Embrace Changes and Mitigate Legal Risks Associated with Opioid Prescribing and the Issue of Overdose: An Updated Blueprint for the Frontline Pain Practitioner and Medical Directors

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Learning Objectives

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OBJECTIVES 1 and 2:

1. Identify Common Trends in Legal Actions against a Prescriber when a Patient Overdoses and Dies.

2. Describe Critical Perspectives Around the Licensing Board’s Request for the chart and a Summary of Care.

Dear Pain Management Practitioner:

- Love, Your licensing board
- PS: You have 21 days to do this!

The typical case goes something like this...
Necessary framework and path forward

Licensing Board Inquiry – Understand Perspectives (and the playing field)

If you have done your job... Then maybe
What questions does the licensing board investigator try to answer? – Critical Perspectives

• Does the record show that the Practitioner issued a Controlled Substance Prescription:
  1. With or Without a proper evaluation, including proper risk communication, prior to issuing a prescription and create a treatment plan?
  2. With or Without ongoing evaluation and risk mitigation, including intake and any other available information?
  3. With or Without proper documentation, including rationale for starting, changing, or stopping opioids? Is the rationale for the prescribed drugs fairly stated in the medical record?

• Is there Without Coordinating Care?

Reminder: Core Responsibilities when Prescribing Controlled Substances

<table>
<thead>
<tr>
<th>DEA Standards</th>
<th>Licensing Board Standards</th>
<th>Position of Trust over the Patient</th>
</tr>
</thead>
</table>

DEA “Standards” for Registrants who Prescribe Controlled Substances

- Legitimate Medical Purpose
- Skillful Counsel of Professional Practice
- Reasonable Steps to Prevent Abuse and Diversion

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Licensing Board and Professional “Standards” and Documentation of Same

- Historical Steps with Patient
  - Patient medical history
  - Prior specific history
  - Risk of Misuse/Abuse
  - Risk of Overdose

- Active Case Plan Steps
  - Range of practice issues
  - Change of documentation between PCP and specialty
  - Provide targeted clinical practice recommendations to inform the treatment plan (related to opioid-related issues)

- Combination of Care and Coordination/Referral
  - Medication for driving, stopping, sleeping, etc.

Sample Licensing Board Guidelines/Rules

- Example is from California and a comparison between the California Pain Guidelines (2014) to the CDC Guidelines (2016)

California Comparison Continued
OBJECTIVES 3 and 4:
3. List three common risk mitigation weaknesses associated with chronic opioid therapy
4. Create an action plan for changing how clinicians address the same with their staff and patients addressing these in daily practice and medical record documentation.

LEGAL PERSPECTIVE:
Three common risk mitigation weaknesses associated with chronic opioid therapy

1. Poor Risk Assessment Process and Follow Through
2. Continued Use of an Ineffective Drug Test Reveals Risk Monitoring
3. Failure to Coordinate Care with Other Healthcare Providers and Lack of Patient Education Related to Transition of Care Issues

Recent Clinical Literature Examining Potentially Inappropriate Prescribing Behavior and Connection to Overdose and Mortality
Comparing PIP to Our Anecdotal Audit Findings

Comparing PIP to Our Anecdotal Audit Findings - 2
Part 2 –
Meet John Smith, Jane Doe, and a Young Guy
Examining three critical areas of risk mitigation weaknesses through case examples

Case Example #1 – John Smith

- Patient is a 62-year-old male
- He was crossing the street and got hit by a bus. Rib fractures, skull bone fracture. Spent several months in the hospital and undergoing rehabilitation.
- Patient was in adverse pain
- He smoked. Is being treated for depression and anxiety.
- Patient has a history of drinking and smoking.
- Patient has a history of aberrant drug-related behaviors, including use of pain relievers, benzodiazepines, and benzodiazepines.
- Patient has a very high CRHIF-R score (high risk).
John Smith’s Risk Assessment History

John Smith – Initial MME
- 75 mg/day fentanyl
- 60 mg buprenorphine, 84 per day

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.
- During visit, provider:
  - Rx FENTANYL, 50mg Q72 = 120 mg MME
  - Rx Oxycodone, 10mg Q8 hours (80mg) = 60mg MME
  - Rx Alprazolam to keep patient from having seizures; supply one: 7 days (1 tablet 0.5 mg)
  - Total MME is 180mg/day
- Requested Drug Test
- Updated SOAP-P-R
- Patient’s BP was 88/64
SAMPLE STATE RULE ON USE OF DRUG TEST RESULTS (INDIANA)

Case Example #2 – Meet Jane Doe

CASE STUDY #2 – JANE DOE – UDT Summary
Case Example #3 – Just a young guy

Patient is a 32 year old.


Patient fell off of construction roof 6 weeks prior, fractured spine, underwent surgery to repair the surgery due ended face of body, resulting in replacement. Needs spine surgery. MRI diagnostic, lower damage. Neurologic follow.

In hospital – eval and UC special of back x rays. As such: none. Current history: hypophosphatemia. No evidence of pathologic condition. To rule out hypothyroidism for hypophosphatemia evaluation needed in further.

Patient has a history of smoking one pack a day for 9 years. Prescribed an inhaler.

Patient prescribed oxynormone tablets and Gabapentin (high dose). Morphine for pain.

Patient recently back from physical rehabilitation. Continued treatment with pain practitioner’s office during rehabilitation for psychosis and pain management.
OBJECTIVES 4 and 5:

4. Create an action plan for changing how clinicians address the same with their staff and patients addressing these in daily practice and medical record documentation.

5. Discuss case examples using a before and after application of the three pronged risk mitigation improvement plan.
Do you prescribe opioids and/or benzodiazepines?

Do you have patients with medical co-morbidities, such as sleep apnea, arthritis?

Do you have patients on more than 90mg MMED?

Do you have patients with substance abuse histories, including FTLD, AUD, and TIC?

Do you have patients with psychiatric disorders, including PTSD?

Do you have patients who have been discharged from other practices because of aberrant drug-related behavior?

START HERE ➔ Ask yourself these questions (and more)

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**Step 1 — Select Three Charts to Review**

- New Patient
- Established Patient — High Risk
- Established Patient — Using opioids >3 years

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**Step 2 — Make a List of Licensing Board and Professional Standards “Directives”**

- Shall/Must
- Should/May
- Shall Not/Must Not

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INDIANA RULE — EVALUATION AND RISK STRATIFICATION

444 IAC 5-6-4 Evaluation and risk stratification by physicians
Authority: IC 25-25-1.5-2, 25-25-9-3-2
Afforded: IC 25-2-3.5, 25-3.5-2.5

Sec. 4 (c) The physician shall document the patient's current opioid medical history and physical exam and obtain or make appropriate tests as indicated.

(1) Before initiating an opioid, the physician shall:
(a) Document the patient's current opioid medical history and physical exam and obtain or make appropriate tests as indicated.
(b) Initiate a written or electronic prescription for opioids only in emergency or life-saving situations as determined by the attending physician or other health care provider.
(c) Review the patient's current opioid medical history and physical exam and obtain or make appropriate tests as indicated.
(d) Document the patient's current opioid medical history and physical exam and obtain or make appropriate tests as indicated.
(e) Document the patient's current opioid medical history and physical exam and obtain or make appropriate tests as indicated.
(f) Document the patient's current opioid medical history and physical exam and obtain or make appropriate tests as indicated.
(g) Document the patient's current opioid medical history and physical exam and obtain or make appropriate tests as indicated.

CDC Opioid Prescribing Guidelines - Checklist

Step 3 –
Review Charts with Directives List in Mind;
Ask: Where am I vulnerable?

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Risk Evaluation and Risk Management

Turn your weaknesses into strengths and change the conversation with the patient.

RISK DOMAINS CHECKLIST – FROM Argoft, et al

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 (e.g., depression, anxiety).
• Sleep-disordered breathing.
• Concurrent benzodiazepine use.
RISK-Behavior Tracking Form Ideas

You cannot effectively talk with a patient about risk issues, if you do not have an overall understanding of the patient's behavioral patterns.

Proper Timing and Use of UDT Results (with or without Aberrant Behaviors)

Addressing the Weaknesses

REPRISE:

Now, how do you handle Jane Doe’s UDT report?

<table>
<thead>
<tr>
<th>UDT</th>
<th>ISSUE</th>
<th>BEHAVIOR</th>
<th>UDT DATES</th>
<th>UDT SUMMARY</th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>1/1/14</td>
<td>Independent - Standard Test</td>
<td>2/2/14</td>
<td>No abnormal behavior identified</td>
<td>Discourage further use of the device at home.</td>
</tr>
<tr>
<td>Yes</td>
<td>5/5/14</td>
<td>Independent - Standard Test</td>
<td>6/6/14</td>
<td>No abnormal behavior identified</td>
<td>Discourage further use of the device at home.</td>
</tr>
<tr>
<td>Yes</td>
<td>7/7/14</td>
<td>Independent - Standard Test</td>
<td>8/8/14</td>
<td>No abnormal behavior identified</td>
<td>Discourage further use of the device at home.</td>
</tr>
</tbody>
</table>
UDT TRIAGE PROTOCOL

Routine

Requires Outreach to Patient in Short Order

Requires IMMEDIATE Attention

Sample Treatment Decisions following Risky Behaviors and Aberrant UDT Results

<table>
<thead>
<tr>
<th>Risk Responses: Positives (note work, cause do not - keep the patient at the center and document otherwise)</th>
<th>Treatment Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discussed the behavior/need</td>
<td>Require more frequent visits</td>
</tr>
<tr>
<td>Require increased UDT* with caution and selectively if known role</td>
<td>Implement opioid supply controls (lower dose units in more frequently issued prescriptions)</td>
</tr>
<tr>
<td>Refer for substance-abuse treatment</td>
<td>Require increased PPAR database checks</td>
</tr>
<tr>
<td>Plan reduction in opioid dose and taper off of medication (terminate the medication)</td>
<td>Refer for mental health evaluation</td>
</tr>
<tr>
<td>Educate patient</td>
<td>Refer to specialty service</td>
</tr>
</tbody>
</table>

*=Serious step (serious step and requires its own literature)
Critical Coordination of Care Issue – I’m out of my Benzodiazepines

- "My primary care physician is out of town and I’m afraid I won’t get seen if I need to wait for him to return; do you have anything similar or equivalent to Tramadol or Clonazepam or similar?"

- "I am not doing well and not dealing with the increased pain I am having because you reduced my opioid last time. I am seeing a psychiatrist to help me cope with the pain, and he told me that I should go back up on my dose of ... to help me deal with the insomnia and anxiety."

Reprise: Now, how do you handle John Smith’s report?
**Step 4A - Create a risk triage plan**

- Learn of Event (see Step 4B)
- Internal Education to Staff and Necessary Practice Updates
- Preserve Chart and Understand Events Regarding Specific Patient
- External Education to Patients and Family Members
- Obtain Legal Input Regarding Status of Specific Patient and Practice Improvements (see Step 4C)
- Ongoing Monitoring with Legal Counsel

**Step 4B – Identify Patients That May be at risk for Overdose Event (Fatal or Non-Fatal) and Review their Charts**

**Other Topic Areas for Consideration:**
- Naloxone and NUE
- Patient Education; Follow-up on Naloxone Availability
- Decisions when Patient Does not Fill Naloxone Prescription
- How you learned about the Overdose Event (Non-Fatal)
- How you learned about the Overdose Event (Fatal)
- Internal and External Responses
- Legal Issues

**Step 4C - Follow through with your plan and update it periodically**

**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
Checklists

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Thank you!