



Embrace Changes and Mitigate Legal Risks Associated with Opioid Prescribing and the Issue of Overdose:

An Updated Blueprint for the Frontline Pain Practitioner and Medical Directors

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Disclosures for Jennifer Bolen, JD

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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



Dear Pain Management Practitioner:

• Love, Your licensing board

• PS: You have 21 days to do this!

This office is in receipt of only one version of the allegations contained in enclosed information is being submitted to you to provide you the opportunity recollection of the incident. Therefore, please submit a narrative setting forth and response to the allegations contained in the complaint. Your response to also include copies of all relevant medical treatment records, pursuant to

The typical case goes something like this . . .

Get	Get Letter *Hit the Panic Button *Reality Sets in
Talk	Talk to Lawyer *Gather Files; Hit Panic Button *Denial takes hold, with Anger as a seat buddy
Make	Make a Choice *Approach with Confidence and Send in Fact Filled, Humble Response; Fight if you have to *Don't Continue Denial and Fight without a helpful framework

Necessary framework and path forward

Freeze	Freeze Records • Copy and Review • NOTE THE FACTS; Avoid Opinion at First
Match	Match Facts Against Standards • Evaluate Strengths and Weaknesses • Identify potential expert support
Prepare	Prepare Response* (assuming advice of counsel is to do this) • Carefully mix case facts with humble description of decision-making • Wait and see, but prepare for possible next steps

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

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

Legitimate Medical Purpose	One or more generally recognized medical indication for the use of the controlled substance
Usual Course of Professional Practice	According to licensing and professional standards, including consideration of licensing board material; Steps of a “Reasonably Prudent” Practitioner
Reasonable Steps to Prevent Abuse and Diversion	Proper Risk Evaluation, Stratification, and Monitoring Protocols, including overdose risk evaluation PDMP, UDT, NALOXONE, OPIOID TRIAL, VISIT FREQUENCY 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
- General medical history - Pain Specific History - Risk of Abuse/Addiction - Risk of Diversion - Risk of Overdose	- Opioid Trial and Some form of Exit Strategy - Treatment Plan for Frequency, Handling MME, POMP utilization, UDT, etc. - Naloxone and Patient Education - Documentation and Process of Informed Consent and Treatment Agreement	- Scope of Practice Issues - Exchange of documentation between PCP and Specialty providers engaged in chronic MEDICATION therapy (not just limited to opioids) - Dealing with Marijuana issues - Rationale for starting, stopping, changing, etc.

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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)





California Comparison Continued

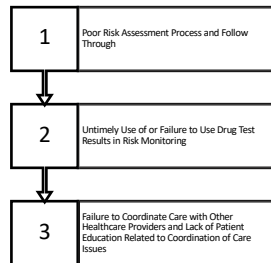
OBJECTIVES 3 and 4:

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.
Rhee AL, Brennan D, Chu HSH, Lind T, Wiley AT, LaRoche MP, Stein BD, Stokes TJ.
J Gen Intern Med. 2016 Jun 1; 31(6):674-681. doi: 10.1007/s11367-016-0325-5. [Epub ahead of print].
PMID: 26848715
2. Controlled Substance Prescribing Patterns: Prescription Behavior Surveillance System, 2009-2013.
Friedman L, Olfender GK, Kivner PW, Arora CM. Centers for Disease Control and Prevention (CDC).
MMWR Surveill Summ. 2015 Oct 16;64(41):10457-10461. doi: 10.15585/mmwr.mm6441a1.
PMID: 26248797
3. Patterns of Opioid Use and Risk of Opioid Overdose Death Among Medicaid Patients.
Garg MK, Fisher-Fahnestock G, Friedman LRA.
Med Care. 2017 Jun;55(6):e18. doi: 10.1097/MLR.0000000000000709.
PMID: 28510018
4. High-risk use by patients prescribed opioids for pain and its role in overdose deaths.
Bauer R, Boudreau J, Whalen C, Davis M, Bradford R, Friedman L, Jones T.
JAMA Intern Med. 2017 May;177(5):759-765.
PMID: 28348751
5. Relationship to Opioid Use Disorder After Nonfatal Opioid Overdose and Associated Risk Mortality: A Cohort Study.
Larochelle MP, Rasmussen Q, Land T, Dugan T, Wang N, Kuhl J, Kung'u D, Lachin D, JM, Wiley AT.
Ann Intern Med. 2016 Aug 7;165(3):177-185. doi: 10.7326/M15-1707. Epub 2016 Jun 16.
PMID: 27051016
6. Association between opioid control status, overdose, and opioid overdose-related deaths.
Brennan AL, Salsman AL, Rhee AL, Brennan D, McGuffee A, Rhee AL, Stein BD.
JAMA. 2017 Apr 19;316(16):1574-1581. doi: 10.1001/jama.2017.1071.
PMID: 28348751

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MME ≥ 100 mg/day
in ≥ 3 mos.

Overlapping Opioid and non-opioid prescriptions in ≥ 3 mos.	≥ 4 prescribers in any quarter	≥ 4 dispensing pharmacies in any quarter	Cash purchase of opioid prescriptions in ≥ 2 consecutive	Receipt of opioids in ≥ 3 mos. With documented pain diag.
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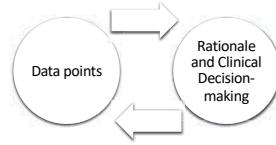
DOI: 10.1002/eqe.2142

PIP Article	Bolen Group Audit Findings	General Suggestions for Improvement
MME >= 100mg/day for >= 3 mos.	Frequent failures to track MME	Track MME
Overlapping Opioid and Benzodiazepine Prescriptions in >= 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 2. Coordinate care with BOD prescriber 3. May be appropriate to discuss reducing Benzodiazepines or limiting term of use or time of reevaluation.
>= 4 prescribers and pharmacists in any quarter	Multiple prescribers often involved people in the same practice or PCP/Internal Medicine, Pain Specialist, and Psychiatrist Multiple pharmacists happen for different reasons. Sometimes not clear in chart.	5. Use POMD 6. Coordinate care with other physicians and pharmacists, especially for complex patient 3. Discuss need to know who treats patient and where medication is filled, what's prescribed, and why.
Cash purchase of opioids on >= 3 occasions	Didn't find in our audit	1. Outside scope of lecture
Receipt of opioids in >= 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 2. Document a specific diagnosis or working diagnosis 3. Evaluate frequently during first year and thereafter per standards

Comparing PIP to Our Anecdotal Audit Findings - 2

PIP Article	Bolton 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	1. UDT Results Triage 2. Ongoing Use of UDT results in Tx 3. Documentation 4. See UDT Lecture

The mindset is to create the “cheese trail” that reflects the prescriber’s rationale at various data points



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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/Phys 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, anorexia/bulimia
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. 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	Alprazolam 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 1-1.5 alcoholic beverages per month	Reported to drink 5-13 alcoholic beverages a month. Alcohol in UDS	Reported as non drinker	Patient reports alcohol abuse not counseled
MME	267mg MME	267mg MME	236mg MME	188mg MME

John Smith – Initial MME

- 75 mcg/day Fentanyl
- 4mg hydromorphone, #6 per day

John Smith's Last Office Visit 3/9/18

- Complained of anxiety, lack of sleep, pain, and alcohol troubles.
- Concerned about running out of alprazolam because his prescribing physician is not available.
- During visit, provider:
 - Rx FENTANYL, 50mcg Q72 = 120 mg MME
 - Rx Oxycodone, 10mg Q6 hours (40mg) = 60mg MME
 - Rx Alprazolam to keep patient from having seizures; supply covers 7 days (1 tablet BID)
- Total MME is 180mg/day
- Requested Drug Test
- Updated SOAPP-R
- Patient's BP was 88/64

John Smith's Last Risk Assessment Responses Mar. 9, 20178

Mar. 9, 2018

1. How often do you use alcohol? ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

2. How often do you use drugs? ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

3. How often do you use prescription drugs? ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

4. How often do you use over-the-counter drugs? ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

5. How often do you use recreational drugs? ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

6. How often do you use illegal drugs? ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

7. How often do you use prescription drugs? ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

8. How often do you use over-the-counter drugs? ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

9. How often do you use recreational drugs? ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

10. How often do you use illegal drugs? ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

John Smith's Drug Test Results – Timing and Utility

Drug	Test 1 03/09/18	Test 2 03/10/18	Test 3 03/14/17	Test 4 03/15/17	Test 5 03/17/17
Alcohol	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected
Amphetamines	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected
Barbiturates	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected
Benzodiazepines	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected
Cocaine	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected
Ecstasy	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected
Heroin	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected
Marijuana	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected
Prescription Drugs	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected
Recreational Drugs	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected
Illegal Drugs	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected

Test results received 03/15/18

Patient overdosed 03/15/18

Test results not returned until after patient's death

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)

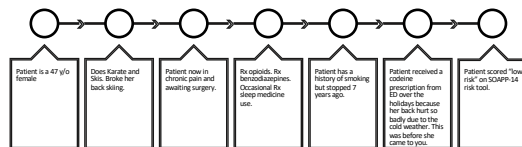
STANDARDS OF PROFESSIONAL CONDUCT AND COMPETENT PRACTICE OF MEDICINE

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 ILC 5-6-8; filed Oct 7, 2014, 12:27 p.m.; 20141103-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 RELEVANT RX	UDT ORDERED	DATE ON LAB REPORT	Date EMR Shows Review	RESULTS	Aberrant?
1/24/15 Rx after OVI = OXYCODONE Patient had prior Rx Tylenol #3	Yes	1/28/15	2/24/15	Gabapentin+ TCA+	Yes, Gabapentin not disclosed, but is Rx from another doctor. Oxycodone Rx given.
2/24/15 Rx is OXYCODONE, Morphine added	Yes	3/1/15	3/24/15	Gabapentin+ Oxycodone + TCA+ Dextromethorphan+	Yes, Dextromethorphan; Missing Rx Opioid (Dey)
3/24/15 Rx for Oxycodone, Morphine, Gabapentin	Yes	4/2/15	4/24/15	Morphine + Gabapentin+ Oxycodone +	Yes, Morphine+ but 6-MAM-NEG Oxycodone+
4/24/15 Rx for Oxycodone, Morphine, Gabapentin	Yes	5/26/15	Reviewed after Patient's death.	Morphine+ 6-MAM+ FENTANYL+ 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	5.8		4.7 - 7.8	
Specific Gravity	NORMAL	1.015		1.000 - 1.035	
Creatinine	NORMAL	147.5 mg/dL		20 - 200 mg/dL	
Tested For	Result	Quantitation	Normalization (ng/mL)	Outcome	Cutoff History
Alcohol Biomarkers					
Ethyl Glucuronide	Positive	> 7500 ng/mL		INCONSISTENT	500 ng/mL
Detection Window 1-2 days. Ethyl glucuronide (EG) is a metabolite of ethanol (ethyl alcohol). Due to its longer detection time, EG may be present in the absence of ethyl sulfate (ES).					
Ethyl Sulfate	Positive	2391 ng/mL		INCONSISTENT	200 ng/mL
Detection Window 2-3 days. Ethyl sulfate (ES) is a metabolite of ethanol (ethyl alcohol) and its presence is specific for recent ethanol use. ES has a shorter half-life than Ethyl glucuronide (EG).					

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	384 ng/mL		INCONSISTENT	100 ng/mL
Detection Window 1-2 days. Active metabolite of Quetiapine (Seroquel, Quipin, Seroquel). Quetiapine is a prescribed dibenzothiazepine derivative that has been clinically used as a neuroleptic agent in the treatment of psychosis.					

Substance	Result	Concentration	Interpretation	Limit
Opiates				
Codine	Positive	500 ng/mL	INCONSISTENT	50 ng/mL
Detection Window 1-2 days. Codine is an opiate with many therapeutic uses. Codine is metabolized into morphine, and trace amounts of hydrocodone.				
Dihydrocodone	Negative			50 ng/mL
Hydrocodone	Positive	500 ng/mL	INCONSISTENT	50 ng/mL
Detection Window 1-2 days. Hydrocodone is a semi-synthetic opioid analgesic. It metabolizes into Dihydrocodone, norhydrocodone, and hydromorphone. Preparations include Vicodin, Lorcet, and Norco.				
Hydromorphone	Negative			50 ng/mL
Morphine	Positive	> 750 ng/mL	INCONSISTENT	50 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, Codine metabolism, or Heroin Metabolism.				
Norhydrocodone	Negative			50 ng/mL

Substance	Result	Concentration	Interpretation	Limit
Fentanyl				
Carfentanyl	Negative			1 ng/mL
Fentanyl	Negative			2 ng/mL
Norfentanyl	Negative			8 ng/mL
Gabapentin				
Gabapentin	Positive	> 10000 ng/mL	INCONSISTENT	1000 ng/mL
Detection Window 1-2 days. Gabapentin, a GABA analog, is marketed under the brand name Neurontin.				
Heroin Metabolite				
6-MAM	Positive	> 375 ng/mL	INCONSISTENT	25 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?

Do you have patients with psychiatric disorders, including PTSD?

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

START HERE → Ask yourself these questions (and more)

Step 1 –
Select Three Charts to Review

New Patient

Established Patient
– High Risk

Established Patient
– Using opioids >3 years

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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.; 20141105-16-8441-00209FRA, eff Nov 1, 2014 [IC 4-22-5-36 suspends the effectiveness of a rule document for 30 days after filing with the Publisher. LSA Document 114-209 was filed Oct 7, 2014.]

CDC Opioid Prescribing Guidelines - Checklist

Checklist for prescribing opioids for chronic pain

WHEN CONSIDERING long-term opioid therapy

1. Do you have a good understanding of the patient's pain problem?
2. Have you obtained records from previous health care providers to supplement your understanding of the patient's pain problem?
3. Have you asked the patient to complete an objective pain assessment tool to document and better understand the patient's specific pain concerns?
4. Have you assessed both the patient's mental health status and risk for substance abuse using available validated screening tools?
5. Have you established a working diagnosis and tailored a treatment plan to meaningful and functional goals with the patient reviewing them from time to time?

WHEN REASSESSING at status and

1. Have you assessed the patient's pain problem and updated your understanding of the patient's pain problem?
2. Have you assessed the patient's mental health status and risk for substance abuse using available validated screening tools?
3. Have you assessed the patient's functional status and updated your understanding of the patient's functional status?
4. Have you assessed the patient's risk for opioid misuse and updated your understanding of the patient's risk for opioid misuse?
5. Have you assessed the patient's risk for opioid use disorder and updated your understanding of the patient's risk for opioid use disorder?
6. Have you assessed the patient's risk for opioid overdose and updated your understanding of the patient's risk for opioid overdose?
7. Have you assessed the patient's risk for opioid addiction and updated your understanding of the patient's risk for opioid addiction?
8. Have you assessed the patient's risk for opioid dependence and updated your understanding of the patient's risk for opioid dependence?
9. Have you assessed the patient's risk for opioid withdrawal and updated your understanding of the patient's risk for opioid withdrawal?
10. Have you assessed the patient's risk for opioid tolerance and updated your understanding of the patient's risk for opioid tolerance?
11. Have you assessed the patient's risk for opioid resistance and updated your understanding of the patient's risk for opioid resistance?
12. Have you assessed the patient's risk for opioid relapse and updated your understanding of the patient's risk for opioid relapse?
13. Have you assessed the patient's risk for opioid craving and updated your understanding of the patient's risk for opioid craving?
14. Have you assessed the patient's risk for opioid compulsions and updated your understanding of the patient's risk for opioid compulsions?
15. Have you assessed the patient's risk for opioid preoccupation and updated your understanding of the patient's risk for opioid preoccupation?
16. Have you assessed the patient's risk for opioid loss of control and updated your understanding of the patient's risk for opioid loss of control?
17. Have you assessed the patient's risk for opioid impaired judgment and updated your understanding of the patient's risk for opioid impaired judgment?
18. Have you assessed the patient's risk for opioid impaired memory and updated your understanding of the patient's risk for opioid impaired memory?
19. Have you assessed the patient's risk for opioid impaired concentration and updated your understanding of the patient's risk for opioid impaired concentration?
20. Have you assessed the patient's risk for opioid impaired decision making and updated your understanding of the patient's risk for opioid impaired decision making?
21. Have you assessed the patient's risk for opioid impaired impulse control and updated your understanding of the patient's risk for opioid impaired impulse control?
22. Have you assessed the patient's risk for opioid impaired social functioning and updated your understanding of the patient's risk for opioid impaired social functioning?
23. Have you assessed the patient's risk for opioid impaired occupational functioning and updated your understanding of the patient's risk for opioid impaired occupational functioning?
24. Have you assessed the patient's risk for opioid impaired academic functioning and updated your understanding of the patient's risk for opioid impaired academic functioning?
25. Have you assessed the patient's risk for opioid impaired legal functioning and updated your understanding of the patient's risk for opioid impaired legal functioning?
26. Have you assessed the patient's risk for opioid impaired financial functioning and updated your understanding of the patient's risk for opioid impaired financial functioning?
27. Have you assessed the patient's risk for opioid impaired family functioning and updated your understanding of the patient's risk for opioid impaired family functioning?
28. Have you assessed the patient's risk for opioid impaired community functioning and updated your understanding of the patient's risk for opioid impaired community functioning?
29. Have you assessed the patient's risk for opioid impaired national functioning and updated your understanding of the patient's risk for opioid impaired national functioning?
30. Have you assessed the patient's risk for opioid impaired global functioning and updated your understanding of the patient's risk for opioid impaired global functioning?



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 (PAIN, 2017; 100-105).

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:

- Illegal drug use; prescription drug use for nonmedical reasons.
- History of substance use disorder or overdose.
- Mental health conditions (eg, depression, anxiety).
- Sleep-disordered breathing.
- Concurrent benzodiazepine use.

RISK-Behavior Tracking Form Ideas

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

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

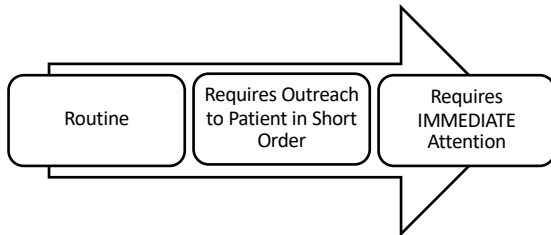
Addressing the Weaknesses

REPRISE:

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

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

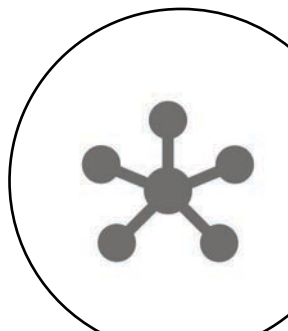
UDT TRIAGE PROTOCOL



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



Uncertainty in Dx	Specialized Tx	Unable to Achieve Goals	Discomfort with Opioid Therapy
Hx of SUD or Substance Abuse		Evidence Suggests Misuse/Abuse	Run out of Ideas - Several Treatments tried without success

Consultations and Referrals – COORDINATION OF CARE - "As Necessary" (Do your charts show you've considered coordination and consults/referrals?)

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

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

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

**Critical Coordination of Care Issue –
I'm out of my Benzodiazepines**

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

POMP Check Shows Last Rx was indeed by the name "other" prescriber and about 10 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 patched 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 BDD?

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

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EDUCATE PATIENTS AND STAFF MEMBERS



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

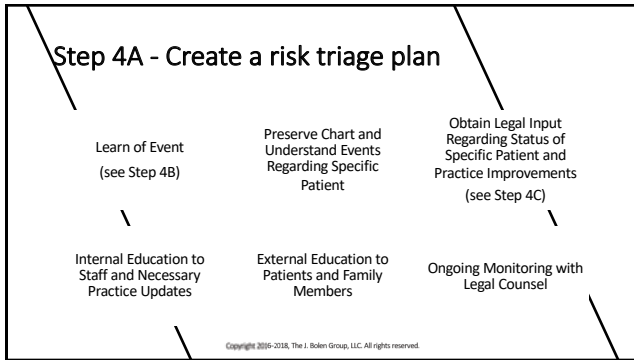
Resources: Websites

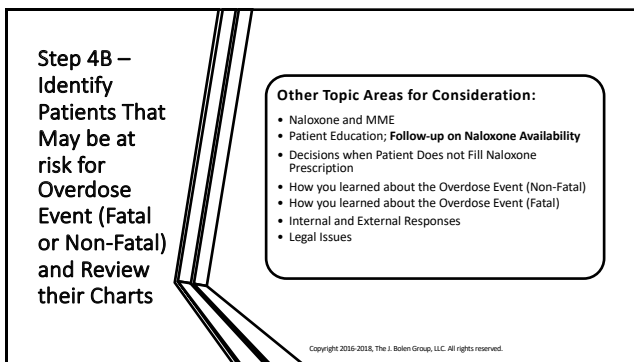
CDC
<http://www.cdc.gov/drugoverdose/prescribing/providers.htm>
• Provider and patient materials, including prescribing checklists, flyers, and posters

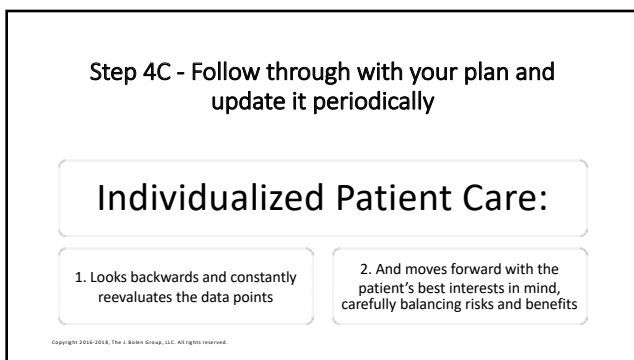
SAMHSA
<http://www.samhsa.gov/etod/opioids>

DHMH Opioid Website
dmh.maryland.gov/medicalid-opioid-due









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 Overdose	CDC and Academy Positions	Informed Consent Process
Treatment Plan	Federation of State Medical Boards	Risk of Overdose	Interaction with Pharmaceuticals	Consequences of Treatment Agreement Violation
Informed Consent	Medicare Guidelines	Other Behavioral Risks	PROM Use	Safe Use
Treatment Agreement	CDC Guidelines	Protocols for Screening and Overall Assessment of Risk and Stratification	Drug Testing	Safe Storage
Periodic Review	Substance Materials	Protocols for Monitoring and 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!

