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

<table>
<thead>
<tr>
<th>Documentation</th>
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<tr>
<td>Evaluation</td>
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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?

1. Do you prescribe opioids and/or benzodiazepines?
2. Do you have patients with medical co-morbidities, such as sleep apnea, asthma?
3. Do you have patients on more than 90mg MME?
4. Do you have patients with substance abuse histories, including ETOH, 6-AM, and THC?
5. Do you have patients who have been discharged from other practices because of aberrant, drug-related behavior?

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

1. New Patient
2. Established Patient – High risk
3. Established Patient – Using opioids >3 years

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”

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

<table>
<thead>
<tr>
<th>Historical Steps with Patient</th>
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<tbody>
<tr>
<td>General medical history</td>
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<tr>
<td>Pain specific history</td>
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<tr>
<td>Risk of abuse/addiction</td>
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<td>Risk of diversion</td>
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<td>Risk of overdose</td>
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<th>Active Care Plan Steps</th>
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<tr>
<td>Opioid trial</td>
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<td>Exit strategy</td>
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<td>Treatment plan for frequency, handling MME, PDMP utilization, drug testing, etc.</td>
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<tr>
<td>Naloxone</td>
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<td>Patient education</td>
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<td>Documentation and process of informed consent and treatment agreement</td>
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<tr>
<th>Coordination of Care and Consultations/Referrals</th>
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<tr>
<td>Scope of practice issues</td>
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<tr>
<td>Exchange of documentation between PCP and Specialty providers engaged in chronic MEDICATION therapy (not just limited to opioids)</td>
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<tr>
<td>Dealing with marijuana issues</td>
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<tr>
<td>Rationale for starting, stopping, changing, etc.</td>
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</table>
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-opiod-dur
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 Epidemic 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 materials 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
  Sarah E. Wexelman, 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 a comprehensive electronic repository of training materials and educational resources to support evidence-based treatment
  LEARN MORE:

- AAFP 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 >
AMA Task Force Recommendations on Naloxone
Step 3 – Make a List of Licensing Board and Professional Standards “Directives”

<table>
<thead>
<tr>
<th>Shall/Must</th>
<th>Shall Not/Must Not</th>
<th>Should/May</th>
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<tbody>
<tr>
<td>Common Examples</td>
<td>Common Examples</td>
<td>Common Examples</td>
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CDC Opioid Prescribing Guidelines - Checklist
Steps 4A through 4E – Review Charts with Directives List in Mind; Ask: Where am I vulnerable?

Step 4A – Checklist Specific
Step 4B – Focused on Documentation of Rational for Doing or Not Doing Something Associated with Controlled Drugs
Step 4C – Patient Education and Reinforcement and Monitoring of Patient Responsibility
Step 4D – Scope of Practice
Step 4E – Financial Issues

Step 5A – Create a risk triage plan

Learn of Event (see Step 5B) ➔ Preserve and Understand Events Regarding Specific Patient ➔ Legal Input Regarding Status of Specific Patient and Practice Improvements (see Step 5C)

Internal Education to Staff and Necessary Practice Updates ➔ External Education to Patients and Family Members ➔ Ongoing Monitoring with Legal Counsel
Step 5B – Identify Patients That You Know Have Had an Overdose Event (Fatal or Non-Fatal)

Review those charts using your list.

Other Topic Areas for Consideration:
- Naloxone and MME
- Patient education; follow-up on naloxone availability
- Decisions when Patient does not fill naloxone prescription
- How you learned about the overdose event (nonfatal)
- How you learned about the overdose event (fatal)
- Internal and external responses
- Legal issues

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

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