PainWeek

Through the Lens of Medical Experts and Litigators: Meaningful Risk Mitigation and Patient Education During Chronic Opioid Therapy

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Title & Affiliation

Jennifer Bolen, JD
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Disclosures

- Consultant to Paradigm Healthcare.

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Background

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Focus of Medical Expert Testimony in a Controlled Substance Prescribing Case

- Whether the prescriber engaged in meaningful medical evaluation and appropriately considered patient risks (abuse, addiction, diversion, medication, medical, and misuse) in the construction of the initial treatment plan and ongoing monitoring.
- Whether the prescriber provided individualized medical care to the patient, based on the patient's specific history and behaviors and progress (or lack of it) toward treatment goals.

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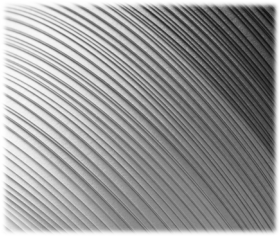
COVID-19 Changes the Playing Field: Requires Enhanced Risk Mitigation



- The COVID-19 pandemic continues to create challenges for pain management practitioners.
- Provider response calls for:
  - Enhanced risk mitigation efforts to ensure proper patient selection, management, and monitoring.
  - Enhanced documentation efforts to signal medical decision-making that is sound and timely.

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Learning Objectives

OBJECTIVE 1
- Summarize examples of current medical licensing board position statements and rules on risk mitigation and documentation for chronic pain management.

OBJECTIVE 2
- Compare government medical expert statements made in actions against prescribers regarding the prescriber's duty to take reasonable steps to prevent abuse and diversion of controlled substances.

OBJECTIVE 3
- List basic educational concepts and resources for patients and practice staff to facilitate prescriber fulfillment of "reasonable steps" to prevent abuse and diversion of and adverse outcomes associated with opioids.

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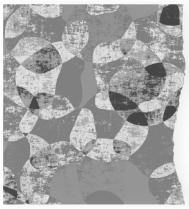

Summarize examples of current medical licensing board position statements and rules on risk mitigation and documentation for chronic pain management.

Objective 1

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REFRESHER:
Say it with me . . . Under federal law (DEA oversight):

A controlled substance prescription is valid only if it is issued:

1. For a . . . , and

- LEGITIMATE MEDICAL PURPOSE
- USUAL COURSE OF PROFESSIONAL PRACTICE
  - INCLUDES "Reasonable Steps to Prevent Abuse and Diversion"

2. By an individual practitioner who is acting in . . . . .

How are these requirements relevant to Medical Expert Testimony?

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AND DO NOT FORGET: Under state "legal/regulatory" framework, most medical licensing boards have:

- Rules for pain management clinic operations.
- Rules for prescribing controlled medication to treat pain.
- FAQs and/or Guidelines that explain the rules.
- While language used to describe these regulatory materials may vary by state, the basic framework is similar.
- Application and scope of these regulatory materials also vary.

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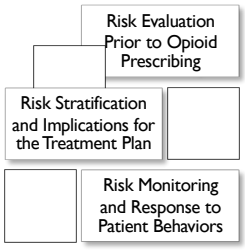
FOCUSING IN ON RISK MITIGATION FOR CHRONIC OPIOID THERAPY – ESSENTIAL PHASES

- **The "risk mitigation" process begins at/before the first encounter and continues throughout the practitioner-patient relationship.**
- **The burden is on the licensed healthcare provider (physician, NP, PA, etc.) to get it right.**
- **The burden never truly shifts to the patient;**
- The provider owes a duty of care to and is in a position of rust over the patient; They must perform at or above the minimum standards established by the legal/regulatory framework as well as the standards set by the medical world.



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What does a medical/nursing licensing board "generally" expect from a controlled substance prescriber as part of the "Usual Course" process)?

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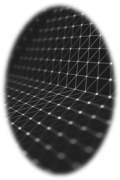
Basic "Domains" of Risks: Duty to Evaluate these areas when the Practitioner-Patient Relationship involves Chronic Opioid Therapy



- Medical Hx and Risks
- Behavioral Hx and Risks
- Current and Prior Medication Regimen and Related Risks
- Risk of Adverse Actions and Overdose
- Risk of Abuse/Diversion/Addiction
- Other Known or Potential Risks, including "Social" Risks

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Common Documentation Challenges in Risk Mitigation

EMRs **do not** contain a quality risk road map

- The patient file must reflect actions and events consistent with standards (Board, etc.).
- The patient file must contain a thoughtful explanation as to the provider's "Why" and "How" for Prescribing and Ongoing Care and Monitoring.

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Common Problems in the Risk Evaluation Process

Time Related

Using the "easiest" risk evaluation tools may mislead you	Working "risk mitigation" tasks into clinical workflow: the right people, with the correct forms and patient input, at the appropriate time.

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Regulatory Directives Guiding Standard of Care Expectations – Risk Mitigation and Documentation

State Licensing Board Examples

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New Hampshire Medical Board: Definition of Risk Assessment

"Risk assessment" [in NH] means a process for predicting a patient's likelihood of misusing or abusing opioids in order to develop and document a level of monitoring for that patient.

SOURCE: New Hampshire Medical Board Rules, Rule 502, Opioid Prescribing, Effective 5/3/16, available online at http://www.gencourt.state.nh.us/rules/state_agencies/med100-600.html (scroll to rule 502.05. Accessed 01/22/21.

Med 502.05 Chronic Pain. If opioids are indicated and prescribed for chronic pain, prescribing licensees shall:

(a) Conduct and document a history and physical examination;

(b) Conduct and document a risk assessment, including, but not be limited to, the use of an evidence-based screening tool such as the Screener and Opioid Assessment for Patients with Pain (SOAPP);

(c) Document the prescription and rationale for all opioids according to Med 501.02(d) and (e);

(d) Prescribe for the lowest effective dose for a limited duration;

(e) Comply with all federal and state controlled substances laws, rules, and regulations;

(f) Utilize a written informed consent that explains the following risks associated with opioids:

(3) Addiction;

(4) Overdose and death;

(5) Physical dependence;

(6) Physical side effects;

(7) Hyperalgesia;

(8) Tolerance; and

(9) Crime victimization;

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Texas Medical Board and Risk Mitigation Concepts in the Treatment of Chronic Pain

Texas Administrative Code

TITLE 22 EXAMINING BOARDS
PART 9 TEXAS MEDICAL BOARD
CHAPTER 170 PRESCRIPTION OF CONTROLLED SUBSTANCES
SUBCHAPTER A PAIN MANAGEMENT

Rules

§170.1 Purpose
§170.2 Definitions
§170.3 Minimum Requirements for the Treatment of Chronic Pain

HOME TEXAS REGISTER TEXAS ADMINISTRATIVE CODE OPEN MEETINGS

https://www.tmb.state.tx.us/page/board-rules
(click on current board rules and then Chapter 170).

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Texas Medical Board: Lead in language to Chapter 170.3

- A physician's treatment of a patient's pain will be evaluated by considering:
  - –whether it meets the generally accepted standard of care, and
  - –whether the following minimum requirements have been met:

Excerpt is from Chapter 170.3, Texas Medical Board Rules, Minimum Requirements for the Treatment of Chronic Pain.
https://www.rules.texas.gov/page/board-rules.

Source Note: The provisions of this §170.3 adopted to be effective January 4, 2007, 31 TexReg 10798; amended to be effective August 4, 2015, 40 TexReg 4898; amended to be effective July 7, 2016, 41 TexReg 4824; amended to be effective July 13, 2020, 45 TexReg 4748

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PRETEND THIS IS NOTEBOOK PAPER

Who	Directive (What)	When
The physician	MUST …	Prior to Prescribing a Controlled or Dangerous Drug
The physician	SHALL …	Periodically, based on individual needs of patient
The physician	MAY …	
The physician	SHOULD …	

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Texas Medical Board and Risk Mitigation

Evaluation of the patient:

A physician is responsible for obtaining a medical history and a physical examination that includes a problem-focused exam specific to the chief presenting complaint of the patient.

The medical record shall document the medical history and physical examination. In the case of chronic pain, the medical record must document:

(i) the nature and intensity of the patient;
(ii) current and past treatments for pain;
(iii) underlying or coexisting diseases and conditions;
(iv) the effect of the pain on physical and psychological function;
(v) any history and potential for substance abuse or diversion, and
(vi) the presence of one or more recognized medical indications for the use of a dangerous or scheduled drug.

Excerpt is from Chapter 170.3, Texas Medical Board Rules, Minimum Requirements for the Treatment of Chronic Pain.
https://www.rules.texas.gov/page/board-rules.

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Texas Medical Board and Risk Mitigation

Prior to prescribing opioids, benzodiazepines, barbiturates, or carisoprodol for the treatment of chronic pain, a physician MUST:

1. **REVIEW** prescription data and history related to the patient, if ay, contained in the Prescription Drug Monitoring Program in accordance with [Texas Regulations].
2. **CONSIDER** obtaining a minimum baseline toxicology drug screen to determine the presence of drugs in a patient, if any.
3. **IF A PHYSICIAN DETERMINES THAT A BASELINE TOXICOLOGY DRUG SCREEN IS NOT NECESSARY, THE PHYSICIAN MUST DOCUMENT** in the medical record his or her **RATIONALE FOR NOT REQUIRING THE TOX TEST.**

Excerpt is from Chapter 170.3, Texas Medical Board Rules, Minimum Requirements for the Treatment of Chronic Pain
https://www.tmb.state.tx.us/page/board-rules

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Texas Medical Board and Risk Mitigation

Periodic review of the treatment of chronic pain:

(A)The physician **MUST SEE** the patient for periodic review at reasonable intervals in view of the individual circumstances of the patient.

(B)Periodic review **MUST ASSESS** progress toward reaching treatment objectives, taking into consideration the history of medication usage, as well as any new information about the etiology of the pain.

(C)DOCUMENT EACH PERIODIC REVIEW in the medical records.

(D)Contemporaneous to periodic review, the physician **MUST NOTE** in the medical record any adjustment in the treatment plan based on the individual medical needs of the patient.

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Excerpt is from Chapter 170.3, Texas Medical Board Rules, Minimum Requirements for the Treatment of Chronic Pain
https://www.tmb.state.tx.us/page/board-rules.

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Texas Medical Board and Risk Mitigation

Periodic review of the treatment of chronic pain CONTINUED

(E) A physician **MUST BASE ANY CONTINUATION OR MODIFICATION OF THE USE OF DANGEROUS AND SCHEDULED DRUGS FOR PAIN MANAGEMENT** on an evaluation of progress toward treatment objectives.

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Excerpt is from Chapter 170.3, Texas Medical Board Rules, Minimum Requirements for the Treatment of Chronic Pain
https://www.tmb.state.tx.us/page/board-rules.

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Texas Medical Board and Risk Mitigation

1. Progress or lack of progress in relieving pain must be documented in the patient's record.
2. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, and/or improved quality of life.
3. Objective evidence of improved or diminished function must be monitored. Information from family members or other caregivers, if offered or provided, must be considered in determining the patient's response to treatment.
4. If the patient's progress is unsatisfactory, the physician must reassess the current treatment plan and consider the use of other therapeutic modalities.

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Excerpt is from Chapter 170.3, Texas Medical Board Rules, Minimum Requirements for the Treatment of Chronic Pain https://www.tmb.state.tx.us/page/board-rules.

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Texas Medical Board and Risk Mitigation

The physician MUST periodically review the patient's compliance with the prescribed treatment plan and reevaluate for any potential for substance abuse or diversion.

In such a review, the physician MUST consider obtaining at a minimum a toxicology drug screen to determine the presence of drugs in a patient, if any.

If a physician determines that a repeat toxicology screen is not necessary, the physician MUST document in the medical record his or her rationale for not completing it.

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Excerpt is from Chapter 170.3, Texas Medical Board Rules, Minimum Requirements for the Treatment of Chronic Pain https://www.tmb.state.tx.us/page/board-rules.

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Texas Medical Board and Risk Mitigation

(6) Consultation and Referral:

The physician must refer a patient with chronic pain for further evaluation and treatment as necessary.

Patients who are at-risk for abuse or addition require special attention.

Patients with chronic pain and histories of substance abuse or with co-morbid psychiatric disorders require even more care.

A consult with or referral to an expert in the management of such patients **must** be considered in their treatment.

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- Excerpt is from Chapter 170.3, Texas Medical Board Rules, Minimum Requirements for the Treatment of Chronic Pain https://www.tmb.state.tx.us/page/board-rules.

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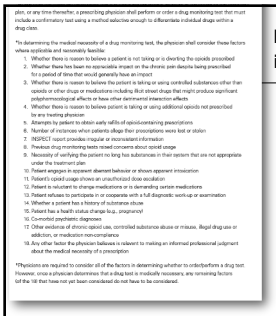
plan, or any time thereafter, a prescribing physician shall perform or order a drug monitoring test that must include a confirmatory test using a method selective enough to differentiate individual drugs within a drug class.

*In determining the medical necessity of a drug monitoring test, the physician shall consider these factors where applicable and reasonably feasible:

1. Whether there is reason to believe a patient is not taking or is diverting the opioids prescribed
2. Whether there has been no appreciable impact on the chronic pain despite being prescribed for a period of time that would generally have an impact
3. Whether there is reason to believe the patient is taking or using controlled substances other than opioids or other drugs or medications including illicit street drugs that might produce significant polypharmacological effects or have other detrimental interaction effects
4. Whether there is reason to believe patient is taking or using additional opioids not prescribed by any treating physician
5. Attempts by patient to obtain early refills of opioid-containing prescriptions
6. Number of instances when patients allege their prescriptions were lost or stolen
7. INSPECT report provides irregular or inconsistent information
8. Previous drug monitoring tests raised concerns about opioid usage
9. Necessity of verifying the patient no long has substances in their system that are not appropriate under the treatment plan
10. Patient engages in apparent aberrant behavior or shows apparent intoxication
11. Patient's opioid usage shows an unauthorized dose escalation
12. Patient is reluctant to change medications or is demanding certain medications
13. Patient refuses to participate in or cooperate with a full diagnostic work-up or examination
14. Whether a patient has a history of substance abuse
15. Patient has a health status change (e.g., pregnancy)
16. Co-morbid psychiatric diagnoses
17. Other evidence of chronic opioid use, controlled substance abuse or misuse, illegal drug use or addiction, or medication non-compliance
18. Any other factor the physician believes is relevant to making an informed professional judgment about the medical necessity of a prescription

*Physicians are required to consider all of the factors in determining whether to order/perform a drug test. However, once a physician determines that a drug test is medically necessary, any remaining factors (of the 18) that have not yet been considered do not have to be considered.

Indiana Medical Board on Using UDT in Risk Mitigation

- Excerpted from Indiana Pain Management Final Prescribing Rule, Indiana Medical Licensing Board, 9/25/14.

Summary created by the Indiana State Medical Association as updated on 10/25/16.

Available online at https://www.in.gov/isdh/28027.htm and https://www.ismanet.org/pdf/legal/IndianaPainManagement_PrescribingFinalRuleSummary.pdf.

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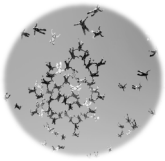

MEDICAL RECORD DOCUMENTATION REQUIREMENTS

LICENSING BOARD RULES AND RELEVANT CHALLENGES IN RISK MITIGATION

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Licensing Board Example on Medical Record Documentation Requirements (Basic)

TEXAS

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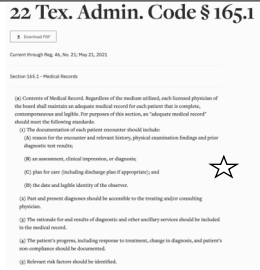
TEXAS Basic Rule on MEDICAL RECORDS

https://casetext.com/regulation/texas-administrative-code/title-22-examining-boards/part-9-texas-medical-board/chapter-165-medical-records/section-1651-medical-records



22 Tex. Admin. Code § 165.1

Download PDF

Current through Reg. 46, No. 21, May 21, 2021

Section 165.1 - Medical Records

(a) Contents of Medical Record. Regardless of the medium utilized, each licensed physician of the board shall maintain an adequate medical record for each patient that is complete, contemporaneous and legible. For purposes of this section, an "adequate medical record" should meet the following standards:

(1) The documentation of each patient encounter should include:

(A) reason for the encounter and relevant history, physical examination findings and prior diagnostic test results;

(B) an assessment, clinical impression, or diagnosis;

(C) plan for care (including discharge plan if appropriate); and

(D) the date and legible identity of the observer.

(2) Past and present diagnoses should be accessible to the treating and/or consulting physician.

(3) The rationale for and results of diagnostic and other ancillary services should be included in the medical record.

(4) The patient's progress, including response to treatment, change in diagnosis, and patient's non-compliance should be documented.

(5) Relevant risk factors should be identified.

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TEXAS & BASIC MEDICAL RECORD-KEEPING REQUIREMENTS

https://casetext.com/regulation/texas-administrative-code/title-22-examining-boards/part-9-texas-medical-board/chapter-165-medical-records/section-1651-medical-records

(6) The written plan for care should include when appropriate:

(A) treatments and medications (prescriptions and samples) specifying amount, frequency, number of refills, and dosage;

(B) any referrals and consultations;

(C) patient/family education; and

(D) specific instructions for follow up.

(7) Include any written consents for treatment or surgery requested from the patient/family by the physician.

(8) Include a summary or documentation memorializing communications transmitted or received by the physician about which a medical decision is made regarding the patient.

(9) Billing codes, including CPT and ICD-9-CM codes, reported on health insurance claim forms or billing statements should be supported by the documentation in the medical record.

(10) All non-biographical populated fields, contained in a patient's electronic medical record, must contain accurate data and information pertaining to the patient based on actual findings, assessments, evaluations, diagnostics or assessments as documented by the physician.

(11) Any amendment, supplementation, change, or correction in a medical record not made contemporaneously with the act or observation shall be noted by indicating the time and date of the amendment, supplementation, change, or correction, and clearly indicating that there has been an amendment, supplementation, change, or correction.

(12) Salient records received from another physician or health care provider involved in the care or treatment of the patient shall be maintained as part of the patient's medical records.

(13) The board acknowledges that the nature and amount of physician work and documentation varies by type of services, place of service and the patient's status. Paragraphs (1) - (12) of this subsection may be modified to account for these variable circumstances in providing medical care.

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Pain Management and Risk Mitigation: A helpful list of items for physicians

Suspicious history:
- Patient referred is already taking controlled substances; especially combinations of narcotics, muscle relaxants, use of sedative/hypnotics
- Soft diagnosis – perhaps based solely on chief complaint
- Multiple doctors and pain physicians in the past
- Patient travelled out of the way to come to your clinic
- Solicitous behavior frequently heard: "You're the best. I always wanted to come to you."
- No past medical records; unable to obtain records from "referring doctor"
- Patient brings records that look old, tattered or suspicious in some other way
- Patient asks for a specific controlled substance (example: prefers Lortab® over Norco)

Suspicious physical exam:
- No abnormal findings
- Abnormal findings in exam room inconsistent with witnessed behavior (patient has normal gait from car to office door, but limps once inside door)
- Exaggerative behaviors, pain is always a 10 on a scale of 1 to 10.
- Uninterpretive imaging
- Presence of injecting behavior (old or recent "track marks" or multiple healed or current abscesses) or marked nasal erythema from insufflation ("snorting")
- Patient smells like marijuana smoke

Equivocal compliance:
- NCSSES shows multiple providers, multiple pharmacies, prescriptions for multiple types and of medications, out of the area doctors, etc.
- UDS is refused or abnormal; patient offers multiple excuses; presence of any illegal substances (marijuana)
- Inconsistent test results over time
- Patient seeks recurrent early refills for lost or stolen prescriptions or for increased opioid use without consultation with prescriber
- Patient has excuses for lost pills (lost my prescription, my dog ate my pills, etc.)

No or equivocal clinical improvement:
- Subjective improvement alone does not count
- Lack of evidence of objective improvement in physical, functional and psychosocial activities,
- Lack of evidence of decreasing use of opioid medications, decreasing visits to emergency rooms, etc.

What you should do when the clinician suspects misuse, abuse or addiction:
- Request picture I.D. or other I.D. and a Social Security number. Photocopy these documents and include in the patient's record.
- Call a previous practitioner, pharmacist or hospital to confirm the patient's story.
- Confirm a telephone number, if provided by the patient.
- Confirm the current address at each visit.
- Investigate suspicious further by presenting and discussing specific concerns with the patient, re-checking NCSSES information. Increase the use of drug screens, talk with family members.

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Position statements available online at https://www.ncmedboard.org/images/uploads/other_pdfs/PS_October2015.pdf.

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Pain Management and Risk Mitigation:
Recommendations for Primary Care

Position statements available online at
https://www.ncmedboard.org/images/uploads/other_pdfs/PS_October2015.pdf.

Recommendations For Primary Care

- Develop an office policy for opioid prescribing and have this clearly posted and available for patients.
- Perform a thorough history and physical at the onset.
- Acute pain patients should be frequently evaluated for physical, functional and psychosocial improvement, adjustments to treatment as needed. It is almost always contraindicated to include refills on opioid prescrip for acute pain.
- Educate your patients about pain and analgesia. Explain the underlying diagnosis causing the pain, the na history of the condition, and how your patient can help the healing process.
- If medically possible, exhaust non-opioid medications and collaborate with other professionals, including ph therapists and pain specialists. Consider nontraditional therapies such as acupuncture and massage therapy.
- Opioids are often not required for acute pain. If you feel a brief course of opioids are indicated and appropria thoughtful and thorough in your discussions and practice.
- Always prescribe a complete pain management program when an opioid is used to treat acute pain:
  - utilize NSAIDS
  - develop and recommend specific exercises
  - utilize other modalities (e.g. heat, ice, massage, topical medications)
- Prescribe opioids intentionally. With the first opioid prescription, set patient responsibilities and the expect that opioids will be discontinued when the pain problem has resolved or is not responding to what you are do
- Write the taper on the prescription (e.g. 1 po every 6 hours for 3 days, 1 po every 8-12 hr for 3 days, 1 po every for 3 days, stop).
- Do not prescribe long-acting or controlled-release opioids (e.g., long-acting oxycodone and oxymorphone, fen patches, long-acting hydromorphone and morphine or methadone) for acute pain.
- Consider performing risk stratification, urine drug monitoring and have a low threshold for accessing monitoring the NCCSRS at the onset of pain care.
- Give clear instructions to take opiates only as prescribed, not more frequently or in greater quantities. Educate patients about the risks of taking opioid analgesics, including, but not limited to: overdose that can slow o their breathing and even lead to death; fractures from falls, especially in patients aged 60 years and drowsiness leading to injury, especially when driving or operating heavy or dangerous equipment; and tole and addiction. Educate your patients about acute pain – tell them it is likely that their acute pain will dim and resolve, and tell them that prolonged (several weeks of) scheduled opioids may actually impair their abil fully recover.
- Patients should be advised to avoid medications that are not part of their treatment plan because they may w the side effects and increase the risk of overdose from opiates.
- Prepare patients that it may be difficult to taper off opioids, particularly from higher dose regimens, even when are eager to do so.
- Consider referrals and consultations with a pain specialist if the patient is not responding to your treatment You may want to do this early in the course of treatment if the patient does not respond to standard firs medications and before you prescribe narcotics. Pain specialists may offer procedures or other intervention will help your patient improve and avoid unnecessary opiate use.
- It is critical to assure that patients are provided with easy to follow and graduated activity instructions that them quickly improve their quality of life in physical, functional and social domains.

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Objective #2

Review various government and defense medical expert statements made in actions against prescribers regarding the prescriber's duty to take reasonable steps to prevent abuse and diversion.

Medical Expert Perspectives: Meaningful Risk Evaluation and Risk Monitoring

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Question:

Testifying medical experts are generally 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

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Answer:

Testifying medical experts are generally 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?

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E. None of the above

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How are Medical Expert Opinions <u>Generally</u> Communicated in Litigation?

Affidavit/Report	Testimony	Case Opinions/Orders
• Qualifications • Review Steps and Findings • Opinions • Resources and Standards	• Deposition • Hearing • Trial	• Excerpted in Administrative Decisions and Orders • Civil and Criminal Court Opinions (by reference and in appeal briefs)

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From US v. Couch and Ruan

EXAMPLE – BASIC GOVERNMENT DISCLOSURE OF MEDICAL EXPERT TESTIMONY IN A CRIMINAL CASE

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Case 1:15-cr-00088-CG-B Document 377-1 Filed 12/02/16 Page 3 of 10

In addition to providing expert opinion testimony related to the patient file reviews, Drs **berg, Vohra,** and **Aultman** may present testimony on the following general topics based or pecialized education, training, and experience:

An overview of the doctor–patient relationship. The standard of care for doctors in treating pain. The various types of pain treatments, including non-drug, non-opioid, and opioid therapies, the effects of each, and the types of injuries/illnesses treated by each. The standards for pain diagnosis and treatment.

The different types of drugs at issue in this case, such as fentanyl, oxycodone, oxymorphone, hydrocodone, hydromorphone, morphine, and benzodiazepines, including drug interactions, contraindications, potentiating effect, and the prescribing of therapeutic versus non-therapeutic amounts. The serious potential for misuse of prescription medications, particularly opioids, and their addictive properties. A physician's duty to watch for signs of abuse, addiction, and diversion, and the "red flags" used to determine whether a patient is an abuser or drug-seeker.

Drug addiction, particularly to opioids, treatment of addiction, and the dangers of overdose and death from drug misuse and abuse. The number of overdoses and overdose patient deaths typically associated with a family or pain management practice, and how a treating pain management physician should respond to his patient's drug overdose and/or overdose death.

Government's Expert Witness Disclosure in United States v. Couch and Ruan

Document 377-1 in United States v. Couch and Ruan, et al., 1:15:CR-0088-CG-B, filed 12/2/16

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Government Expert Witness Testimony Disclosures
(extracted from US v. Couch and Ruan, 1:15-CR-0088-CG, Document 377-1, filed 12/2/16)

Dr. Greenberg, specifically, will also provide the following general expert opinion testimony at trial:

- The most important quality of the doctor patient relationship is the recognition of the phrase that every first year medical student is indoctrinated with, which is, "First, do no harm."
- The next important piece of the doctor-patient relationship is honesty. The doctor must assure his patients that he will not lie to them about their medical conditions or their treatments.
- When physicians become confused and are unable to properly diagnose and treat their patients, then the standard of practice in the United States is that those physicians should refer their difficult patients to consultants who are experts in fields such as neurology, psychiatry, physical medicine & rehabilitation, toxicology, and addiction medicine.
- The number of overdose, and overdose patient deaths, in carefully managed deaths in family practice and pain management practices is normally extremely low. However, when the physicians in charge of treatment abdicate their responsibilities to honestly convey the risks associated with any given treatment, tragedies such as overdose death can occur.

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titration of upward doses. These types of safety practicing chronic pain specialists make it clear from the very beginning that opioid drugs will only at best produce a one to two-point improvement in any patient's pain score.

- It is the physician's duty to warn his patients whenever he or she decides to prescribe powerful narcotic and/or sedative hypnotic drugs. This should include specific information delivered to the patient that the narcotic and sedative hypnotic drugs prescribed may in fact cause the death of the patient. Such informed consent must be documented into the medical record and patients should be offered multiple safer therapies whenever possible.
- It is the physician's duty to carefully monitor his patients for any signs of drug abuse, addiction, and/or drug diversion.
- Astute physicians will quickly recognize non-compliant patient behaviors, such as illicit drugs showing up in urine drug screens, or the lack of prescribed medication, and/or alcohol being utilized, along with powerful narcotic and sedative hypnotic drugs. It is the physician in charge's duty to confront noncompliant patients in a straightforward manner. Such confrontation of noncompliant patients is essential for the safe practice of chronic pain medicine. Physicians who refuse to confront noncompliant patients cause them great harm and all too often, premature death. In addition, safety-based physicians utilize the state controlled substances prescription monitoring program (PMP) on a frequent basis as these programs curtail drug abuse, drug addiction, and commercial drug diversion criminal rings.

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From US v. Nasher (SDWV 2019)

EXAMPLE –MEDICAL EXPERT METHODOLOGY AND ITEMS USED IN REVIEWING RECORDS AS PREPARATION FOR TESTIMONY IN A CRIMINAL CASE

PainWeek

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Example of Medical Expert Testimony in a Pre-Trial Hearing – Judge's Summary in Opinion Allowing Expert Testimony (US v. Nasher, SDWV, 2019)

a legitimate guide-post. His methodology in reviewing the patient charts included looking at the diagnosis, treatment and the documentation. Dr. Kennedy stated that the manner in which he reviewed the patient charts is accepted in the medical community as the proper framework, and that he applied these guidelines in reviewing the defendant's patients' charts. Dr. Kennedy prepared an expert report, dated September 2, 2018, opining, in sum, that:

> In reviewing the 19 medical charts that you

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Medical Expert "Methodology": Pre-Trial Hearing in a Criminal Case

- (US v. Nasher, SDWV, 2019)

> Nasher were not for a legitimate purpose. In supporting this position I would note: [p]ast medical treatment histories were frequently not obtained. [. . .] Physical examinations were uniformly documented by rote and not credible. [. . .] The follow up encounter documentation in the charts is performed by rote, non-credible, and not medically legitimate. [. . .] Toxicology screening to assure compliance was not credible. [. . .] Appropriate patient/physician relationships were not maintained.

(ECF no. 66-2). Dr. Kennedy based his review of the nineteen patients' charts upon the Federation of State Medical Boards' Model Policy for Use of Opioids in the Management of Pain, published in 2013. Dr. Kennedy stated that this model policy has been adopted by many states, including West Virginia. Dr. Kennedy also stated that he relied upon the Drug Enforcement Practitioner's Manual, which outlines DEA policies on prescribing schedule medications. Dr. Kennedy also reviewed surveillance footage in reaching his opinions.

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From US v. Lopez (SDNY 2019)

EXAMPLE – GOVERNMENT'S MEDICAL EXPERT TESTIMONY IN A CRIMINAL CASE

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Medical Expert Testimony – Seth Waldman, MD (US v. Lopez)
(2/14/19 Trial Testimony as Witness for the Prosecution)

Q. What are you looking for when you review those charts?
A. Well, we are looking for a number of things. First we are looking for documentation. We want to make sure that the rationale for why you are using these medications is spelled out. We want to make sure that the diagnosis, the reason for the prescription is clear in the chart, that the thought

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Medical Expert Testimony – Seth Waldman, MD

(US v. Lopez)
2/14/19 Trial Testimony as the Government's Medical Expert

We need to know about their background, as I said, medical issues they have had before, surgeries they have had in detail, medicines they've tried, medicines they are taking, psychiatric history, drug abuse history, social history, family history. All of those things are part of the initial evaluation.
Q. I was having just a little bit of trouble hearing you. Could you perhaps move closer to the microphone.
A. Sure.
Q. You mentioned social history. Why would you take a patient's social history?
A. Well, it's important know if the patient smokes. It's important to know if the patient uses any drugs, the patient takes intravenous narcotics. You know, that is a relevant

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Medical Expert Testimony – Seth Waldman, MD

Q. Are doctors required to keep records of a patient's visit?
A. Yes.
Q. Can a physician acting in the usual course of professional practice properly rely solely on a patient's self-report of pain to prescribe oxycodone?
A. No, usually not.
Q. Why is that?
A. Opioid pain medications are a special case because they are valuable in terms of being sold and diverted. They have very,

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(US v. Lopez)
2/14/19 Trial Testimony as the Government's Medical Expert

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Medical Expert Testimony – Seth Waldman, MD

very powerful negative side effects. People can overdose easily if they are not prescribed properly.

In this country we have a tremendous problem with misuse. The vast majority of narcotic pain medicines that are prescribed are not used by the people for whom they are prescribed. Somewhere in the neighborhood of 70 percent is not actually consumed.

As a result the doctor has a duty to make sure that the patient is not hurting themselves by the use of these medicines, but also make sure that the public is not being harmed by the excessive medicine that the doctor is prescribing and it's going out some someplace that they don't anticipate.

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(US v. Lopez)
2/14/19 Trial Testimony as the Government's Medical Expert

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Medical Expert Testimony – Seth Waldman, MD

Q. In what stage in your treatment would you consider prescribing opioids?

A. It depends on the circumstances. Sometime very early. It depends on how severe the pain is, and what are the things you're doing at the same time.

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(US v. Lopez)
2/14/19 Trial Testimony as the Government's Medical Expert

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Medical Expert Testimony – Seth Waldman, MD

Case 1:18-cr-00006-DLC Document 92 Filed 03/13/19 Page 81 of 233 607
J2EPLOP3 Waldman - Direct

Q. Would you have considered other treatment options prior to prescribing opioids?

A. It would be unusual to only use opioids as the first treatment option.

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(US v. Lopez)
2/14/19 Trial Testimony as the Government's Medical Expert

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Medical Expert Testimony – Seth Waldman, MD

Q. And if opioids are prescribed to a patient, what strength should be used?
A. The lowest strength possible. And the CDC has a saying for that. They say, start low, go slow.
Q. Why is that?
A. For a couple of reasons. The most important is that we don't know what the side effects of the opioid will be. We can always give more, but we can't take it back. And if you give too much opioid pain medication, you can cause the patient to stop breathing, or you could cause the patient to have interactions with other medicines or become addicted. We try to expose people as little as possible to drugs in general, but particularly to opioids.

PainWeek
(US v. Lopez)
2/14/19 Trial Testimony as the Government's Medical Expert

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Medical Expert Testimony – Seth Waldman, MD

Q. In what circumstances would it be inappropriate to prescribe opioids?
A. So you can use opioid pain medications when you feel they're necessary, as a clinician, as a doctor or a nurse practitioner or physician's assistant. You can prescribe them when you think they are indicated for a legitimate medical need and as part of your usual practice.
You should have found that there's a condition that warrants it. You should have made sure that anything else that you could do to minimize the pain has already either being done or has been done and failed. And you should be doing anything you can to correct the underlying problem so that the patient will recover and then not need opioids so that you can minimize the time that they're exposed to them.

PainWeek
(US v. Lopez)
2/14/19 Trial Testimony as the Government's Medical Expert

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Medical Expert Testimony – Seth Waldman, MD

Q. And would you conduct a physical examination before issuing a prescription for a higher-strength opioid?
A. Almost always, yes.
Q. What about when prescribing an additional opioid?
A. Almost always.
Q. And why would you do those physical examinations?
A. Well, the purpose of the physical examination is to see if something has changed with the patient's physical condition. So there are times when there is a painful complaint, we have a certain amount of information about what's causing it, but then we're not clear on exactly why it's hurting so much, but then a new symptoms arises.
And when the new symptoms arises, it becomes clear that, in fact, we're really not just looking at a disc

PainWeek
(US v. Lopez)
2/14/19 Trial Testimony as the Government's Medical Expert

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Medical Expert Testimony – Seth Waldman, MD

Q. Mr. Waldman, have you formed an opinion on whether the prescription for oxycodone was issued outside the usual course of professional practice?
A. I think this was written outside of the course of usual practice.
Q. Why is that?
A. The change in the prescription from 10 to 30 doesn't seem

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(US v. Lopez)
2/14/19 Trial Testimony as the Government's Medical Expert

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Medical Expert Testimony – Seth Waldman, MD

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J2enlop4 Waldman - Direct

to have any basis in the medical condition of the patient. In fact, the chart documents that the patient doesn't have a change in their pain when they are using the narcotic or not. The number, the pain scale is low, the patient states that they are feeling better. If you needed to give some kind of pain medication, even if it had to be an opioid, that might be a reason to continue the prior prescription, but it would certainly not be a reason to triple the dose on the next prescription.

PainWeek
(US v. Lopez)
2/14/19 Trial Testimony as the Government's Medical Expert

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Medical Expert Testimony – Seth Waldman, MD

Q. What would you expect to see discussed at a patient visit where the pain medication had just tripled in strength and the patient reports no change in their pain levels?
A. Well, you would have to first make sure that the patient was actually using the medication. You know, if somebody had tripled the dose of medicine and reported no change in their pain, I would wonder whether they were actually taking the medication at all. I would like to know if they're having side effects of the medication. It is hard to answer, because you would try not to be in this circumstance.

PainWeek
(US v. Lopez)
2/14/19 Trial Testimony as the Government's Medical Expert

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Medical Expert Testimony – Seth Waldman, MD

Q. What is aberrant behavior?
A. Aberrant behavior are any kinds of behaviors that indicate that the patient might be seeking more narcotics not because of an underlying medical condition but because they are either diverting it or overusing the medicine themselves. Something like being out early, requesting to go up on the dose of medicine even though everything is OK, losing medications frequently, that kind of thing.
Q. What, if any, of aberrant behavior did you see during the course of that video?
A. I would be suspicious about asking to increase the dose. The patient asked about adding Subsys, the patient asked about adding a fentanyl patch, the patient asked about increasing the number of pills from 90 to 120 not based on the fact that they said they were hurting more, but they just asked.

(US v. Lopez)
2/14/19 Trial Testimony as the Government's Medical Expert

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Medical Expert Testimony – Seth Waldman, MD

Q. What is that opinion?
A. I believe that was outside of the course of usual practice.
Q. Why is that?
A. The patient had been presumably off opioid pain medications for three months, returned for a follow up and was given a refill prescription without any information regarding what was wrong with him. He simply received a refill prescription. We don't know whether he used any of the medication or he did not use any of the medication and what had happened to his pain in the interim.

(US v. Lopez)
2/14/19 Trial Testimony as the Government's Medical Expert

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From US v. Schneider

EXAMPLE – BASIC GOVERNMENT MEDICAL EXPERT TESTIMONY IN A CRIMINAL CASE

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Government Medical Expert Testimony Regarding Aberrant Behaviors and the Risk/Benefit Analysis

report anxiety and they would just start treating anxiety with benzodiazepines without proper assessment, without treating the patient with what would be considered more first line treatments like antidepressants or counseling.

Q What, if any, patterns did you see regarding the substance abuse histories that were not taken?

A There was a pattern of not paying attention to those very important risk factors.

Q What, if any, patterns did you see regarding the monitoring for addictive behavior?

A All of the deaths I reviewed had warning signs of self-escalation, early refills, aberrant urine drug screens, et cetera. They all had warning signs and they were ignored, which tells me there was no adequate monitoring.

Q What, if any, patterns did you see regarding the types of controlled substances being prescribed?

A Well, there was increasing doses of opioids and early refills given and rotations to other drugs without

Trial Testimony of Graves Owen, MD (for the Government) in *US v. Schneider*, 6:07-CR-10234, Doc. 623, Filed 4/4/11 (Convicted).

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Q Now, you mentioned something called aberrant behaviors. What's an aberrant behavior?

A An aberrant behavior is when something occurs that was not authorized or is unexpected.

Q And what are some examples of that?

A Increasing your medication without consent from the physician; a urine drug screen that has illegal drugs in it, or has prescribed drugs that shouldn't be there because you don't prescribe them; or the urine drug screen that does not contain the drug you are prescribing.

Q How about early refills, is that an aberrant behavior at times?

A Yes. Because it's one of the few warning signs that

Government Expert Testimony Regarding Aberrant Behaviors and the Risk/Benefit Analysis

somebody is losing control of their drugs. Inability to self-regulate is one of the only clinically detectable signs we have to detect addiction as it's starting.

Q Now, did you see those patterns documented in the medical records you reviewed?

A Yes.

Q And what patterns did you see with regards to taking corrective action based on those aberrant behaviors?

A I never saw any corrective action taken.

PainWeek Trial Testimony of Graves Owen, MD (for the Government) in *US v. Schneider*, 6:07-CR-10234, Doc. 623, Filed 4/4/11 (Convicted).

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Government Medical Expert Testimony Regarding Aberrant Behaviors and the Risk/Benefit Analysis

Q Would these aberrant behaviors have put the clinic's providers on notice of anything?

A Yes.

Q And what?

A That she is developing addictive problems.

Q Did you find information that the clinic's providers reacted to these aberrant behaviors in any way?

A No.

Q Can you give us some examples of the aberrant behaviors of the clinic's -- in the clinic's records?

A Early refill request. Aberrant urine drug screens. those kinds of items.

Q Did she indicate that she was drinking under age?

A I don't remember.

Q Let me hand you your report in the K--------- case and hopefully you can review that real quickly and refresh your recollection on that issue.

(Off-the-record.)

A Yes.

Q And in Lacey's situation when non-euphoric drugs were not effective, what did the clinic do in response to that?

A They gave very euphoric drugs.

Q Is that an appropriate response in your opinion?

A No.

Trial Testimony of Graves Owen, MD (for the Government) in *US v. Schneider*, 6:07-CR-10234, Doc. 623, Filed 4/4/11 (Convicted).

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Risk Mitigation: Do Not Ignore Red Flags including Alcohol and Marijuana Use

GOVERNMENT MEDICAL EXPERT (TOXICOLOGIST) IN CYNTHIA CADET MD, DEA DECISION & ORDER (2011);

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Does it matter if the prescriber performs: (1) toxicology tests? (2) PDMP checks?

Dr. Kennedy found the Respondent's controlled substance patient monitoring to be deficient in numerous respects. From the reviewed patient charts, Dr. Kennedy gleaned that an initial, in-office urine drug screen was frequently executed during the patients' initial visit to the office but repeated only occasionally. Govt. Ex. 55 at 14. It was Dr. Kennedy's observation that even a drug screen anomaly did not alter the seemingly inexorable continuation of controlled substance prescribing from the Respondent. *Id.* Dr. Kennedy also noted that the Respondent did not utilize out-of-office toxicology tests, or obtain out-of-State prescription monitoring program or outside pharmacy drug profiles. Furthermore, the charts contained only rare evidence of contact with primary care physicians, treating physicians, pharmacists, or other health care providers. *Id.*

Cynthia M. Cadet, MD, DEA Decision and Order, Federal Register, Vol. 76, No. 67 (Thursday, April 7, 2011), available online at https://www.deadiversion.usdoj.gov/fed_regs/actions/2011/fr0407_5.htm.

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Does it matter if the prescriber monitors and addresses "red flags"?

The identified shortcomings of controlled substance patient monitoring systems was of particular significance where Dr. Kennedy identified specific evidence that he identified as "red flags" of possible or likely diversion. In addition to providing incomplete and/or inconsistent information on his patient questionnaires, SM's file reflected a positive urine screen test for the presence of benzodiazepines, opiates, and oxycodone, significant potential depression, and the failure to disclose information about his Kentucky-based primary care and orthopedics treating physicians, and his physical therapist. Govt. Exs. 69, 132 at 6. Other red flags noted by Dr. Kennedy in the reviewed charts included the relatively young age of the Respondent's chronic pain patients,[45] incomplete history information provided by the patients, periodically significant gaps between office visits,[46] referrals from friends, relatives, or advertising, but not other physicians,[47] and the fact that a relatively high number of patients were traveling significant distances to American Pain for pain treatment, although no physician employed at that facility had any specialized training in pain management.[48]

Cynthia M. Cadet, MD, DEA Decision and Order, Federal Register, Vol. 76, No. 67 (Thursday, April 7, 2011), available online at http://www.deadiversion.usdoj.gov/fed_regs/actions/2011/fr0407_5.htm.

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Does it matter if the prescriber: (1) Performs an assessment for Cannabis Use Disorder? (2) Tests for THC?

Cynthia M. Cadet, MD, DEA Decision and Order, Federal Register, Vol. 76, No. 67 (Thursday, April 7, 2011), available online at https://www.deadiversion.usdoj.gov/fed_regs/actions/2011/fr0407_5.htm.

The evidence establishes that the Respondent engaged in a course of practice wherein she prescribed controlled substances to patients irrespective of the patients' need for such medication and ignoring any and all red flags that could or did indicate likely paths of diversion. The testimony of Dr. Kennedy, the DEA regulations, and the Florida Standards make clear that physicians prescribing controlled substances do so under an obligation to monitor the process to minimize the risk of diversion. The patient charts reflect that the Respondent, contrary to her obligations as a DEA registrant, did not follow up in the face of multiple red flags. The Respondent's disregard of her obligations as a DEA registrant and Federal and State laws related to controlled substances militate in favor of revocation.

By ignoring her responsibilities to monitor the controlled substance prescriptions she was authorizing to minimize diversion, and by participating in an insufficiently documented and thoughtful process for the issuance of potentially dangerous controlled substances, the Respondent created a significant potential conduit for the unchecked diversion of controlled substances. *See Holloway*

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Does it matter if you assess for a Cannabis Use Disorder when you prescribe chronic opioid therapy? Does it matter if you drug test for THC?

Performing the tasks that Dr. Kennedy opined were required by a prudent practitioner would have revealed, at a minimum, that SM had an addiction to pain killers, was abusing marijuana, was receiving controlled substance prescriptions from another physician and was in the midst of some manner of significant emotional-psychological event. None of that was done. In the case of SM, the Respondent did what she apparently routinely did: She prescribed controlled substances without performing the steps that were required to ensure that the prescriptions were being issued for a legitimate medical purpose. In the case of SM, while it is possible, even likely, that increased curiosity and professional attention and action on the Respondent's part could have saved his life, that determination is not required for a disposition of this case. While experts could argue the point of which medication actually killed him, there seems very little room for argument that the Respondent's poor *prescribing practices* were very problematic relative to this decedent and serve as a grave reminder of the potential consequences of failing to take the steps required by a prudent registrant to ensure the safety of the public. Consideration of the Respondent's conduct under Factor 5 balances significantly in favor of revocation.

Cynthia M. Cadet, MD, DEA Decision and Order, Federal Register, Vol. 76, No. 67 (Thursday, April 7, 2011), available online at https://www.deadiversion.usdoj.gov/fed_regs/actions/2011/fr0407_5.htm.

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Sampling of Medical Expert Statements About Standards of Care and Duties in DEA Administrative Cases

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General Concepts – Medical Experts in DEA Cases

Medical Expert Issues (Part of the Practitioner Library)	General Position	Case Example
Boilerplate usage in medical records	Very problematic; Documentation of facts and clinical rationale critical to following logic in controlled substance prescribing cases.	Khan-Jaffery, Pompy
Failure to counsel patient and reassess treatment plan when patient demonstrates aberrant behavior (chronic alcohol use, use of illicit substances, failure to use prescribed controlled drugs, failure to show for appointments, breaks in treatment, self-escalation, etc.)	This is the essence of medical care and patient counseling, as well as clinical decision-making following aberrant or problematic patient behaviors must be addressed in some detail in the medical record and logically tied to ongoing decisions regarding use of controlled substances.	Khan-Jaffery, Baker, others
Failure to perform appropriate patient evaluations for risk.	Multiple positions in this area, addressing multiple domains of risks and expected clinical responses and documentation requirements.	Khan-Jaffery, Baker, others

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Specific Resources

- See **Drug Enforcement Administration,** Lesly Pompy, MD, Decision and Order, Fed. Reg., Vol. 84, No. 208, October 28, 2019, p. 57749, *57754. Alcohol and Opioids; Risk Mitigation; MDL05 PainWeek OnDemand Program.*
- **See Drug Enforcement Administration,** Kaniz F. Khan-Jaffery, MD, Decision and Order, Fed. Reg., Vol. 85, No. 146, Wednesday, July 29, 2020, available online at https://www.deadiversion.usdoj.gov/fed_regs/actions/2020/fr0729_4.pdf, *Alcohol and Opioids; Risk Mitigation; MDL06 PainWeek OnDemand Program.*

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Cannabis Use Disorder: A persisting pattern of cannabis use that results in clinically significant functional impairment in two or more domains (e.g., school, work, social and recreational activities, interpersonal relationships), within a 12-month period. Cannabis use disorder can be classified as mild, moderate, or severe.[15]

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SOURCE: https://store.samhsa.gov/product/preventing-use-marijuana-focus-women-and-pregnancy, at p. 10.

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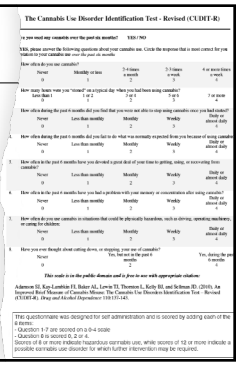
Risk Mitigation Tool You Can Use to Screen for Cannabis Use Disorder (CUDIT-R)

SOURCE: Adamson SJ, Kay-Lambkin FJ, Baker AL, et al. An improved brief measure of cannabis misuse: the Cannabis Use Disorders Identification Test-Revised (CUDIT-R). Drug Alcohol Depend. 2010;110(1-2):137-143. doi:10.1016/j.drugalcdep.2010.02.017, available online at https://pubmed.ncbi.nlm.nih.gov/20347232/.



The Cannabis Use Disorder Identification Test - Revised (CUDIT-R)

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Objective 3

OPPORTUNITIES FOR PATIENT & STAFF EDUCATION DURING THE COVID-19 ERA

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NEVER FORGET:

Informed Consent for Treatment Involving Controlled Substances IS A PROCESS – NOT JUST A PIECE OF PAPER

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General Educational Areas for Patients

Goals of pain management and practice approach to measuring function and treatment outcomes	Use of drug testing and other tools used by the practice to monitor patient and treatment safety	Risk Mitigation (Safe Use, Safe Storage, Safe Disposal of Controlled Medication	Naloxone Kits and Reasoning	Coordinating Care and Use of Referrals

SAMPLE SOURES FOR PATIENT EDUCATIONAL MATERIAL: https://www.cdc.gov/drugoverdose/patients/index.html; https://www.fda.gov/patients; https://store.samhsa.gov/?f[0]=publication_target_audience:6038

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PRE-COVID: INFORMED CONSENT

- *The foundation for informed consent pre-COVID-19 typically included:*
  - 1. Risks associated with the use of controlled substances,
  - 2. Expected benefits the patient may derive from the use of the medications contemplated under the treatment plan,
  - 3. Special issues regarding treatment, including the requirement of filling a naloxone prescription in the patient's individual case, and
  - 4. Treatment alternatives to controlled substance therapy.
- Patient education also typically covered a discussion regarding the things that might put the patient at risk of an accidental overdose, including drug-drug interactions (opioids and ETOH, opioids and BZO) and the safe storage, use, and disposal of controlled medication.

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DURING COVID: Patient Informed Consent Process (Education) Should Also Address:

- The complications raised by COVID-19 in terms of risks:
  - If a patient contracts COVID-19, risk of respiratory depression is significant and may be more problematic when patient is using opioids during illness.
  - Anxiety is heightened and the temptation is great to reach for something "to calm the nerves." Consider whether telemedicine is a viable way to reeducate the patient and provide coordinated care opportunities.
  - Consider whether telemedicine is a viable way to perform medication counts and improve efforts to track opioid and related controlled medication use or use of medication that has a sedative effect on patient.

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Patient Education Tool – Reduce Stress and Anxiety During COVID

Stress and Anxiety in Chronic Pain Patients is nothing new.

Use this as an additional educational tool to show that you are trying to keep your patients safe and that you are showing them non-drug tools to help themselves.

Available online at https://store.samhsa.gov/product/Feeling-Stressed-or-Anxious-About-the-COVID-19-Pandemic/PEP20-01-01-015?referer=from_search_result

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Critical Areas of Patient Education

Consult/New Patient	Established Patient (less than 1 year)	Established Patient (stable, > 1 year)	Established Patient (high risk)
Importance of Careful Evaluation;	Boundaries set by opioid trial	Reevaluation and Potential Exit Strategies	Need for Boundaries
No "rubber-stamping"	Reevaluation of goals and role of medication	Reconsidering non-drug and non-opioid treatment	Need for Consultations and Referrals
Prescribing considerations and opioid trial (if appropriate)	Ongoing risk evaluation	Ongoing safe use, storage, and disposal	Consequences if non-compliance
Exit strategy	Safe use, storage, and disposal	Overdose Prevention	Ongoing safe use, storage, and disposal
Safe use, storage, and disposal	Overdose Prevention		Overdose Prevention
Overdose Prevention			

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Educational Sources for Practice Staff – New Items Posted on Websites Listed Below

Centers for Disease Control & Prevention

- https://www.cdc.gov/drugoverdose/providers/index.html

Substance Abuse Mental Health Services Administration

- Guidance for Law Enforcement and First Responders on Naloxone Administration During the Time of COVID (5/8/20), available online at https://www.samhsa.gov/sites/default/files/guidance-law-enforcement-first-responders-administering-naloxone.pdf.
- Considerations for the Care and Treatment of Mental and Substance Use Disorders in the COVID-19 Epidemic: March 20, 2020 Revised: May 7, 2020, available online at https://www.samhsa.gov/sites/default/files/considerations-care-treatment-mental-substance-use-disorders-covid19.pdf.

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Sample Self-Audit Tasks

Give yourself 10 points for each task accomplished

Completed ?	Task
	Review current licensing board guidelines and/or rules on opioid prescribing, including chronic pain management.
	Create a checklist of "shall" and "should" (or similar terminology" used by your licensing board to identify the prescribing standard of care in your state (or to identify what it takes to prescribe for a legitimate medical purpose while acting in the usual course of professional practice).
	Review a couple of charts and see where you stand on your medical record documentation.
	Make a checklist of necessary improvements.
	Review current practice forms and templates focused on Risk Evaluation, Stratification, and Monitoring. Review your charting of this information. Do you have complete charts readily available and do they contain an initial and follow-up notes reflecting the steps taken by the provider to evaluate risk and present provider findings and medical decision-making that is individualized to the patient with minimal boilerplate and carried forward irrelevant information? Is the treatment plan consistent with the risk findings? Does the treatment plan include exit strategies for the opioids if the patient fails treatment goals?
◯	Compare timing of receipt of drug test results with the timing of provider counseling of the patient regarding unexpected results. Are providers responding in a timely and appropriate fashion based on the individual patient's situation? Or do charts show unreasonable delays in provider response to inappropriate test results?
	Update charts and forms with what you've learned during audit and incorporate relevant COVID-19-related disclosures (telemedicine, additional risks if faced with COVID) and educational material.

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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

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OUTPUT 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)

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



GOVERNMENT POSITION | **IMPLICATIONS** | **LESSONS LEARNED**

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Key Areas of Treatment Planning & Potential Documentation Weaknesses



New Patient Phase

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

Early "Established" Patient Phase

1. Establish a Treatment Plan with a Genuine Trial Period and "Measurable" Goals (which are measured)
2. Carefully address dose increases, additional medication
3. Timely use of early phase monitoring and response to patient behaviors and developing facts
4. Document treatment rationale, including use of (or consideration of) consults and referrals

Inherited or Long-Term Patient

1. Reevaluate what was done or not done in the past
2. Avoid the appearance of "rubber-stamping"
3. Document ongoing treatment rationale, including consideration and use of consults and referrals

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Case-Based Learning

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Case Based Learning: The Patient

The case of Mrs. Mason, a new patient seeking treatment for chronic pain.

67 years old
Significant pain
Growing limitations in mobility
Pain condition is chronic, with recent acute exacerbation of pain state

Based on your review of medical records and discussion with the patient, **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 severe findings at multiple levels and these are believed to be pain generators tied to her complaints of chronic pain.

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.

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Case Based Learning: The Question

Which answer most completely reflects the steps you should take to ensure you're acting in the "usual course of professional practice" and undertaking 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.

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Case Based Learning: The Answer

Which answer most completely reflects the steps you should take to ensure you're acting in the "usual course of professional practice" and undertaking 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.

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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.

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Additional Resources (Attendee Library)

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Faculty Contact Information

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THANK YOU!

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