



## 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

Created and presented by:  
Jennifer Bolen, JD

## Disclosures for Jennifer Bolen, JD



- Consultant - Generation Partners
- Consultant - Abbott/Alere Toxicology
- Consultant - MTL Solutions, LLC
- Consultant - MyMOMD
- Consultant - Paradigm Labs
- Consultant - Pernix Therapeutics
- Consultant - ReCept Pharmacy
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## Learning Objectives

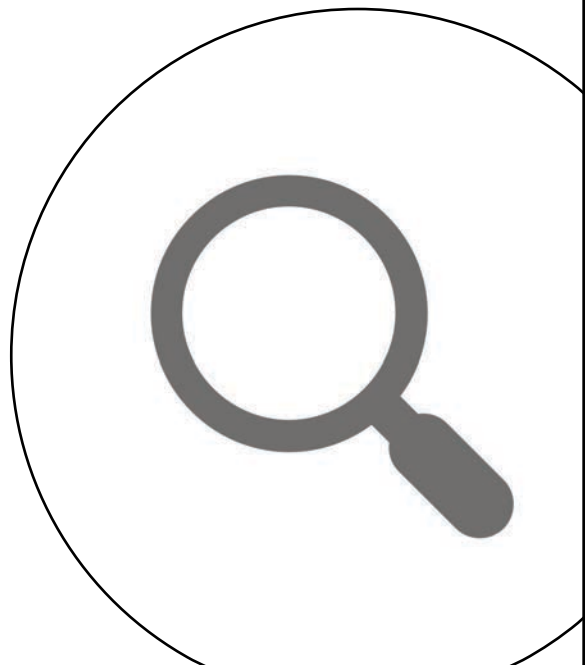
|          |                                                                                                                                                                                      |
|----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Identify | Identify common trends in legal actions against prescribers when a patient overdoses and dies                                                                                        |
| Describe | Describe critical perspectives around a proper response to the licensing board's request for the chart and a summary of care.                                                        |
| List     | List three common risk mitigation weaknesses associated with chronic opioid therapy                                                                                                  |
| Explain  | 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. |
| Discuss  | Discuss case examples using a before and after application of the three pronged risk mitigation improvement plan.                                                                    |

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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



|                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                               |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <div style="border: 1px solid black; padding: 10px; margin-bottom: 20px; text-align: center;"> <p>Dear Pain Management Practitioner:</p> </div> <ul style="list-style-type: none"> <li>• Love, Your licensing board</li> <br/> <li>• PS: You have 21 days to do this!</li> </ul> | <p>This office is in receipt of only one version of the allegations contained in the enclosed information is being submitted to you to provide you the opportunity recollection of the incident. Therefore, please submit a <b>narrative</b> setting forth and response to the allegations contained in the complaint. <b>Your response to also include copies of all relevant medical treatment records, pursuant to</b></p> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                    |                                                                                                                                                                 |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>The typical case goes something like this . . .</p>                                                                                                                                                                                                                                                                                                 | <table border="1"> <tr> <td style="text-align: center; vertical-align: middle;">Get</td> <td> <p>Get Letter</p> <ul style="list-style-type: none"> <li>•Hit the Panic Button</li> <li>•Reality Sets in</li> </ul> </td> </tr> </table>                                              | Get                                                                                                                                                                                                                                | <p>Get Letter</p> <ul style="list-style-type: none"> <li>•Hit the Panic Button</li> <li>•Reality Sets in</li> </ul>                                             |
|                                                                                                                                                                                                                                                                                                                                                        | Get                                                                                                                                                                                                                                                                                 | <p>Get Letter</p> <ul style="list-style-type: none"> <li>•Hit the Panic Button</li> <li>•Reality Sets in</li> </ul>                                                                                                                |                                                                                                                                                                 |
|                                                                                                                                                                                                                                                                                                                                                        | <table border="1"> <tr> <td style="text-align: center; vertical-align: middle;">Talk</td> <td> <p>Talk to Lawyer</p> <ul style="list-style-type: none"> <li>•Gather Files; Hit Panic Button</li> <li>•Denial takes hold, with Anger as a seat buddy</li> </ul> </td> </tr> </table> | Talk                                                                                                                                                                                                                               | <p>Talk to Lawyer</p> <ul style="list-style-type: none"> <li>•Gather Files; Hit Panic Button</li> <li>•Denial takes hold, with Anger as a seat buddy</li> </ul> |
| Talk                                                                                                                                                                                                                                                                                                                                                   | <p>Talk to Lawyer</p> <ul style="list-style-type: none"> <li>•Gather Files; Hit Panic Button</li> <li>•Denial takes hold, with Anger as a seat buddy</li> </ul>                                                                                                                     |                                                                                                                                                                                                                                    |                                                                                                                                                                 |
| <table border="1"> <tr> <td style="text-align: center; vertical-align: middle;">Make</td> <td> <p>Make a Choice</p> <ul style="list-style-type: none"> <li>•Approach with Confidence and Send in Fact-Filled, Humble Response; Fight if you have to</li> <li>•OR Continue Denial and Fight without a helpful framework</li> </ul> </td> </tr> </table> | Make                                                                                                                                                                                                                                                                                | <p>Make a Choice</p> <ul style="list-style-type: none"> <li>•Approach with Confidence and Send in Fact-Filled, Humble Response; Fight if you have to</li> <li>•OR Continue Denial and Fight without a helpful framework</li> </ul> |                                                                                                                                                                 |
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Necessary  
framework  
and path  
forward

|         |                                                                                                                                                                                                                                                          |
|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Freeze  | <b>Freeze Records</b> <ul style="list-style-type: none"> <li>• Copy and Review</li> <li>• NOTE THE FACTS; Avoid Opinion at First</li> </ul>                                                                                                              |
| Match   | <b>Match Facts Against Standards</b> <ul style="list-style-type: none"> <li>• Evaluate Strengths and Weaknesses</li> <li>• Identify potential expert support</li> </ul>                                                                                  |
| Prepare | <b>Prepare Response*</b> (assuming advice of counsel is to do this) <ul style="list-style-type: none"> <li>• Carefully mix case facts with humble description of decision-making</li> <li>• Wait and see, but prepare for possible next steps</li> </ul> |

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

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

## If you have done your job . . . Then maybe

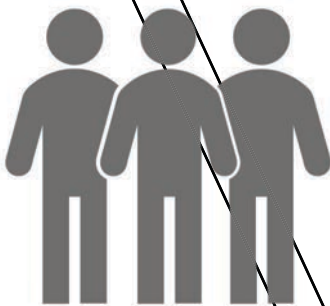
I am reporting to you the results of the review by the [SOME STATE] Board of Medical Examiners (the “Board”) of the complaint filed regarding the above-referenced individual. In the course of the inquiry, the Board considered your response.

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 assuring 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

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DEA “Standards”  
for Registrants  
who Prescribe  
Controlled  
Substances

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

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## Licensing Board and Professional “Standards” and Documentation of Same

| Historical Steps with Patient                                                                                                                                                                            | Active Care Plan Steps                                                                                                                                                                                                                                                                                        | Coordination of Care and Consultations/Referrals                                                                                                                                                                                                                                                                               |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> <li>• General medical history</li> <li>• Pain Specific History</li> <li>• Risk of Abuse/Addiction</li> <li>• Risk of Diversion</li> <li>• Risk of Overdose</li> </ul> | <ul style="list-style-type: none"> <li>• Opioid Trial and Some form of Exit Strategy</li> <li>• Treatment Plan for Frequency, Handling MME, PDMP utilization, UDT, etc.</li> <li>• Naloxone and Patient Education</li> <li>• Documentation and Process of Informed Consent and Treatment Agreement</li> </ul> | <ul style="list-style-type: none"> <li>• Scope of Practice Issues</li> <li>• Exchange of documentation between PCP and Specialty providers engaged in chronic MEDICATION therapy (not just limited to opioids)</li> <li>• Dealing with Marijuana issues</li> <li>• Rationale for starting, stopping, changing, etc.</li> </ul> |

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### Sample Licensing Board Guidelines/Rules

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

| COMPARISON OF PRESCRIBING GUIDELINES FOR CONTROLLED SUBSTANCES (OPIODS) FOR CHRONIC PAIN                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
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| Centers for Disease Control and Prevention (CDC)<br>Prescriber Guidelines for Chronic Pain                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Medical Board of California (MBC)<br>Prescriber Guidelines for Substances for Pain                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <p>CDC recommendations are based upon the following assessment:</p> <ul style="list-style-type: none"> <li>• No evidence of long-term benefits from opioids in pain and function for chronic pain with outcomes examined at least 3 year later.</li> <li>• Extensive evidence shows the possible harms of opioids (including abuse and dependence, overdose, myocardial infarction, motor vehicle crashes), and</li> <li>• Extensive evidence suggests benefits of alternative treatments compared with long-term opioid therapy, including nonpharmacologic therapy and nonopioid pharmacologic therapy, with less harm.</li> </ul> <p>These guidelines are intended for primary care physicians who are treating patients with chronic pain (i.e., pain lasting longer than three months or past the time of normal tissue healing) in outpatient settings.</p> <p>The recommendations are not intended as for guidance on use of opioids as part of medication-assisted treatment for opioid use disorders (i.e., for patients who are in active cancer treatment, palliative care, or end of life care).</p> <p>The three sections/categories below are based upon CDC recommendations.</p> <ul style="list-style-type: none"> <li>• Non-pharmacologic therapy and non-opioid pharmacologic therapy preferred for chronic pain</li> <li>• Before starting opioid therapy for pain, providers should establish treatment goals with all patients, including realistic goals for pain and function</li> <li>• Providers should not initiate opioid therapy without consideration of how therapy will be discontinued if unsuccessful</li> <li>• Providers should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety</li> </ul> | <p>MBC's guidelines are intended to improve outcomes of patient care and to prevent overdose deaths due to opioid use. They particularly address the use of opioids in the long-term treatment of chronic pain.</p> <p>MBC recommendations are based upon:</p> <p><b>Special patient populations including:</b> Emergency Departments, Urgent Care Clinics, Acute Pain, End-of-Life Pain, Cancer Pain, Older Adults, Pediatric Patients, Pregnant Women, Patients Covered by Workers' Compensation, Patients with History of Use Disorder, Psychiatric Patients, Patients Prescribed Benzodiazepines and Patients Prescribed Methadone or Buprenorphine for Treatment of a Substance Use Disorder.</p> <p>These guidelines are intended for all physicians practicing in California.</p> <p>These guidelines are not meant for the treatment of patients in hospice or palliative care settings or to treat treatment where improved function is not anticipated and pain relief is the primary goal.</p> <p><b>Emergency Departments (ED) or Urgent Care Clinics</b></p> <ul style="list-style-type: none"> <li>• Physicians should avoid the routine prescribing of opioid therapy for a patient with an acute exacerbation of chronic non-cancer pain seen in the ED.</li> <li>• If opioids are prescribed on discharge, the prescription should be for the lowest practical dose for a limited duration (e.g., 4-5 days).</li> <li>• The prescriber should consider the patient's risk for opioid misuse, abuse, or dependence.</li> <li>• The physician should, if practicable, honor existing patient-physician pain contracts/treatment agreements and consider past prescription patterns from information sources such as prescription drug monitoring programs.</li> </ul> |

Comparison of Prescribing Guidelines

Indicates differences between the guidelines

Page 1

| COMPARISON OF PRESCRIBING GUIDELINES FOR CONTROLLED SUBSTANCES (OPIOIDS) FOR CHRONIC PAIN                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
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| <b>DETERMINING WHEN TO INITIATE OR CONTINUE OPIOIDS FOR CHRONIC PAIN (Continued)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
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| COMPARISON OF PRESCRIBING GUIDELINES FOR CONTROLLED SUBSTANCES (OPIOIDS) FOR CHRONIC PAIN                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
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## California Comparison Continued

### OBJECTIVES 3 and 4:

3. List three common risk mitigation weaknesses associated with chronic opioid therapy

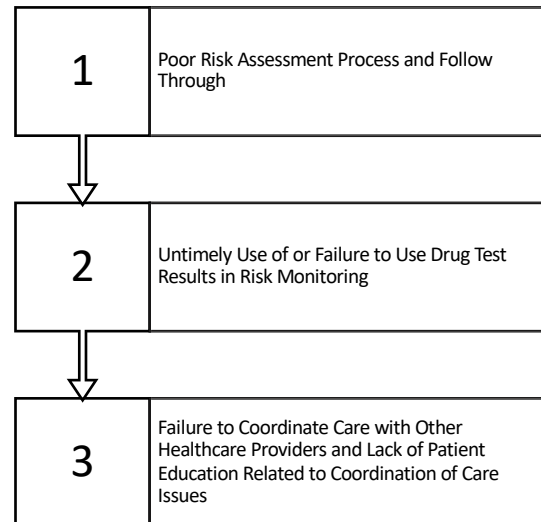
4. Create an action plan for changing how clinicians address the same with their staff and patients addressing these in daily practice and medical record documentation.





## LEGAL PERSPECTIVE:

Three common risk mitigation weaknesses associated with chronic opioid therapy



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

### A QUICK PUB MED SEARCH

1. [Potentially Inappropriate Opioid Prescribing, Overdose, and Mortality in Massachusetts, 2011-2015.](#)  
Rose AJ, Bernson D, Chui KKH, Land T, Walley AY, LaRochelle MR, Stein BD, Stopka TJ.  
J Gen Intern Med. 2018 Jun 14. doi: 10.1007/s11606-018-4532-5. [Epub ahead of print]  
PMID: 29948815  
[Similar articles](#)
2. [Controlled Substance Prescribing Patterns—Prescription Behavior Surveillance System, Eight States, 2013.](#)  
Paulozzi LJ, Strickler GK, Kreiner PW, Koris CM; Centers for Disease Control and Prevention (CDC).  
MMWR Surveill Summ. 2015 Oct 16;64(9):1-14. doi: 10.15585/mmwr.mm6409a1.  
PMID: 26469747  
[Similar articles](#)
3. [Patterns of Opioid Use and Risk of Opioid Overdose Death Among Medicaid Patients.](#)  
Garg RK, Fulton-Kehoe D, Franklin GM.  
Med Care. 2017 Jul;55(7):e61-e68. doi: 10.1097/MLR.0000000000000738.  
PMID: 28614178  
[Similar articles](#)
4. [High-risk use by patients prescribed opioids for pain and its role in overdose deaths.](#)  
Gwira Baumbatt JA, Wiedeman C, Dunn JR, Schaffner W, Paulozzi LJ, Jones TF.  
JAMA Intern Med. 2014 May;174(5):796-801.  
PMID: 24589873  
[Similar articles](#)
5. [Medication for Opioid Use Disorder After Nonfatal Opioid Overdose and Association With Mortality: A Cohort Study.](#)  
LaRoche MR, Bernson D, Land T, Stopka TJ, Wang N, Xuan Z, Bagley SM, Liebschutz JM, Walley AY.  
Ann Intern Med. 2018 Aug 7;169(3):137-145. doi: 10.7326/M17-3107. Epub 2018 Jun 19.  
PMID: 29913516  
[Similar articles](#)
6. [Association between opioid prescribing patterns and opioid overdose-related deaths.](#)  
Bohnert AS, Valenstein M, Bair MJ, Ganoczy D, McCarthy JF, Ilgen MA, Blow FC.  
JAMA. 2011 Apr 6;305(13):1315-21. doi: 10.1001/jama.2011.370.  
PMID: 21467284  
[Similar articles](#)

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## Six Types of Potentially Inappropriate Opioid Prescribing Behaviors (PIP)

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

|                                                                      |                                     |                                               |                                                             |                                                                         |
|----------------------------------------------------------------------|-------------------------------------|-----------------------------------------------|-------------------------------------------------------------|-------------------------------------------------------------------------|
| Overlapping Opioid and Benzodiazepine Prescriptions in $\geq$ 3 mos. | $\geq$ 4 prescribers in any quarter | $\geq$ 4 dispensing pharmacies in any quarter | Cash purchase of opioid prescriptions on $\geq$ 3 occasions | Receipt of opioids in $\geq$ 3 mos. Without a documented pain diagnosis |
|----------------------------------------------------------------------|-------------------------------------|-----------------------------------------------|-------------------------------------------------------------|-------------------------------------------------------------------------|

*J Gen Intern Med.* 2018 Jun 14. doi: 10.1007/s11606-018-4532-5. [Epub ahead of print]

### Potentially Inappropriate Opioid Prescribing, Overdose, and Mortality in Massachusetts, 2011-2015.

Rose AJ<sup>1,2</sup>, Bensen D<sup>3</sup>, Chui KK<sup>4</sup>, Land T<sup>3</sup>, Walley AV<sup>5,3</sup>, LaRoche MR<sup>5</sup>, Stein BD<sup>6,7</sup>, Stocka T<sup>4,8</sup>.

#### Author Information

#### Abstract

**BACKGROUND:** Potentially inappropriate prescribing (PIP) may contribute to opioid overdose.

**OBJECTIVE:** To examine the association between PIP and adverse events.

**DESIGN:** Cohort study.

**PARTICIPANTS:** Three million seventy-eight thousand thirty-four individuals age  $\geq$  18, without disseminated cancer, who received prescription opioids between 2011 and 2015.

**MAIN MEASURES:** We defined PIP as (a) morphine equivalent dose  $\geq$  100 mg/day in  $\geq$  3 months; (b) overlapping opioid and benzodiazepine prescriptions in  $\geq$  3 months; (c)  $\geq$  4 opioid prescribers in any quarter; (d)  $\geq$  4 opioid-dispensing pharmacies in any quarter; (e) cash purchase of prescription opioids on  $\geq$  3 occasions; and (f) receipt of opioids in 3 consecutive months without a documented pain diagnosis. We used Cox proportional hazards models to identify PIP practices associated with non-fatal opioid overdose, fatal opioid overdose, and all-cause mortality, controlling for covariates.

**KEY RESULTS:** All six types of PIP were associated with higher adjusted hazard for all-cause mortality, four of six with non-fatal overdose, and five of six with fatal overdose. Lacking a documented pain diagnosis was associated with non-fatal overdose (adjusted hazard ratio [AHR] 2.21, 95% confidence interval [CI] 2.02-2.41), as was high-dose opioids (AHR 1.68, 95% CI 1.59-1.76). Co-prescription of benzodiazepines was associated with fatal overdose (AHR 4.23, 95% CI 3.85-4.65). High-dose opioids were associated with all-cause mortality (AHR 2.18, 95% CI 2.14-2.23), as was lacking a documented pain diagnosis (AHR 2.05, 95% CI 2.01-2.09). Compared to those who received opioids without PIP, the hazard for fatal opioid overdose with one, two, three, and  $\geq$  four PIP subtypes were 4.24, 7.05, 10.28, and 12.99 (test of linear trend,  $p < 0.001$ ).

**CONCLUSIONS:** PIP was associated with higher hazard for all-cause mortality, fatal overdose, and non-fatal overdose. Our study implies the possibility of creating a risk score incorporating multiple PIP subtypes, which could be displayed to prescribers in real time.

**KEYWORDS:** mortality; opioids; overdose; potentially inappropriate prescribing

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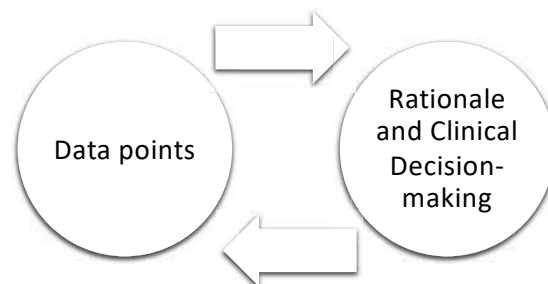
| PIP Article                                                             | Bolen Group Audit Findings                                                                                                                                                                                          | General Suggestions for Improvement                                                                                                                                                                               |
|-------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| MME $\geq$ 100mg/day for $\geq$ 3 mos.                                  | Frequent failures to track MME                                                                                                                                                                                      | Track MME                                                                                                                                                                                                         |
| Overlapping Opioid and Benzodiazepine Prescriptions in $\geq$ 3 mos.    | Sometimes overlapping involves more than one opioid and more than one Benzodiazepine, along with sleep medication, muscle relaxants, etc. and rationale not documented; coordination of care missing.               | 1. Document rationale for combination prescribing<br>2. Coordinate care with BZO prescriber<br>3. May be appropriate to discuss reducing Benzodiazepines or limiting term of use or time of reevaluation.         |
| $\geq$ 4 prescribers and pharmacists in any quarter                     | Multiple prescribers often involved people in the same practice or PCP/Internal Medicine, Pain Specialist, and Psychiatrist<br><br>Multiple pharmacists happen for different reasons. Sometimes not clear in chart. | 1. Use PDMP<br>2. Coordinate care with other physicians and pharmacists, especially for complex patient<br>3. Discuss need to know who treats patient and where medication is filled, what's prescribed, and why. |
| Cash purchase of opioids on $\geq$ 3 occasions                          | Didn't find in our audit                                                                                                                                                                                            | 1. Outside scope of lecture                                                                                                                                                                                       |
| Receipt of opioids in $\geq$ 3 mos. without a documented pain diagnosis | Found mixed results on pain diagnosis. Sometimes specific diagnosis after workup. Other times, general diagnosis and failure to reevaluate after initial opioid trial period.                                       | 1. Perform a thorough evaluation<br>2. Document a specific diagnosis or working diagnosis<br>3. Evaluate frequently during first year and thereafter per standards                                                |

## Comparing PIP to Our Anecdotal Audit Findings

## Comparing PIP to Our Anecdotal Audit Findings - 2

| PIP Article   | Bolen Group Audit Findings                                                               | Remedy                                                                                                                                                                     |
|---------------|------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| NOT MENTIONED | INCONSISTENT OR LACK OF USE OF ANY RISK ASSESSMENT PLAN or SUMMARY OF FINDINGS           | See Sample Tool                                                                                                                                                            |
| NOT MENTIONED | Delayed timing in review of UDT results and use of those results in treatment of patient | <ol style="list-style-type: none"> <li>1. UDT Results Triage</li> <li>2. Ongoing Use of UDT results in Tx</li> <li>3. Documentation</li> <li>4. See UDT Lecture</li> </ol> |

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

| DATA POINT             | Initial OV                                        | 6 months in                                                                                             | 1 year in                                                                     | Month of OD                                                                |
|------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------|----------------------------------------------------------------------------|
| SOAPP/Psych Testing    | High risk Depression Scale                        | SOAPP scores 12 (high risk)                                                                             | Still high risk                                                               | SOAPP-R last OV                                                            |
| Anxiety                | Reports anxiety                                   | Reports anxiety                                                                                         | Anxiety not reported/documented                                               | Suffering from insomnia, panic attacks, anxiousness/stress                 |
| Depression             | Reports feeling more sad than usual (depressed)   | Patient has psych history of depression documented, and reports feeling more sad than usual (depressed) | Continues to see a psychologist                                               | Receiving 3 forms of antidepressant.<br>Patient reports depression         |
| Use of Diphenhydramine | Positive in UDS on second visit                   | Positive in UDS at 6 months                                                                             | Positive in UDS at 18 months                                                  | Positive in last UDS                                                       |
| Multiple Opioids       | Fentanyl and Hydromorphone                        | Fentanyl and Hydromorphone                                                                              | Fentanyl and Hydromorphone                                                    | Fentanyl and Oxycodone                                                     |
| Use of Benzodiazepines | Taking 1mg Alprazolam BID                         | Same                                                                                                    | Oxazepam appears in UDS along with Alprazolam                                 | Afraid will run out of Alprazolam because prescribing provider unavailable |
| Smoker                 | Current every day smoker- 1 PPD                   | Current every day smoker                                                                                | Reported as a former smoker, but Cotinine continues to appear positive in UDS | Reported as former smoker                                                  |
| Drinker                | Patient drinks 1-13 alcoholic beverages per month | Reported to drink 1-13 alcoholic beverages a month- Alcohol in UDS                                      | Reported as non drinker                                                       | Patient reports alcohol abuse- not counseled                               |
| MME                    | 267mg MME                                         | 267mg MME                                                                                               | 216mg MME                                                                     | 180mg MME                                                                  |

Opioid Dose Calculator <http://www.agencymeddirectors.wa.gov/calculator/dosecalculator.htm>

**Opioid Dose Calculator**

Instructions: Fill in the mg per day\* for whichever opioids your patient is taking. The web page will automatically calculate the total morphine equivalents per day.

Patient's Name: John Smith  
Today's Date: August 24, 2018

Morphine equivalents:

| Opioid (oral or transdermal):    | mg per day:* |
|----------------------------------|--------------|
| Codine                           | 0            |
| Fentanyl transdermal (in mcg/hr) | 75 180       |
| Hydrocodone                      | 0            |
| Hydromorphone                    | 24 96        |
| Methadone†                       | 0            |
| Morphine                         | 0            |
| Oxycodone                        | 0            |
| Oxymorphone                      | 0            |
| Tapentadol                       | 0            |
| Tramadol                         | 0            |
| <b>Total</b>                     | <b>276</b>   |

## 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 SOAPP-R
- Patient's BP was 88/64

## John Smith's Last Risk Assessment Responses Mar. 9, 2018

SOAPP - R Mar. 9, 2018

The following are some questions given to patients who are on or being considered for medication for their pain. Please answer each question as honestly as possible. There are no right or wrong answers.

| JOHN SMITH                                                                                   | NEVER<br>0 | SELDOM<br>1 | SOMETIMES<br>2 | OFTEN<br>3 | VERY OFTEN<br>4 |
|----------------------------------------------------------------------------------------------|------------|-------------|----------------|------------|-----------------|
| 1. How often do you have mood swings?                                                        |            |             |                |            | ✓               |
| 2. How often have you felt a need for higher doses of medication to treat your pain?         |            |             |                |            | ✓               |
| 3. How often have you felt impatient with your doctors?                                      |            | ✓           |                |            |                 |
| 4. How often have you felt that things are just too overwhelming that you can't handle them? |            |             |                |            | ✓               |
| 5. How often is there tension in the home?                                                   |            |             |                |            | ✓               |
| 6. How often have you counted pain pills to see how many are remaining?                      |            |             |                |            | ✓               |
| 7. How often have you been concerned that people will judge you for taking pain medication?  |            |             |                |            | ✓               |
| 8. How often do you feel bored?                                                              |            |             |                |            | ✓               |
| 9. How often have you taken more pain medication than you were supposed to?                  |            |             |                |            | ✓               |
| 10. How often have you worried about being left alone?                                       |            |             |                | ✓          |                 |
| 11. How often have you felt a craving for medication?                                        |            |             |                |            | ✓               |
| 12. How often have others expressed concern over your use of medication?                     |            |             |                |            | ✓               |
| 13. How often have any of your close friends had a problem with alcohol or drugs?            | ✓          |             |                |            |                 |

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Phone: 877-532-6228 Fax: 212-512-1821 Email: info@intuitive.com  
The SOAPP-R and SOAPP-R patient worksheet were developed with  
a grant from the National Institutes of Health (R01DA024335, T32DA013401).

John Smith

|                                                                                              | NEVER<br>0 | SELDOM<br>1 | SOMETIMES<br>2 | OFTEN<br>3 | VERY OFTEN<br>4 |
|----------------------------------------------------------------------------------------------|------------|-------------|----------------|------------|-----------------|
| 14. How often have others told you that you had a bad temper?                                |            |             |                |            | ✓               |
| 15. How often have you felt consumed by the need to get pain medication?                     |            |             |                | ✓          | all the time    |
| 16. How often have you run out of pain medication early?                                     |            |             |                |            |                 |
| 17. How often have others kept you from getting what you deserve?                            |            | ✓           |                |            |                 |
| 18. How often, in your lifetime, have you had legal problems or been arrested?               | ✓          |             |                |            |                 |
| 19. How often have you attended an AA or NA meeting?                                         | ✓          |             |                |            |                 |
| 20. How often have you been in an argument that was so out of control that someone got hurt? | ✓          |             |                |            |                 |
| 21. How often have you been sexually abused?                                                 | ✓          |             |                |            |                 |
| 22. How often have others suggested that you have a drug or alcohol problem?                 | ✓          |             |                |            |                 |
| 23. How often have you had to borrow pain medications from your family or friends?           | ✓          |             |                |            |                 |
| 24. How often have you been treated for an alcohol or drug problem?                          | ✓          |             |                |            |                 |

## John Smith's Drug Test Results – Timing and Utility

| Assession<br>Collection Date | Test 5<br>3/09/18 | Test 4<br>1/12/18 | Test 3<br>12/14/17 | Test 2<br>10/11/17 | Test 1<br>9/13/17 |                               |
|------------------------------|-------------------|-------------------|--------------------|--------------------|-------------------|-------------------------------|
| <b>Drug</b>                  |                   |                   |                    |                    |                   |                               |
| Oxycodone                    | 25                | 100               | 190                | 219                | 245               |                               |
| Oxycodone                    | Not Detected      | Not Detected      | Not Detected       | 110                | Not Detected      |                               |
| Alprazolam                   | Not Detected      | 299               | 367                | 371                | 219               |                               |
| Alprazolam                   | Not Detected      | 2121              | >2778              | 1850               | 1159              | RX MED*                       |
| Tramadol                     | 1565              | Not Detected      | Not Detected       | Not Detected       | Not Detected      |                               |
| Alcohol, Ethyl               | 0.179             | Not Detected      | Not Detected       | Not Detected       | Not Detected      |                               |
| Hydrocodone                  | Not Detected      | >10000            | 4411               | >4567              | >4082             |                               |
| Oxycodone                    | 1970              | Not Detected      | Not Detected       | Not Detected       | Not Detected      | RX MED in 3/18<br>(not prior) |
| Oxycodone                    | 504               | Not Detected      | Not Detected       | Not Detected       | Not Detected      |                               |
| Noroxycodone                 | 7457              | Not Detected      | Not Detected       | Not Detected       | Not Detected      |                               |
| Noroxycodone                 | 309               | Not Detected      | Not Detected       | Not Detected       | Not Detected      |                               |
| Fentanyl                     | 35                | 8                 | 8                  | 14                 | 11                | RX MED                        |
| Norfenitanyl                 | 674               | 344               | 239                | 418                | 188               |                               |
| Tramadol                     | Not Detected      | PRESENT           | Not Detected       | Not Detected       | Not Detected      |                               |
| O-Desmethylnaloxone          | Not Detected      | PRESENT           | Not Detected       | Not Detected       | Not Detected      |                               |
| N-Desmethylnaloxone          | Not Detected      | PRESENT           | Not Detected       | Not Detected       | Not Detected      |                               |
| Tramadol                     | Not Detected      | PRESENT           | Not Detected       | PRESENT            | PRESENT           |                               |
| 1,3 dioxolene piperazine     | PRESENT           | PRESENT           | PRESENT            | PRESENT            | PRESENT           |                               |
| Ibuprofen                    | Not Detected      | PRESENT           | PRESENT            | PRESENT            | PRESENT           |                               |
| Naproxen                     | PRESENT           | Not Detected      | Not Detected       | Not Detected       | Not Detected      |                               |
| Diphenhydramine              | PRESENT           | PRESENT           | Not Detected       | Not Detected       | Not Detected      |                               |

Test results received 3/12/18

Patient overdosed 3/18/18

Test results not reviewed until after patient's death

Legend:   
 [ ] Present and Not Detected    [ ] Absent but Detected    [ ] Drugs Present, No Medication List Provided

## John Smith's Last UDT Timeline

LAST OV  
and UDT  
SAMPLE

• Mar. 9, 2018

LAST UDT  
REPORT

• Mar. 12, 2018

Patient  
Overdosed  
and died

• Mar. 18, 2018

## SAMPLE STATE RULE ON USE OF DRUG TEST RESULTS (INDIANA)

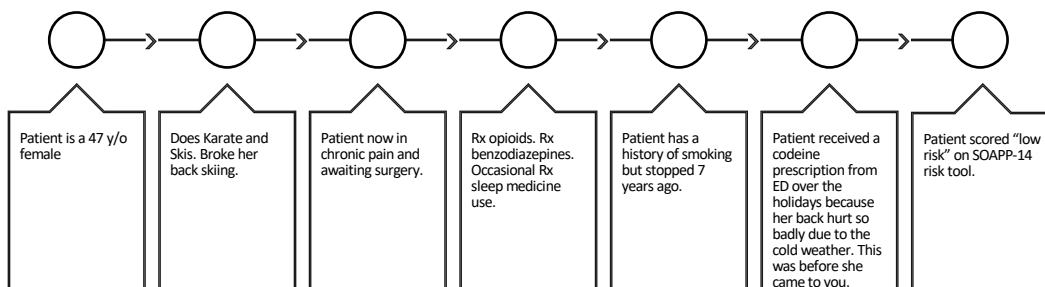
### STANDARDS OF PROFESSIONAL CONDUCT AND COMPETENT PRACTICE OF MEDICINE

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 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.]; filed Aug 22, 2016, 11:30 a.m.: 20160921-IR-844150415FRA)*

## Case Example #2 – Meet Jane Doe





## CASE STUDY #2 – JANE DOE – UDT Summary

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

## 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.

Patient fell off of orphanage roof in early years – fractured spine; unrepaired. Injured in Iraq. Six surgeries since ended tour of duty, including hip replacement. Needs spine surgery. PTSD diagnosis. Liver damage. Necrotizing fasciitis.

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**

|                  |        |             |                |
|------------------|--------|-------------|----------------|
| Oxidants         | NORMAL | 0.0         | 0 - 200        |
| pH               | NORMAL | 5.6         | 4.7 - 7.8      |
| Specific Gravity | NORMAL | 1.015       | 1.003 - 1.035  |
| Creatinine       | NORMAL | 147.5 mg/dL | 20 - 200 mg/dL |

| Tested For                                                                                                                                                                                               | Result   | Quantitation | Normalization (ng/mL) | Outcome      | Cutoff    | History |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|--------------|-----------------------|--------------|-----------|---------|
| <b>Alcohol Biomarkers</b>                                                                                                                                                                                |          |              |                       |              |           |         |
| Ethyl Glucuronide                                                                                                                                                                                        | Positive | > 7500 ng/mL |                       | INCONSISTENT | 500 ng/mL |         |
| Detection Window 1-2 days. Ethyl glucuronide (EtG) is a metabolite of ethanol (ethyl alcohol). Due to its longer detection time, EtG may be present in the absence of ethyl sulfate (EtS).               |          |              |                       |              |           |         |
| Ethyl Sulfate                                                                                                                                                                                            | Positive | 2191 ng/mL   |                       | INCONSISTENT | 200 ng/mL |         |
| Detection Window 2-3 days. Ethyl sulfate (EtS) is a metabolite of ethanol (ethyl alcohol) and its presence is specific for recent ethanol use. EtS has a shorter half-life than Ethyl glucuronide (EtG). |          |              |                       |              |           |         |

**Antidepressants, not otherwise specified**

|                                                                                                                                                                                        |          |             |  |              |           |  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|-------------|--|--------------|-----------|--|
| Bupropion                                                                                                                                                                              | Negative |             |  |              | 100 ng/mL |  |
| Desmethylvenlafaxine                                                                                                                                                                   | Positive | > 750 ng/mL |  | INCONSISTENT | 50 ng/mL  |  |
| Detection Window 1-2 days. Desmethylvenlafaxine, or desvenlafaxine, is an antidepressant prescribed as Pristiq. It is also the metabolite of the antidepressant venlafaxine (Effexor). |          |             |  |              |           |  |
| Hydroxybupropion                                                                                                                                                                       | Negative |             |  |              | 100 ng/mL |  |
| Venlafaxine                                                                                                                                                                            | Positive | 1226 ng/mL  |  | INCONSISTENT | 100 ng/mL |  |
| Detection Window 1-2 days. Venlafaxine is an antidepressant prescribed as Effexor. Its metabolite, desmethylvenlafaxine is also a prescribed antidepressant (Pristiq)                  |          |             |  |              |           |  |

**Antipsychotics**

|                                                                                                                                                                                                                                        |          |           |  |              |           |  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|-----------|--|--------------|-----------|--|
| 9-Hydroxyrisperidone                                                                                                                                                                                                                   | Negative |           |  |              | 100 ng/mL |  |
| Norquetiapine                                                                                                                                                                                                                          | Positive | 394 ng/mL |  | INCONSISTENT | 100 ng/mL |  |
| Detection Window 1-2 days. Active metabolite of Quetiapine (Ketiopinor, Quepin, Seroquel). Quetiapine is a prescribed dibenzothiazepine derivative that has been clinically used as a neuroleptic agent in the treatment of psychosis. |          |           |  |              |           |  |

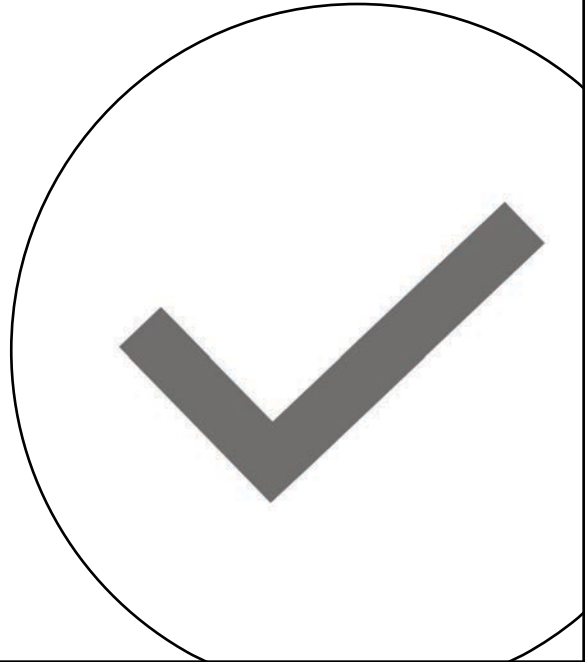
| Minimums                                                                                                                                                                                            | negative | 50 ng/mL    |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|-------------|
| <b>Opiates</b>                                                                                                                                                                                      |          |             |
| Codeine                                                                                                                                                                                             | Positive | 550 ng/mL   |
| Detection Window 1-2 days. Codeine is an opiate with many therapeutic uses. Codeine is metabolized into morphine, and trace amounts of hydrocodone.                                                 |          |             |
| Dihydrocodeine                                                                                                                                                                                      | Negative | 50 ng/mL    |
| Hydrocodone                                                                                                                                                                                         | Positive | 531 ng/mL   |
| Detection Window 1-2 days. Hydrocodone is a semi-synthetic opioid analgesic. It metabolizes into Dihydrocodeine, norhydrocodone, and hydromorphone. Preparations include Vicodin, Lortab and Norco. |          |             |
| Hydromorphone                                                                                                                                                                                       | Negative | 50 ng/mL    |
| Morphine                                                                                                                                                                                            | Positive | > 750 ng/mL |
| Detection Window 1-2 days. The presence of Morphine has been confirmed. Possible sources can include (but are not limited to) Morphine drugs, Codeine metabolism, or Heroin Metabolism.             |          |             |
| Norhydrocodone                                                                                                                                                                                      | Negative | 50 ng/mL    |

| benzoylglucuronide                                                                                                                                                 | negative | 50 ng/mL      |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|---------------|
| <b>Fentanyl</b>                                                                                                                                                    |          |               |
| Carfentanil                                                                                                                                                        | Negative | 1 ng/mL       |
| Fentanyl                                                                                                                                                           | Negative | 2 ng/mL       |
| Norfentanyl                                                                                                                                                        | Negative | 8 ng/mL       |
| <b>Gabapentin</b>                                                                                                                                                  |          |               |
| Gabapentin                                                                                                                                                         | Positive | > 15000 ng/mL |
| Detection Window 1-2 days. Gabapentin, a GABA analog, is marketed under the brand name Neurontin.                                                                  |          |               |
| <b>Heroin Metabolite</b>                                                                                                                                           |          |               |
| 6-MAM                                                                                                                                                              | Positive | > 375 ng/mL   |
| Detection Window up to 1 day. 6-MAM is a unique metabolite of the illicit drug heroin. The presence of 6-MAM has been confirmed and indicates recent heroin usage. |          |               |

**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?

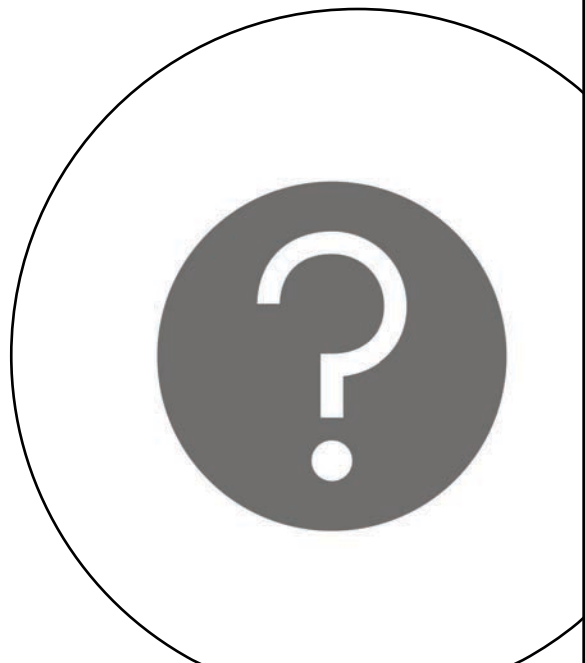
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Do you have patients with psychiatric disorders, including PTSD?

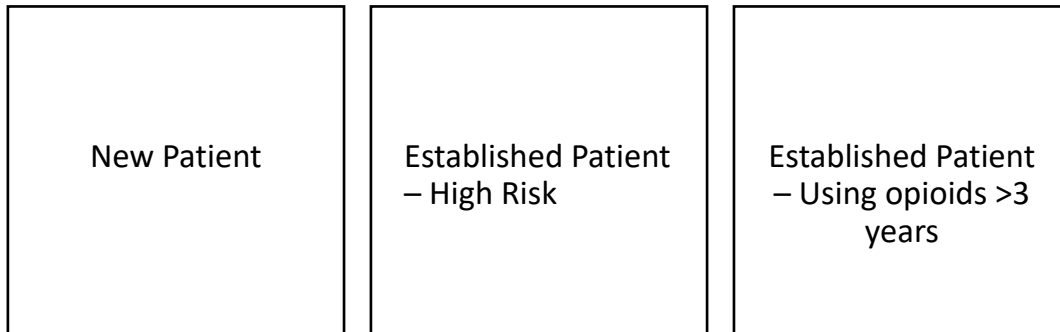
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Do you have patients who have been discharged from other practices because of aberrant, drug-related behavior?

START HERE → Ask yourself these questions (and more)

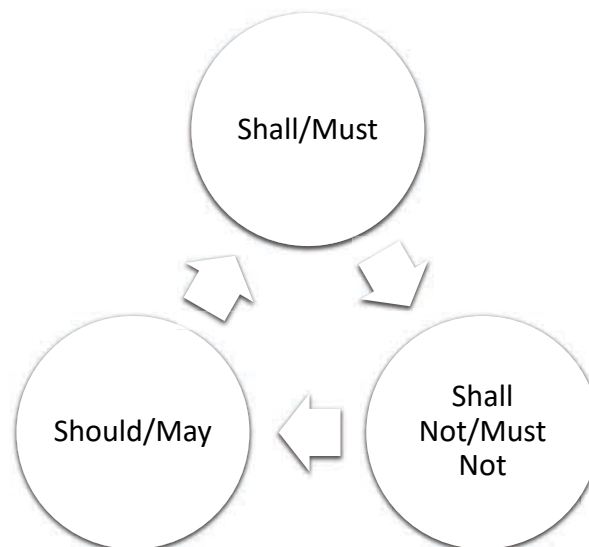


## Step 1 – Select Three Charts to Review



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## Step 2 – Make a List of Licensing Board and Professional Standards “Directives”



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# 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-844140289FRA, 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

### 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

#### GOALS

##### 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, < 20 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).

#### NOTES

##### 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-OPPIOID THERAPIES

- Use alone or combined with opioids, as indicated.
- Non-opioid medications (eg, NSAIDs, TCAs, SNRIs, well-controlled).
- 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.

Slow drug titration: 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 of 3 individual question scores (0/10; improvement from baseline is clinically meaningful)

1. What number from 0–10 best describes your pain in the past week?
  - 0 = “no pain”; 10 = “worst you can imagine”
2. 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”
3. 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 ORDER MORE:  
WWW.CDC.GOV/ODASD/OPRE/PRESCRIBINGGUIDELINE

March 2015



Step 3 –  
Review Charts with  
Directives List in Mind;

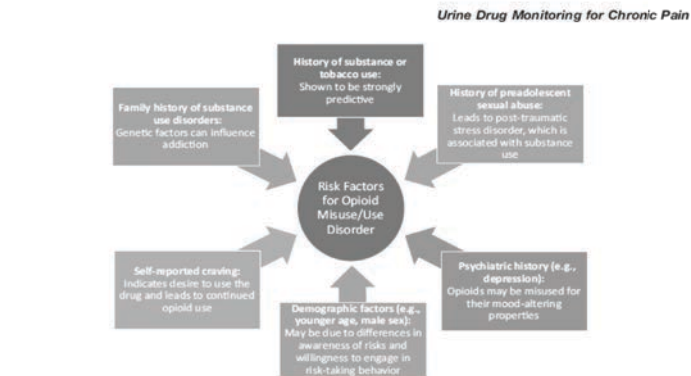
Ask: Where am I  
vulnerable?

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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 Argoff, et al



**Figure 3** Explanations for risk factors of opioid misuse and opioid use disorder [19,97,102–107].

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

Risk of Overdose  
– No Universal  
Standard yet, but  
SAMHSA and  
CDC, and Ohio

### EVALUATING RISK OF HARM OR MISUSE

**Known risk factors** include:

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## 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.

### JBG-IP-2002-2018-RISK SIGNALS-ABERRANT BEHAVIOR CHECKLIST

**INSTRUCTIONS:** This document is known as an Aberrant Behavior Check List and Follow-up Record. Record this information so you can locate it easily and use it throughout your office's relationship with the patient. Each time a patient returns for a follow-up visit, and in connection with any telephone communications with the patient, caregiver, or family member, assess and document potential aberrant behaviors. Alone, or in combination, these behaviors may be suggestive of prescription drug abuse or drug diversion. Remember, aberrant behaviors can be anything that is outside the documented treatment plan.

| OBSERVED CHANGES IN APPEARANCE                                                                                             | GENERAL RISK FACTORS                                                                                                         |
|----------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|
| Unkempt                                                                                                                    | Drug escalation                                                                                                              |
| Disheveled                                                                                                                 | High-dose MME/day (Narrow-Margin MME)                                                                                        |
| Sleepy Looking                                                                                                             | Resonance/fluorine or antidepressants with opioids                                                                           |
| Sedation                                                                                                                   | Participant in treatment for addiction                                                                                       |
| Nervous or jittery looking                                                                                                 | OR Opioids for acute pain or opioid-naïve patients                                                                           |
| Swelling of face or extremities (with or without edema, both, and open sores)                                              | Methadone Rx for opioid-naïve patient                                                                                        |
| Unexplained weight gain or loss                                                                                            | Recent release from, or current enrollment in, an abstinence, maintenance, or detox program (not methadone or buprenorphine) |
| <b>GENERAL RISK FACTORS</b>                                                                                                | Sleep apnea or sleep-disordered breathing                                                                                    |
| Personal history addiction and/or opioid abuse                                                                             | CCPD                                                                                                                         |
| History of, or evidence of current substance use disorder                                                                  | Competitive heart failure                                                                                                    |
| History of, or current mental health disorder or psychiatric illness                                                       | Kidney or liver dysfunction                                                                                                  |
| Unresolved depression/mental health disorder risk of suicide (All patients should be screened during not evaluation)       | Dental or hepatic disease                                                                                                    |
| Family history addiction                                                                                                   | Painkillers from, or difficulty accessing medical care                                                                       |
| Prescription opioid abuse                                                                                                  | Pain from MVA                                                                                                                |
| Use of common oral (OPI) medications (some contain alcohol and other CNS depressants that should not be used with alcohol) | Lack of family support                                                                                                       |
| Alcohol use                                                                                                                | Age < 65                                                                                                                     |
| Marijuana use                                                                                                              | <b>MEDICATION ISSUES</b>                                                                                                     |
| Smoker                                                                                                                     | Changes made to administration (oral and snort, snuff, and inject, etc.)                                                     |
| Criminal history                                                                                                           | Unusual interest in potential abuse issues associated with medication                                                        |
| Receiving multiple medication regimens                                                                                     | Increases doses without authorization                                                                                        |
| Obtain opioid preparations such as extended-release or long-acting opioids that may increase risk of overdose              | Using opioid for euphoria or purposeful sedation                                                                             |

| MEDICATION ISSUES                                                                                           | PSYCHOLOGICAL ISSUES                                                            |
|-------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|
| MEDICATION HOARDING                                                                                         | "Out of the world" behavior regarding medications                               |
| USES MEDS IN RESPONSE TO STRESSORS                                                                          | Manipulation issues between patient and caregiver or family member              |
| USES MEDS TO TREAT NON-PAIN STRESSORS                                                                       | Negative mood changes                                                           |
| Using pain medications during times when pain is less severe                                                | Isolation                                                                       |
| USES UNSANCTIONED MEDICATION                                                                                | Concerns of unusual behaviors as identified by family members                   |
| ONLY OPIOIDS WORK                                                                                           | Opioid withdrawal symptoms                                                      |
| RELUCTANCE TO CHANGE MEDS OR LOWER DOSES DESPITE STABILIZATION OR NEGATIVE EFFECTS AND DETRIMENTAL FUNCTION | Demanding behaviors in the medical office or over the telephone                 |
| INSISTS ON IN OPIOID                                                                                        | Abusive behavior in the waiting room                                            |
| Asks for "something for my nerves"                                                                          | Abusive behavior at the pharmacy                                                |
| <b>ACTIVITY ISSUES</b>                                                                                      | <b>ACTION PLAN</b>                                                              |
| REQUESTS SPECIFIC DRUGS                                                                                     | 1. All other issues to bring them up to you                                     |
| ABUSED ALCOHOL                                                                                              | 2. Consider and discuss with patient the potential for medication use and abuse |
| ABUSED ILLEGAL DRUGS                                                                                        | 3. Discuss and discuss with patient the potential for medication use and abuse  |
| CAR ACCIDENT                                                                                                | 4. Discuss and discuss with patient the potential for medication use and abuse  |
| ARRESTED                                                                                                    | 5. Discuss and discuss with patient the potential for medication use and abuse  |
| SOLD OR GAVE AWAY OPIOIDS                                                                                   | 6. Discuss and discuss with patient the potential for medication use and abuse  |
| LOST OR STOLEN PRESCRIPTIONS/MEDS                                                                           | 7. Discuss and discuss with patient the potential for medication use and abuse  |
| EARLY OR FREQUENT REFILLS                                                                                   | 8. Discuss and discuss with patient the potential for medication use and abuse  |
| DOCTOR SHOPPING                                                                                             | 9. Discuss and discuss with patient the potential for medication use and abuse  |
| RECENT CARE FOR NON-FATAL OPIOID OR POISONING                                                               | 10. Discuss and discuss with patient the potential for medication use and abuse |
| MULTIPLE ED OR URGENT CARE VISITS                                                                           | 11. Discuss and discuss with patient the potential for medication use and abuse |
| Multiple contacts between appointments                                                                      | 12. Discuss and discuss with patient the potential for medication use and abuse |
| Weekend telephone calls to your answering service                                                           | 13. Discuss and discuss with patient the potential for medication use and abuse |
| Missed appointments                                                                                         | 14. Discuss and discuss with patient the potential for medication use and abuse |
| Shows/changes medications from friends/family                                                               | 15. Discuss and discuss with patient the potential for medication use and abuse |
| Fills pain medications but not maintenance medications (insistent to non-opioid pharmacotherapy)            | 16. Discuss and discuss with patient the potential for medication use and abuse |

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

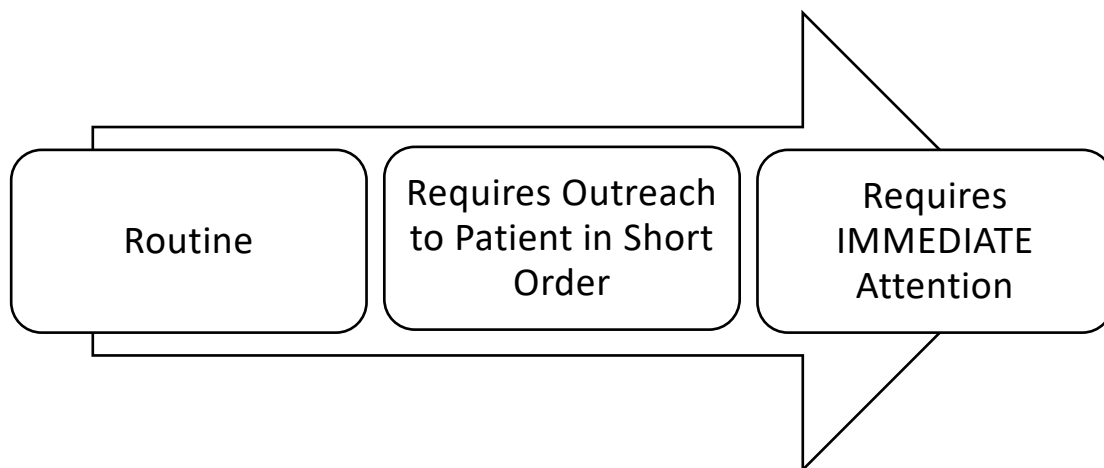
Addressing the Weaknesses

## REPRISE:

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

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

## UDT TRIAGE PROTOCOL

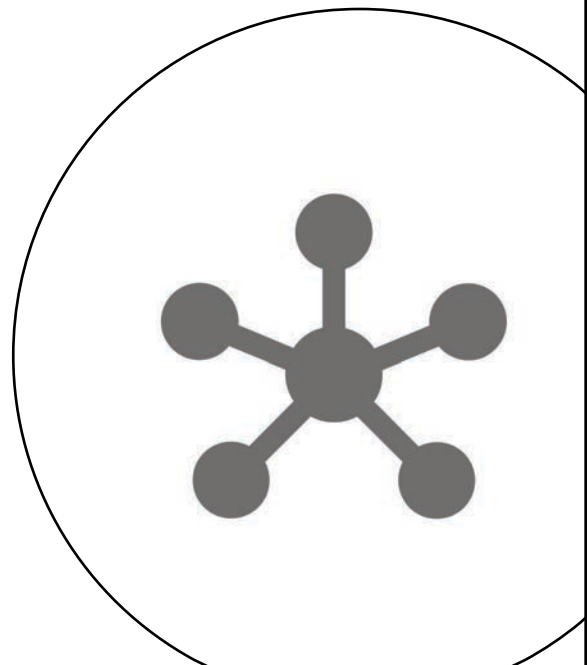


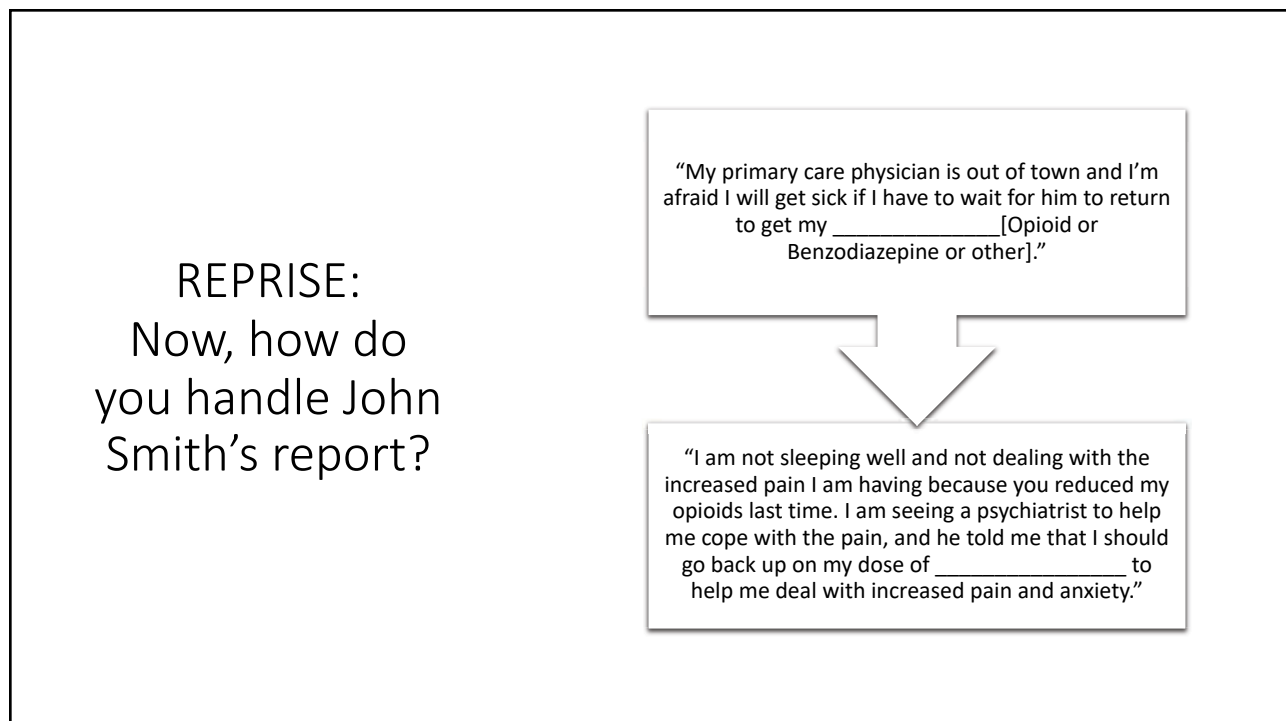
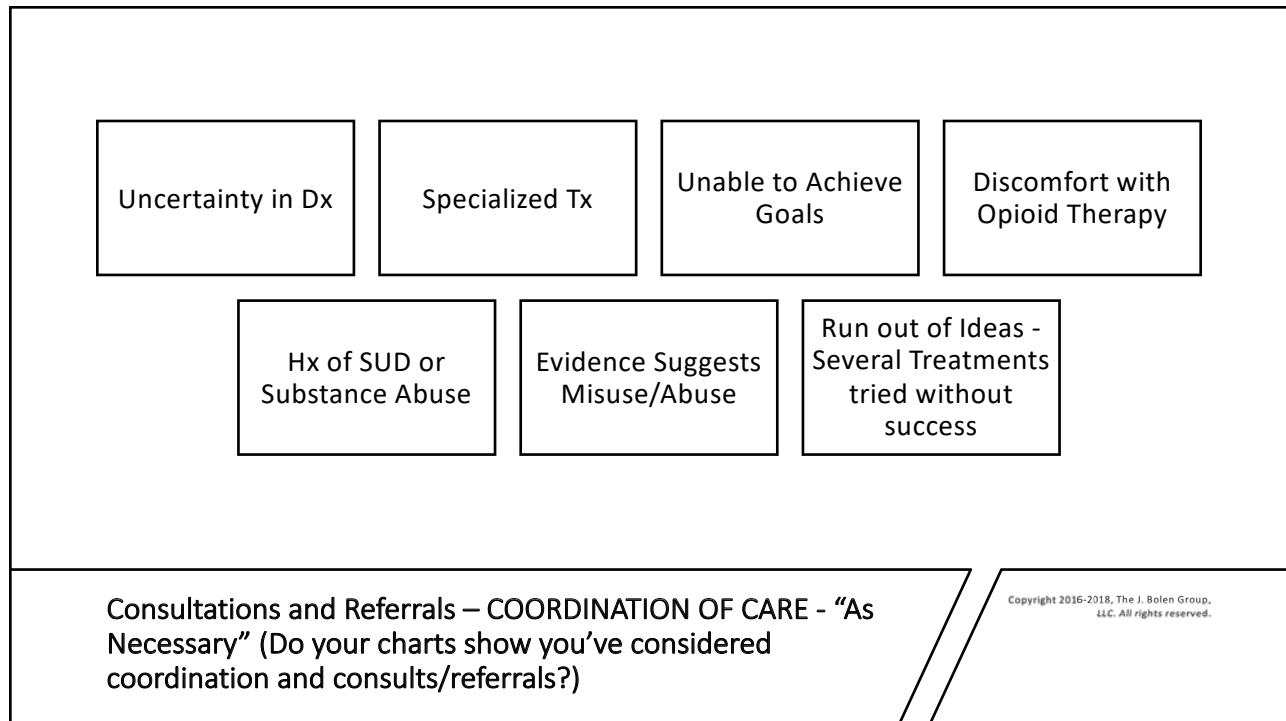
## Sample Treatment Decisions following Risky Behaviors and Aberrant UDT Results

| 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





## 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].”

PDMP 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?

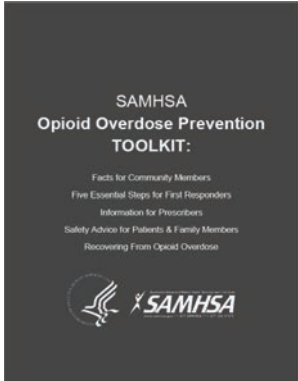
4. What if the patient tells you he is using alcohol?

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

## 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



**SAMHSA**  
**Opioid Overdose Prevention**  
**TOOLKIT:**

Facts for Community Members  
Five Essential Steps for First Responders  
Information for Prescribers  
Safety Advice for Patients & Family Members  
Recovering From Opioid Overdose

 **SAMHSA**

## EDUCATE PATIENTS AND STAFF MEMBERS

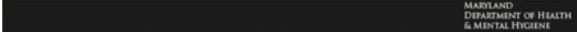
- <https://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit-Updated-2016/All-New-Products/SMA16-4742>

### 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/atod/opioids>

**DHMH Opioid Website**  
[dhmh.maryland.gov/medicaid-opioid-dur](http://dhmh.maryland.gov/medicaid-opioid-dur)



MD  
MARYLAND  
DEPARTMENT OF HEALTH  
& MENTAL HYGIENE

## 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

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## 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

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## 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

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## 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                |

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Thank you!

