The Year of the Looking Glass: An Exercise on Risk Mitigation and Documentation

With an Update on Informed Consent and Treatment Agreements

Disclosures

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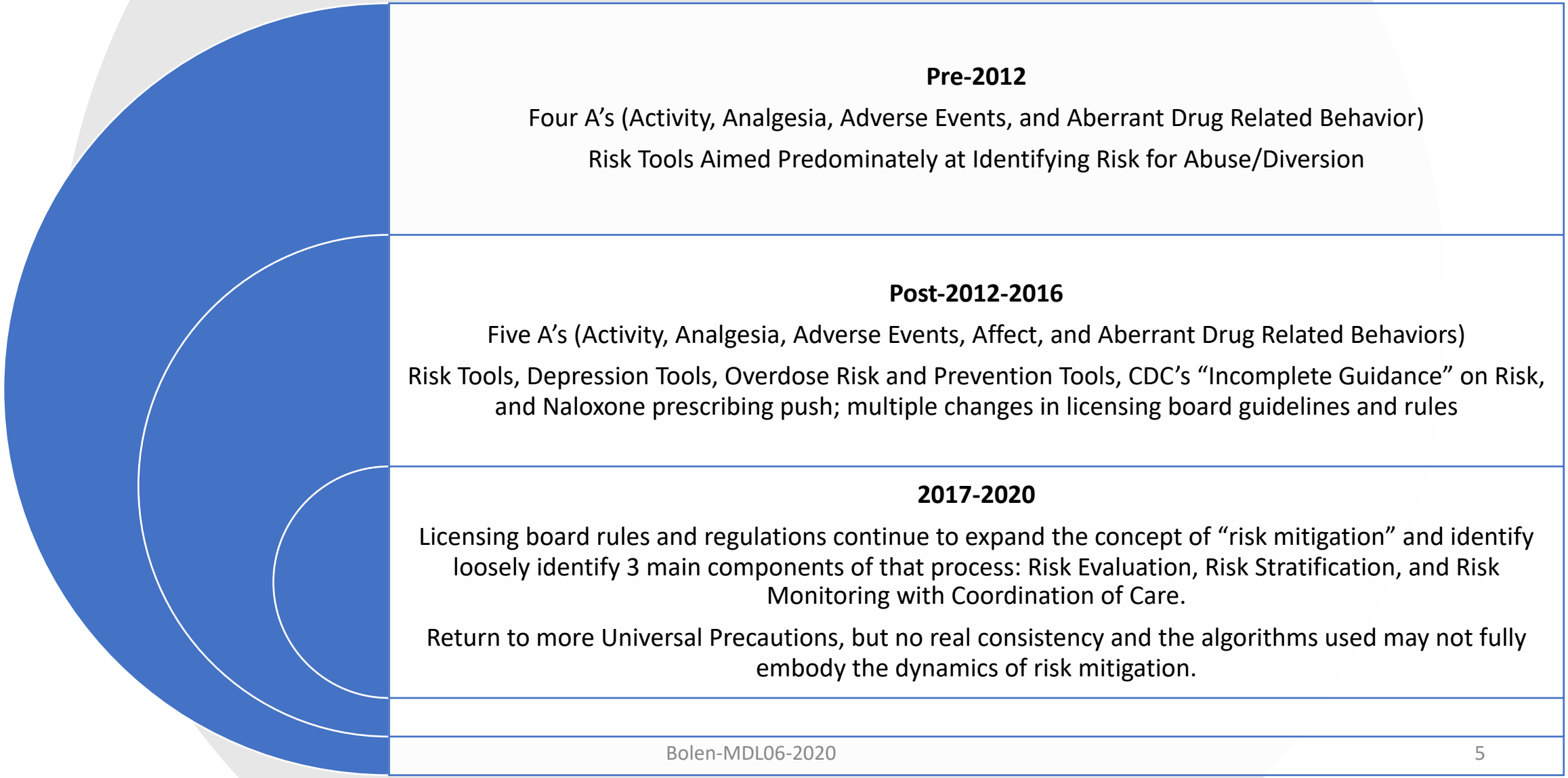
Learning Objectives

- Examine basic components and requirements for “risk mitigation” in the context of chronic pain management.
- Evaluate a case example designed to distinguish incomplete risk evaluation and monitoring and to facilitate improvement in practitioner documentation of the risk mitigation process.
- Review informed consent and treatment agreement concepts.

Part 1 - Risk Mitigation in Controlled Substance Prescribing: Looking Backwards to Move Forward

A Lawyer's Perspective on the Medical-Legal Evolution of Risk Mitigation in Chronic Pain Management



Looking Glass Year - 2006

DEA Statement of Risk Evaluation and Monitoring

"Moreover, as a condition of being a DEA registrant, a physician who prescribes controlled substances has an obligation to take reasonable measures to prevent diversion. [21 U.S.C. 823(f)]."

"The overwhelming majority of physicians in the United States who prescribe controlled substances do, in fact, exercise the appropriate degree of medical supervision—as part of their routine practice during office visits—to minimize the likelihood of diversion or abuse."

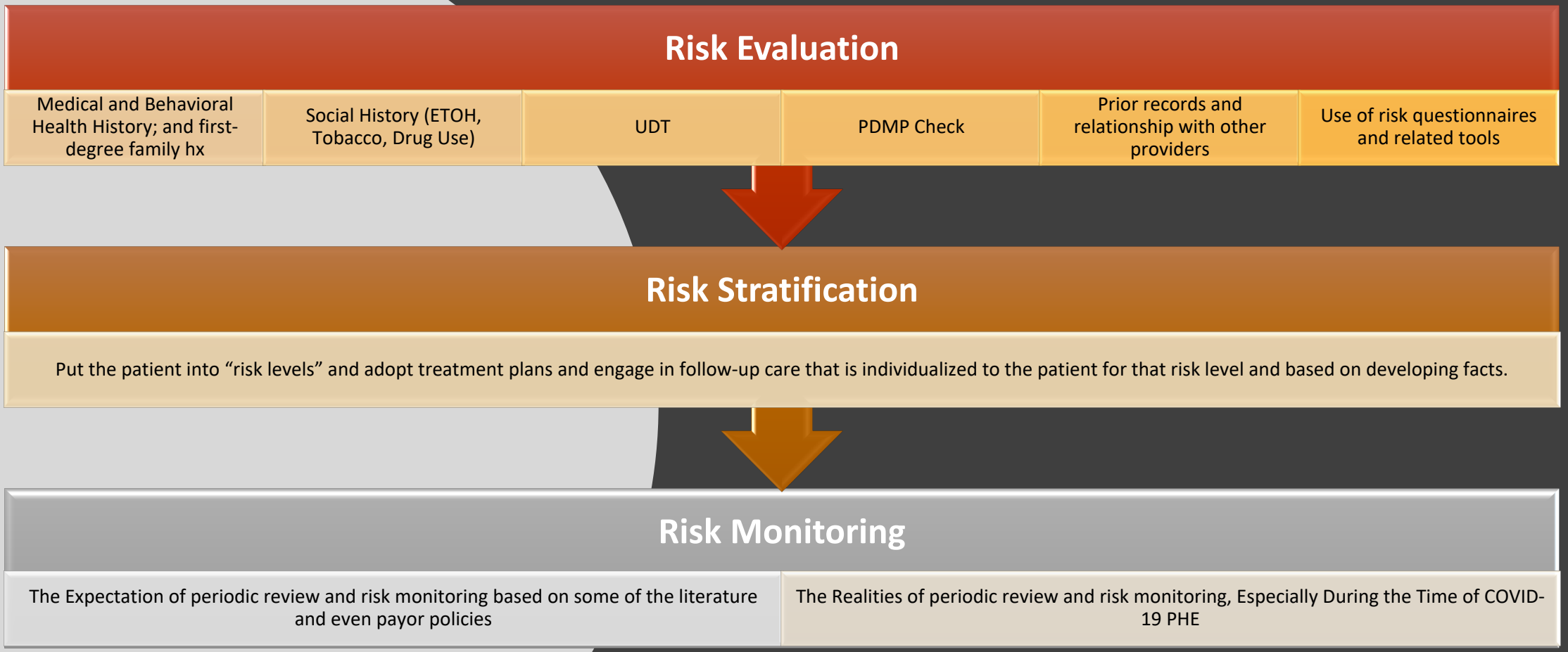
"Again, each patient's situation is unique, and the nature and degree of physician oversight should be tailored accordingly, based on the physician's sound medical judgment and consistent with established medical standards."

SOURCE: DEA Final Policy Statement, Notice, FR Doc E6-14517 [Federal Register: September 6, 2006 (Volume 71, Number 172)] [Notices] [Page 52715-52723] From the Federal Register Online via GPO Access [wais.access.gpo.gov] [DOCID:fr06se06-137], Available online at https://www.deadiversion.usdoj.gov/fed_regs/notices/2006/fr09062.htm

Looking Glass Year - 2020

"I found Respondent's [the physician's] credibility to be dubious and her counseling on the record to be insufficient, but the record was clear that, whether or not Respondent actually counseled patients with inconsistent urine screens or alcohol metabolites, she did not adequately document that counseling to demonstrate that she was actively resolving the issues. The ALJ cited to numerous DEA cases that demonstrate that 'requiring patients to take a drug test services little purpose, if any, if the registrant ignores the test results.'"

SOURCE: DEA Decision and Order in Kaniz F. Khan-Jaffery, July 29, 2020, available as a handout and online at https://www.deadiversion.usdoj.gov/fed_regs/actions/2020/fr0729_4.pdf (internal citations omitted).

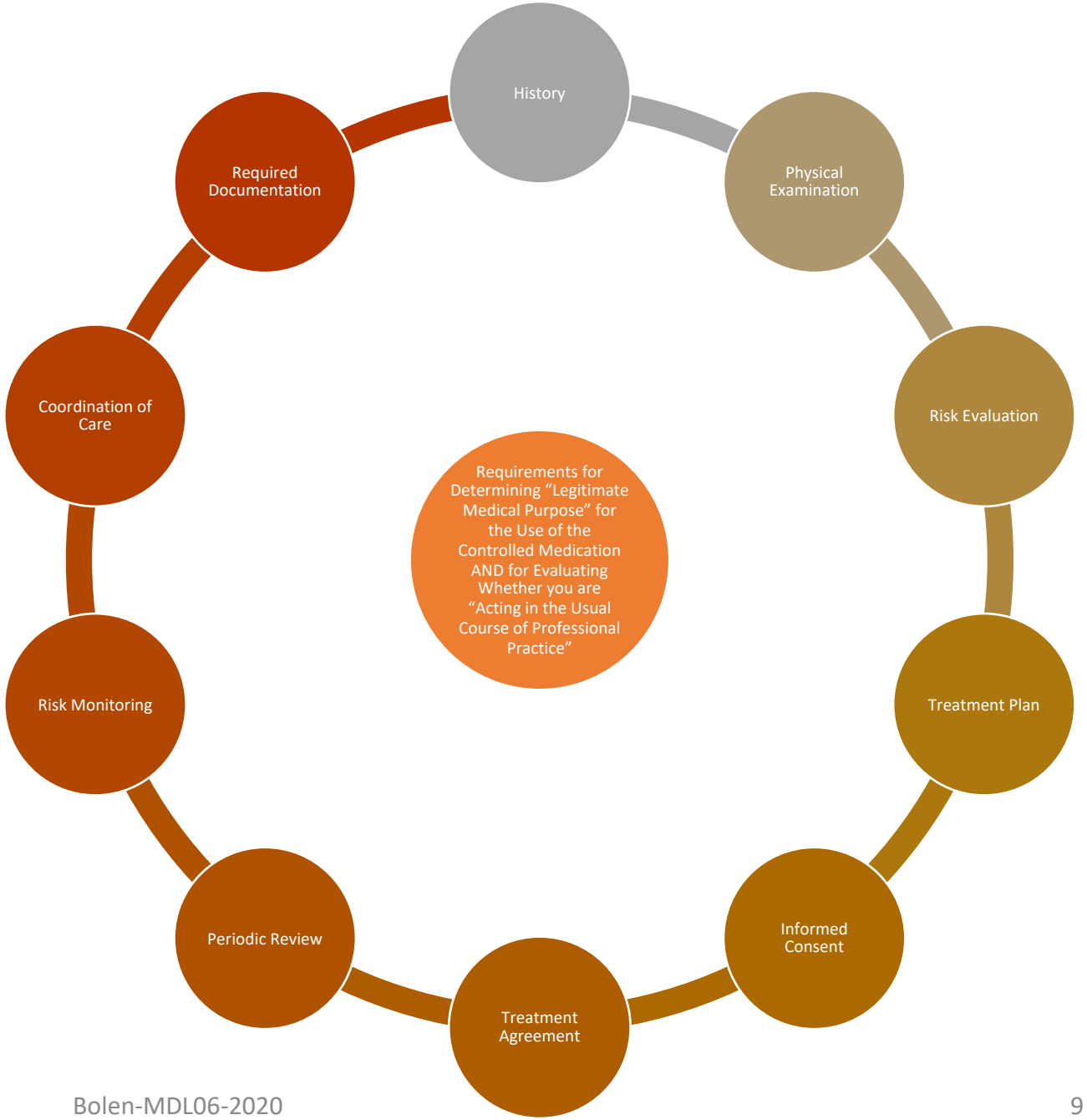


A Lawyer’s Perspective: Three Major Components of the “Risk Mitigation Process”

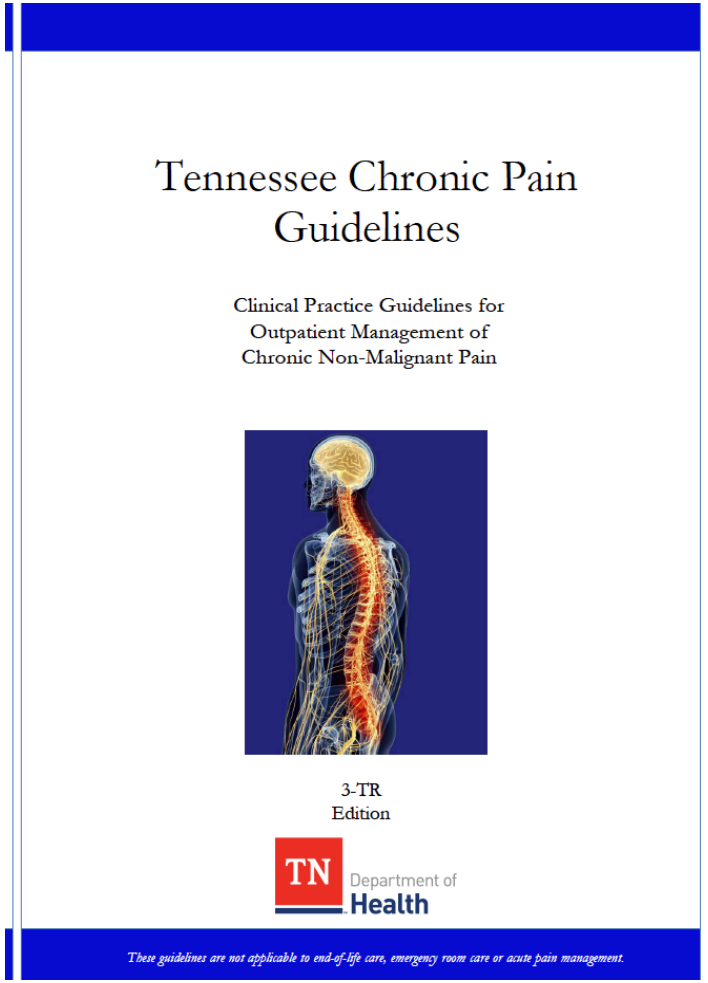
REPRISE:

Foundation for MOST State Licensing Board Pain Management Prescribing Rules/Guidelines, derived from the FSMB Model Policy.

SOURCES: Bolen, J., A personal Compendium of Cases, FSMB, Professional Society Material, and State Licensing Board Material (2000-2020); and FSMB Model Guidelines for the Chronic Use of Opioid Analgesics (2017), available online at https://www.fsmb.org/siteassets/advocacy/policies/opioid_guidelines_as_adopted_april-2017_final.pdf;



Sample State Licensing Board Requirement for Risk Evaluation (Tennessee; Dec. 2019)



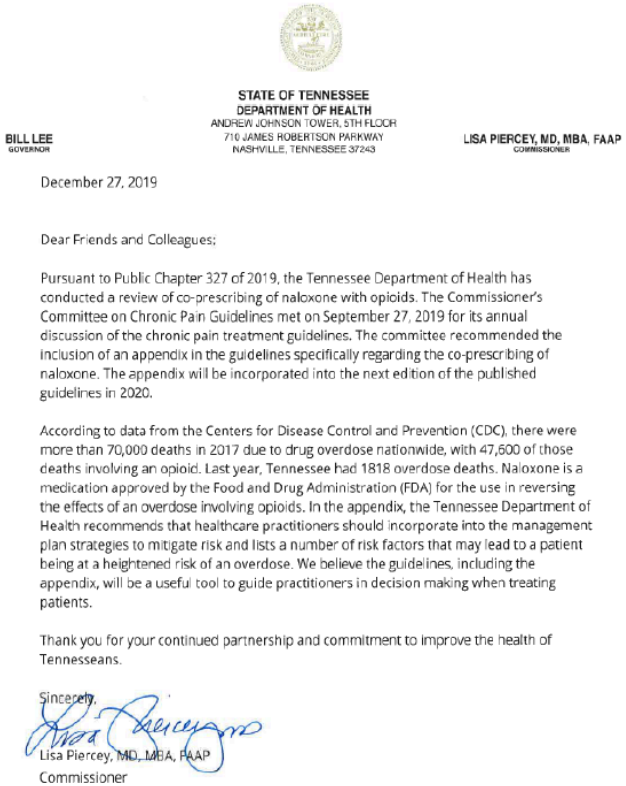
Tennessee Chronic Pain Guidelines

Clinical Practice Guidelines for Outpatient Management of Chronic Non-Malignant Pain

3-TR Edition

TN Department of Health

These guidelines are not applicable to end-of-life care, emergency room care or acute pain management.



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LISA PIERCEY, MD, MBA, FAAP
COMMISSIONER

December 27, 2019

Dear Friends and Colleagues;

Pursuant to Public Chapter 327 of 2019, the Tennessee Department of Health has conducted a review of co-prescribing of naloxone with opioids. The Commissioner's Committee on Chronic Pain Guidelines met on September 27, 2019 for its annual discussion of the chronic pain treatment guidelines. The committee recommended the inclusion of an appendix in the guidelines specifically regarding the co-prescribing of naloxone. The appendix will be incorporated into the next edition of the published guidelines in 2020.

According to data from the Centers for Disease Control and Prevention (CDC), there were more than 70,000 deaths in 2017 due to drug overdose nationwide, with 47,600 of those deaths involving an opioid. Last year, Tennessee had 1818 overdose deaths. Naloxone is a medication approved by the Food and Drug Administration (FDA) for the use in reversing the effects of an overdose involving opioids. In the appendix, the Tennessee Department of Health recommends that healthcare practitioners should incorporate into the management plan strategies to mitigate risk and lists a number of risk factors that may lead to a patient being at a heightened risk of an overdose. We believe the guidelines, including the appendix, will be a useful tool to guide practitioners in decision making when treating patients.

Thank you for your continued partnership and commitment to improve the health of Tennesseans.

Sincerely,

Lisa Piercey, MD, MBA, FAAP
Commissioner

Available online at https://www.tn.gov/content/dam/tn/health/healthprofboards/pain-management-clinic/ChronicPainGuidelines.pdf

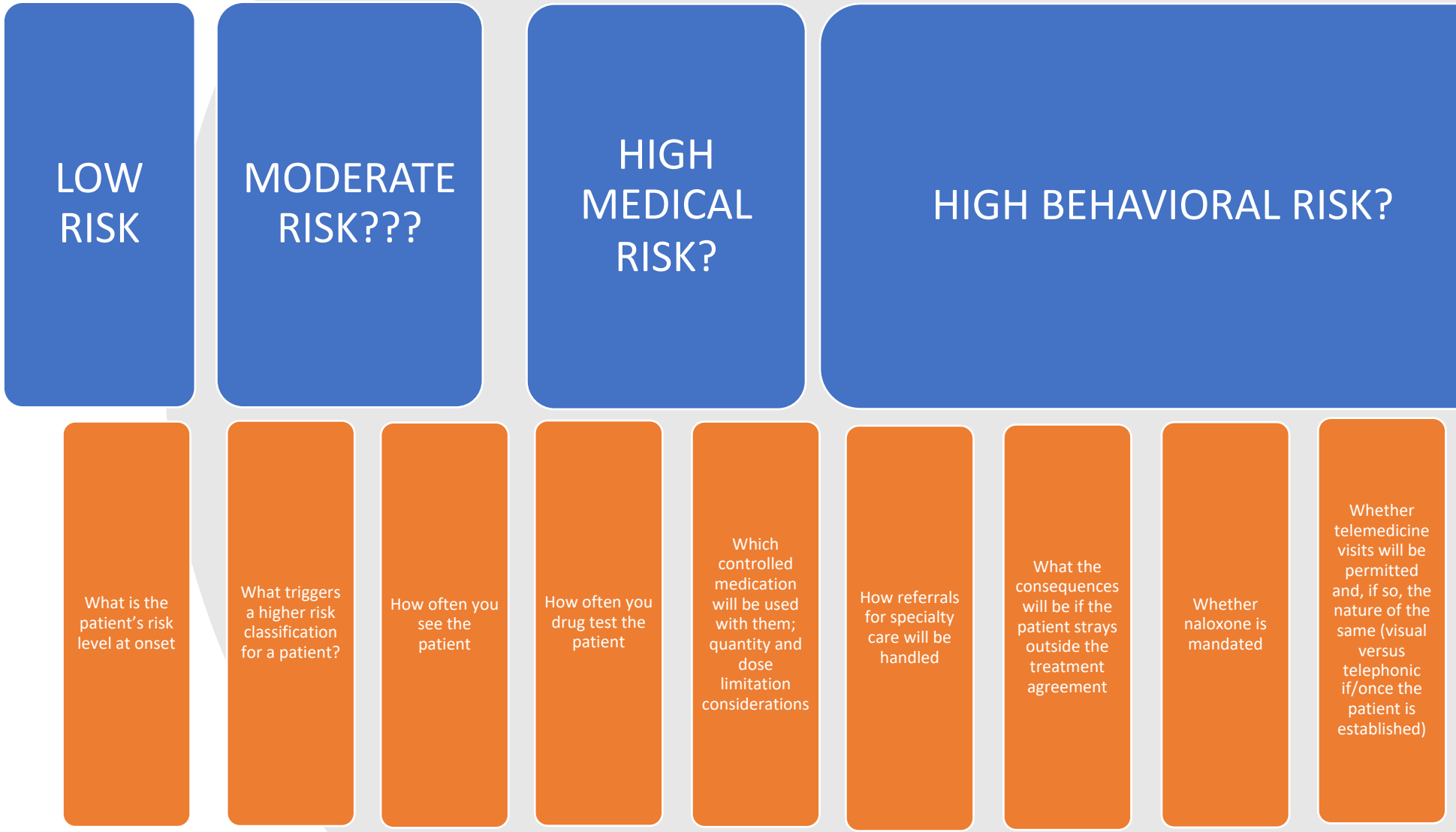
Sample State Licensing Board Requirement for Risk Evaluation (Tennessee; Dec. 2019)

D. Assessment of Risk for Abuse

1. The prescriber shall assess the patient's risk for misuse, abuse, diversion and addiction using a validated risk assessment tool prior to initiating opioid therapy. **(See Risk Assessment Tools Appendix)**
2. The prescriber should obtain a Urine Drug Test (UDT) (or a comparable test on oral fluids) prior to initiating opioid therapy. **(See Urine Drug Testing Appendix)**
3. Based on the combined information of the validated risk assessment results, the Controlled Substances Monitoring Database (CSMD) results and the UDT results and past records, an initial assessment should be made about a patient's risk of misuse, abuse or diversion of medications. The prescribing of opioids, if medically indicated, shall take this risk assessment information into account in the prescribing of opioids and the patient's treatment plan. **(See CSMD Appendix)**

Available online at https://www.tn.gov/content/dam/tn/health/healthprofboards/pain-management-clinic/ChronicPainGuidelines.pdf

Where are We Today with Risk Stratification?



Sample State Licensing Board Requirement for Risk Stratification and Monitoring (Tennessee; Dec. 2019)

- Available online at https://www.tn.gov/content/dam/tn/health/healthprofboards/pain-management-clinic/ChronicPainGuidelines.pdf

B. Ongoing Therapy

1. Patients on opioid doses of 120mg MEDD or greater should be referred to a pain specialist for a consultation and/or management. If a provider cannot make the required consultation as outlined above, then he/she shall clearly document why not.
2. Clinicians should review the patient's history of controlled substance prescriptions using the Controlled Substance Monitoring Database (CSMD) data to determine whether the patients receiving opioid dosages or potentially dangerous combinations
3. Providers must continually monitor the patient for signs of abuse, misuse or diversion. A UDT (or a comparable oral fluids screen or test) should be done twice a year at a minimum. **(See Urine Drug Testing Appendices)**
4. Based on the combined information of patient behavior, collateral information, the CSMD results, the UDT (or Oral Fluids Test) results and past records, an ongoing risk assessment should be made about a patient's risk of misuse, abuse or diversion of medications. The prescribing of opioids, if medically indicated, shall take this risk assessment information into account on an ongoing basis. Adjustments to the patient's treatment should occur in a timely manner based on this information. Inconsistent results from the treatment plan should be addressed immediately and documented action taken as appropriate.
5. Emergency department physicians should keep the specialist and the primary care provider informed about changes in a patient's condition and any emergent incidents or conditions.
6. Opioids are to be discontinued when the risks, side effects, lack of efficacy or presence of medication or aberrant behavior outweigh the benefits. Opioids sometimes have to be discontinued due to financial or third-party coverage issues. A taper of opioids may or may not be indicated, depending on the clinical situation. **(see Tapering Protocol Appendix)**
7. Appropriate documentation of CSMD query should be included in the medical record. **(see CSMD Appendix)**
8. Clinicians should offer or arrange evidence based treatment for patients with substance use disorder. Referral to an Addiction Specialist may be appropriate in some cases.

C. Women's Health

1. The provider should discuss a method to prevent unintended pregnancy with every woman of child-bearing age who has reproductive capacity when opioids are initiated. **(See Women of Child Bearing Age Appendix and Pregnant Women Appendix)**

Important Point to Remember

DEA Material

- ZERO reference to risk mitigation in DEA laws or regulations, except where harm or death to a patient is an enhancement.
- Many references to risk evaluation and monitoring, with articulation of risk stratification levels in DEA Decisions and Orders.
- 2006 DEA Final Policy Statement reference to risk mitigation, suggesting individualized assessment and steps to prevent abuse and diversion; IT'S ABOUT THE NATURE AND DEGREE OF MEDICAL SUPERVISION OVER THE PATIENT.
- 2006 DEA Final Policy Statement contains a reference to Treatment Agreements.

Licensing Board Material

- For chronic pain management, most licensing boards require/recommend an appropriate risk evaluation and use of risk monitoring based on the patient's risk status or level.
- The extent of the board's description as to "WHAT" is required varies. Some states have supportive guidelines that explain the board's thinking and expectations; Other states, not so much.

Part 2 - The Prescribing Standard and Risk Mitigation and Documentation – Case Example

SOURCE: DEA Decision and Order in Kaniz F. Khan-Jaffery, July 29, 2020, available as a handout and online at https://www.deadiversion.usdoj.gov/fed_regs/actions/2020/fr0729_4.pdf.

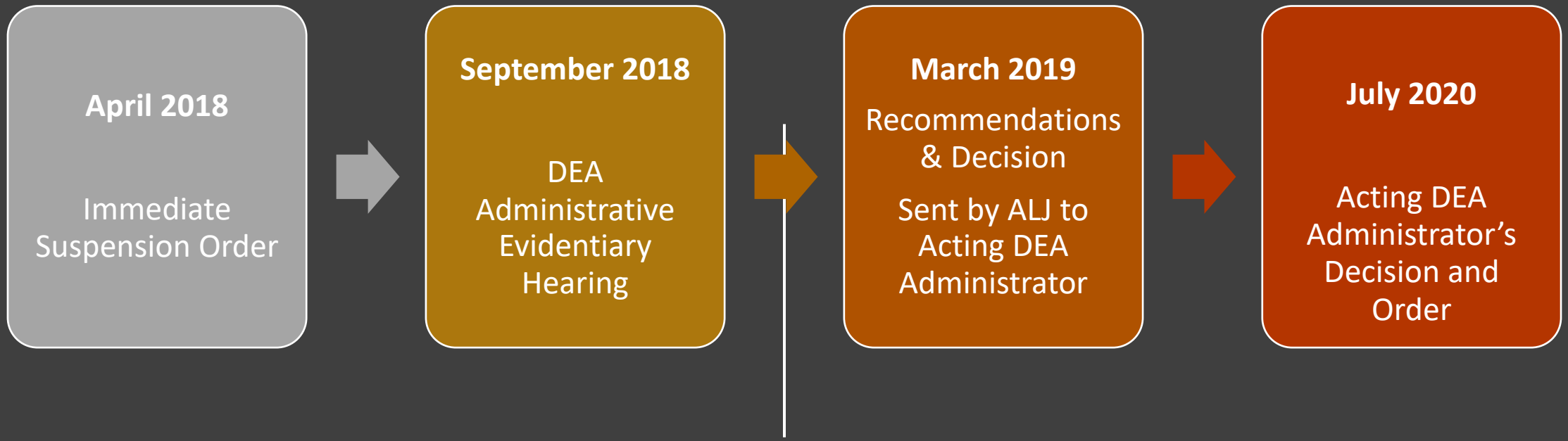
Khan-Jaffery, DEA Decision & Order: Case Background

- Physician licensed in New Jersey and Registered to Prescribe CS.
- Pharmacy data showed the physician was high-volume for controlled medication.
- Physician saw 50-55 patients per day.
- Physician put controls in place, including required referrals and UDT.
- Government presented a medical expert.
- Defense presented a medical expert, a medical record documentation expert, and the respondent-physician testified. A patient also testified.
- Case involved an undercover "patient" and review of other real patient charts.
- The case focuses on addressing aberrant UDT results and the documentation of patient counseling following such a result. This is the main reason this case is relevant to this course, although other "standard of care" issues are raised.

SOURCE: DEA Decision and Order in Kaniz F. Khan-Jaffery, July 29, 2020, available as a handout and online at https://www.deadiversion.usdoj.gov/fed_regs/actions/2020/fr0729_4.pdf.

Khan-Jaffery - Case Timeline

ALJ = Administrative Law Judge



- SOURCE: DEA Decision and Order in Kaniz F. Khan-Jaffery, July 29, 2020, available as a handout and online at https://www.deadiversion.usdoj.gov/fed_regs/actions/2020/fr0729_4.pdf.

Looking Glass Year - 2020

”Respondent paints herself as an ‘appropriate steward of her controlled substance license’…Further, she argued that ‘with her lack of venality and her cautious approach to her practice, it is submitted that respondent is exactly the kind of practitioner who should be encouraged…I disagree.”

“Respondent’s practice incorporated some safeguards to prevent the diversion of opioids, such as, monthly urine screens, diagnostic testing, and recommending alternative treatments, but the safeguards were not fully implemented in a meaningful way, because she never documented their resolution, if they were in fact resolved.”

SOURCE: DEA Decision and Order in Kaniz F. Khan-Jaffery, July 29, 2020, available as a handout and online at https://www.deadiversion.usdoj.gov/fed_regs/actions/2020/fr0729_4.pdf.

Looking Glass – Year 2020

- "The plain meaning of the term 'plan' cannot be, as Respondent suggests, merely identifying the breach and documenting the end results after a discussion."
- "Respondent's own testimony demonstrates why it cannot. Regarding [Patient LM] who tested positive three times in a row for unprescribed Suboxone, Respondent could not remember why she had not cut the patient's dosage even through she testified that after the third positive test, she realized counseling wasn't successful."
- "The unchanged prescriptions following these visits could not be adequate documentation for a plan to address counseling about a patient's breach of a pain agreement [that the Respondent already knew was not successful]. . . ".

SOURCE: DEA Decision and Order in Kaniz F. Khan-Jaffery, July 29, 2020, available as a handout and online at https://www.deadiversion.usdoj.gov/fed_regs/actions/2020/fr0729_4.pdf.

The Prescribing Standard and "Usual Course of Professional Practice" Response to Inconsistent UDT Results (Risk Monitoring)

- **Unexpected Negative UDT Results for Prescribed Medication are "Inconsistent" with the Treatment Plan and MUST be addressed and documented:**
  - The prescriber must take steps to reconcile the matter with the patient.
- **The prescriber should document sufficiently detailed counseling of the patient (rather than just a benign boilerplate statement of "counseled the patient."**
  - This documentation should include a statement of the patient's response to the practitioner's inquiries and the practitioner's action plan (reevaluation of the patient's situation based on these new facts).
  - This documentation should also include and the action plan and supportive decision-making (prescribe, change the treatment plan, not prescribe or reduce amount of drug, etc.).
- **TAKEAWAY:** Review UDT results in a timely fashion. Counsel or talk to the patient to try to gain more information about the inconsistent drug test results. Discuss the information gained in the medical record and take appropriate steps – see the patient, if necessary. Decide what you're going to do and document your reasoning for doing or not doing something.

- **SOURCE:** DEA Decision and Order in Kaniz F. Khan-Jaffery, July 29, 2020, available as a handout and online at https://www.deadiversion.usdoj.gov/fed_regs/actions/2020/fr0729_4.pdf.

The Prescribing Standard in a DEA Administrative Case (Khan-Jaffery) and the Level of Documentation Required for Inconsistent UDT Results

- **IN KHAN-JAFFERY, THE UNDERLYING STATE LICENSING BOARD LAW FOR NEW JERSEY CONTAINED:** A regulation requiring the prescriber to address and document an inconsistent UDT result. NJ requires that there must be documentation of the plan AFTER addressing the inconsistent result.
- **THE DEA REGISTRANT PHYSICIAN'S POSITION VIA HER MEDICAL EXPERTS:** The "automatic" chart counseling note tied to "UDT results" constitutes adequate documentation of counseling and the fact that the UDT results were addressed.
- **THE DEA ADMINISTRATOR'S FINDING: Auto-populated Notes in an EMR ARE INSUFFICIENT DOCUMENTATION OF COMPLIANCE WITH THE NEW JERSEY REGULATION ON [RISK MONITORING].**
- **TAKEAWAY: Watch out for boilerplate chart entries. Take reasonable steps to enter individualized patient data and specific rationale for medical decisions;** Tie the UDT results, to the counseling and response action, and to adjustments (if any) in the treatment plan and ongoing prescribing rationale. Also consider coordination of care needs.
- **SOURCE:** DEA Decision and Order in Kaniz F. Khan-Jaffery, July 29, 2020, available as a handout and online at https://www.deadiversion.usdoj.gov/fed_regs/actions/2020/fr0729_4.pdf.

The Prescribing Standard and Risk Mitigation: Does a Patient Have to Be Dismissed for Inconsistent Urines?

- **GOVERNMENT & DEFENSE EXPERTS:** No. The prescriber is not tied to any specific action when he/she discovers an inconsistent urine; But the response must make sense for the individual patient.
- In general, ”acting in the usual course of professional practice” requires the practitioner to take reasonable steps to re-establish the norm with the patient (if possible) and to document efforts and a plan to get the patient’s use of controlled medication back under control.
- **TAKEAWAY:** Inconsistent urine screens MUST BE ADDRESSED, COUNSELED, and DOCUMENTED.
- **TAKEAWAY:** Make sure your documentation is clear and that you articulate a thoughtful plan; Do not rely on boilerplate or statements that are not individualized to the patient.

- SOURCE: DEA Decision and Order in Kaniz F. Khan-Jaffery, July 29, 2020, available as a handout and online at https://www.deadiversion.usdoj.gov/fed_regs/actions/2020/fr0729_4.pdf.

The Prescribing Standard and Risk Mitigation (Monitoring): Addressing UDT Results Positive for Non-Prescribed Controlled Substances

- **The standard of care (as set forth in the New Jersey regulations] requires the prescriber to address the test results with the patient in a timely fashion and document the conversation and ongoing treatment plan, including any adjustments and referrals.**
- **NEW JERSEY LAW:** NJ has a regulation that requires prescribers
  - 1. "to assess the patient prior to issuing each prescription to determine whether the patient is experiencing problems associated with physical and psychological dependence and document the results of that assessment,"
  - 2. "to monitor compliance with the treatment agreement . . . ,
  - 3. "to discuss with the patient any breaches that reflect that the patient is not taking drugs as prescribed or is taking drugs, illicit or prescribed by other prescribers, AND
  - 4. "to document within the patient record the plan after that discussion."
- **TAKEAWAY:** Know your state rules! Many states do not spell out requirements the way NJ does, but the same or similar standards are used in licensing board, DEA, and criminal cases. This is a DEA administrative case and it resulted in the registrant's loss of her DEA #.

- **SOURCE:** DEA Decision and Order in Kaniz F. Khan-Jaffery, July 29, 2020, available as a handout and online at https://www.deadiversion.usdoj.gov/fed_regs/actions/2020/fr0729_4.pdf.

The Prescribing Standard and Risk Mitigation: Addressing Patients who use Alcohol

- Alcohol and opioids do not mix. While one drink may not be problematic, experts are likely to testify that counseling/education on the topic is part of the standard of care. It is in NJ.
- **GOVERNMENT'S EXPERT:** Prescriptions issued to one patient was not issued in the usual course of professional practice because the prescriber never addressed the alcohol positive UDT results with the patient. Once again, the boilerplate charting hurt the physician.
  - Multiple positives for alcohol metabolites requires the prescriber to discontinue controlled substance therapy.
- **NEW JERSEY LAW:** NJ regulations require "a discussion about the risks that shall include the 'danger of taking opioid drugs with alcohol' before the initial prescription and prior to the third prescription. It also states that the [prescriber] shall include a note in the patient record that the required discussions took place.
- **TAKEAWAY: USE CAUTION WHEN TESTING FOR ALCOHOL. Testing for it and ignoring the results is problematic. Not testing for it is equally problematic. DO NOT IGNORE ALCOHOL USE.**

- **SOURCE:** DEA Decision and Order in Kaniz F. Khan-Jaffery, July 29, 2020, available as a handout and online at https://www.deadiversion.usdoj.gov/fed_regs/actions/2020/fr0729_4.pdf.

Case Result in Khan-Jaffery, Decision & Order: REGISTRATION REVOKED

- The Administrative Law Judge recommended a sanction short of revocation.
- The ACTING DEA ADMINISTRATOR DISAGREED WITH THE ALJ and REVOKED THE PHYSICIAN'S REGISTRATION
- In the end: the Physician issued 17 prescriptions to real patients, and 6 to the UC. Each of these were found to be beneath the standard of care and outside the usual course of professional practice.
- The physician failed to conduct a physical exam in the case of the undercover officer.
- The physician failed to document discussions of a plan and assess the risk of abuse, addiction, or diversion after inconsistent urine screens – all in violation of state law/regulations.
- The physician essentially failed to take responsibility for her actions; Administrator found her credibility lacking and that she offered no measure of trust whereby he could accept the ALJ's recommendation of a sanction short of revocation and involving monitoring.

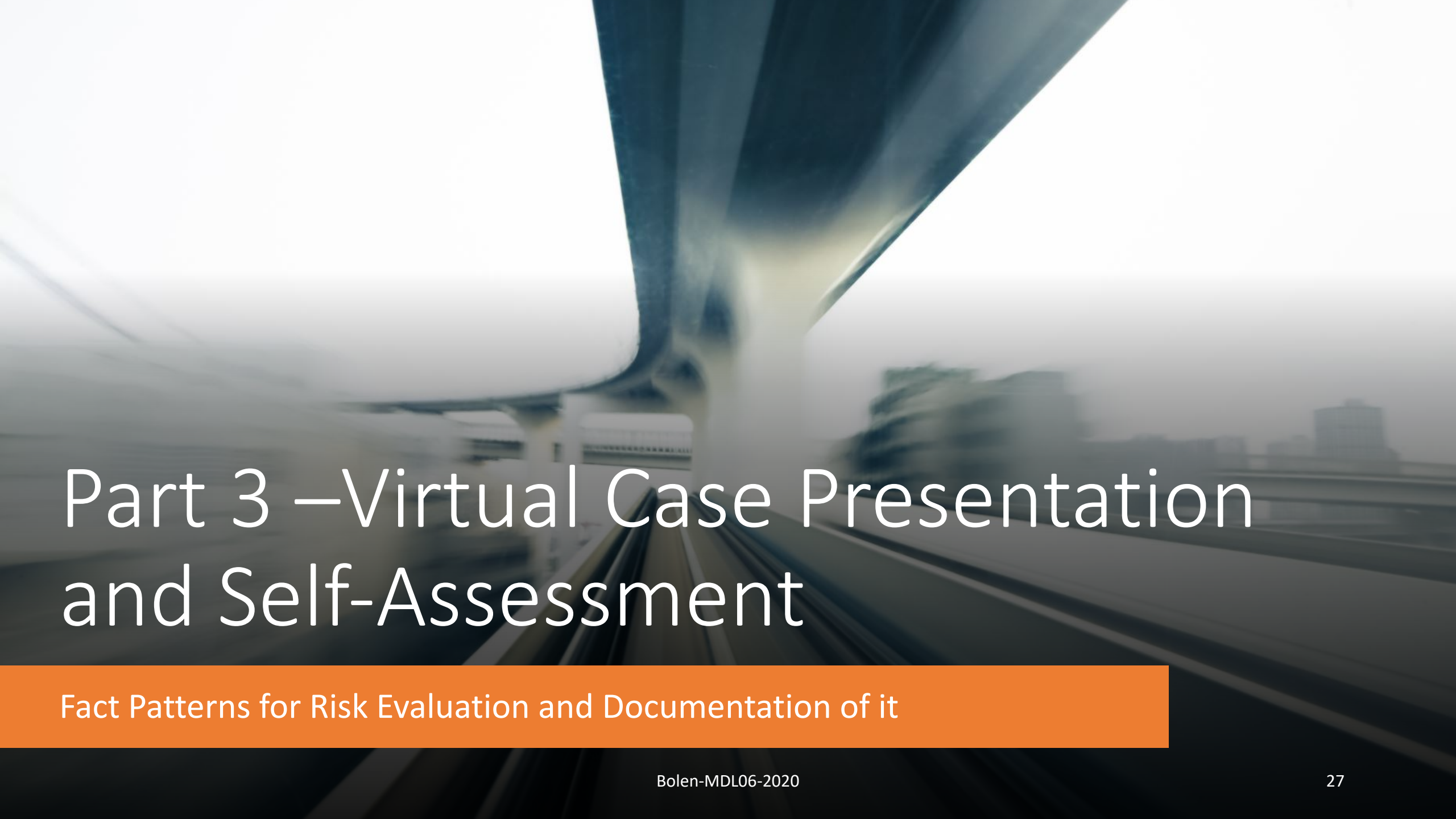
- **SOURCE:** DEA Decision and Order in Kaniz F. Khan-Jaffery, July 29, 2020, available as a handout and online at https://www.deadiversion.usdoj.gov/fed_regs/actions/2020/fr0729_4.pdf.

ACTING DEA ADMINISTRATOR'S CONCLUSION IN KHAN-JAFFERY REGARDING DOCUMENTATION

- "Although the evidence of her struggles with her software system is relatable at a basic level to every human being who has experienced technological frustrations, it again shows a passing of blame and an unwillingness to accept responsibility for a legal requirement and a requirement of the applicable standard of care and the usual course of professional practice in her field to document her prescribing practices and decisions."
- "Documentation of the discretion that Respondent had been implementing in her prescribing practices in the face of inconsistent urine screens is similar to accepting responsibility for her actions, because it memorializes her decisions with permanence. None of the recordkeeping in the Government's evidence demonstrates the rationale behind her prescribing decisions and she demonstrated through her testimony that her memory is not reliable to fill in the gaps."

- "Although the [administrative law judge] ultimately recommended a sanction short of revocation, I cannot agree, because there is insufficient evidence in the record to demonstrate that the Respondent can be entrusted with a registration. … Respondent has not given [the Acting DEA Administrator] a reason to extend [his authority] to monitor her compliance."

- **SOURCE:** DEA Decision and Order in Kaniz F. Khan-Jaffery, July 29, 2020, available as a handout and online at https://www.deadiversion.usdoj.gov/fed_regs/actions/2020/fr0729_4.pdf.



Part 3 –Virtual Case Presentation and Self-Assessment

Fact Patterns for Risk Evaluation and Documentation of it

Ground Rules for Case Example/Self-Reflection Evaluation

- 1. Abbreviated to illustrate points rather than address every nuance.
- 2. One goal is to demonstrate that proper risk evaluation involves more than just a patient self-administered questionnaire place in the chart.
- 3. A second goal is to demonstrate that it is very risk to rely on boiler plate phrases, such as “performed risk evaluation” without additional documented analysis showing your thought process and tie to medical decision-making in the treatment plan.

The Case of Mrs. Jones

Reflection –
Poor Risk Evaluations May Cause Trouble and Fall Below the Prescribing Standards Used in DEA and Board Cases

- BACKGROUND:
- Mrs. Jones is 52 y/o and she is a new patient in your practice. She was referred to you by her family doctor.
- Mrs. Jones has been using hydrocodone for the last three months. Her pain is getting worse.
- Mrs. Jones has a legitimate medical purpose for the use of the opioids, the self-reflection exercise for this case is to think about actions that demonstrate 'acting in the usual course of professional practice' and labeling those that clearly do not. Should Mrs. Jones be on opioids? If so, how might you show an active and current management of her risks balanced with the expected treatment benefits and goals

Mrs. Jones – Initial Risk Evaluation

- The Record Shows the Following Steps were taken by the practitioner at Mrs. Jones' initial office visit
  - ✓ Presented Mrs. Jones with the ORT and asked her to fill it out. She scored 0, but didn't answer one question.
  - ✓ Asked Mrs. Jones about drinking, smoking, and use of illicit drugs. She drinks socially and smokes about 3 cigarettes per day, but only when she gets anxious. She also advised she has occasionally used marijuana edibles but is converting to CBD because marijuana is illegal in "the state."
  - ✓ Reviewed the cover letter from the patient's family physician and her chart, which contains diagnostic reports supporting at least one probable pain generator and the other physician's original rationale for use of opioids in treatment plan.
  - ✓ Performed a urine drug test using a cup and it was negative for all drugs screened, including illicit drugs. Mrs. Jones said she last took her medication just prior to coming in for her office visit.
  - ✓ Checked the prescription drug monitoring database, which shows the only prescribers used by Mrs. Jones in the past year are her family doctor (for hydrocodone) and an area psychiatrist (for anti-depressants).
- ✓ Risk Stratification Level Selected following this first visit
  - ✓ Low Risk
- ✓ Practitioner prescribed Hydrocodone 10-325 Q6 hours and issued a prescription for 120 tablets. Practitioner also prescribed Gabapentin to help Mrs. Jones with her anxiety.

How would you rate the initial risk evaluation of Mrs. Jones?

Would it meet licensing board standards?

Was the provider acting in the usual course of professional practice or outside of it when evaluating the initial patient visit?

- Does it change your mind if you learn that the provider gave Mrs. Jones THE OLD ORT risk assessment tool with the scoring illustrated on the form?
- What do you do to improve documentation of risk evaluation when you discover the patient failed to complete the risk assessment questionnaire?

Case Example and Self-Reflection: The Case of Samantha

- Samantha is a 38 y/o veterinarian who works with large animals and operates her own truck all over a 5-county, rural region.
- Samantha was kicked three years ago by a draft horse, resulting in a torn ACL and meniscus, and damage to her lumbar and thoracic spine.
- Samantha underwent physical therapy, tried other non-drug treatments, and non-opioid treatments.
- Samantha's family physician referred her to your practice, and you've been seeing her for two years now.

Case Example and Self-Reflection: The Case of Samantha

- You prescribe Samantha oxycodone, 10mg tablets, BID-TID, as needed.
- Samantha's properly evaluated and documented initial risk evaluation shows her to be "low risk" and she has been compliant with UDT, PDMP, and Medication Counts.
- You have been seeing Samantha every two to three months and she has been a cooperative and pleasant patient.
- During her last office visit, you asked Samantha to provide a urine sample and had your office staff give you the screen (immunoassay) results, which were negative for Oxycodone, but positive for Opiates, and negative for all illicit drugs.

Case Example and Self-Reflection: The Case of Samantha

- You tried to review the drug screen results prior to Samantha's departure, but you were interrupted by an important phone call and Samantha had already departed the office.
- You requested a confirmation (definitive LCMS) test and asked that the laboratory tell you whether Samantha had oxycodone or its metabolites in her urine.
- You reviewed the final laboratory report and learn that Samantha's urine was negative for oxycodone and all relevant metabolites; the test was also positive for hydrocodone and hydromorphone.
- Samantha's next visit is not for another 45 days.

Case Example and Self-Reflection: The Case of Samantha

- **QUESTION:** Based on what we've learned about the prescribing standard of care and counseling patients for inconsistent drug test results, which answer best summarizes an appropriate clinical and risk mitigation response to Samantha's individual patient facts?

Reflect on these Responses and their value to balancing quality pain care while acting in the usual course of professional practice

- Is it enough to call Samantha back into the office and, if she doesn't appear the next day, to terminate her care?
- Does it help to document that you reviewed the final lab report and make a note to obtain another urine sample on Samantha's next visit? Is that enough to satisfy the "prescribing standard of care"?
- Is it best to discontinue Samantha's oxycodone and instead prescribe her hydrocodone? Is it as simple as a switch in prescriptions?

Reflect on these Responses and their value to balancing quality pain care while acting in the usual course of professional practice

- How does the risk mitigation stack up if you:
  - Move Samantha's appointment up so that you are scheduled to see her in the next week or two;
  - During the appointment, talk with Samantha about the drug test results and ask her to tell you how she is using her medication and why she was taking an unsanctioned medication;
  - Document this conversation and, before releasing Samantha, make sure her PDMP and medication count is current, obtain another urine sample to determine whether she's still using hydrocodone (given that she recently received a new prescription for oxycodone from you), and educate her about her inappropriate behavior tell her that you will now see her more frequently until adjustments can be made in her treatment plan and further evaluations performed to ensure the benefits of opioid therapy outweigh the risks;
  - Remind her of her obligations under the treatment plan and obtain her agreement to contact your office if her current medication plan is not addressing her pain; Let her know that you may wish her to perform updated imaging if her pain continues to increase;
  - Document your medical decision-making as it relates to issuing her a more limited supply of medication because you will be seeing her more frequently and make it clear that for the foreseeable future the use of multiple SII prescriptions, each for a 30-day supply, is no longer permitted.
  - Schedule Samantha's return visit and let her know that you are willing to continue taking care of her with opioids, but only if she demonstrates compliance under this new plan.
  - Place flag in Samantha's file for other providers to see regarding the plan adjustment and aberrant UDT.

What does a Licensing Board Label as Failure to Meet the Prescribing Standard?

In the matter of Ebenezer K. Quainoo, MD, before the Maryland State Board of Physicians, Case No. 2217-0007A, Consent Order agreeing to probation and entered 9/3/2019 as a public document. Provided as a handout to accompany this lecture for educational purposes only. Note: There is much legal procedure and related items behind each board case. The educational focus for MDL05 is on the action and documentation failures listed by the Medical Experts and adopted by the board.

The Maryland State Board of Physicians may reprimand, probate, suspend, or revoke a license if the licensee:

- Fails to meet appropriate standards as determined by appropriate peer review for the delivery of quality medical and surgical care performed in an outpatient surgical facility, office, hospital, or any other location in [Maryland]; and

- Fails to keep adequate medical records as determined by appropriate peer review.

- **SOURCE:** In the matter of Ebenezer K. Quainoo, MD, Maryland State Board of Physicians, Consent Order in Case #2217-0007A, at p. 1, citing Maryland Medical Practice Act and other authorities.

Cited failures on risk mitigation, informed consent, and treatment agreement - 1

- Resource: Quainoo, Licensing Board Consent Order, Maryland, 2019; See handout.

History and Physical Exam	Risk Evaluation	Treatment Plan	Informed Consent and Treatment Agreement	Documentation
Failed to document or establish physical findings to support prescribing	Failed to perform an opioid risk assessment to assess the patient's risk for opioid misuse, abuse, diversion prior to prescribing opioids	Inappropriately prescribed opioids to a patient who was also receiving benzodiazepines from another practitioner	Did not have the patient sign a treatment agreement until two years after MD initiated prescribing.	Progress notes are inadequate in that they appear to have multiple sections that are copied from previous notes, such as history of present illness, physical examination and assessments
Imaging studies showed no sign of fracture or lumbar disc disease; negative imaging studies.	Failed to document or undertake an objective work-up for the event of drug withdrawal seizures and failed to document or undertake a follow-up on the patient's mental health history.	Inappropriately prescribed high-dose opioid therapy in combination with benzodiazepines	MD didn't provide sufficient informed consent education	Progress notes contain inconsistent notations about medications prescribed
Failed to establish a basis to prescribe opioid medication	Failed to document substance abuse in the lifestyle/risk factors, despite a hospital admissions note during the treatment period for the patient showed polysubstance abuse and current illicit drug use	Inappropriately prescribed two extended release opioid medications concurrently without an appropriate (and documented) rationale	MD didn't address aberrant drug test results and thus deviated from treatment agreement	Progress notes that contain other inadvertent errors like a history of present illness for a completely different patient

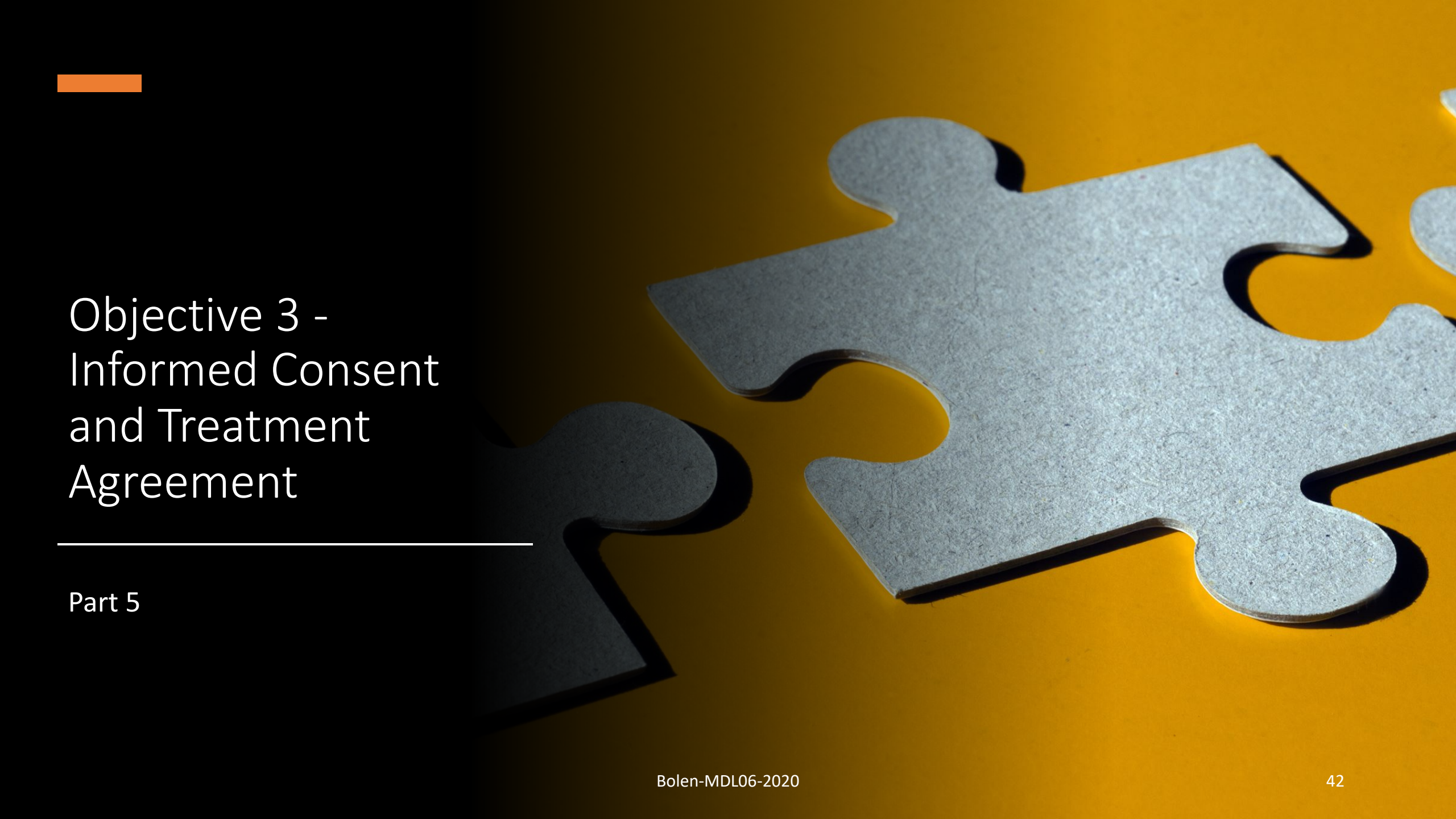
Cited failures on risk mitigation and informed consent and treatment agreement - 2

- Resource: Quainoo, Licensing Board Consent Order, Maryland, 2019; See handout.

History and Physical Exam	Risk Evaluation	Treatment Plan	Informed Consent and Treatment Agreement	Documentation
Physical findings in each clinical note remain unchanged, and lumbar and knee x-rays did not demonstrate significant abnormalities	Inappropriately placed a patient on high-dose opioid therapy on intake and without verifying her prior opioid usage or ordering UDT	Failed to discuss the patient's history of depression with her or collaborate with a mental health professional		Failed to document coordination of care efforts
Failed to verify patient's prior opioid usage or corroborate pathological findings on imaging studies prior to placing the patient on high-dose opioid therapy		Failed to adequately document HOW HE determined his medical plan for the patient		Poorly kept patient medication lists
Prescribed escalating doses of opioids without establishing appropriate objective findings or a clinical indication to support such prescribing		Prescribed high-dose opioid therapy over a three-year period without adequate justification, clear clinical indication, and without clear benefit or increased function, and not correlated increase in prescribing with a worsening of symptoms or progression of disease		

Objective 3 - Informed Consent and Treatment Agreement

Part 5



POMPY CASE (2019)(Michigan) – Guidelines for Informed Consent/Treatment Agreement

- "The physician should discuss the risks and benefits of the use of controlled substances with the patient . . . The patient should receive prescriptions from one physician and one pharmacy where possible…The physician may use a written agreement between the physician and the patient if the patient is determined to be at high risk for medical abuse or have a history of substance abuse. The written agreement's patient responsibilities include 'urine/serum medication levels screening when requested; number and frequency of all prescription refills; and reasons for which drug therapy may be discontinued.'"
- **SOURCE: Drug Enforcement Administration,** Lesly Pompy, MD, Decision and Order, Fed. Reg., Vol. 84, No. 208, October 28, 2019, p. 57749, *57754.*

Reminder – Informed Consent

- It’s a process, not just a piece of paper.
- Relates to ethical concept
- Can be in same piece of paper as treatment agreement, but most licensing boards separate the concepts now. The “Looking Glass” tells us this was not always the case, and many boards used to be ok with documentation that the “discussion” took place.
  - Recent DEA Administrative Case Decisions suggest that Medical Experts are looking for documentation of WHAT was discussed and not mere boilerplate terminology.
  - Similarly, Medical Experts are looking for counseling documentation that covers the substance as individualized to the patient.

American Medical Association

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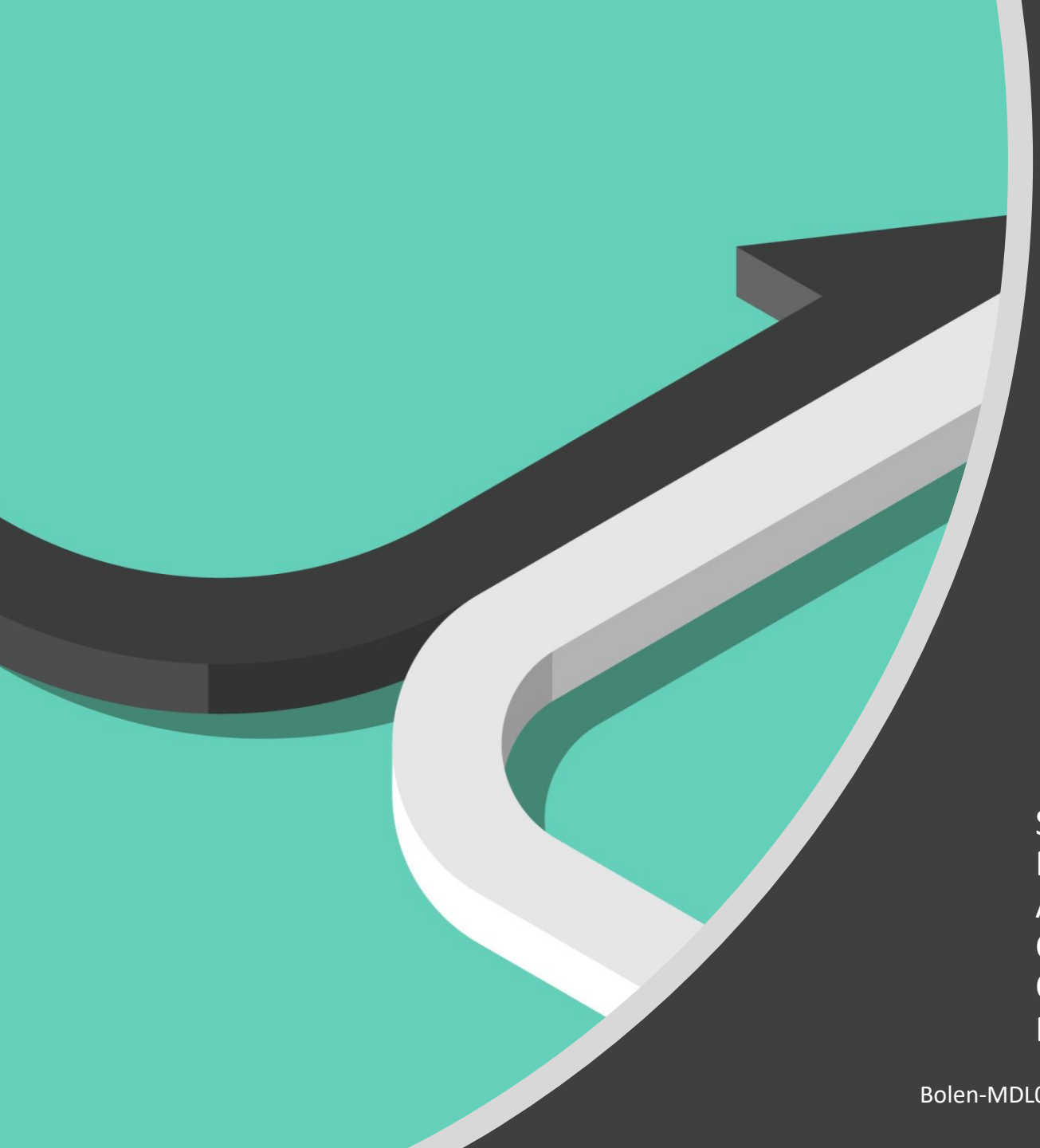
E-8.08 Informed Consent

The patient's right of self-decision can be effectively exercised only if the patient possesses enough information to enable an intelligent choice. The patient should make his or her own determination on treatment. The physician's obligation is to present the medical facts accurately to the patient or to the individual responsible for the patient's care and to make recommendations for management in accordance with good medical practice. The physician has an ethical obligation to help the patient make choices from among the therapeutic alternatives consistent with good medical practice. Informed consent is a basic social policy for which exceptions are permitted:



The Prescribing Standard and Informed Consent: A wrongful death case

SOURCE: Wrongful Death Case: Appeal on Denial of Motion for Summary Judgment: Patricia Halloran, etc., v. Ajay N. Kiri, MD and Farmingdale Wellness Center (Civil Case in NY State, index 21037/15E9616; Decision and Order of the NY State Supreme Court, Appellate Division, First Department, issued 06/13/2019.

Failure to Monitor Risks and Address Informed Consent Education with Patient

- Woman died of acute intoxication by combined effect of fentanyl, heroin, oxycodone, and alprazolam.
- Patient had a history of seeing multiple providers, early refills, seeking opioids, unsanctioned dose escalations.
- Patient saw one provider who commented on her track marks and addiction; He offered her MAT, but she refused.

- State Wrongful Death Case: Appeal on Denial of Motion for Summary Judgment: Patricia Halloran, etc., v. Ajay N. Kiri, MD and Farmingdale Wellness Center (Civil Case in NY State, index 21037/15E9616; Decision and Order of the NY State Supreme Court, Appellate Division, First Department, issued 06/13/2019.

Failure to Monitor Risks and Address Informed Consent Education with Patient

- Patient first saw Dr. Kiri in August 2012 (note the date). She told him she'd been seeing an orthopaedic surgeon but wanted a more local doctor.
- Dr. Kiri refilled her high-dose oxycodone prescription, but discontinued OxyContin. Instead, Dr. Kiri prescribed fentanyl patches.
- Dr. Kiri's charts contained notes indicating that he wanted to "discuss need to lower medication. Patient actively asked for more."
- Dr. Kiri later began prescribing alprazolam to the patient for her anxiety. He never lowered her opioid dose and never contacted her orthopaedic surgeon. He continued treating her until she died.

- State Wrongful Death Case: Appeal on Denial of Motion for Summary Judgment: Patricia Halloran, etc., v. Ajay N. Kiri, MD and Farmingdale Wellness Center (Civil Case in NY State, index 21037/15E9616; Decision and Order of the NY State Supreme Court, Appellate Division, First Department, issued 06/13/2019.

Failure to Monitor Risks and Address Informed Consent Education with Patient

- A wrongful death and negligence case was brought on behalf of the decedent against Dr. Kiri and others. The case also alleges malpractice and lack of informed consent.
- The plaintiff's theory of liability is that Dr. Kiri prescribed the patient opioids though her medical records showed illicit drug use and opioid seeking behavior, and, as a result, Dr. Kiri enhanced and encouraged decedent's behavior until her accidental overdose.

- State Wrongful Death Case: Appeal on Denial of Motion for Summary Judgment: Patricia Halloran, etc., v. Ajay N. Kiri, MD and Farmingdale Wellness Center (Civil Case in NY State, index 21037/15E9616; Decision and Order of the NY State Supreme Court, Appellate Division, First Department, issued 06/13/2019.

Failure to Monitor Risks and Address Informed Consent Education with Patient

- Dr. Kiri appealed the lower court's decision to deny his motion to dismiss the complaint (tied to proximate cause issues).
- The court REJECTED Dr. Kiri's medical experts because their opinions were not probative as to causation [of the patient's death] and because they were conclusory and contradicted by the Medical Examiner's report.
- Dr. Kiri argued that his "acts or omissions could not qualify as legal proximate cause because [his patient] used illicit drugs or evinced drug-seeking behavior before Dr. Kiri.

- State Wrongful Death Case: Appeal on Denial of Motion for Summary Judgment: Patricia Halloran, etc., v. Ajay N. Kiri, MD and Farmingdale Wellness Center (Civil Case in NY State, index 21037/15E9616; Decision and Order of the NY State Supreme Court, Appellate Division, First Department, issued 06/13/2019.

Failure to Monitor Risks and Address Informed Consent Education with Patient

- The court REJECTED THIS ARGUMENT because it misses the point:
- The plaintiff's theory of liability rests on the fact that Dr. Kiri's prescribing of high-dose opioid therapy for more than a year, despite the medical records showing aberrant, drug related behavior, escalated, enhanced, and encouraged [the patient's] behavior.
- An accidental overdose is NOT an unforeseeable result of prescribing or overprescribing opioids to a patient who displays signs of addiction.

- State Wrongful Death Case: Appeal on Denial of Motion for Summary Judgment: Patricia Halloran, etc., v. Ajay N. Kiri, MD and Farmingdale Wellness Center (Civil Case in NY State, index 21037/15E9616; Decision and Order of the NY State Supreme Court, Appellate Division, First Department, issued 06/13/2019.

Failure to Monitor Risks and Address Informed Consent Education with Patient

- The decedent/patient's procurement and use of illicit drugs were likewise not unforeseeable in light of the indicia of addiction or misuse noted in her medical records.
- "Because the decedent's use of illicit drugs was not unforeseeable, her drug use was not an intervening cause and did not amount to a separate act of negligence that independently caused her death.
- "Causation will be determined in connection with whether Dr. Kiri's treatment of decedent fell below the applicable standard of care, which is not at issue on this appeal." …
- The plaintiff is arguing that, at some point during his 14-month treatment of decedent, Dr. Kiri should have collected her recent medical records or, at least, contacted her treating orthopaedist to create a treatment plan. This presents an issue for the jury.

- State Wrongful Death Case: Appeal on Denial of Motion for Summary Judgment: Appeal on Denial of Motion for Summary Judgment: Patricia Halloran, etc., v. Ajay N. Kiri, MD and Farmingdale Wellness Center (Civil Case in NY State, index 21037/15E9616; Decision and Order of the NY State Supreme Court, Appellate Division, First Department, issued 06/13/2019.

Failure to Monitor Risks and Address Informed Consent Education with Patient

- Dr. Kiri's medical experts' opinions WERE CONCLUSORY because they did not set forth what reasonably foreseeable risks should have been disclosed by Dr. Kiri to [the decedent] regarding his prescriptions of [alprazolam]. Dr. Kiri's experts said [the decedent] knew of the consequences of combining her prescriptions with alcohol and illicit drugs and that she was fully advised of the dangers of opioids; The MEDICAL RECORDS DO NOT SUPPORT THIS.
- **Just because a patient should know about risks, a prescriber is not let of the hook to perform and record informed consent education.**

- State Wrongful Death Case: Appeal on Denial of Motion for Summary Judgment: Appeal on Denial of Motion for Summary Judgment: Patricia Halloran, etc., v. Ajay N. Kiri, MD and Farmingdale Wellness Center (Civil Case in NY State, index 21037/15E9616; Decision and Order of the NY State Supreme Court, Appellate Division, First Department, issued 06/13/2019.

Texas Medical Board – Telemedicine and Informed Consent

4. Does the standard of care still apply in a telemedicine visit during the disaster declaration?

Yes, the standard of care applies whether a patient is seen via telemedicine or an in-person visit. The standard is no different whether the encounter is via technology or in-person. To that end, physicians should always attempt to ensure patient continuity of care.

http://www.tmb.state.tx.us/idl/1BDA79E4-958A-B895-A61F-CAF8F58D221A

Texas Medical Board – Telemedicine and Informed Consent

6. What are the requirements for documenting a telemedicine visit?

The medical record standards do not change based on the setting by which the patient is seen. Items such as relevant findings, tests ordered, treatment recommendations, and consent should be documented. Verification of a patient's identity is extremely important in a telephone-only encounter. For example, collection of a patient's driver license number and comparison to practice records is a possible method of identification.

Appropriate and detailed medical records are also needed to support billing for services. Board regulations regarding improper billing remain in effect.

http://www.tmb.state.tx.us/idl/1BDA79E4-958A-B895-A61F-CAF8F58D221A

INFORMED CONSENT TIMING & PROCESS

Evaluation	• History • Past Treatments
Treatment Plan	• Non-Drug • Drug Treatments
Informed Consent	• Specific to Treatment Plan • Can be generalized to some degree

TREATMENT AGREEMENT TIMING & PROCESS

Treatment Agreement

- Agree to Risk Evaluation
- Agree to Terms
- Agree to Consequences

Risk Evaluation

- Various domains of risk (medical, behavioral, history abuse, diversion)

Risk Monitoring

- Consequences if aberrant behavior and violation of agreement
- Keep patient but remove problematic dug treatments
- Refer for specialized care
- Coordination of Care

Update Your Informed Consent and Treatment Agreement Process

Informed Consent

- As needed, based on the individual facts of the patient and updated knowledges of risks and special issues – like COVID-19, telemedicine, etc.

Treatment Agreement

- Yearly, unless a public health or similar emergency requires a more immediate update.

Educate Your Patients

A real informed consent process

Key Items to Consider Adding to Informed Consent Based on COVID-19

- Examine risk of respiratory depression with the use of opioids and other medication and how COVID-19 signs and symptoms may increase risk of an adverse event.
- Examine whether increased risks if patient has existing renal and hepatic issues in light of ongoing use of opioids and signs/symptoms of COVID
- Critical focus on need for naloxone in a home “emergency kit” because patient uses controlled substances and COVID is not under control. Increased education here.
- Update (and probably a separate) informed consent to include or be specific to telemedicine use

Key Items to Consider Adding to Treatment Agreement Based on COVID-19

1	Use of telemedicine for medication counts
2	Use of telemedicine for oral fluid sample collection
3	Use of telemedicine visits for check-in at a frequency greater than office visit schedule prior to COVID-19
4	Use of telemedicine if behavioral health treatment is needed
5	Use of telemedicine to verify naloxone prescription filled

Thank you for coming to PainWeek OnDemand!

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- We hope to see you for MDL07 – the last part of this series on Periodic Review, Risk Monitoring, and Coordination of Care.