There are STILL payors who do not promote balance and quality pain care.
5. There WILL ALWAYS be people against opioids and people who benefit from opioids.

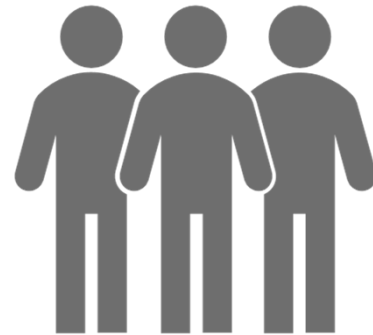
A proactive look at a sad reality

Physician Liability in Overdose Deaths?

Common Theories in Cases Against Doctors

- **Prescribing**

- Without a proper evaluation, including risk assessment, including risk of overdose event
- Without ongoing evaluation and risk mitigation, including naloxone
- Without the proper documentation, including rationale for starting, changing, not stopping opioids; Failure to document rationale for combinations of controlled substances



The mindset is to create the “cheese trail” that reflects the prescriber’s rationale at various data points

Data points

Rationale
and Clinical
Decision-
making

Discussion of
Common Themes
in Enforcement
Actions Against
Prescribers and
Pharmacists

Documentation

Evaluation

Monitoring

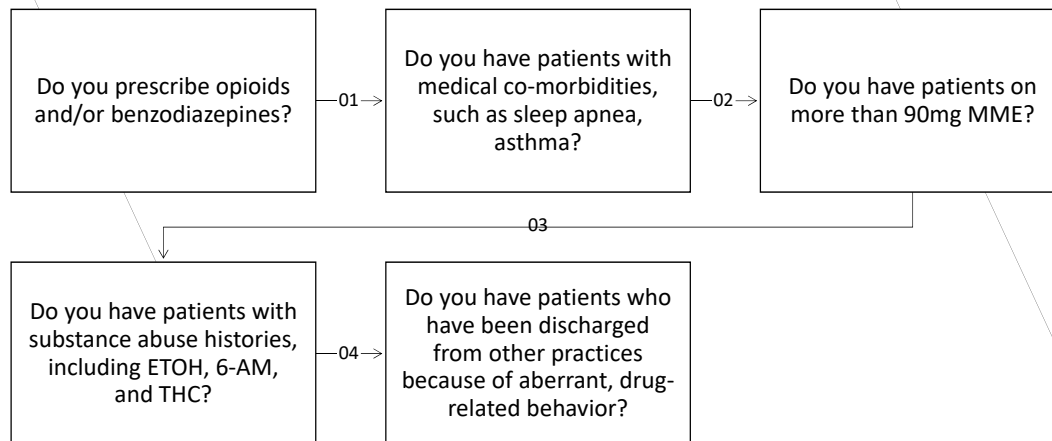
Response

Patient Risk Mitigation & Risk Education

Overdose Events (Fatal or Nonfatal):

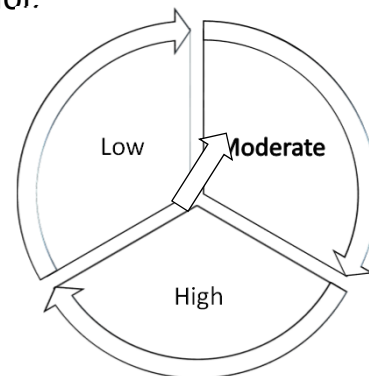
Steps you can take to mitigate against them AND Steps
you can take when they do happen

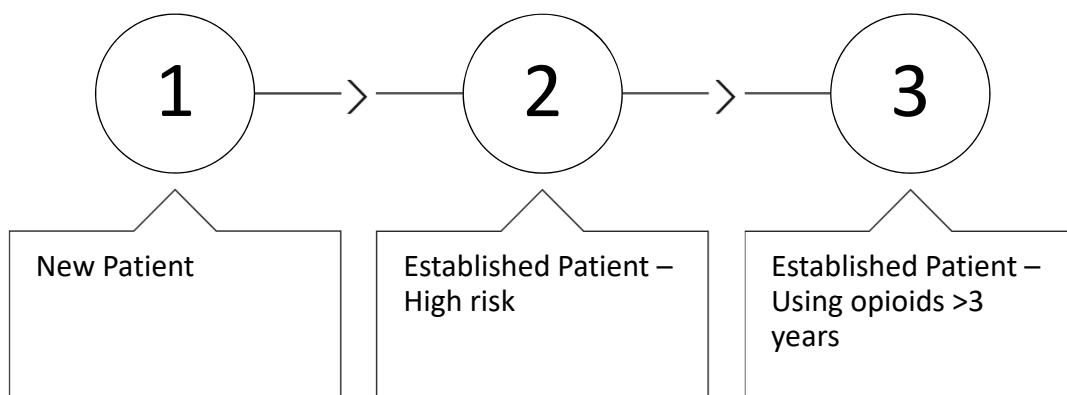
Overdose Event: Is your practice at risk?



Audience Input: Risk-o-Meter Exercise

- Spin the Risk-O-Meter
- Name a risky behavior and tell us how you deal with risk mitigation and patient education surrounding the behavior.





Step 1 – Identify 3 Charts

Rules for Controlled Substance Prescribing

Rules for Pain Clinic Operations

Guidelines for Prescribing Chronic Opioid Therapy (or similar wording)

Guidelines for Office-Based Opioid Treatment (or similar wording)

Step 2 – Review State Licensing Board Administrative Rules and Guidelines

STATE SPECIFIC REQUIREMENTS WILL BE INSERTED AT EACH PWE PROGRAM

- Materials derived from state licensing board programs

Remember Core
Responsibilities
when Prescribing
Controlled
Substances

DEA Standards

Licensing Board
Standards

Position of Trust over
the Patient

DEA Standards for Registrants

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

Reasonable Steps to Prevent Abuse and Diversion

- Proper Risk Evaluation, Stratification, and Monitoring Protocols, including overdose risk evaluation
- PDMP
- UDT
- NALOXONE
- Visit frequency
- Many other “reasonable steps”

Licensing Board and Professional Standards (Clinical and Documentation of Same)

Historical Steps with Patient

- General medical history
- Pain specific history
- Risk of abuse/addiction
- Risk of diversion
- Risk of overdose

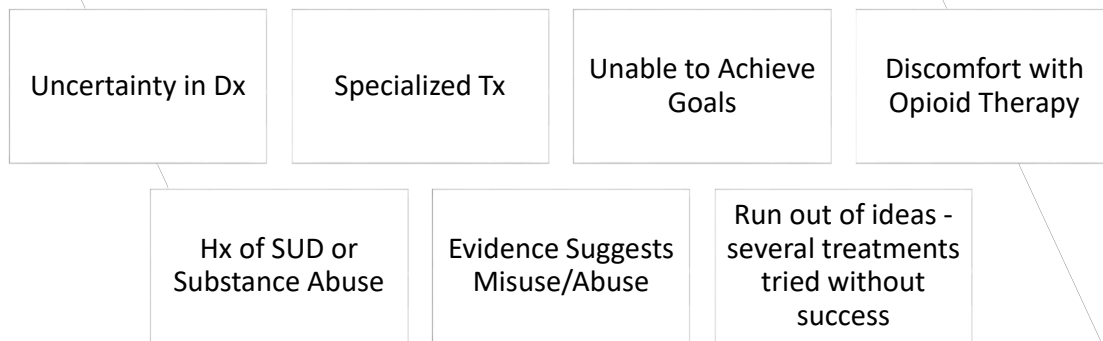
Active Care Plan Steps

- Opioid trial
- Exit strategy
- Treatment plan for frequency, handling MME, PDMP utilization, drug testing, etc.
- Naloxone
- Patient education
- Documentation and process of informed consent and treatment agreement

Coordination of Care and Consultations/Referrals

- Scope of practice issues
- Exchange of documentation between PCP and Specialty providers engaged in chronic MEDICATION therapy (not just limited to opioids)
- Dealing with marijuana issues
- Rationale for starting, stopping, changing, etc.

Consultations and Referrals – Documentation Tips – “As Necessary”
(Does your chart show you’ve considered these things?)



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

AMA **END the EPIDEMIC**

The AMA Opioid Task Force recommends that physicians take three actions to help ensure safe storage and disposal of expired, unwanted or unused medications:

- 1. Talk** to your patients about proper use of opioid analgesics
- 2. Remind** your patients to safely store medicines away from children and never share prescriptions
- 3. Urge** your patients to safely dispose of expired, unwanted, and unused medications, using pharmacy and law enforcement "Take Back" resources

[LEARN MORE >](#)

AMA **Task Force Recommendations**

<p>Register for and use your state PDMP to make more informed prescribing decisions</p> <p>TAKE ACTION ></p>	<p>Ensure you have the education and training on effective, evidence-based treatment</p> <p>TAKE ACTION ></p>	<p>Support and advocate for comprehensive care for patients in pain and those with a substance use disorder</p> <p>TAKE ACTION ></p>
<p>Removing stigma is essential to ending the nation's opioid epidemic</p> <p>TAKE ACTION ></p>	<p>Expand access to naloxone in the community and through co-prescribing</p> <p>TAKE ACTION ></p>	<p>Work with your patients to promote safe storage and disposal of opioids and all medications</p> <p>TAKE ACTION ></p>

Select national education resources for physicians and other health care professionals

The CO*RE/ASAM Opioid Prescribing: Safe Practice, Changing Lives

American Society of Addiction Medicine

Education

[LEARN MORE >](#)

The ASAM Fundamentals of Addiction Medicine

American Society of Addiction Medicine

Education

[LEARN MORE >](#)

The ASAM Treatment of Opioid Use Disorder Course

American Society of Addiction Medicine

Education

[LEARN MORE >](#)

AMA CME – opioid primer

AMA

Education

A Primer on the Opioid Morbidity and Mortality Crisis: What Every Prescriber Should Know

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Buprenorphine waiver training

American Academy of Addiction Psychiatry

Education

[LEARN MORE >](#)

SAMHSA Opioid Overdose Prevention Toolkit

Education

SAMHSA Opioid Overdose Prevention Toolkit equips health care providers, communities, and local governments with material to develop practices and policies to help prevent opioid-related overdoses and deaths.

[LEARN MORE >](#)

Why It's Inappropriate Not to Treat Incarcerated Patients with Opioid Agonist Therapy

American Medical Association

Reducing Stigma

Treatment

AMA Journal of Ethics. September 2017, Volume 19, Number 9: 922-930.

Sarah E. Wakeman, MD

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A Primer on Antagonist-Based Treatment of Opioid Use Disorders in the Office Setting

PCSS-MAT

Treatment

[LEARN MORE >](#)

Preparation and Administration of Extended-Release Naltrexone

PCSS-MAT

Treatment

[LEARN MORE >](#)

XR-Naltrexone: A Step-by-Step Guide

American Academy of Addiction Psychiatry

Treatment

Created by Adam Bisaga, MD

[LEARN MORE >](#)

Providers' Clinical Support System For Medication Assisted Treatment

PCSS-MAT

Education

Treatment

PCSS-MAT is comprehensive electronic repository of training materials and educational resources to support evidence-based treatment

AAPM pain physician locator

American Academy of Pain Medicine

Treatment

[LEARN MORE >](#)

Naloxone

Access to life-saving
NALOXONE
improves nationwide;
co-prescriptions increase

Physicians' advocacy matters

> Medical societies have helped **nearly every state enact enhanced naloxone access laws.**

> In the first 2 months of 2017, **32,659** naloxone prescriptions were dispensed, noting a **record 340 percent increase** from 2016.



Co-prescribing naloxone to
a patient at risk of overdose
can help save lives.

[Learn more](#)

AMA Opioid Task Force naloxone recommendations

Naloxone

Updated August 2017

[DOWNLOAD >](#)

Putting Naloxone Into Action!

PCSS-O

Naloxone

[LEARN MORE >](#)

When Seconds Count: "Opioid Overdose Resuscitation" card

American Society of Anesthesiologists

Naloxone

[LEARN MORE >](#)

Naloxone Distribution from the ED for patients at-risk for Opioid Overdose

American College of Emergency
Physicians

Naloxone

[LEARN MORE >](#)

Public Policy Statement on the Use of Naloxone for the Prevention of Drug Overdose Deaths

American Society of Addiction Medicine

Naloxone

[LEARN MORE >](#)

Overdose prevention tools and best practices


Naloxone

Harm Reduction Coalition

[LEARN MORE >](#)

[View More](#)

<https://cme.ama-assn.org/Activity/4896593/Detail.aspx>
[Maryland Board of Medicine](#)



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A Primer on the Opioid Morbidity and Mortality Crisis: What Every Prescriber Should Know

This e-learning module incorporates animation, infographics, and storytelling to raise physician awareness about prescription opioid-related morbidity and mortality, factors influencing opioid-related harm, and what steps can be taken to promote the safe use of this important class of medications. Topics include the burden of chronic pain in the United States, trends in opioid prescribing and opioid-related harms that have developed over the past 20 years, factors influencing the development of the "opioid epidemic," and risk factors for unintentional overdose and development of opioid use disorder. In addition, some attention is devoted to the intersection of prescription opioid misuse with the resurgence in heroin use and addiction, and how the clinical practice environment for pain management and opioid prescribing has been influenced by the public and private sector. Finally, recommendations for promoting safe opioid use in different patient populations are offered. Funding for developing this module was made possible (in part) by the Provider's Clinical Support System for Opioid Therapies (grant no. 5H79T1025595) from SAMHSA. The views expressed in this module do not necessarily reflect the official policies of the Department of Health and Human Services, nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government. Should you have technical questions, please contact the AMA Unified Service Center at 800-621-8335. Should you have questions regarding the content, please contact Barry Dickinson at barry.dickinson@ama-assn.org.

Register

FREE

Activity Price

531 Registered Users


Credits

0.75 Credits > AMA > AMA PRA
Category 1 Credit™

0 Credits > AMA > Certificate of
Participation for Non-Physicians

Activity Information

A Primer on the Opioid Morbidity and Mortality Crisis: What Every Prescriber Should Know
Release Date: January 30, 2017
Expiration Date: December 31, 2019




Help save lives: Co-prescribe naloxone to patients at risk of overdose

Naloxone saves lives

The nation's opioid epidemic claimed more than 33,000 lives in 2015, but first responders would have been even higher if it weren't for the life-saving opioid antagonist, naloxone. For more than 40 years, naloxone has been used to reverse the effects of opioid addiction. Recent developments of naloxone have created opportunities for:

- From 1996 through June 15, 2014, researchers found that community-based naloxone distribution programs, including provision of naloxone to physicians, community groups or 24-hour opioid overdose reversal centers in the United States.
- In the first 6 weeks of 2015, the number of naloxone prescriptions written by physicians increased by 36 percent nationwide compared to the week period of 2014. The number of physicians prescribing naloxone increased by almost 42 percent over the same time period.
- "This crisis must leave us nervous about addiction, there is a 15 to 21 percent reduction in repeat overdose deaths."
- Since late 2010, the rate of overdoses in the United States now regularly increases to three per second – resulting in thousands of lives saved.¹

Co-prescribing naloxone is supported by a broad range of stakeholders including the World Health Organization,² U.S. health agencies (CDC, SAMHSA), state departments of health,³ and many patient, consumer and other advocacy groups⁴.



Additional considerations when co-prescribing naloxone

Determining whether to co-prescribe naloxone raises many issues, including initiating a discussion about the risk of addiction. The potential negative impact on patients who are prescribed opioids is significant. Avoiding this risk allows the addition of naloxone, if applicable, and helps to ensure the patient can drive home safely someday by the appropriate timing in use of an analgesic. Though co-prescribing naloxone is not a perfect solution, it provides a timely option to a case that otherwise may not be available as a timely measure. In addition,

- Co-prescribing naloxone has been shown to reduce serious primary important risks, and may help prevent future serious events of the potential liability of opioid use.
- Patient education that offers the following information is essential:⁵
- Physicians can provide their best care by providing naloxone to be acceptable.⁶
- Co-prescribing naloxone does not increase liability risk.⁷

Practical resources for more information

- Prescribing Naloxone to Patients for Opioid Overdose**: [http://www.ama-assn.org/practicing/your-practice/drugsanddevices/2015/prescribing-naloxone-to-patients-for-opioid-overdose](#) | Prescriber Clinical Support
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- Naloxone Distribution Sites for the Patient at Risk for Opioid Overdose**: [http://www.](#)

AMA Task Force Recommendations on Naloxone

Step 3 – Make a List of Licensing Board and Professional Standards “Directives”

Shall/Must

Common Examples

Common Examples

Shall Not/Must Not

Common Examples

Common Examples


Should/May

Common Examples

Common Examples

CDC Opioid Prescribing Guidelines - Checklist

Checklist for prescribing opioids for chronic pain	
For primary care providers treating adults (18+) with chronic pain ≥ 3 months, excluding cancer, palliative, and end-of-life care	
<p>WHEN TO START</p> <p>When CONSIDERING long-term opioid therapy</p> <ul style="list-style-type: none"> □ Set realistic goals for pain and function based on diagnosis (eg, weak around the block). □ Check that non-opioid therapies tried and optimized. □ Discuss benefits and risks (eg, addiction, overdose) with patient. □ Evaluate risk of harm or misuse. <ul style="list-style-type: none"> • Discuss risk factors with patient. • Check prescription drug monitoring program (PDMP) data. • Check urine drug screen. □ Set criteria for stopping or continuing opioids. □ Assess baseline pain and function (eg, PEG scale). □ Schedule initial reassessment within 1–4 weeks. □ Prescribe short-acting opioids using lowest dosage on product labeling; match duration to scheduled reassessment. <p>RENEWING without patient visit</p> <ul style="list-style-type: none"> □ Check that return visit is scheduled ≤ 3 months from last visit. <p>When REASSESSING at return visit</p> <p>Continue opioids only after confirming clinically meaningful improvements in pain and function without significant risks or harm.</p> <ul style="list-style-type: none"> □ Assess pain and function (eg, PEG), compare results to baseline. □ Evaluate risk of harm or misuse: <ul style="list-style-type: none"> • Observe patient for signs of over-sedation or overdose risk. • If yes: Taper dose. • Check PDMP. • Check for opioid use disorder if indicated (eg, difficulty controlling use). • If yes: Refer for treatment. □ Check that non-opioid therapies optimized. □ Determine whether to continue, adjust, taper, or stop opioids. □ Calculate opioid dosage morphine milligram equivalent (MME). <ul style="list-style-type: none"> • If > 50 MME/day total (> 50 mg hydrocodone, > 33 mg oxycodone), increase frequency of follow-up; consider offering naloxone. • Avoid > 90 MME/day total (> 90 mg hydrocodone, > 60 mg oxycodone), or carefully justify; consider specialist referral. □ Schedule reassessment at regular intervals (≤ 3 months). 	<p>REFERENCE</p> <p>EVIDENCE ABOUT OPIOID THERAPY</p> <ul style="list-style-type: none"> • Benefits of long-term opioid therapy for chronic pain not well supported by evidence. • Short-term benefits usual to moderate for pain; inconsistent for function. • Insufficient evidence for long-term benefits in low back pain, headache, and fibromyalgia. <p>NON-OPIOID THERAPIES</p> <p>Use alone or combined with opioids, as indicated:</p> <ul style="list-style-type: none"> • Non-opioid medications (eg, NSAIDs, TCAs, SNRIs, anti-convulsants). • Physical treatments (eg, exercise therapy, weight loss). • Behavioral treatment (eg, CBT). • Procedures (eg, intra-articular corticosteroids). <p>EVALUATING RISK OF HARM OR MISUSE</p> <p>Known risk factors include:</p> <ul style="list-style-type: none"> • Illegal drug use, prescription drug use for nonmedical reasons. • History of substance use disorder or overdose. • Mental health conditions (eg, depression, anxiety). • Sleep-disordered breathing. • Concurrent benzodiazepine use. <p>Urine drug testing: Check to confirm presence of prescribed substances and for undisclosed prescription drug or illicit substance use.</p> <p>Prescription drug monitoring program (PDMP): Check for opioids or benzodiazepines from other sources.</p> <p>ASSESSING PAIN & FUNCTION USING PEG SCALE</p> <p>PEG scale = average 3 individual questions scored. 100% improvement from baseline is clinically meaningful.</p> <p>61. What number from 0–10 best describes your pain in the past week? 0 = “no pain”; 10 = “worst you can imagine”</p> <p>62. What number from 0–10 describes how, during the past week, pain has interfered with your enjoyment of life? 0 = “not at all”; 10 = “complete interference”</p> <p>63. What number from 0–10 describes how, during the past week, pain has interfered with your general activity? 0 = “not at all”; 10 = “complete interference”</p>

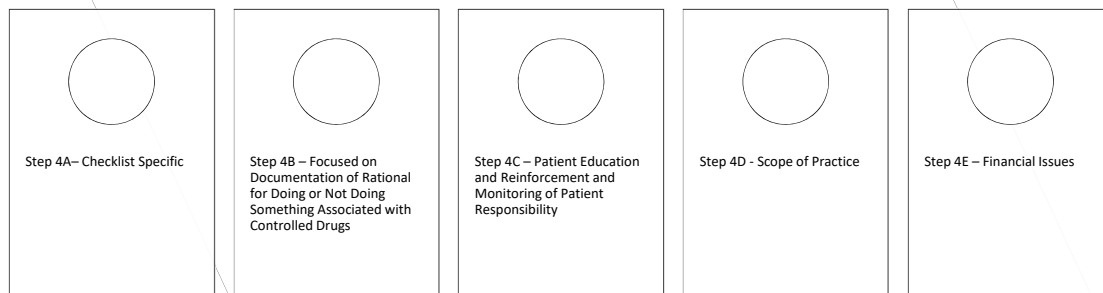


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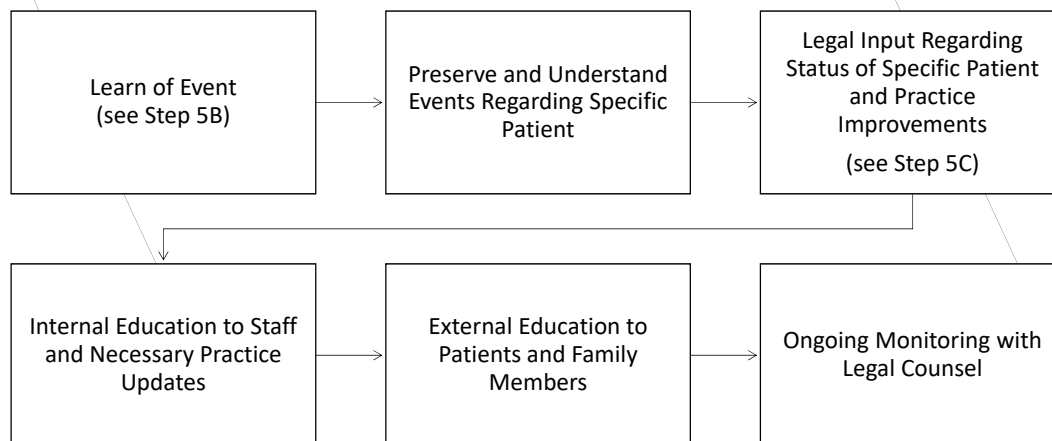
TO LEARN MORE
WWW.CDC.GOV/DRUGOVERDOSE/PRESCRIBINGGUIDELINE

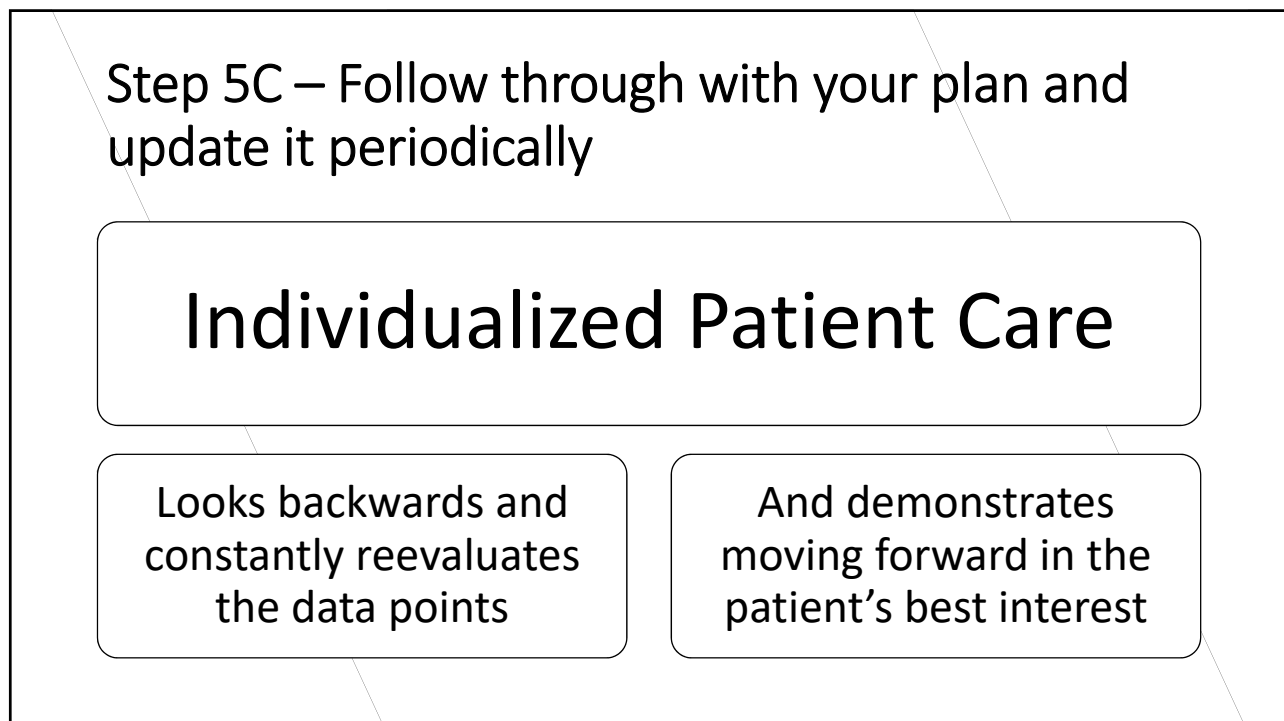
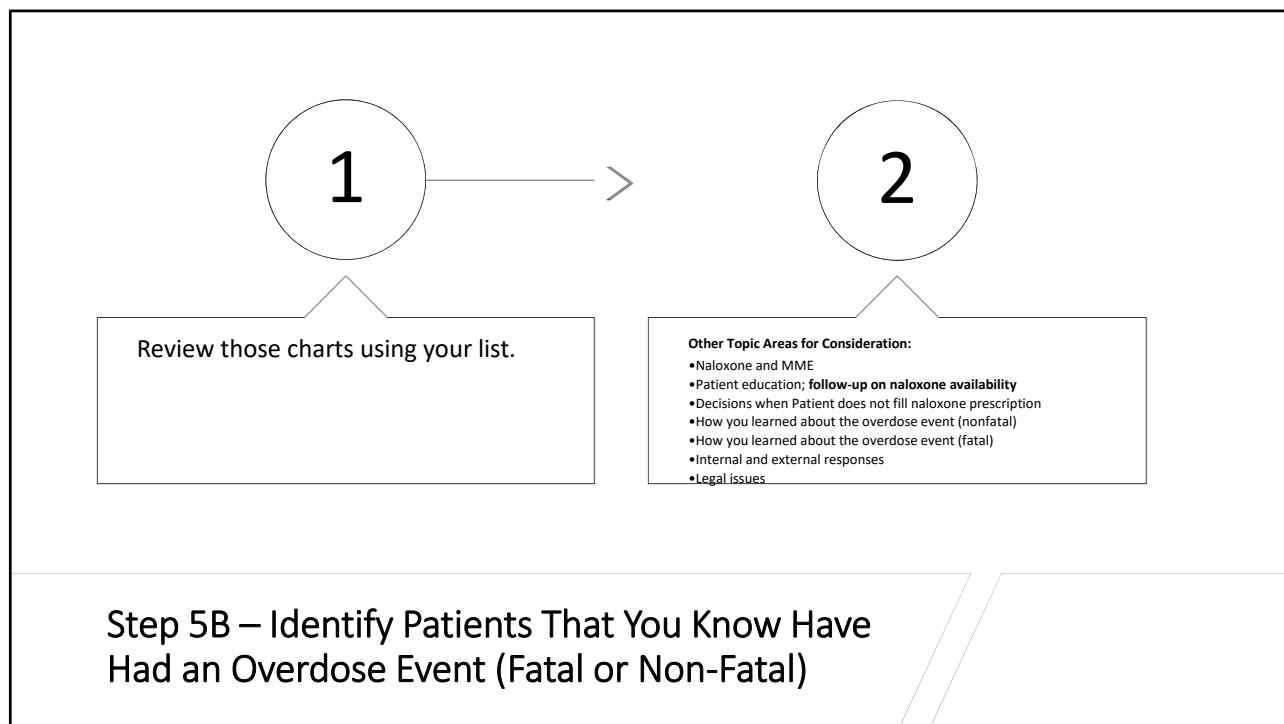
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Steps 4A through 4E – Review Charts with Directives List in Mind; Ask: Where am I vulnerable?



Step 5A – Create a risk triage plan







Minimizing Risk and Navigating the Pain and
Addiction Channel

How do you make sure
you leave markers of
your good intent?

Make Documentation and Education Your Priorities

Checklists

Key Resources for
Patient Education
Materials

Key Resources for
Prescriber
Materials

Checklists

Licensing Board Directives	Professional Society and Basic Regulatory Guidance on Chronic Opioid Therapy	Risk Assessment Tools, Stratification, and Monitoring	Internal Education	Patient and Family Member Education
History and Physical Examination	American Academy of Pain Medicine	Risk of Abuse/Addiction	Current State Requirements	Risks of Opioid Use
Risk Evaluation	American Association for Clinical Chemistry	Risk of Diversion	CDC and Academy Positions	Informed Consent Process
Treatment Plan	Federation of State Medical Boards	Risk of Overdose	Interaction with Pharmacists	Consequences if Treatment Agreement Violation
Informed Consent	Medicare Guidance	Other Behavioral Risks	PDMP Use	Safe Use
Treatment Agreement	CDC Guidelines	Protocols for Scoring and Overall Assessment of Risk and Stratification	Drug Testing	Safe Storage
Periodic Review	SAMHSA Materials	Protocols for Monitoring tied to Risk Stratification	Opioid Trials and Exit Strategies	Safe Disposal
Consultations and Referrals	Other	Protocols for Coordination of Care	Business Relationships	Naloxone
Documentation Requirements		Referral Plan and Overdose Event Plan	Self-Audit	Exit Strategies and Boundaries



Overdose Event Reporting

Developing Risk Monitoring Programs for 2018



Summary and Discussion

1

Reminder on how we got here

2

Who will fight for you?

3

Self-audit to get yourself on track; Teach your staff and referral sources (or define how you will interact if you are the referring provider); Teach your patients; Educate other stakeholders when possible.

Thank you!

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