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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Disclosures for Jennifer Bolen, JD

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- Consultant - Abbott/Alere Toxicology
- Consultant - MTL Solutions, LLC
- Consultant - MyMOMD
- Consultant - Paradigm Labs
- Consultant - Pernix Therapeutics
- Consultant - ReCept Pharmacy
- Consultant - Westox Labs

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# Learning Objectives

<table>
<thead>
<tr>
<th>Identify</th>
<th>Identify common trends in legal actions against prescribers when a patient overdoses and dies.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Describe</td>
<td>Describe critical perspectives around a proper response to the licensing board’s request for the chart and a summary of care.</td>
</tr>
<tr>
<td>List</td>
<td>List three common risk mitigation weaknesses associated with chronic opioid therapy.</td>
</tr>
<tr>
<td>Explain</td>
<td>Explain how to 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.</td>
</tr>
<tr>
<td>Discuss</td>
<td>Discuss case examples using a before and after application of the three pronged risk mitigation improvement plan.</td>
</tr>
</tbody>
</table>

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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 . . .

<table>
<thead>
<tr>
<th>Get</th>
<th>Get Letter</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Hit the Panic Button</td>
</tr>
<tr>
<td></td>
<td>Reality Sets in</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Talk</th>
<th>Talk to Lawyer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Gather Files; Hit Panic Button</td>
</tr>
<tr>
<td></td>
<td>Denial takes hold, with Anger as a seat buddy</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Make</th>
<th>Make a Choice</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Approach with Confidence and Send in Fact-Filled, Humble Response; Fight if you have to</td>
</tr>
<tr>
<td></td>
<td>OR Continue Denial and Fight without a helpful framework</td>
</tr>
</tbody>
</table>
Necessary framework and path forward

<table>
<thead>
<tr>
<th>Freeze</th>
<th>Freeze Records</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Copy and Review</td>
</tr>
<tr>
<td></td>
<td>• NOTE THE FACTS; Avoid Opinion at First</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Match</th>
<th>Match Facts Against Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Evaluate Strengths and Weaknesses</td>
</tr>
<tr>
<td></td>
<td>• Identify potential expert support</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Prepare</th>
<th>Prepare Response* (assuming advice of counsel is to do this)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Carefully mix case facts with humble description of decision-making</td>
</tr>
<tr>
<td></td>
<td>• Wait and see, but prepare for possible next steps</td>
</tr>
</tbody>
</table>

---

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

<table>
<thead>
<tr>
<th>What the Board sees through the eyes of the complainant</th>
<th>What you see (and think) when confronted with a Board letter</th>
<th>Reconciling the realities and embracing necessary changes/updates to your program</th>
</tr>
</thead>
<tbody>
<tr>
<td>Someone has died</td>
<td>What? Why didn’t they tell me sooner?</td>
<td>What is in your charts that shows your rationale for each medication?</td>
</tr>
<tr>
<td>You were prescribing them opioids and other medication</td>
<td>Yes, they were in pain.</td>
<td>What type of risk monitoring were you doing? Did anything slip through the cracks? UOT Timing? Risk Status? Coordination of Care?</td>
</tr>
<tr>
<td>They died within a week or of getting their last prescription from you</td>
<td>What? Why didn’t they tell me sooner?</td>
<td>Did you have prior contact with the family member? Anything in writing? How about patient education?</td>
</tr>
<tr>
<td>The complainant is a family member who knows the person who died and the story is compelling</td>
<td>Uh-oh.</td>
<td>Do your records speak for you?</td>
</tr>
<tr>
<td>The complainant usually articulates facts that you either didn’t know, didn’t fully explore, or ignored. The Board wants to see the story your records tell.</td>
<td>1.  No one told me. 2. They told me, but I didn’t respond. 3. They told me, but my lawyer said not to respond. 4. I did everything right.</td>
<td>Does your attorney speak pain? Do you need experts? The answer depends on many things.</td>
</tr>
<tr>
<td>The board wants a full explanation. You have important legal rights, but the board is watching how you handle your response.</td>
<td>My attorney will solve everything. Right.?</td>
<td></td>
</tr>
</tbody>
</table>

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12/4/18
If you have done your job... Then maybe

I am reporting to you the results of the review by the Board of Medical Examiners (the “Board”) of the complaint filed regarding the above-referenced 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 distressing to the complainant, but do not provide any basis to initiate disciplinary action.

The Board initiated this review because of its duty to safeguard the public by assureing that you, as a physician licensed to practice in this State, are complying with applicable statutes, regulations, and accepted standards of practice. As such, this matter is administratively closed.

This disposition of the complaint is being placed in the confidential files of the Board. Please be aware that, within this context, the complainant will be appropriately advised of the Board’s handling of this matter.

What questions does the licensing board investigator try to answer? – Critical Perspectives

- Does the record show that the Practitioner Issue a Controlled Substance Prescription:
  - With or Without a proper evaluation, including proper risk assessment, and did he/she arrive at a diagnosis and create a treatment plan with goals and measurable milestones?
  - With or Without ongoing evaluation and risk mitigation, including timely use of the state’s PDMP, UDT results, naloxone, and other control measures?
  - With or Without the proper documentation, including rationale for starting, changing, not stopping opioids; Is the rationale for the prescribed drugs clearly stated in the medical record?
  - With or Without Coordinating Care?

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Reminder: Core Responsibilities when Prescribing Controlled Substances

DEA Standards | Licensing Board Standards | Position of Trust over the Patient

DEA “Standards” for Registrants who Prescribe Controlled Substances

<table>
<thead>
<tr>
<th>Legitimate Medical Purpose</th>
<th>One or more generally recognized medical indication for the use of the controlled substance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Usual Course of Professional Practice</td>
<td>According to licensing and professional standards, including consideration of licensing board material; Steps of a “Reasonably Prudent” Practitioner</td>
</tr>
<tr>
<td>Reasonable Steps to Prevent Abuse and Diversion</td>
<td>Proper Risk Evaluation, Stratification, and Monitoring Protocols, including overdose risk evaluation; PDMP, UDT, NALOXONE, OPIOID TRIAL, VISIT FREQUENCY; Many other “reasonable steps”</td>
</tr>
</tbody>
</table>
Licensing Board and Professional “Standards”
and Documentation of Same

<table>
<thead>
<tr>
<th>Historical Steps with Patient</th>
<th>Active Care Plan Steps</th>
<th>Coordination of Care and Consultations/Referrals</th>
</tr>
</thead>
<tbody>
<tr>
<td>• General medical history</td>
<td>• Opioid Trial and Some form of Exit Strategy</td>
<td>• Scope of Practice Issues</td>
</tr>
<tr>
<td>• Pain Specific History</td>
<td>• Treatment Plan for Frequency, Handling MME, PDMP utilization, UDT, etc.</td>
<td>• Exchange of documentation between PCP and Specialty providers engaged in chronic MEDICATION therapy (not just limited to opioids)</td>
</tr>
<tr>
<td>• Risk of Diversion</td>
<td>• Naloxone and Patient Education</td>
<td>• Dealing with Marijuana issues</td>
</tr>
<tr>
<td>• Risk of Overdose</td>
<td>• Documentation and Process of Informed Consent and Treatment Agreement</td>
<td>• Rationale for starting, stopping, changing, etc.</td>
</tr>
</tbody>
</table>

Sample Licensing Board Guidelines/Rules

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

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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. Untimely Use of or Failure to Use Drug Test Results in Risk Monitoring
3. Failure to Coordinate Care with Other Healthcare Providers and Lack of Patient Education Related to Coordination of Care Issues

A QUICK PUB MED SEARCH

Recent Clinical Literature Examining Potentially Inappropriate Prescribing Behavior and Connection to Overdose and Mortality

1. Potentially Inappropriate Opioid Prescribing, Overdose, and Mortality in Massachusetts, 2011-2015
   - PMID: 29665230
   - Broker articles

2. Controlled Substance Prescribing Patterns and Prescription Behavior Surveillance System, Eighth
   - Shostal, J. 2013
   - PMID: 23930612
   - Broker articles

3. Patterns of Opioid Use and Risk of Opioid-Related Death Among Medicaid Patients
   - PMID: 29001175
   - Broker articles

4. High-risk use by patients prescribed opioids for pain and its risk in overdose deaths
   - PMID: 24394873
   - Broker articles

5. Medication for Opioid Use Disorder After Nonfatal Opioid Overdose and Association With Mortality: A Cohort Study
   - PMID: 29891502
   - Broker articles

6. Association between opioid prescribing patterns and opioid overdose-related deaths
   - PMID: 24268768
   - Broker articles

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Six Types of Potentially Inappropriate Opioid Prescribing Behaviors (PIP)

MME $\geq$ 100mg/day in $\geq$ 3 mos.

<table>
<thead>
<tr>
<th>Overlapping Opioid and Benzo Prescriptions in $\geq$ 3 mos.</th>
<th>$\geq$ 4 prescribers in any quarter</th>
<th>$\geq$ 4 dispensing pharmacies in any quarter</th>
<th>Cash purchase of opioids in $\geq$ 3 occasions</th>
<th>Receipt of opioids in $\geq$ 3 mos. without a documented pain diagnosis</th>
</tr>
</thead>
</table>

- Frequent failures to track MME
- Sometimes overlapping involves more than one opioid and more than one Benzo prescriber along with sleep medication, muscle relaxants, etc. and rationale not documented; coordination of care missing.
- Multiple prescribers often involved people in the same practice or PCP/Internal Medicine, Pain Specialist, and Psychiatrist
- Multiple pharmacists happen for different reasons. Sometimes not clear in chart.
- Didn’t find in our audit
- Found mixed results on pain diagnosis. Sometimes specific diagnosis after workup. Other times, general diagnosis and failure to reevaluate after initial opioid trial period.

Comparing PIP to Our Anecdotal Audit Findings

<table>
<thead>
<tr>
<th>PIP Article</th>
<th>Bolen Group Audit Findings</th>
<th>General Suggestions for Improvement</th>
</tr>
</thead>
</table>
| MME $\geq$ 100mg/day for $\geq$ 3 mos. | Frequent failure to track MME | Track MME
1. Document rationale for combination prescribing
2. Coordinate care with BZD prescriber
3. May be appropriate to discuss reducing Benzo prescriptions or limiting time of use or time of reevaluation.

1. Use PDMP
2. Coordinate care with other physicians and pharmacists, especially for complex patient
3. Discuss need to know who treats patient and when medication is filled, what’s prescribed, and why.

- Outside scope of lecture
1. Perform a thorough evaluation
2. Document a specific diagnosis or working diagnosis
3. Evaluate frequently during first year and thereafter per standards.
Comparing PIP to Our Anecdotal Audit Findings - 2

<table>
<thead>
<tr>
<th>PIP Article</th>
<th>Bolen Group Audit Findings</th>
<th>Remedy</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</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Ongoing Use of UDT results in Tx</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Documentation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>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 y/o male
- He was crossing the street and got hit by a bus. Rib fractures. Collar bone fracture. Leg fracture. Spent several months in the hospital and undergoing rehabilitation. Patient now in chronic pain.
- Rx opioids. Rx benzodiazepines. Occasional Rx antidepressant use.
- Patient has a history of drinking and smoking.
- Patient has a history of aberrant drug related behaviors, including use of diphenhydramine and trazodone.
- Patient has a very high SOAPP-R score (high risk).
# John Smith’s Risk Assessment History

<table>
<thead>
<tr>
<th>DATA POINT</th>
<th>Initial OV</th>
<th>6 months in</th>
<th>1 year in</th>
<th>Month of OD</th>
</tr>
</thead>
<tbody>
<tr>
<td>SOAPP/Psych Testing</td>
<td>High risk Depression Scale</td>
<td>SOAPP scores 12 (high risk)</td>
<td>Still high risk</td>
<td>SOAPP-R last OV</td>
</tr>
<tr>
<td>Anxiety</td>
<td>Reports anxiety</td>
<td>Reports anxiety</td>
<td>Anxiety not reported/documented</td>
<td>Suffering from insomnia, panic attacks, amnesia/stress</td>
</tr>
<tr>
<td>Depression</td>
<td>Reports feeling more sad than usual (depressed)</td>
<td>Patient has past history of depression documented, and reports feeling more sad than usual (depressed)</td>
<td>Continues to see a psychologist</td>
<td>Resuming 3 forms of antidepressants. Patient reports depression</td>
</tr>
<tr>
<td>Use of Diphenhydramine</td>
<td>Positive in UDS on second visit</td>
<td>Positive in UDS at 6 months</td>
<td>Positive in UDS at 18 months</td>
<td>Positive in last UDS</td>
</tr>
<tr>
<td>Multiple Opioids</td>
<td>Fentanyl and Hydromorphone</td>
<td>Fentanyl and Hydromorphone</td>
<td>Fentanyl and Hydromorphone</td>
<td>Fentanyl and Oxydodone</td>
</tr>
<tr>
<td>Use of Benzodiazepines</td>
<td>Taking 1mg Alprazolam BID</td>
<td>Same</td>
<td>Oxazepam appears in UDS along with Alprazolam</td>
<td>Afraid will run out of Alprazolam because prescribing provider unavailable</td>
</tr>
<tr>
<td>Smoker</td>
<td>Current every day smoker: 1 PPD</td>
<td>Current every day smoker</td>
<td>Reported as a former smoker, but Cotinine continues to appear positive in UDS</td>
<td>Reported as former smoker</td>
</tr>
<tr>
<td>Drinker</td>
<td>Patient drinks 1-12 alcoholic beverages per month</td>
<td>Reported to drink 1-11 alcoholic beverages a month- Alcohol in UDS</td>
<td>Reported as non drinker</td>
<td>Patient reports alcohol abuse- not counseled</td>
</tr>
</tbody>
</table>

### MME
- 267mg MME
- 267mg MME
- 216mg MME
- 180mg MME

---

### John Smith – Initial MME
- 75 mcg/day Fentanyl
- 4mg hydromorphone, #6 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, 50mcg Q72 = 120 mg MME
  - Rx Oxycodone, 10mg Q6 hours (40mg) = 60mg MME
  - Rx Alprazolam to keep patient from having seizures; supply covers 7 days (1 tablet BID)
- Total MME is 180mg/day
- Requested Drug Test
- Updated SOAP-R
- Patient’s BP was 88/64

John Smith’s Last Risk Assessment Responses
Mar. 9, 20178
John Smith’s Drug Test Results – Timing and Utility

John Smith’s Last UDT Timeline

- Mar. 9, 2018
- Mar. 12, 2018
- Mar. 18, 2018
SAMPLE STATE RULE ON USE OF DRUG TEST RESULTS (INDIANA)

STANDARDS OF PROFESSIONAL CONDUCT AND COMPETENT PRACTICE OF MEDICINE

listed in subsection (b) if the physician reasonably determines following a review of less than all of the factors listed in subsection (b) that a drug monitoring test is medically necessary.

(d) Nothing about subsection (b) shall be construed to prohibit the physician from performing or ordering a drug monitoring test at any other time the physician considers appropriate.

(e) If a test performed under subsection (a), or conducted under subsection (d), reveals inconsistent medication use patterns or the presence of illicit substances, a review of the current treatment plan shall be required. Documentation of the revised treatment plan and discussion with the patient must be recorded in the patient's chart. (Medical Licensing Board of Indiana; 844 IAC 5-6-8; filed Oct 7, 2014, 12:27 p.m.: 20141105-IR-844140289FRA, eff Nov 1, 2014. [IC 44-22-2-36 suspends the effectiveness of a rule document for 30 days after filing with the Publisher. LSA Document #14-289 was filed Oct 7, 2014, 11:30 a.m.: 20160921-IR-844150415FRA]

Case Example #2 – Meet Jane Doe

- Patient is a 47 y/o female
- Does Karate and Ski. Broke her back skiing.
- Patient now in chronic pain and awaiting surgery.
- Rx opioids. Rx benzodiazepines. Occasional Rx sleep medicine use.
- Patient has a history of smoking but stopped 7 years ago.
- Patient received a codeine prescription from ED over the holidays because her back hurt so badly due to the cold weather. This was before she came to you.
- Patient scored "low risk" on SOAP-14 risk tool.
### CASE STUDY #2 – JANE DOE – UDT Summary

<table>
<thead>
<tr>
<th>INITIAL OFFICE VISIT and RELEVANT RX</th>
<th>UDT ORDERED</th>
<th>DATE ON LAB REPORT</th>
<th>Date EMR Shows Review</th>
<th>RESULTS</th>
<th>Aberrant?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/24/15 RX after OV = OXYCODONE Patient had prior Rx Tylenol #3</td>
<td>Yes</td>
<td>1/28/15</td>
<td>2/24/15</td>
<td>Gabapentin+ TCA+</td>
<td>Yes, Gabapentin not disclosed, but is Rx from another doctor. Oxycodone Rx given.</td>
</tr>
<tr>
<td>2/24/15 Rx is OXYCODONE, Morphine added</td>
<td>Yes</td>
<td>3/1/15</td>
<td>3/24/15</td>
<td>Gabapentin+ Oxycodone - TCA+ Dextromethorphan+</td>
<td>Yes, Dextromethorphan; Missing Rx Opioid (Oxy)</td>
</tr>
<tr>
<td>3/24/15 Rxs for Oxycodeone, Morphine, Gabapentin</td>
<td>Yes</td>
<td>4/2/15</td>
<td>4/24/15</td>
<td>Morphine+ Gabapentin+ Oxycodone +</td>
<td>Yes, Morphine+ but 6-MAM-NEG Oxycodone+</td>
</tr>
<tr>
<td>4/24/15 Rxs for Oxycodeone, Morphine, Gabapentin</td>
<td>Yes</td>
<td>5/26/1</td>
<td>Reviewed after Patient's death.</td>
<td>Morphine+ 6-MAM+ FENTANYL+ Oxycodone+</td>
<td>Patient overdosed and died.</td>
</tr>
</tbody>
</table>

### Case Example #3 – Just a young guy

Patient is a 33 y/o male

Adopted. Birth mother was an alcoholic. Served in the Marines. Combat in Iraq. Married and recently divorced.


Rx opioids – start and DC opioids off and on through care, as add naltrexone. Cannot tolerate Buprenorphine. Rx multiple psychiatric medications. Rx sleep medication. Rx Gabapentin. Multiple suicide attempts.

Patient has a history of smoking but now uses chewing tobacco. Prescribed an inhaler.

Patient prescribed naltrexone tablets and Gabapentin (high dose). NSAIDs for pain.

Patient recently back from alcohol rehabilitation. Continued treatment with pain practitioner’s office during rehabilitation for psychiatric and pain management.
### Specimen Validity - Validity Test Panel

<table>
<thead>
<tr>
<th>Tested For</th>
<th>Result</th>
<th>Quantitation</th>
<th>Normalization (ng/mL)</th>
<th>Outcome</th>
<th>Cutoff</th>
<th>History</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxidants</td>
<td>NORMAL</td>
<td>0.0</td>
<td>0 - 200</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>pH</td>
<td>NORMAL</td>
<td>5.6</td>
<td>4.7 - 7.8</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>NORMAL</td>
<td>1.015</td>
<td>1.003 - 1.005</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Creatinine</td>
<td>NORMAL</td>
<td>147.5 mg/dL</td>
<td>20 - 200 mg/dL</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Alcohol Biomarkers**

- **Ethyl Glucuronide**: Positive > 7500 ng/mL. INCONSISTENT 500 ng/mL. Detection Window 1-2 days. Ethyl glucuronide (EIG) is a metabolite of ethanol (ethyl alcohol). Due to its longer detection time, EIG may be present in the absence of ethyl sulfate (EIS).
- **Ethyl Sulfate**: Positive ≥ 2191 ng/mL. INCONSISTENT 200 ng/mL. Detection Window 2-3 days. Ethyl sulfate (EIS) is a metabolite of ethanol (ethyl alcohol) and its presence is specific for recent ethanol use. EIS has a shorter half-life than Ethyl glucuronide (EIG).

### Antidepressants, not otherwise specified

<table>
<thead>
<tr>
<th>Antidepressant</th>
<th>Result</th>
<th>Quantitation</th>
<th>Normalization (ng/mL)</th>
<th>Outcome</th>
<th>Cutoff</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bupropion</td>
<td>Negative</td>
<td>&gt; 750 ng/mL</td>
<td>INCONSISTENT 30 ng/mL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Desmethylvenlafaxine</td>
<td>Positive</td>
<td>&gt; 7500 ng/mL</td>
<td>INCONSISTENT</td>
<td>90 ng/mL</td>
<td></td>
</tr>
<tr>
<td>Hydroxybupropion</td>
<td>Negative</td>
<td>&gt; 1226 ng/mL</td>
<td>100 ng/mL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Venlafaxine</td>
<td>Positive</td>
<td>&gt; 1226 ng/mL</td>
<td>INCONSISTENT 100 ng/mL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Anabpsychotics**

- **9-Hydroxyrisperidone**: Negative > 100 ng/mL
- **Norquetiapine**: Positive ≥ 294 ng/mL. INCONSISTENT 100 ng/mL. Detection Window 1-2 days. Active metabolite of Quetiapine (Ketipinor, Querpin, Serquet). Quetiapine is a prescribed dibenzothiazepine derivative that has been clinically used as a neuroleptic agent in the treatment of psychosis.
<table>
<thead>
<tr>
<th>Substance</th>
<th>Detection Window</th>
<th>Concentration (ng/mL)</th>
<th>Metabolism</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Opiates</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Codeine</td>
<td>Positive</td>
<td>≤500 ng/mL</td>
<td>INCONSISTENT</td>
</tr>
<tr>
<td>Dihydrocodeine</td>
<td>Negative</td>
<td>≤50 ng/mL</td>
<td>INCONSISTENT</td>
</tr>
<tr>
<td>Hydrocodone</td>
<td>Positive</td>
<td>≤531 ng/mL</td>
<td>INCONSISTENT</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>Negative</td>
<td>≤50 ng/mL</td>
<td>INCONSISTENT</td>
</tr>
<tr>
<td>Morphine</td>
<td>Positive &gt; 750 ng/mL</td>
<td>INCONSISTENT</td>
<td>50 ng/mL</td>
</tr>
<tr>
<td>Norhydrocodone</td>
<td>Negative</td>
<td>≤50 ng/mL</td>
<td>INCONSISTENT</td>
</tr>
<tr>
<td><strong>Fentanyl</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carfentanil</td>
<td>Negative</td>
<td>≤1 ng/mL</td>
<td></td>
</tr>
<tr>
<td>Fentanyl</td>
<td>Negative</td>
<td>≤2 ng/mL</td>
<td></td>
</tr>
<tr>
<td>Norfentanyl</td>
<td>Negative</td>
<td>≤8 ng/mL</td>
<td></td>
</tr>
<tr>
<td><strong>Gabapentin</strong></td>
<td><strong>Positive &gt; 15000 ng/mL</strong></td>
<td><strong>INCONSISTENT</strong></td>
<td>1000 ng/mL</td>
</tr>
<tr>
<td><strong>Heroin Metabolite</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6-MAM</td>
<td>Positive &gt; 37 ng/mL</td>
<td>INCONSISTENT</td>
<td>25 ng/mL</td>
</tr>
</tbody>
</table>

Detection Window and concentrations are approximate and can vary based on individual factors.
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, asthma?

Do you have patients on more than 90mg MME?

Do you have patients with substance abuse histories, including ETOH, 6-AM, and THC?

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)
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

844 IAC 5-6-4 Evaluation and risk stratification by physician
Authority: IC 25-22.5-2-7; IC 25-22.5-13-2
Affected: IC 25-1-9; IC 25-22.5

Sec. 4. (a) The physician shall do the physician's own evaluation and risk stratification of the patient by doing the following in the initial evaluation of the patient:
(1) Performing an appropriately focused history and physical exam and obtain or order appropriate tests, as indicated.
(2) Making a diligent effort to obtain and review records from previous health care providers to supplement the physician’s understanding of the patient's chronic pain problem, including past treatments, and documenting this effort.
(3) Asking the patient to complete an objective pain assessment tool to document and better understand the patient's specific pain concerns.
(4) Assessing both the patient's mental health status and risk for substance abuse using available validated screening tools.
(5) After completing the initial evaluation, establishing a working diagnosis and tailoring a treatment plan to meaningful and functional goals with the patient reviewing them from time to time.

(b) Where medically appropriate, the physician shall utilize nonopioid options instead of or in addition to prescribing opioids.
(Medical Licensing Board of Indiana; 844 IAC 5-6-4; filed Oct 7, 2014; 12:27 p.m.; 20141105-IR-8441-40289.R.A. eff Nov 1, 2014 [IC 4-22-2-36 suspends the effectiveness of a rule document for 30 days after filing with the Publisher. LSA Document #14-289 was filed Oct 7, 2014.])

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

Rational Urine Drug Monitoring in Patients Receiving Opioids for Chronic Pain: Consensus Recommendations, by Charles E. Argoft, MD,* Daniel P. Alford, MD, MPH,† Jeffrey Fudin, PharmD, DAIPM, FCCP, FASHIP,‡ et al., Pain Medicine 2017; 0: 1–21

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.

Risk of Overdose
– No Universal Standard yet, but SAMHSA and CDC, and Ohio
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>INITIAL OFFICE VISIT and RELEVANT RX</th>
<th>UDT ORDERED</th>
<th>DATE ON LAB REPORT</th>
<th>Date EMR Shows Review</th>
<th>RESULTS</th>
<th>Aberrant?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/24/15 RX after OV = OXYCODONE Patient had prior Rx Tylenol #3</td>
<td>Yes</td>
<td>1/28/15</td>
<td>2/24/15</td>
<td>Gabapentin+ TCA+</td>
<td>Yes, Gabapentin not disclosed, but Rx from another doctor. Oxycodeone Rx given.</td>
</tr>
<tr>
<td>2/24/15 Rx is OXYCODONE, Morphine added</td>
<td>Yes</td>
<td>3/1/15</td>
<td>3/24/15</td>
<td>Gabapentin+ Oxycodeone - TCA+ Dextromethorphan+</td>
<td>Yes, Dextromethorphan; Missing Rx Opioid (Oxy)</td>
</tr>
<tr>
<td>3/24/15 Rx for Oxycodeone, Morphine, Gabapentin</td>
<td>Yes</td>
<td>4/2/15</td>
<td>4/24/15</td>
<td>Morphine + Gabapentin+ Oxycodeone +</td>
<td>Yes, Morphine+ but 6-MAM-NEG Oxycodeone+</td>
</tr>
<tr>
<td>4/24/15 Rx for Oxycodeone, Morphine, Gabapentin</td>
<td>Yes</td>
<td>5/26/1</td>
<td>Reviewed after Patient’s death.</td>
<td>Morphine+ 6-MAM+ FENTANYL+ Oxycodeone+</td>
<td>Patient overdosed and died.</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

| Risk Responses - Possibilities (some work, some do not – keep the patient at the center and document rationale) |
|-------------------------------------------------|-------------------------------------------------|-------------------------------------------------|
| Discussed the behavior/result                   | Require more frequent visits                    | Require increased PDMP database checks          |
| Require increased UDT* with caution and selectively if known risks | Implement opioid supply controls (fewer dosage units in more frequently issued prescriptions) | Propose a change of medication, dosing, formulation, etc. |
| Refer for substance abuse treatment              | Refer for mental health evaluation               | Refer to specialty service                      |
| Plan reduction in opioid dose and taper off of medication (Terminate the medication) | Buprenorphine                                    | Withdrawal from care* (serious step and requires its own lecture) |
| Educate                                         | Give more strikes (wait and see)                | Other                                           |

### Addressing the Weaknesses

#### Coordination of Care
Consultations and Referrals – COORDINATION OF CARE - “As Necessary” (Do your charts show you’ve considered coordination and consults/referrals?)

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

REPRISE: Now, how do you handle John Smith’s report?

“My primary care physician is out of town and I’m afraid I will get sick if I have to wait for him to return to get my [Opioid or Benzodiazepine or other].”

“I am not sleeping well and not dealing with the increased pain I am having because you reduced my opioids 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 increased pain and anxiety.”
Critical Coordination of Care Issue –
I’m out of my Benzodiazepines

"My primary care physician is out of town and I’m afraid I will get sick if I have to wait for him to return to get my [Opioid or Benzodiazepine or other]."

POMP Check Shows Last Rx was indeed by the name “other” prescriber and about 30 days ago. Patient seems like he’s due for a refill and not prescribing may cause seizures or withdrawal.

WHAT IF TIME:

1. What if the patient’s “other” prescriber switched their benzodiazepine from Alprazolam to Clonazepam at the last visit, and patient is now out of Alprazolam and tells you his provider is out of town and he needs his Alprazolam?

2. What if the patient’s BP during the office visit with you this same day is 80/60?

3. What if the patient tells you that he is having trouble sleeping and thinks he has sleep apnea?

4. What if the patient tells you he is using alcohol?

What do you do? What do you document? How do you handle the patient’s request for the BZD?

Patient Risk Mitigation & Risk Education

Overdose Events (Fatal or Non-Fatal):
Steps you can take to mitigate against them AND Steps you can take when they do happen
EDUCATE PATIENTS AND STAFF MEMBERS

- https://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit-Updated-2016/All-New-Products/SMA16-4742

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/atox/opioids

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

<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 Positional</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 Pharmacist</td>
<td>Consequences of Treatment Agreement Violation</td>
</tr>
<tr>
<td>Informed Consent</td>
<td>Medicare Guidance</td>
<td>Other Behavioral Risks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment Agreement</td>
<td>CDC Guidelines</td>
<td>Protocols for Opioid Addiction and Overall Assessment of Risk and Stratification</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Periodic Review</td>
<td>SAMHSA Materials</td>
<td>Protocols for Monitoring and Risk Stratification</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Consultations and Referrals</td>
<td>Other</td>
<td>Protocols for Coordination of Care</td>
<td></td>
<td></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>
</tbody>
</table>

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Thank you!