Jennifer Bolen, JD

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

Disclosures

Jennifer Bolen, JD

- Consultant to Generation Partners
- Consultant to Abbott
- Consultant to MTL Solutions, LLC
- Owner/Partner in Laboratory Revenue Partners, LLC
- Guest Speaker, Pernix Therapeutics

Objectives – Embrace Changes and Prevent Overdose

1

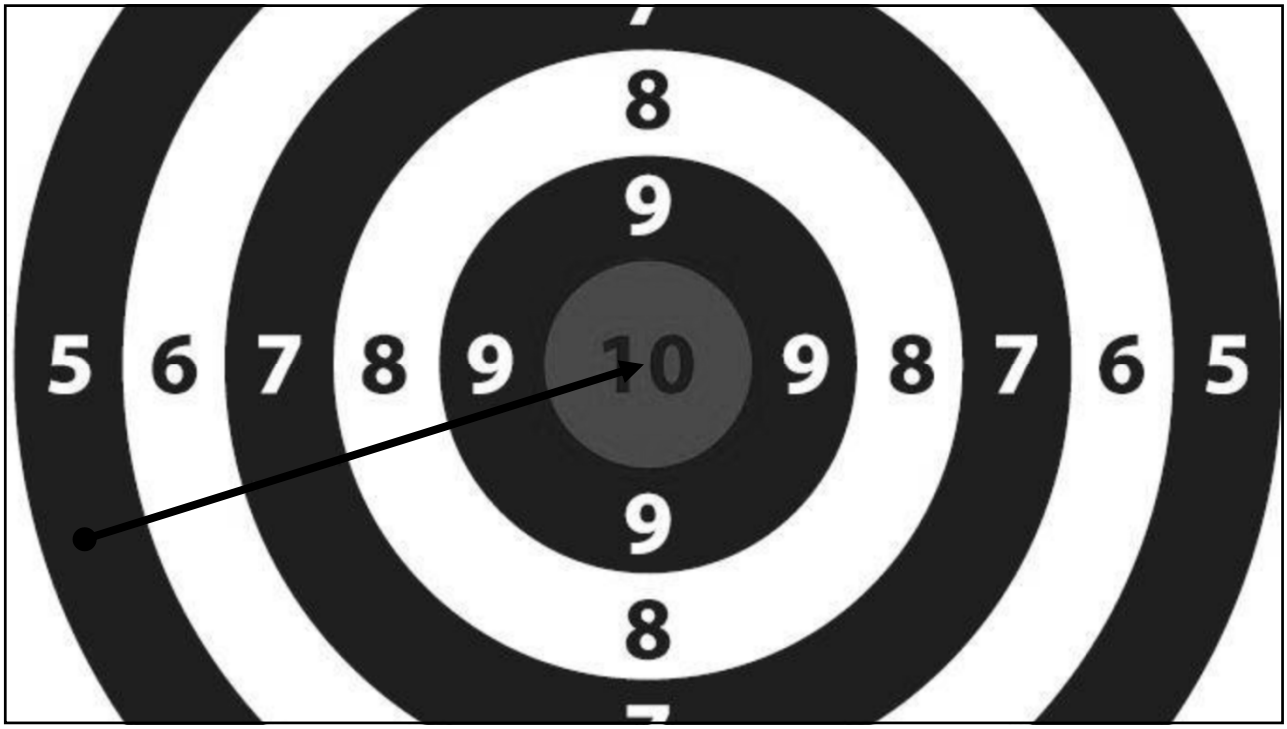
Identify common theories of liability raised in cases charging physicians with inappropriate prescribing resulting in the death of a patient.

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.

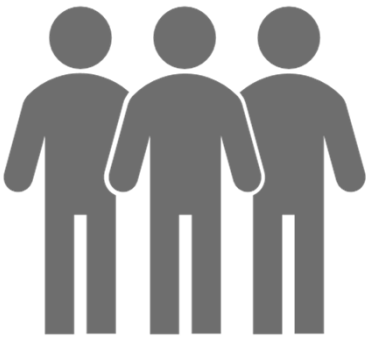
5. There WILL ALWAYS be people against opioids and people who benefit from opioids.

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

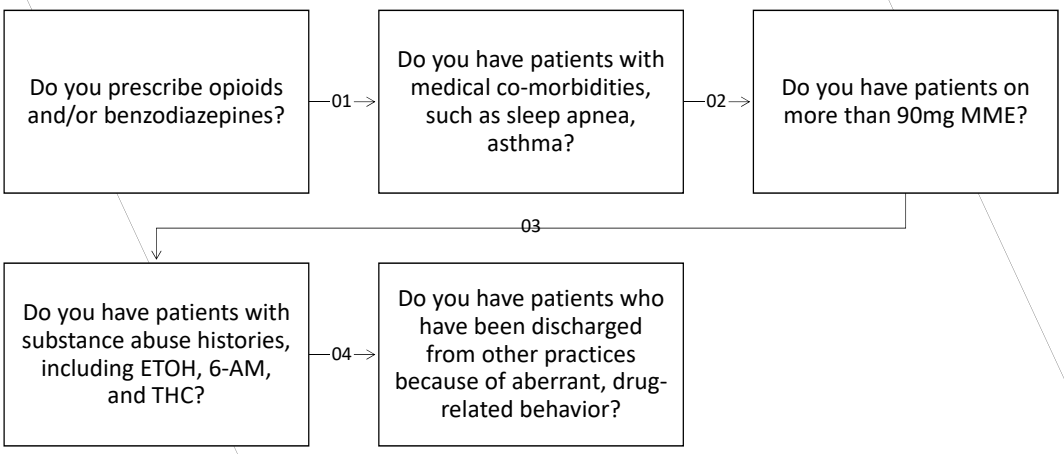
Evaluation	Monitoring	Response

Patient Risk Mitigation & Risk Education

Overdose Events (Fatal or Nonfatal):

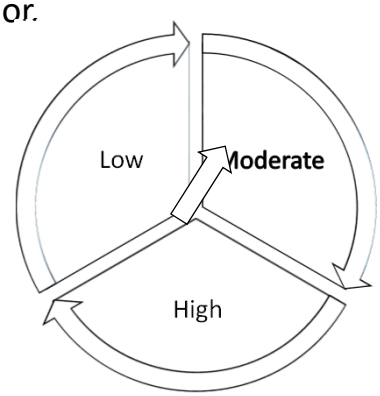
Steps you can take to mitigate against them AND Steps you can take when they do happen

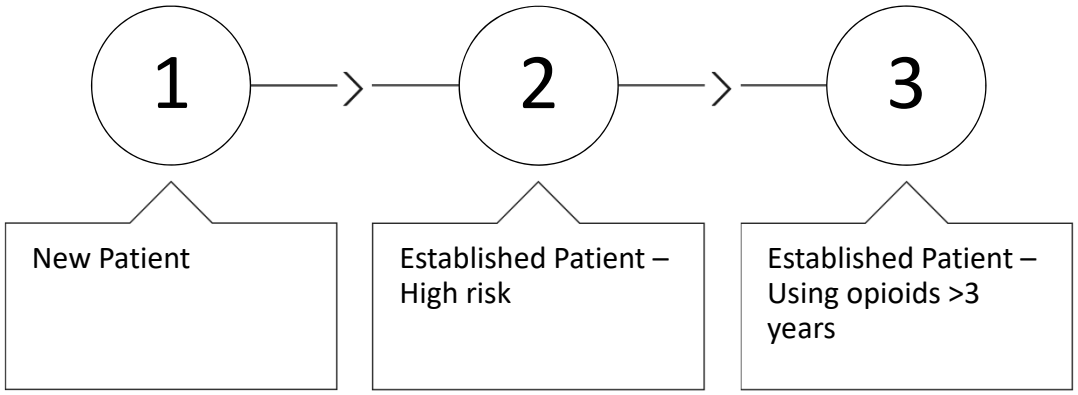
Overdose Event: Is your practice at risk?



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?)

- Uncertainty in Dx
- Specialized Tx
- Unable to Achieve Goals
- Discomfort with Opioid Therapy
- Hx of SUD or Substance Abuse
- Evidence Suggests Misuse/Abuse
- Run out of ideas - several treatments tried without success

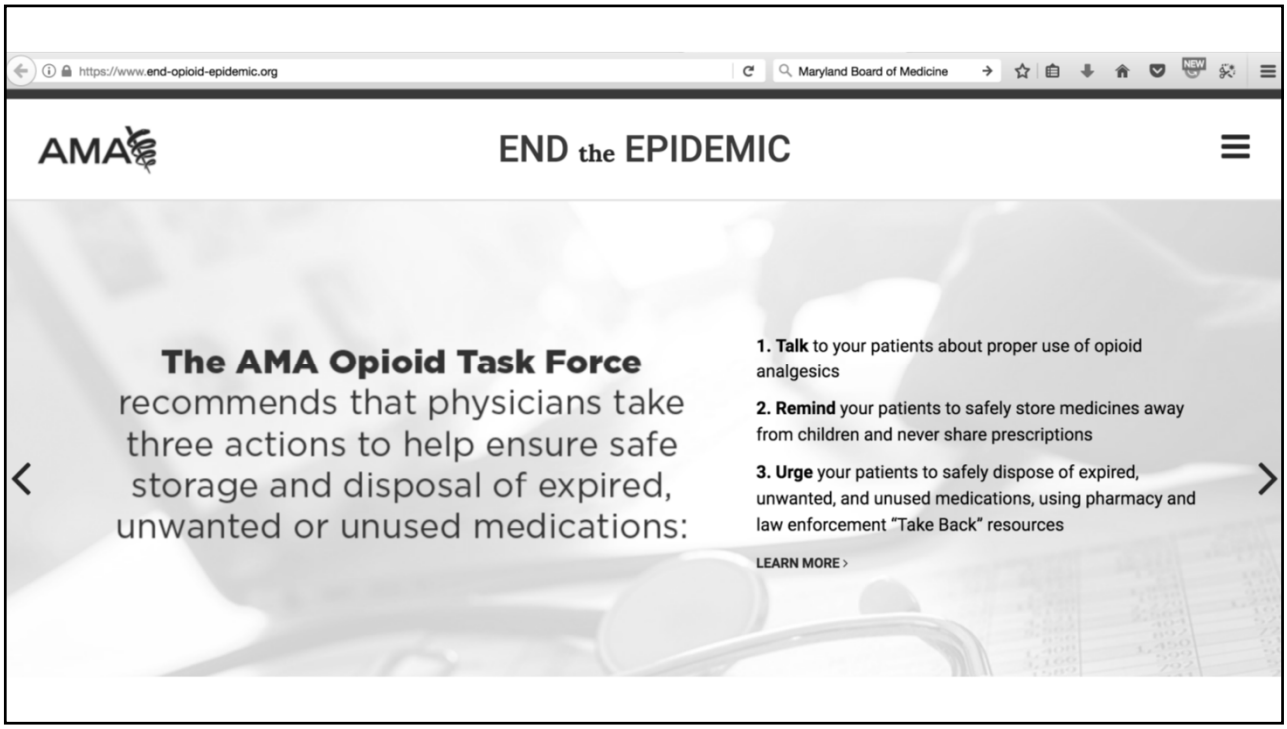
Resources: Websites

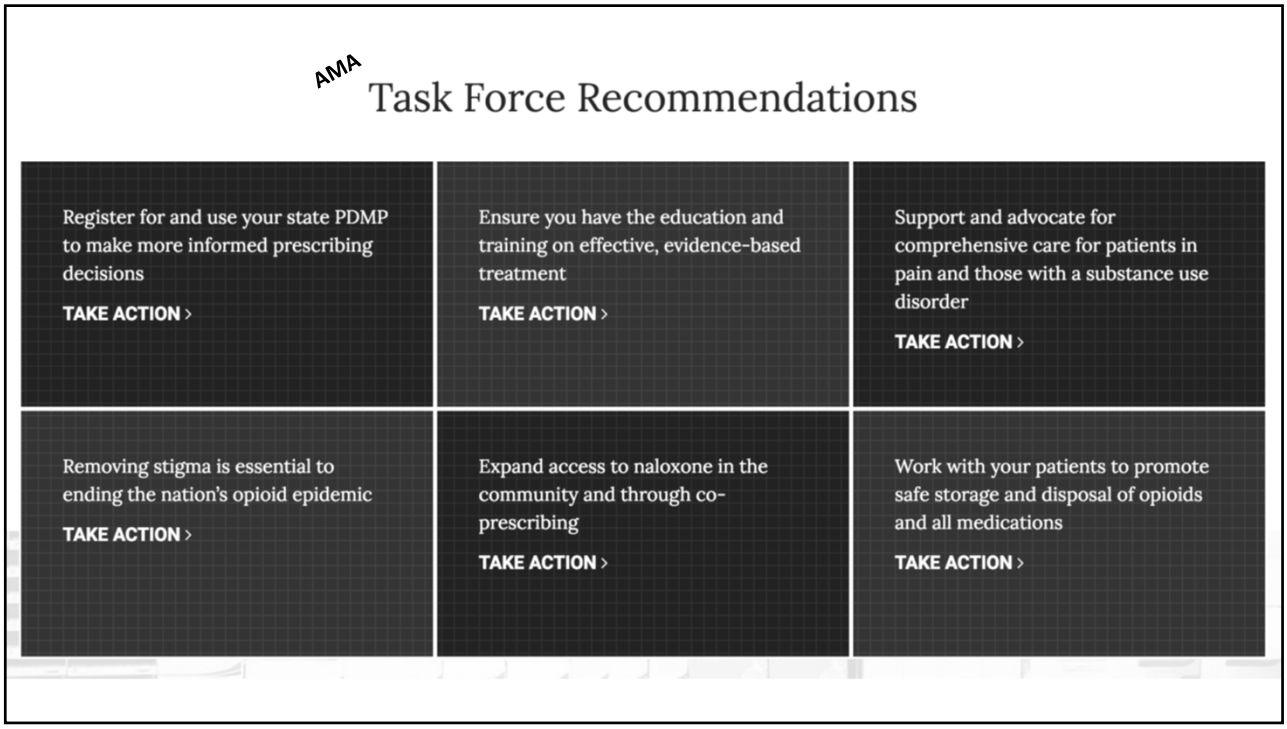
CDC
http://www.cdc.gov/drugoverdose/prescribing/providers.htm
- Provider and patient materials, including prescribing checklists, flyers, and posters

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

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

MARYLAND DEPARTMENT OF HEALTH & MENTAL HYGIENE


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

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
LEARN MORE ›

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
LEARN MORE ›

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 ›

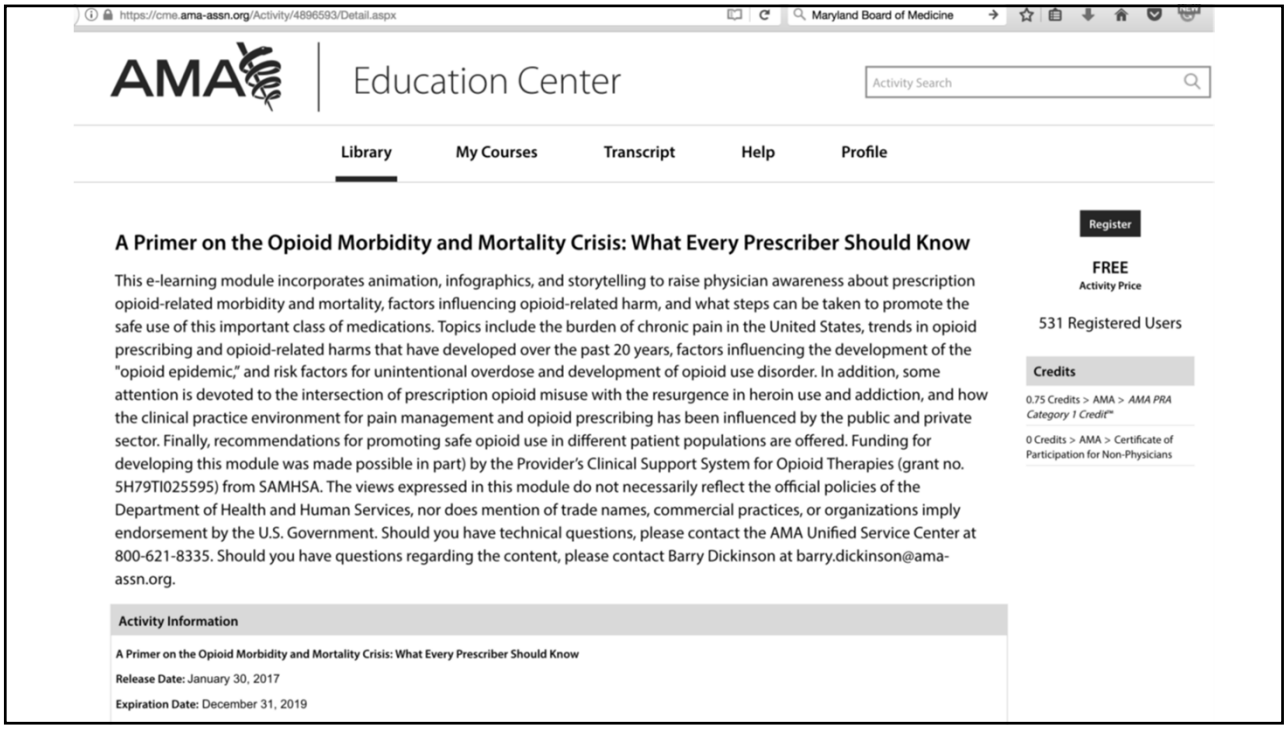
Overdose prevention tools and best practices

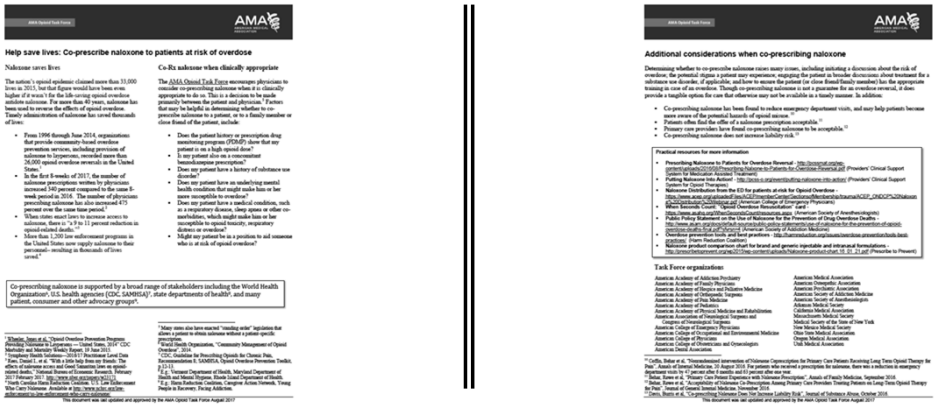
Naloxone

Harm Reduction Coalition

LEARN MORE ›

View More




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

Naloxone saves lives

Co-Rx naloxone when clinically appropriate

Additional considerations when co-prescribing naloxone

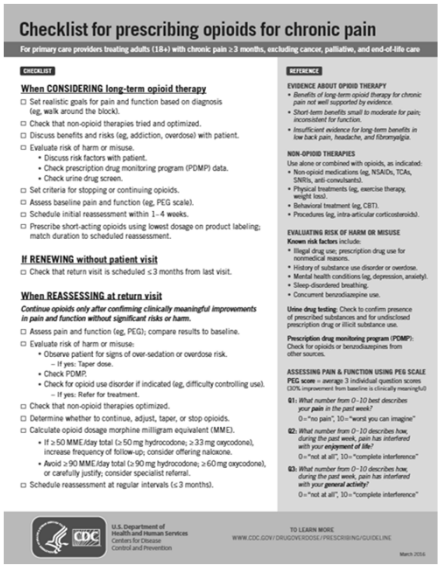
Task Force organizations

AMA Task Force Recommendations on Naloxone

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

Shall/Must	Shall Not/Must Not	Should/May
Common Examples	Common Examples	Common Examples
Common Examples	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

CHECKLIST

When CONSIDERING long-term opioid therapy

- ☐ Set realistic goals for pain and function based on diagnosis (eg, walk 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.
  - 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.

If RENEWING without patient visit

- ☐ Check that return visit is scheduled ≤ 3 months from last visit.

When REASSESSING at return visit

Continue opioids only after confirming clinically meaningful improvements in pain and function without significant risks or harm.

- ☐ Assess pain and function (eg, PEG); compare results to baseline.
- ☐ Evaluate risk of harm or misuse:
  - 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).
  - 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).

REFERENCE

EVIDENCE ABOUT OPIOID THERAPY

- *Benefits of long-term opioid therapy for chronic pain not well supported by evidence.*
- *Short-term benefits small to moderate for pain; inconsistent for function.*
- *Insufficient evidence for long-term benefits in low back pain, headache, and fibromyalgia.*

NON-OPIOID THERAPIES

Use alone or combined with opioids, as indicated:

- 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).

EVALUATING RISK OF HARM OR MISUSE

Known risk factors include:

- 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.

Urine drug testing: Check to confirm presence of prescribed substances and for undisclosed prescription drug or illicit substance use.

Prescription drug monitoring program (PDMP): Check for opioids or benzodiazepines from other sources.

ASSESSING PAIN & FUNCTION USING PEG SCALE

PEG score = average 3 individual question scores (30% improvement from baseline is clinically meaningful)

Q1: *What number from 0–10 best describes your pain in the past week?*
0 = "no pain", 10 = "worst you can imagine"

Q2: *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"

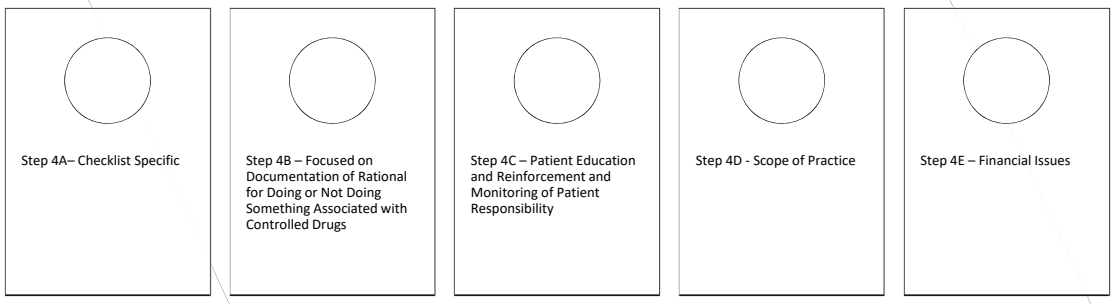
Q3: *What number from 0–10 describes how, during the past week, pain has interfered with your general activity?*
0 = "not at all", 10 = "complete interference"

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

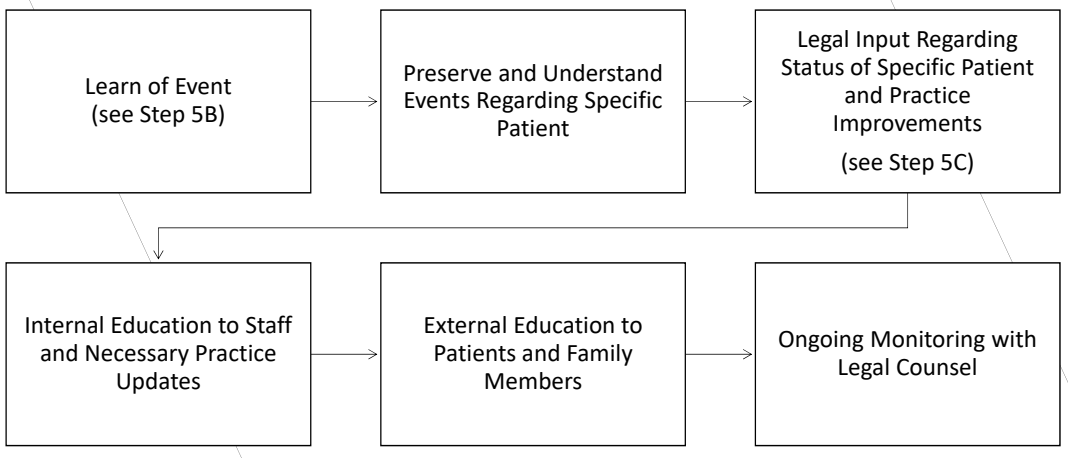
TO LEARN MORE
WWW.CDC.GOV/DRUGOVERDOSE/PRESCRIBING/GUIDELINE

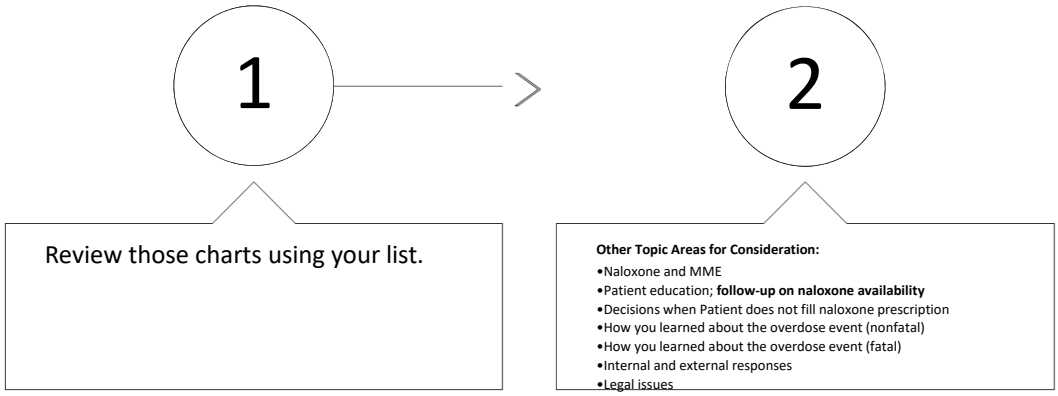
March 2016

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



Step 5A – Create a risk triage plan





Step 5B – Identify Patients That You Know Have Had an Overdose Event (Fatal or Non-Fatal)

Step 5C – Follow through with your plan and update it periodically

Individualized Patient Care

Looks backwards and constantly reevaluates the data points

And demonstrates moving forward in the patient's best interest

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!

jbolen@legalsideofpain.com
865-755-2369