Through the Lens of Medical Experts and Litigators:

Meaningful Risk Mitigation and Patient Education

Prepared and Presented by Jen Bolen, JD for PainWeek and PainWeekEnd

1

Disclosures

- Ms. Bolen serves as a Consultant to Paradigm Labs.

2

Background

- Medical experts and lawyers spend a great deal of time in court cases arguing about the extent and nature of risk mitigation and patient education necessary to demonstrate the prescriber issued a valid controlled substance prescription.
- The general focus of medical expert testimony is on whether the prescriber:
  - Engaged in clinically meaningful medical and risk evaluation and used appropriate ongoing monitoring practices, and did so in a way that shows:
    - Individualized medical care for the patient.

3

Background continued . . .

- A proactive approach to patient risk assessment is necessary to protect the patient's access to quality pain care.
  - It helps the provider create a care framework that allows other practitioners to confidently assume care of patients and understand the medical decision-making around the prescribing of controlled medication or decision to go another route.
- The main goal of this course is to increase awareness of expert witness standards in unlawful opioid prescribing cases and to use examples of expert witness testimony to facilitate a prescriber's self-audit of their own risk mitigation practices.
- A secondary goal of this course is to help attendees improve their documentation of risk mitigation processes and patient education efforts.

4

Objectives

- 1. Identify **key steps in meaningful risk evaluation of new patients** and **risk monitoring of established patients.**
  - Review common areas of risk
  - Identify common risk mitigation tools and ways to use them to improve clinical evaluation and documentation of the prescriber's thought processes.
- 2. Explain how to create a **platform for documenting clinical risk stratification** and use it
  - Discuss how to support improved documentation of an individualized treatment plan
  - Review clinical decision-making concerning the decision to prescribe or not prescribe controlled medication to the patient.
    - This documentation platform includes provider consideration of:
      - Boundaries for treatment plan (medication – nature and dose)
      - Use of BH interventions
      - Use of non-drug treatment
      - Ongoing monitoring tools
      - Visit Frequency
      - Use of Prescription Drug Monitoring Databases
      - Use of Drugs of Abuse Testing
      - Use of referrals for specialty evaluation
- 3. Describe the importance of patient education on topics such as safe use, storage, disposal of controlled medication, and overdose prevention, and review ways to improve provider documentation of these efforts.

5

Expert Viewpoints

Government
Defense

Criminal Case
Examples

6

REPRISE:
What makes a Controlled Substance Prescription Valid?

How are these requirements relevant to Expert Witness Testimony?

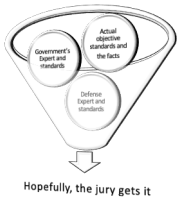
LEGITIMATE MEDICAL PURPOSE

USUAL COURSE OF PROFESSIONAL PRACTICE

INCLUDING:
"Reasonable Steps to Prevent Abuse and Diversion"

7

How do the Expert Witness Standards work in Criminal Case Jury Instructions (Federal)?



Hopefully, the jury gets it

8

Common Opinions Given by GOVERNMENT EXPERTS in Inappropriate Opioid Prescribing Cases

Evaluation	Dosing; Quantity; Combinations; Chronicity	Monitoring
• Trends toward presenting a standard that avoids prescribing controlled medication on the first visit and overall long-term use of opioids. • Often suggests that a provider should obtain a patient's Criminal History before prescribing controlled medication. • Characterized as if the current prescriber has to go back and start all over again with each patient.	• Focuses on patients on doses over 90mg MME. • Focuses on the overall dosing and number of pills. • Focuses on the use of combination opioid-opioid products and opioid-non-opioid products. • Often takes the position that opioids and benzodiazepines should NEVER be prescribed together. • Characterized as if 90mg MME is a legal prescribing boundary.	• Focuses on risk monitoring that goes beyond the paperwork. • Focuses on risk monitoring that looks to the whole patient and risks and not just drug-related risks. • Focuses on monitoring patient risk through behavioral health and other referrals. • Characterized as if such referrals are readily available to all patients.

9

Question #1

- Testifying medical experts are expected to use which of the following "legal standards" when presenting their opinions about whether a defendant/physician has prescribed for a legitimate medical purpose while acting in the usual course of professional conduct?
  - A. Standard of care from licensing board
  - B. Standard of care from professional societies to which they belong
  - C. Subjective application of how they prescribe controlled substances in their practice
  - D. Objective application of generally accepted medical practices and applicable licensing board guidance/rules on controlled substance prescribing
  - E. None of the above

10

Expert Perspective: Meaningful Risk Evaluation and Risk Monitoring

Objective #1 – Identify key steps in meaningful risk evaluation of new patients and risk monitoring of established patients

11

What your licensing board "generally" expects from you (the Process)

- History & Physical Examination
- Risk Evaluation
- Diagnosis and Treatment Plan
- Informed Consent and Treatment Agreement
- Periodic Review and Risk Monitoring
- Consultations and Referrals
- Proper Documentation

12

Basic "Domains" of Risk

- Pain History and Specific Medical Risks
- Historical Behavioral Risks
- Current and Prior Medication Used and Related Risks
- Overdose Risk
- Risk of Abuse/Diversion/Addiction
- Other Known or Potential Risks

13

Common Challenges in the Risk Evaluation Process

Paper Related		
EMRs do not contain a quality risk road map	The file must reflect actions and events consistent with standards (Board, etc.)	The file must contain a thoughtful explanation as to the Provider's "Why" and "How" for the Treatment Plan

14

Example of Expert Testimony:
Failure to Perform an Adequate History and Exam and Role in Risk Mitigation
Discussion and Examples

15

Example of Expert Testimony:

Failure to Obtain and Review Diagnostic Information and Role in Risk Mitigation

Discussion about the challenges of diagnostic information, including dated material, false records, and weak findings

16

Example of Expert Testimony:

Failure to Appreciate the Purpose of the Risk Tool and to Use a Validated Risk Assessment Tool

Discussion about "purpose" behind the various risk assessment tools and overall impact on Risk Evaluation, Stratification, and Monitoring

17

Example of Expert Testimony: Improper Scoring of Risk Evaluation Tools

Discussion and Examples

18

Common Problems in the Risk Evaluation Process

Time Related	
The "easiest" risk tools may mislead you	It's important to dedicate time on the front end to evaluate risk (before prescribing)

19

Question #2

- Which risk assessment tools generally identify the potential for drug abuse, potential diversion, and drug-related aberrant behavior?
- A. Screening for Brief Intervention and Treatment (SBIRT)
- B. ORT, SOAPP-R, COM
- C. PHQ-9
- D. GAD-7
- E. None of the above

20

Discussion and Examples

Example of Expert Testimony: Failure to Keep Medication Lists Updated Leads to Ineffective Translation of PDMP and UDT

21

Explain how to create a platform for documenting clinical risk evaluation and stratification

Objective #2

22

INPUT

Medical Risks

Which items are more reflective of higher risk for an adverse outcome with chronic opioid therapy?

Inclusion criteria

Exclusion criteria

Behavioral Risks

Risk Tool Scores

Inclusion criteria

Exclusion criteria

Medication Risks

Based on identified medical and behavioral risks and current/proposed medication regimen, how do the medications impact the patient's risk level?

Type of medication, Dose of medication, Medication Combinations

Overdose Risks

23

MEDICAL RISKS & IMPACT ON OVERDOSE RISK EVALUATION

Discussion and Worksheet

LOW RISK

MODERATE RISK

HIGH MEDICAL RISK

24

BEHAVIORAL RISKS & IMPACT ON OVERDOSE RISK EVALUATION
Discussion and Worksheet

LOW RISK

MODERATE RISK

HIGH BEHAVIORAL RISK

25

MEDICATION RISKS & IMPACT ON OVERDOSE RISK EVALUATION
Discussion and Worksheet

LOW RISK

MODERATE RISK

HIGH-RISK MEDICATION

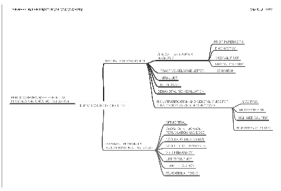
26

OUTPUT – Discussion and Worksheet – Considerations and Documentation

- Boundaries for treatment plan (medication – nature and dose)
- Use of Behavioral Health interventions
- Use of non-drug treatment
- Ongoing monitoring tools
- Visit Frequency
- Use of Prescription Drug Monitoring Databases
- Use of Drugs of Abuse Testing
- Use of referrals for specialty evaluation
- Exit Strategy (Treatment Failures, Consequences for Non-Compliance)

27

RISK PROFILE AND RISK MONITORING MAP (HANDOUT)



28

Using the Risk Profile to Structure the Treatment Plan

Translating Risk Information into Action and Treatment Boundaries

29

Risk Profiling and Monitoring Must be More than "Window-Dressing"

GOVERNMENT POSITION

IMPLICATIONS

LESSONS LEARNED

30

Key Areas of Treatment Planning & Documentation Weaknesses

New Patient Phase

1. Initial Evaluation
2. Background Documentation
3. Initial Decision to Prescribe a Controlled Medication

Early Established Patient Phase

1. Establishing a Treatment Plan with a Genuine Trial Period and "Measurable" Goals (which are measured)
2. Dose increases, additional medication
3. Early phase monitoring and addressing of patient behaviors
4. Documentation of early treatment rationale, including use of consults and referrals

Inherited or Long-Term Patient

1. Reevaluation of what was done or not done in the past
2. Appearance of "rubber-stamping"
3. Documentation of Ongoing Treatment Rationale, including consults and referrals

31

The Importance of Patient Education to Risk Mitigation

Objective #3 - Describe the importance of patient education on topics such as safe use, storage, disposal of controlled medication, and overdose prevention, and review ways to improve provider documentation of these efforts.

32

Critical Areas of Patient Education

Consult/New Patient

Importance of Careful Evaluation;
No "rubber-stamping"
Prescribing considerations and opioid trial (if appropriate)
Exit strategy
Safe use, storage, and disposal
Overdose Prevention

Established Patient
(less than 1 year)

Boundaries set by opioid trial
Reevaluation of goals and role of medication
Ongoing risk evaluation
Safe use, storage, and disposal
Overdose Prevention

Established Patient
(stable, > 1 year)

Reevaluation and Potential Exit Strategies
Reconsidering non-drug and non-opioid treatment
Ongoing safe use, storage, and disposal
Overdose Prevention

Established Patient
(high risk)

Need for Boundaries
Need for Consultations and Referrals
Consequences if non-compliance
Ongoing safe use, storage, and disposal
Overdose Prevention

33

Experts & Risk Mitigation

Case Study Question

34

Case Based Learning Scenario – The Scenario

Ms. Mason is a new patient to you and she is seeking treatment for chronic pain.

There appears to be a legitimate medical purpose for the use of opioids - documented history of back surgery and a hip replacement; a fall about 6 months ago and new imaging showing that she has several moderate to serve findings at multiple levels.

Prior to prescribing her a trial of opioids, proper controlled substance prescribing protocols require you to demonstrate that you have evaluated Ms. Mason and established a care plan that shows you considered her individual medical circumstances together with her evaluated risk profile.

35

Case Based Learning Question

- **Which answer most completely reflects the steps you are expected to take to ensure effective risk evaluation, stratification, and monitoring when considering the use of chronic opioid therapy with a patient?**

- A. Give Ms. Mason a drug test and if she passes prescribe opioids and see her back in two months.
- B. Use Ms. Mason's ORT score to assign her a risk level and perform a urine drug test; Prescriber her opioids and see her in a month.
- C. Review prior records and initial items specifically related to the legitimate medical purpose for the use of opioids. Evaluate her medical and behavioral risks, order a UDT, perform prescription database inquiry, and summarize overall risks, including medication-related risks and risk of overdose; Detail rationale. Write down a treatment plan that includes the specific period of the opioid trial and the measurable outcomes for success, along with the timing of reevaluation and plan for ongoing risk monitoring. Educate her on safe use and storage of her opioids and guarding against potential opioid toxicity; Issue a prescription for naloxone. Create an exit strategy.
- D. Use Ms. Mason's ORT score and see her back in one month; Make sure she's signed her treatment agreement and informed consent. Order a UDT.
- E. None of the above.

36

Additional Resources (Attendee Library)

37

Things you should do . . . soon!

1. Download your Licensing Board's Guidelines and Rules on Opioid Prescribing

2. Diagram your risk evaluation, stratification, and monitoring process

3. List out the tools and the "purpose buckets" for them; Plan on how you will use them with your patients

4. Educate your staff and patients

5. Review Risk-Related Resources and Ask for Help

38

Resources

- Ducharme J and Moore S, Opioid Use Disorder Assessment Tools and Drug Screening, Missouri Medicine, 318:116:4, July/Aug 2019.
- U.S. Department of Health and Human Services (2019, May). Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations. Retrieved from U. S. Department of Health and Human Services website: https://www.hhs.gov/ash/advisory-committees/pain/reports/index.html And https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf
- Lawrence R, Mogford D, Colvin L, Systematic review to determine which validated risk assessment tools can be used to assess risk of problematic analgesic use in patients with chronic pain, Br. J. Anaesth. 2017; 119:1092-109.
- Jones T, Lockatch S, Moore TM, Validation of a New Risk Assessment Tool: The Brief Risk Interview, J. Opioid Manag., 2015; 11:171-183.
- Jones T, Moore TM, Levy J. et al.: A Comparison of Various Risk Assessment Methods for Patients Receiving Chronic Pain Management, Clin. J. Pain, 2012;28:93-100.
- CMS, MACRA/MIPS Quality Measure, Quality ID #414: Evaluation or Interview for Risk of Opioid Misuse–National Quality Strategy Domain: Effective Clinical Care–Meaningful Measure Area: Prevention and Treatment of Opioid and Substance Use Disorders (2020), available online at https://qpp.cms.gov/docs/QPP_quality_measure_specifications/CQM-Measures/2019_Measure_414_MIPSCQM.pdf.
- US v. Roggow (2012), Testimony of Ted Parran, MD and Howard Heit, MD
- US v. Zolot (2011-2014), Testimony of Carol Warfield, MD
- US v. Ruan and Couch (2017), Testimony of various experts
- US v. Hofstetter, et al (2020), Testimony of various experts

39

Contact Information

- Jen Bolen, JD
- 865-755-2369 (text first)
- jbolen@legalsideofpain.com

THANK YOU!

40