PainWeek

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

Jennifer Bolen, JD

1

Title & Affiliation

Jennifer Bolen, JD
Founder
Legal Side of Pain

PainWeek

2

Disclosures

- Consultant to Paradigm Healthcare.

PainWeek

3

Background

PainWeek

4

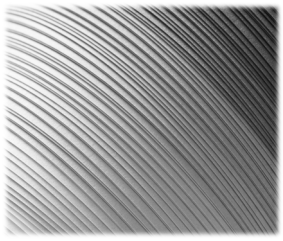
Focus of Medical Expert Testimony in a Controlled Substance Prescribing Case

- Whether the prescriber engaged in meaningful medical and risk 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, including individualized and timely risk monitoring and response.
- Legal standards vary with the type of case; Terminology used by medical experts and lawyers also vary.
- Case decision in US Supreme Court case (Ruan) (to be discussed in this talk).

PainWeek

5

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



- The pandemic continues to create challenges for medical practitioners.
- Controlled substance prescribers (all types) should consider:
  - 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.

PainWeek

6

Learning Objectives

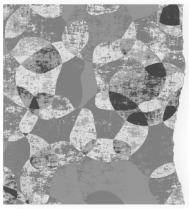
OBJECTIVE 1
- Summarize examples of current medical licensing board position statements and rules on risk mitigation and documentation for chronic pain management.

OBJECTIVE 2
- Examine 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.

painweek

7



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

Objective 1

painweek

8

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?

painweek

9

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.

PainWeek

10

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

State Licensing Board Examples

PainWeek

11

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

PainWeek

12

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;

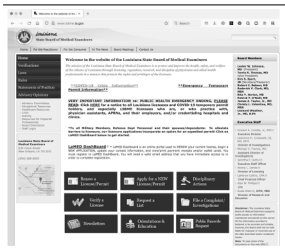
(8) Tolerance; and

(9) Crime victimization;

PAINWEEK

13

Louisiana Framework



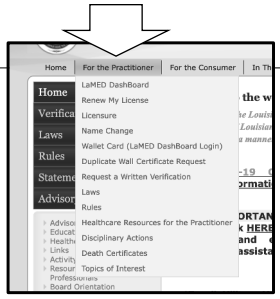
http://www.lsbme.la.gov/

PAINWEEK

14

Louisiana

Laws
Rules
Statements of Position
Advisory Opinions
Topics of Interest



PAINWEEK

15

Louisiana Rules

http://www.lsbme.la.gov/licensure/rules

Subchapter B. Medications Used in the Treatment of Non-Cancer-Related Chronic or Intractable Pain

§6915. Scope of Subchapter

A. The rules of this Subchapter govern physician responsibility for providing effective and safe pain control for patients with noncancer-related chronic or intractable pain.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), 1270(B)(6) and 1285(B).
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners LR 23:727 (June 1997), amended LR 26:693 (April 2000).

§6917. Definitions

A. As used in this Subchapter, unless the content clearly states otherwise, the following terms and phrases shall have the meanings specified.

Board—the Louisiana State Board of Medical Examiners.

Chronic Pain—pain which persists beyond the usual course of a disease, beyond the expected time for healing from bodily trauma, or pain associated with a long term-incurable or intractable medical illness or disease.

Controlled Substance—any substance defined, enumerated or included in federal or state statute or regulations 21 C.F.R. §§1308.11-15 or R.S. 40:964, or any substance which may hereafter be designated as a controlled substance by amendment or supplementation of such regulations and statute.

Diversion—the conveyance of a controlled substance to a person other than the person to whom the drug was prescribed or dispensed by a physician.

Intractable Pain—a chronic pain state in which the cause of the pain cannot be eliminated or successfully treated without the use of controlled substance therapy and, which in the generally accepted course of medical practice, no cure of the cause of pain is possible or no cure has been achieved after reasonable efforts have been attempted and documented in the patient's medical record.

Noncancer-Related Pain—that pain which is not directly related to symptomatic cancer.

Physical Dependence—the physiological state of neuroadaptation to controlled substance which is

PainWeek.

16

Louisiana

Title 46, Part XLV

PROFESSIONAL AND OCCUP.

characterized by the emergence of a withdrawal syndrome if the controlled substance use is stopped or decreased abruptly, or if an antagonist is administered. Withdrawal may be relieved by readministration of the controlled substance.

Physician—physicians and surgeons licensed by the Board.

Protracted Basis—utilization of any controlled substance for the treatment of noncancer-related chronic or intractable pain for a period in excess of 12 weeks during any 12-month period.

Substance Abuse (may also be referred to by the term *Addiction*)—a compulsive disorder in which an individual becomes preoccupied with obtaining and using a substance, despite adverse social, psychological, and/or physical consequences, the continued use of which results in a decreased quality of life. The development of controlled substance tolerance or physical dependence does not equate with substance abuse or addiction.

Tolerance—refers to the physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect or a reduced effect is observed with a constant dose. Controlled substance tolerance refers to the need to increase the dose of the drug to achieve the same level of analgesia. Controlled substance tolerance may or may not be evident during controlled substance treatment.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), 1270(B)(6) and 1285(B).
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners LR 23:727 (June 1997), amended LR 26:693 (April 2000).

§6919. General Conditions/Prohibitions

A. The treatment of noncancer-related chronic or intractable pain with controlled substances constitutes legitimate medical therapy when provided in the course of professional medical practice and when fully documented in the patient's medical record. A physician duly authorized to practice medicine in Louisiana and to prescribe controlled substances in this state shall not, however, prescribe, dispense, administer, supply, sell, give, or otherwise use for the purpose of treating such pain, any controlled substance unless done in strict compliance with applicable state and federal laws and the rules enumerated in this Subchapter.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), 37:1270(B)(6) and 37:1285(B).
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners LR 23:727 (June 1997), amended LR 26:694 (April 2000).

§6921. Use of Controlled Substances, Limitations

A. Requisite Prior Conditions. In utilizing any controlled substance for the treatment of noncancer-related chronic or intractable pain on a protracted basis, a physician shall comply with the following rules.

1. Evaluation of the Patient. Evaluation of the patient shall initially include relevant medical, pain, alcohol and substance abuse histories, an assessment of the impact of pain on the patient's physical and psychological functions, a review of previous diagnostic studies, previously utilized therapies, an assessment of coexisting illnesses, diseases, or conditions, and an appropriate physical examination.

2. Medical Diagnosis. A medical diagnosis shall be established and fully documented in the patient's medical record, which indicates not only the presence of noncancer-related chronic or intractable pain, but also the nature of the underlying disease and pain mechanism if such are determinable.

3. Treatment Plan. An individualized treatment plan shall be formulated and documented in the patient's medical record which includes medical justification for controlled substance therapy. Such plan shall include documentation that other medically reasonable alternative treatments for relief of the patient's noncancer-related chronic or intractable pain have been considered or attempted without adequate or reasonable success. Such plan shall specify the intended role of controlled substance therapy within the overall plan, which therapy shall be tailored to the individual medical needs of each patient.

4. Informed Consent. A physician shall ensure that the patient and/or his guardian is informed of the benefits and risks of controlled substance therapy. Discussions of risks and benefits should be noted in some format in the patient's record.

B. Controlled Substance Therapy. Upon completion and satisfaction of the conditions prescribed in §6921.A, and upon a physician's judgment that the prescription, dispensation, or administration of a controlled substance is medically warranted, a physician shall adhere to the following rules.

1. Assessment of Treatment Efficacy and Monitoring. Patients shall be seen by the physician at appropriate intervals, not to exceed 12 weeks, to assess the efficacy of treatment, assure that controlled substance therapy remains indicated, and evaluate the patient's progress toward treatment objectives and any adverse drug effects. Exceptions to this interval shall be adequately documented in the patient's record. During each visit, attention shall be given to the possibility of decreased function or quality of life as a result of controlled substance treatment. Indications of substance abuse or diversion should also be evaluated. At each visit, the physician should seek evidence of under treatment of pain.

2. Drug Screen. If a physician reasonably believes that the patient is suffering from substance abuse or that he is diverting controlled substances, the physician shall obtain a drug screen on the patient. It is within the physician's discretion to decide the nature of the screen and which type of drug(s) to be screened.

3. Responsibility for Treatment. A single physician shall take primary responsibility for the controlled substance therapy employed by him in the treatment of a patient's noncancer-related chronic or intractable pain.

4. Consultation. The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation, and consultation with or referral to an expert in the management of such patients.

5. Medications Employed. A physician shall document in the patient's medical record the medical necessity for the use of more than one type or schedule of controlled substance employed in the management of a patient's noncancer-related chronic or intractable pain.

6. Treatment Records. A physician shall document and maintain in the patient's medical record, accurate and complete records of history, physical and other examinations and evaluations, consultations, laboratory and diagnostic reports, treatment plans and objectives, controlled substance and other medication therapy, informed consents, periodic assessments, and reviews and the results of all other attempts at analgesia which he has employed alternative to controlled substance therapy.

7. Documentation of Controlled Substance Therapy. At a minimum, a physician shall document in the patient's medical record the date, quantity, dosage, route, frequency of administration, the number of controlled substance refills authorized, as well as the frequency of visits to obtain refills.

C. Termination of Controlled Substance Therapy. Evidence or behavioral indications of substance abuse or diversion of controlled substances shall be followed by tapering and discontinuation of controlled substance therapy. Such therapy shall be reinitiated only after referral to and written concurrence of the medical necessity of continued controlled substance therapy by an addiction medicine specialist, a pain management specialist, a psychiatrist, or other substance abuse specialist based upon his physical examination of the patient and a review of the referring physician's medical record of the patient.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), 37:1270(B)(6), and 37:1285(B).
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 23:727 (June 1997), amended LR 26:694 (April 2000).

§6923. Effect of Violation

A. Any violation of or failure of compliance with the provisions of this Subchapter, §§6915-6923, shall be deemed a violation of R.S. 37:1285.A(6) and (14), providing cause for the board to suspend or revoke, refuse to issue, or impose probationary or other restrictions on any license held or applied for by a physician to practice medicine in the state of Louisiana culpable of such violation.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), 37:1270(B)(6), and 37:1285(B).
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 23:728 (June 1997), amended LR 26:695 (April 2000).

49 Louisiana Administrative Code July 2021

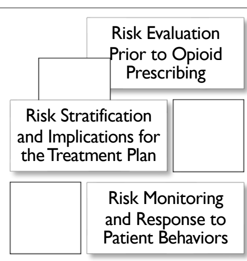
Louisiana Administrative Code July 2021 50

http://www.lsbme.la.gov/licensure/rules

PainWeek.

17

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



PainWeek.

18

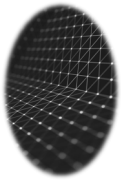
FOCUSING IN ON RISK MITIGATION FOR CHRONIC OPIOID THERAPY – ESSENTIAL PHASES

- **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 for "risk mitigation" in a medical sense never shifts to the patient;** The provider owes a duty of care to and is in a position of rust over the patient; The provider must perform at or above the minimum standards established by the legal/regulatory framework as well as the standards set by the medical world.

PainWeek

19

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

PainWeek

20

Louisiana REPRISE – FOCUS ON RISK MITIGATION

§6921. Use of Controlled Substances, Limitations

A. Requisite Prior Conditions. In utilizing any controlled substance for the treatment of noncancer-related chronic or intractable pain on a protracted basis, a physician shall comply with the following rules.

1. Evaluation of the Patient. Evaluation of the patient shall initially include relevant medical, pain, alcohol and substance abuse histories, an assessment of the impact of pain on the patient's physical and psychological functions, a review of previous diagnostic studies, previously utilized therapies,

49

PainWeek

- http://www.lsbme.la.gov/lic

21

Louisiana REPRISE – FOCUS ON RISK MITIGATION

- http://www.lsbme.la.gov/licensure/rules

an assessment of coexisting illnesses, diseases, or conditions, and an appropriate physical examination.

2. Medical Diagnosis. A medical diagnosis shall be established and fully documented in the patient's medical record, which indicates not only the presence of noncancer-related chronic or intractable pain, but also the nature of the underlying disease and pain mechanism if such are determinable.

3. Treatment Plan. An individualized treatment plan shall be formulated and documented in the patient's medical record which includes medical justification for controlled substance therapy. Such plan shall include documentation that other medically reasonable alternative treatments for relief of the patient's noncancer-related chronic or intractable pain have been considered or attempted without adequate or reasonable success. Such plan shall specify the intended role of controlled substance therapy within the overall plan, which therapy shall be tailored to the individual medical needs of each patient.

painweek

22

Louisiana REPRISE – FOCUS ON RISK MITIGATION

- http://www.lsbme.la.gov/licensure/rules

B. Controlled Substance Therapy. Upon completion and satisfaction of the conditions prescribed in §6921.A, and upon a physician's judgment that the prescription, dispensation, or administration of a controlled substance is medically warranted, a physician shall adhere to the following rules.

1. Assessment of Treatment Efficacy and Monitoring. Patients shall be seen by the physician at appropriate intervals, not to exceed 12 weeks, to assess the efficacy of treatment, assure that controlled substance therapy remains indicated, and evaluate the patient's progress toward treatment objectives and any adverse drug effects. Exceptions to this interval shall be adequately documented in the patient's record. During each visit, attention shall be given to the possibility of decreased function or quality of life as a result of controlled substance treatment. Indications of substance abuse or diversion should also be evaluated. At each visit, the physician should seek evidence of under treatment of pain.

2. Drug Screen. If a physician reasonably believes that the patient is suffering from substance abuse or that he is diverting controlled substances, the physician shall obtain a drug screen on the patient. It is within the physician's discretion to decide the nature of the screen and which type of drug(s) to be screened.

3. Responsibility for Treatment. A single physician shall take primary responsibility for the controlled substance therapy employed by him in the treatment of a patient's noncancer-related chronic or intractable pain.

painweek

23

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.

painweek

24

Common Problems in the Risk Evaluation Process

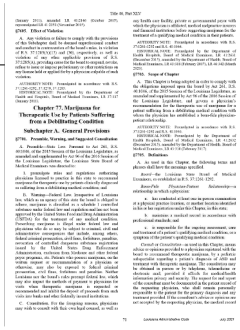
Time Related

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.

PAINWEEK

25

Louisiana & Marijuana for Therapeutic Use



Title 46, Part XLV

Chapter 77. Marijuana for Therapeutic Use by Patients Suffering from a Debilitating Condition

Subchapter A. General Provisions

§7701. Preamble, Warning, and Suggested Consultation

§7703. Definitions

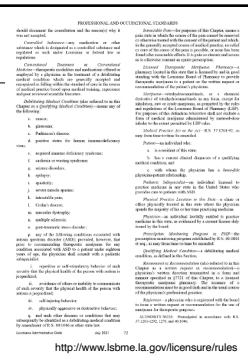
§7705. Scope of Chapter

PAINWEEK

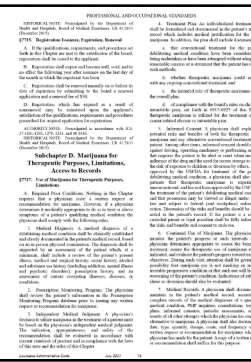
http://www.lsbme.la.gov/licensure/rules

26

Louisiana



PROFESSIONAL AND OCCUPATIONAL STANDARDS



PROFESSIONAL AND OCCUPATIONAL STANDARDS

Subchapter D. Marijuana for Therapeutic Purposes, Limitations, Access to Records

§7717. Use of Marijuana for Therapeutic Purposes, Limitations

PAINWEEK

http://www.lsbme.la.gov/licensure/rules

27

Louisiana

Title 46, Part XLV

B. Termination of Use. A physician shall refuse to initiate or re-initiate or shall terminate the use of marijuana with respect to a patient on any date that the physician determines, becomes aware, knows, or should know that:

1. the patient is not a qualifying candidate for the use of marijuana under the conditions and limitations prescribed by this Section;

2. the patient has failed to demonstrate clinical benefit from the use of marijuana; or

3. the patient has engaged in diversion, excessive use, misuse, or abuse of marijuana or has otherwise consumed or disposed of the drug other than in compliance with the directions and indications for use given by the physician.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1261-1292, 1270, and 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Health Hospitals, Board of Medical Examiners, LR 41:2633 (December 2015), amended by the Department of Health, Board of Medical Examiners, LR 43:319 (February 2017), LR 45:1472 (October 2019).

§7719. Board Access to Records

for the physician's patient as defined by and in and con with the rules of this Chapter.

B. Approved Form. Direction provided to a pha substantially in the form of the written requ recommendation form prescribed in the Appendix t rules (§7729) shall be presumptively deemed to sati requirements of this Section.

C. Manner of Transmission. A written requ recommendation for therapeutic marijuana sh transmitted by the physician or physician's design licensed therapeutic marijuana pharmacy by facsimi another electronic manner that provides for medica information privacy and security and is in complian rules promulgated by the Louisiana Board of Pharma pharmacy shall be selected by the patient from a licensed therapeutic marijuana pharmacies.

AUTHORITY NOTE: Promulgated in accordance w 37:1261-1292, 1270, and 40:1046.

HISTORICAL NOTE: Promulgated by the Departm Health Hospitals, Board of Medical Examiners, LR (December 2015), amended by the Department of Health, Medical Examiners LR 43:320 (February 2017), LR

PainWeek

http://www.lsbme.la.gov/licensure/rules

28

Louisiana

PROFESSIONAL AND OCCUPATIONAL STANDARDS

—THIS IS NOT A PRESCRIPTION—

PHYSICIAN RECOMMENDATION FORM

Section A. Patient's Physician Information (Required)

1. Legal First Name	2. Middle Initial	3a. Legal Last Name	3b. Suffix (Jr., Sr., III, etc.)
4a. Full Professional Address (street, city (in LA), zip code) 4b. e-mail address 4c. fax number			
5. City	6. State	7. Zip Code	8. Telephone Number
9a. LSBME Registration No. for Therapeutic Marijuana No. ______		9b. Schedule I No. (Board of Pharmacy) for Therapeutic Marijuana No. ______	

Section B. Patient Information (Required)

10. Legal First Name	11. Middle Initial	12a. Legal Last Name	12b. Suffix (Jr., Sr., III, etc.)
13. Date of Birth	14. Full Address of Patient [street, city (in LA), zip code]		

Section C. Patient's Debilitating Medical Condition(s) (Required)

This patient has been diagnosed with the following debilitating medical condition: (A minimum of one condition must be checked)

___ Acquired Immune Deficiency Syndrome ___ Cachexia or Wasting Syndrome ___ Cancer ___ Crohn's Disease ___ Epilepsy ___ Multiple Sclerosis ___ Muscular Dystrophy ___ Positive Status for Human Immunodeficiency Virus ___ Spasticity ___ Seizure Disorders ___ Glaucoma ___ Parkinson's Disease ___ Severe Muscle Spasms	___ Intractable Pain ___ Post-Traumatic Stress Disorder ___ Any of the following conditions associated with autism spectrum disorder: ___ (i) repetitive or self-stimulatory behavior of such severity that the health of the person with autism is jeopardized; ___ (ii) avoidance of others or inability to communicate of such severity that the physical health of the person with autism is jeopardized; ___ (iii) self-injuring behavior; ___ (iv) physically aggressive or destructive behavior.

Section D. Form, Amount, Dose, and Instructions for Use of Therapeutic Marijuana (Required)

Section E. Certification, Signature and Date (Required)

By signing below, I attest that the information entered on this recommendation is true and accurate. I further attest that the above-named individual is my patient, who suffers from a debilitating medical condition and that this recommendation is submitted by and in conformity with Louisiana Law, R.S. 40:1046, and administrative rules promulgated by the Louisiana State Board of Medical Examiners, LAC 46:XLV.Chapter 77.

Signature of Physician: X______________________

Date:____________

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1261-1292, and R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Health Hospitals, Board of Medical Examiners, LR 41:2635 (December 2015), amended by the Department of Health, Board of Medical Examiners, LR 43:320 (February 2017), LR 45:1472 (October 2019).

http://www.lsbme.la.gov/licensure/rules

PainWeek

29

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 …	

PainWeek

30

NORTH CAROLINA

Pain Management and Risk Mitigation:
Recommendations for Primary Care

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.

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

31

Objective #2

Examine medical expert testimony regarding
the prescriber's duty to take reasonable steps to prevent abuse and diversion
(acting in the usual course of professional practice).

Medical Expert Perspectives: Meaningful Risk Evaluation and Risk Monitoring

32

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

33

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?

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

PainWeek

34

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)

PainWeek

35

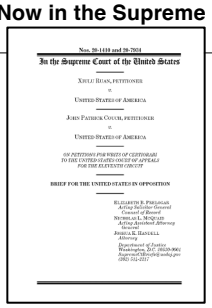
The Ruan Case – Pending Decision by the United States Supreme Court

BATTLE OVER STANDARDS

PainWeek

36

Pending Now in the Supreme Court of the United States



Nos. 20-1410 and 20-7051

In the Supreme Court of the United States

XIULU RUAN, PETITIONER

v.

UNITED STATES OF AMERICA

JOHN PATRICK COUCH, PETITIONER

v.

UNITED STATES OF AMERICA

ON PETITIONS FOR WRITS OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

ELIZABETH B. PRELOGAR
Solicitor General
Counsel of Record
NICHOLAS L. MCQUAID
Acting Assistant Attorney General
JESSICA R. HANSELL
Attorney
Department of Justice
Washington, D.C. 20530-0001
SupremeCtBriefs@usdoj.gov
(202) 514-2217

QUESTION PRESENTED

Whether the district court abused its discretion in declining a requested jury instruction on the ground that it would have required acquittal on charges of the unauthorized distribution of controlled substances, in violation of 21 U.S.C. 841, based on petitioners' own "subjective view" of the "usual course of medical practice."

PainWeek

37

What could this case mean for opioid prescribers?

- **MAYBE . . .**
  - More clarity in the legal standard for controlled substance prescribing (legitimate medical purpose while acting in the usual course of professional practice).
- **ARGUMENT CENTERS ON . . .**
  - Objective vs. subjective standards.

PainWeek

38

From the Government's Supreme Court Brief

While the district court offered to give a different instruction including "good faith language," Pet. App. 136a, it declined to give petitioners' particular proposed instruction, *id.* at 135a. As most relevant here, it determined that the instruction embodied "a subjective view of what is the usual course of professional practice," when "the standard should be an objective one." *Id.* at 134a. The court also concluded that the proposed language requiring proof that a physician operated as a "drug pusher" was legally incorrect. *Id.* at 104a.

PainWeek

39

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

40

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

PainWeek

41

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.

PainWeek

42

From US v. Lopez (SDNY 2019)

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

PainWeek

43

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

PainWeek

44

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

PainWeek

45

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,

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

46

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.

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

47

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

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

48

Medical Expert Testimony – Seth Waldman, MD

Case 1:18-cr-00006-DLC Document 92 Filed 03/13/19 Page 107 of 233 633
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

49

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

50

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.

PainWeek

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

51

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.

painweek

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

52

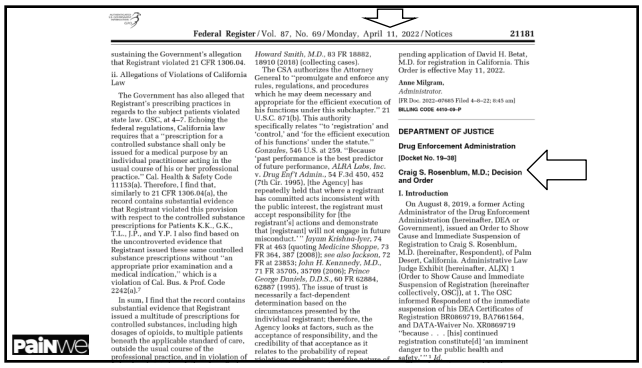
Risk Mitigation: Do Not Ignore Red Flags including Alcohol and Marijuana Use

DEA ADMINISTRATIVE CASE: In re Craig S. Rosenbaum, MD (California)
2022 Decision and Order Showing Interplay of Medical Board Rules, Guidelines and Relation to "Usual Course of Professional Practice"

Craig S. Rosenbaum, MD, DEA Decision and Order, Federal Register, Vol. 87, No. 69 (Monday, April 11, 2022)(pp. 21181-21209), available online at https://www.govinfo.gov/app/details/FR-2022-04-11/2022-07727

painweek

53



Federal Register / Vol. 87, No. 69 / Monday, April 11, 2022 / Notices 21181

sustaining the Government's allegation that Registrant violated 21 CFR 1306.04.

ii. Allegations of Violations of California Law

The Government has also alleged that Registrant's prescribing practices in regards to the subject patients violated state law. OSC, at 4–7. Echoing the federal regulations, California law requires that a "prescription for a controlled substance shall only be issued for a medical purpose by an individual practitioner acting in the usual course of his or her professional practice." Cal. Health & Safety Code 11153(a). Therefore, I find that, similarly to 21 CFR 1306.04(a), the record contains substantial evidence that Registrant violated this provision with respect to the controlled substance prescriptions for Patients K.K., G.K., T.L., I.P., and Y.P. I also find based on the uncontroverted evidence that Registrant issued these same controlled substance prescriptions without "an appropriate prior examination and a medical indication," which is a violation of Cal. Bus. & Prof. Code 2242(a).[7]

In sum, I find that the record contains substantial evidence that Registrant issued a multitude of prescriptions for controlled substances, including high dosages of opioids, to multiple patients beneath the applicable standard of care, outside the usual course of the professional practice, and in violation of

Howard Smith, M.D., 83 FR 18882, 18910 (2018) (collecting cases).

The CSA authorizes the Attorney General to "promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter." 21 U.S.C. 871(b). This authority specifically relates "to 'registration' and 'control,' and 'for the efficient execution of his functions' under the statute." *Gonzales*, 546 U.S. at 259. "Because 'past performance is the best predictor of future performance, *ALRA Labs, Inc.* v. *Drug Enf't Admin.*, 54 F.3d 450, 452 (7th Cir. 1995), [the Agency] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [the registrant's] actions and demonstrate that [registrant] will not engage in future misconduct.'" *Jayam Krishna-Iyer*, 74 FR at 463 (quoting *Medicine Shoppe*, 73 FR 364, 387 (2008)); *see also Jackson*, 72 FR at 23853; *John H. Kennedy, M.D.*, 71 FR 35705, 35709 (2006); *Prince George Daniels, D.D.S.*, 60 FR 62884, 62887 (1995). The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual registrant; therefore, the Agency looks at factors, such as the acceptance of responsibility, and the credibility of that acceptance as it relates to the probability of repeat

pending application of David H. Betat, M.D. for registration in California. This Order is effective May 11, 2022.

Anne Milgram,
Administrator.

[FR Doc. 2022-07605 Filed 4-6-22; 8:45 am]
BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 19–38]

Craig S. Rosenblum, M.D.; Decision and Order

I. Introduction

On August 8, 2019, a former Acting Administrator of the Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause and Immediate Suspension of Registration to Craig S. Rosenblum, M.D. (hereinafter, Respondent), of Palm Desert, California. Administrative Law Judge Exhibit (hereinafter, ALJX) 1 (Order to Show Cause and Immediate Suspension of Registration (hereinafter collectively, OSC)), at 1. The OSC informed Respondent of the immediate suspension of his DEA Certificates of Registration BR0893719, BA7661564, and DATA-Waiver No. XR0869719 "because . . . [his] continued registration constitute[d] 'an imminent danger to the public health and

painwe

54

DEA Decision and Order – Rosenbaum (April 11, 2022)

Craig S. Rosenbaum, MD, DEA Decision and Order, Federal Register, Vol. 87, No. 69 (Monday, April 11, 2022)(pp. 21181-21209), available online at https://www.govinfo.gov/app/details/FR-2022-04-11/2022-07727.

at 1. The Government's arguments include that Respondent prescribed dangerously high dosages of controlled substances for years without performing initial physical examinations and evaluations, without performing periodic urine drug screens (hereinafter, UDSes), without addressing aberrant UDSes, without justifying increased dosages, without justifying dangerous controlled substance combination prescribing, and without adequately resolving indicia of abuse and diversion. *Id.* The Government presented its case with two witness, the DI and its expert witness, Timothy Munzing, M.D., and with about 1,750 pages from Respondent's medical records. *See id.* at 43. According to the Government, Respondent's ''insistence that he simply did not document his reasoning or actions was not credible,'' his ''recollection was faulty,'' he ''essentially admitted that he knew and was okay with his patient's drug abuse,'' and was ''nowhere near contrite.'' *Id.* at 1.

55

The Rosenbaum Decision and Order shows . . .

- Importance of truly evaluating patient drug use history – current and past.
- Importance of Reviewing Toxicology Testing (THC+, BZO+ and many other examples).
- Importance of using information gained from PDMP Checks.
- Importance of monitoring patients for "risk flags" – "risky behaviors."
- Potential indicators of risk - Marijuana and Opioids; Marijuana and Benzodiazepines.
- Many other examples in the case decision.

Craig S. Rosenbaum, MD, DEA Decision and Order, Federal Register, Vol. 87, No. 69 (Monday, April 11, 2022)(pp. 21181-21209), available online at https://www.govinfo.gov/app/details/FR-2022-04-11/2022-07727.

56

DEA Decision and Order – Rosenbaum (April 11, 2022)

THC and Opioids – Absence of Risk Evaluation (drug use – current and past)

Craig S. Rosenbaum, MD, DEA Decision and Order, Federal Register, Vol. 87, No. 69 (Monday, April 11, 2022)(pp. 21181-21209), available online at https://www.govinfo.gov/app/details/FR-2022-04-11/2022-07727.

Based on my review of the record evidence regarding R.B.'s first visit with Respondent, I find substantial record evidence that Respondent issued a controlled substance prescription to R.B., for 90 tablets of oxycodone 30 mg, without documenting his knowledge of R.B.'s medical history based on input directly from R.B.'s previous physician or physician assistant, without documenting that he addressed R.B.'s in-house, positive THC urine drug screen, and without documenting that he assessed R.B. for the risk of opioid abuse. Tr. 155–56 (Dr. Munzing's testimony, including that he ''do[es]n't see any further history and specifics in detail regarding other drug use,'' that ''there's no kind of detailed evaluation of both current and also past drug use and is there any history,'' that he ''do[es]n't see any kind of opioid risk tool or other screening for—there's SOAPP . . . and also the ORG, Opioid Risk Tool, that gives you an idea about risk for abuse,'' and that he ''do[es]n't see any specifics in past medical records that would verify a lot of this . . . [s]o you're going essentially from zero . . . immediately to 135, so . . . [he has] great concerns about that visit''); MBC Guide to the Laws, at 60–61.

Also concerning R.B.'s second visit with Respondent, there is substantial record evidence that the in-house UDS was again positive for THC and was also positive for oxycodone, opioid, and benzodiazepine. GX 14B, at 71; *see also* Tr. 157–58. However, there is no record evidence that Respondent ever issued R.B. a prescription for THC or for a benzodiazepine. *See, e.g.*, Tr. 1114–15. I credit Dr. Munzing's testimony, and I find substantial record evidence that this second-visit, in-house UDS was aberrant and that Respondent's medical record for this visit with R.B. does not document that he addressed this aberrancy in any way. *Id.* at 157–58; *supra* sections II, III.D., and III.E.

Accordingly, I find further substantial record evidence that Respondent issued the second 90 tablet oxycodone 30 mg prescription for R.B. beneath the applicable standard of care and outside the usual course of professional practice. GX 14B, at 71; MBC Guide to the Laws, at 60–61.

57

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.

painweek

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_3.htm.

58

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]

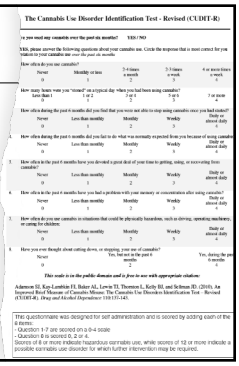
painweek

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

59

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)

painweek

60

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

PainWeek

61

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

PainWeek

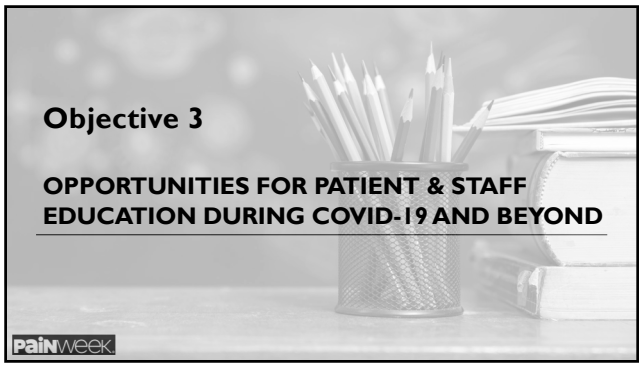
62

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.*

PainWeek

63



64

65

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

painweek

66

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.

PainWeek

67

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.

PainWeek

68

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.

PainWeek

69

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			

PAINWEEK

70

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.

PAINWEEK

71

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.

PAINWEEK

72

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

painweek

73

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)

painweek

74

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



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

painweek

75

Key Areas of Risk Evaluation, Treatment Planning & Core Documentation Planning

New Patient

1. Thorough Initial Evaluation; Proper Risk Evaluation

2. Prior Medical Records – Obtain and Review

3. Documentation of Medical Reasoning – Rationale for Prescribing Controlled Medication

painweek

76

Key Areas of Treatment Planning & Potential Documentation Weaknesses

Early "Established" Patient Phase

1. Treatment Plan contains a genuine opioid trial period and "Measurable" Goals (which are actually measured)

2. Documentation clearly states medical rationale for medication selection, dose, dose increases, other medication; Demonstrates efforts to educate patient on safety issues.

3. Documentation reveals appropriate use of risk monitoring and TIMELY response to patient behaviors and developing facts.

4. Documentation continues to make treatment rationale clear and considers consults and referrals.

painweek

77

Key Areas of Treatment Planning & Potential Documentation Weaknesses

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

painweek

78

Case-Based Learning

painweek

79

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.

painweek

80

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.

painweek

81

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.

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.

painweek

82

Faculty Contact Information

Jen Bolen, JD
865-755-2369 (please text first due to call scheduling)
jbolen@legalsideofpain.com

THANK YOU!

painweek

83