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

I am reporting to you the results of the review by the [STATE] Board of Medical Examiners of the ‘Board’ of the complaint filed regarding the [professional] individual… In the course of the inquiry, the Board considered your response.

The Board has completed its review of the facts related to this matter and has determined that the issues identified were not sufficient to constitute a violation of the law, the code of ethics, or the rules governing the practice of medicine. Therefore, the Board is not taking any further action in this matter.

The Board, in its discretion, determines that the best interest of the public and the profession is served by taking no action in this matter. The Board has decided that the matter should be closed.

This disposition of the complaint is being placed in the confidential file of the Board. If you have any further questions or concerns about this matter, please contact the Board’s executive director at [Phone number].
What questions does the licensing board investigator try to answer? — Critical Perspectives

- Does the record show that the Practitioner issued a Controlled Substance Prescription?

  - With or Without a proper evaluation, including proper risk
    assessment, and with adequate documentation of the evaluation
    and rationale for prescribing or continuing the prescription?

  - With or Without ongoing evaluation and risk mitigation, including
    review of the patient’s RMP, UDDI results, database, and other
    controlled substances?

  - With or Without the proper documentation, including rationale for
    starting, changing, or stopping opioids, is the rationale for the
    prescribed drugs clearly stated in the medical record?

  - With or 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

<table>
<thead>
<tr>
<th>Legitimate Medical Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>True or more generally recognized medical indication for the use of the controlled substance</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Usual Course of Professional Practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>According to licensing and professional standards, including consideration of the patient’s medical history and other factors</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reasonable Steps to Prevent Abuse and Diversion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proper Risk Evaluation, Identification, and Reporting, including controlled substance evaluations</td>
</tr>
<tr>
<td>PMP - UDIC, NAXICONE, OPPDO, TRAIL, VIGITEL, RISE-ON, others</td>
</tr>
<tr>
<td>Many other “reasonable steps”</td>
</tr>
</tbody>
</table>

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Licensing Board and Professional “Standards” and Documentation of Same

Historical Steps with Patient:
- Family medical history
- Prior specific history
- Risk of abuse/addiction
- Risk of overdose

Acute Care: Risk Step:
- Dose and route of pain control
- Treatment Plan for frequency, dosing, MME, ADEP utilization
- Education and patient education
- Documentation and impact of informed consent and treatment agreement

Combination of Care and Communication/Method:
- Reason for Practice issues
- Exchange of information between PCP and specialty
- Provide targeted clinical
- Protocol for managing and potential patient education
- Meeting with multidisciplinary
- Medication for differing, stopping, tapering

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. Ordinarily Use of an Failure to Link Drug Test Results in Risk Monitoring

3. Failure to Coordinate Care with Other Healthcare Providers and Lack of Patient Education Related to Management of Care Issues

Recent Clinical Literature Examining Potentially Inappropriate Prescribing Behavior and Connection to Overdose and Mortality
Six Types of Potentially Inappropriate Opioid Prescribing Behaviors (PPI)

| MME >/= 100mg/day in >/= 3 mos. |

Comparing PIP to Our Anecdotal Audit Findings

<table>
<thead>
<tr>
<th>PIP Article</th>
<th>Body Group Audit Findings</th>
<th>General Suggestions for Improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Meeting PI criteria for 3 consecutive quarters</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not Meeting PI criteria for 12 consecutive quarters</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of patients prescribed higher than 15mg/day of any opioid</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of patients prescribed higher than 100mg/day of any opioid</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of patients prescribed higher than 45mg/day of any opioid</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of patients prescribed higher than 75mg/day of any opioid</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of patients prescribed higher than 10mg/day of any opioid</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Comparing PIP to Our Anecdotal Audit Findings - 2

<table>
<thead>
<tr>
<th>PIP Article</th>
<th>Body Group Audit Findings</th>
<th>General Suggestions for Improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOT MENTIONED</td>
<td>INCONSISTENT OR LACK OF USE OF ANY RISK ASSESSMENT PLAN OR SUMMARY OF FINDINGS</td>
<td>See Sample Tool</td>
</tr>
<tr>
<td>NOT MENTIONED</td>
<td>Delayed timing in review of UDT results and use of those results in treatment of patient</td>
<td>1. UDT Results Triage 2. Ongoing Use of UDT results in Tx 3. Documentation 4. See UDT Lecture</td>
</tr>
</tbody>
</table>
The mindset is to create the “cheese trail” that reflects the prescriber’s rationale at various data points.

Part 2 – Meet John Smith, Jane Doe, and a Young Guy
Examining three critical areas of risk mitigation: weakness through case examples

Case Example #1 – John Smith

Patient is a 33 year male.

He was crossing the street and got hit by a bus. Able to return home.
Able to return home for several months in the hospital and undergoing rehabilitation.

Patient was in extensive pain.

In episodes, he experienced episodes of depression.

Patient has a history of drinking and smoking.

Patient has a history of aberrant drug-related behaviors, including use of oxycodone/paracetamol and oxycodone.

Patient has a very high ADRP score (high risk).
### John Smith’s Risk Assessment History

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complained of anxiety</td>
<td>Lack of sleep, pain, and alcohol troubles.</td>
</tr>
<tr>
<td>Concerned about running</td>
<td>Out of alprazolam because his prescribing physician is not available.</td>
</tr>
<tr>
<td>During visit, provider:</td>
<td>- Rx FENTANYL, 50mg Q12h = 120 mg MME</td>
</tr>
<tr>
<td></td>
<td>- Rx Oxycodone, 10mg Q6h hours (60mg) = 60mg MME</td>
</tr>
<tr>
<td></td>
<td>- Rx Alprazolam to keep patient from having seizures;</td>
</tr>
<tr>
<td></td>
<td>- supply oxycodone 7 days (1 tablet BID)</td>
</tr>
<tr>
<td></td>
<td>Total MME 180mg/day</td>
</tr>
<tr>
<td></td>
<td>Requested Drug Test</td>
</tr>
<tr>
<td></td>
<td>Updated SOAPPE</td>
</tr>
<tr>
<td></td>
<td>Patient’s BP was 88/64</td>
</tr>
</tbody>
</table>
SAMPLE STATE RULE ON USE OF DRUG TEST RESULTS (INDIANA)

CASE STUDY #2 – JANE DOE – UDT Summary

<table>
<thead>
<tr>
<th>METAL SPECI TEST and DESIGNATE SITE</th>
<th>UDT RESULTS</th>
<th>DATA ON LAB REPORT</th>
<th>DATA ON CLINIC RECORD</th>
<th>RESULTS</th>
<th>Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Client A</td>
<td>5/6/16</td>
<td>3/6/16</td>
<td>Independent</td>
<td>TCA</td>
<td>3/6/16</td>
</tr>
<tr>
<td>Client B</td>
<td>5/6/16</td>
<td>3/6/16</td>
<td>Independent</td>
<td>TCA</td>
<td>3/6/16</td>
</tr>
<tr>
<td>Client C</td>
<td>5/6/16</td>
<td>3/6/16</td>
<td>Independent</td>
<td>TCA</td>
<td>3/6/16</td>
</tr>
<tr>
<td>Client D</td>
<td>5/6/16</td>
<td>3/6/16</td>
<td>Independent</td>
<td>TCA</td>
<td>3/6/16</td>
</tr>
</tbody>
</table>

Case Example #2 – Meet Jane Doe

- February 12th
- February 20th
- March 1st
- March 20th
- April 1st
- April 20th
- May 1st
- May 20th
- June 1st
- June 20th
- July 1st
- July 20th
- August 1st
- August 20th
- September 1st
- September 20th
- October 1st
- October 20th
- November 1st
- November 20th
- December 1st
- December 20th

CASE STUDY #2 – JANE DOE – UDT Summary

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<td>3/6/16</td>
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<td>TCA</td>
<td>3/6/16</td>
</tr>
</tbody>
</table>
Case Example #3 – Just a young guy

Patient is a 21-year-old male.

Admitted with an acute illness, related to the blisters. Consultant ordered, progressed and responded.

Patient had a history of cocaine use, but was otherwise healthy. No allergies or adverse reactions were noted.

Patient fell off of the back of a bus in early April – sustained injury, resulting in a hip fracture. No symptoms since early April.

Patient was treated with IV antibiotics, IV fluids, and pain management. Pain was controlled with IV narcotics.

Patient has been treated with oral antibiotics and physical therapy. No further treatment required.

Patient prescribed analgesics and anti-inflammatory medications. Medication schedule:

- Ibuprofen (800mg) q6h
- Naproxen (500mg) q6h

Pain was relieved with the above medications. Patient was discharged with a follow-up appointment.

Patient's physical therapy continued with a focus on strengthening exercises.

Patient prescribed analgesics and anti-inflammatory medications. Medication schedule:

- Ibuprofen (800mg) q6h
- Naproxen (500mg) q6h
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 80mg OMM?

Do you have patients with substance abuse histories, including ETOH, hhc, and THC?

Do you have patients with psychiatric disorders, including PTSD?

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

START HERE ➔ Ask yourself these questions (and more)

---

**Step 1 —**

Select Three Charts to Review

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

---

**Step 2 —**

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

- Shall/Must
- Should/May
- Shall Not/Must Not
INDIANA RULE – EVALUATION AND RISK STRATIFICATION

644 IAC 7-6-6 Evaluation and risk stratification by physicians

Subpart B: 28-3-4-6; 28-3-5-4-6

Annexed: 28-3-4-6; 28-3-5-6

Sec. 6. (c) The physician should document in the patient’s medical record, in a legible manner, the

evaluation and risk stratification performed and the treatment plan. The treatment plan

should be reviewed and updated at least every 30 days.

(b) The physician must document the patient’s pain management plan, including the

treatment goals and the types of medications prescribed.

(c) The physician must document the patient’s readiness for treatment, including

the patient’s willingness to participate in the treatment plan.

(d) The physician must document the patient’s response to treatment, including

the patient’s improvement or lack of improvement.

(e) The physician must document the patient’s adherence to the treatment plan, including

the patient’s willingness to comply with the treatment plan.

(f) The physician must document the patient’s satisfaction with the treatment plan, including

the patient’s willingness to recommend the treatment plan to others.

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

[Image of a flowchart or diagram]

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.

(Rotational Urine Drug Monitoring in Patients Receiving opioids for Chronic Pain: Consensus Recommendations, by Charles C. Argoft, MD,* Daniel F. Alford, MD, MPH,* Jeffrey Fudos, PharmD, DANPA, FCP, FASHP et al., Pain Medicine 2017; 0: 0-0)
RISK-Behavior Tracking Form Ideas

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?
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: Possibilities (note work, cause not - keep the patient at the center and document decisions)</th>
<th>Discussion/Feedback</th>
<th>Require more frequent visits</th>
<th>Require increased SIDP database checks</th>
<th>Implement special supply controls (lower dosage units in more frequently issued prescriptions)</th>
<th>Propose a change of medication, dosing, formulation, etc.</th>
<th>Refer for substance abuse treatment</th>
<th>Refer for mental health evaluation</th>
<th>Refer to specialty care</th>
<th>Plan reduction in opioid dose and taper off of medication (facilitate the medication)</th>
<th>Disposition</th>
<th>Prescribe</th>
<th>Withdraw from care* (serious step and requires its own timeline)</th>
<th>Educate</th>
<th>Give more choices ( både and care)</th>
<th>Other</th>
</tr>
</thead>
</table>

Addressing the Weaknesses
Coordination of Care
Critical Coordination of Care Issue – I’m out of my Benzodiazepines

1. What if the person has limited access to the leftover medication and it’s not available?
2. What if the person is in crisis or very ill?
3. What if the person has limited access to the leftover medication and it’s not available?
4. What if the person is in crisis or very ill?
5. What if the person “fails” to come back another time?
6. What if the person “fails” to come back another time?
Patient Risk Mitigation & Risk Education

Educate Patients and Staff Members

- [Link to CDC website]
- [Link to SAMHSA website]
- [Link to Opioid-Related Website]
Step 4A - Create a risk triage plan

- Learn of Event (see Step 4B)
- Preserve Chart and Understand Events Regarding Specific Patient
- Obtain Legal Input Regarding Status of Specific Patient and Practice Improvements (see Step 4C)
- Internal Education to Staff and Necessary Practice Updates
- External Education to Patients and Family Members
- 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 N/A
- 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
<table>
<thead>
<tr>
<th>Learning Readiness</th>
<th>Academic Readiness</th>
<th>Risk Assessment</th>
<th>Health &amp; Safety</th>
<th>Parent and Family Engagement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Academic Standards</td>
<td>Academic Standards</td>
<td>Risk Factors</td>
<td>Health Indicators</td>
<td>Parental Involvement</td>
</tr>
<tr>
<td>Language</td>
<td>Mathematics</td>
<td>Physical Health</td>
<td>Mental Health</td>
<td>Communication Skills</td>
</tr>
<tr>
<td>Social Skills</td>
<td>Critical Thinking</td>
<td>Safety Guidelines</td>
<td>Nutrition</td>
<td>Support Networks</td>
</tr>
<tr>
<td>Technology</td>
<td>Creative Problem Solving</td>
<td>Emergency Instructions</td>
<td>Physical Activity</td>
<td>Community Resources</td>
</tr>
<tr>
<td>Emotional Well-being</td>
<td>Interpersonal Skills</td>
<td>First Aid Procedures</td>
<td>Sleep Habits</td>
<td>[empty]</td>
</tr>
</tbody>
</table>

---

**Checklists**

---

**Thank you!**