Embrace Changes and Mitigate Legal Risks Associated with Opioid Prescribing:

Renewed Focus on Risk Evaluation and Risk Mitigation

Jennifer Bolen, JD

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Disclosures for Jennifer Bolen, JD

- Consultant/Independent Contractor: Paradigm Labs/Paradigm Healthcare, relationship does not fully meet the disclosure requirement because I am not talking about a specific product at a CME event. However, I am disclosing this out of an abundance of caution and because this company will be at PainWeek and PainWeekends, and because I occasionally provide non-CME lectures for them.
- Advisory Board: Innovative Laboratory Solutions/Best Test Cups - relationship does not involve any fees, but disclosing out of an abundance of caution.

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Course Objectives

Identify	• Identify common trends in legal actions against opioid prescribers.
List and Describe	• List three common weaknesses associated with documentation of risk assessment of patients for chronic opioid therapy. • Describe how they can contribute to bad legal outcomes.
Explain and Use	• Explain how to create a risk mitigation action plan and supporting documentation.

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OBJECTIVE 1:

Identify common trends in legal actions against opioid prescribers.

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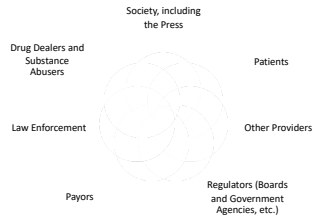
Who is examining your prescribing habits? What do all have in common?



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Current Case/Investigative Trends

-

2019

- Investigation and charging/settlement of cases involving Pain Specialists and Large Pain Care Medical Groups
  - McCollum, et al – US District Court, Civil Whistleblower Fraud Case is Pending on Medically Unnecessary Prescribing, Medically Unnecessary Drug Testing, and other issues, South Carolina
  - Comprehensive Pain Specialists, et al – US District Court, Criminal Case Conviction of Owners, Federal Whistleblower Case is Pending on Topic of Urine Drug Testing), Nashville, Tennessee
- Other cases and investigations before licensing boards and administrative agencies

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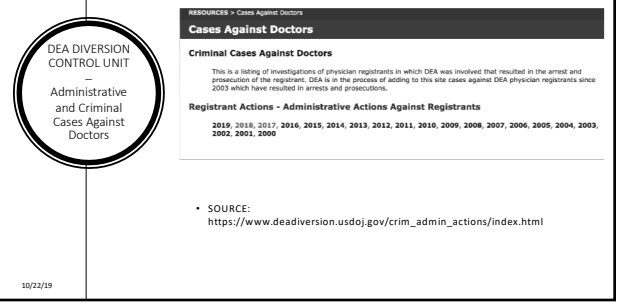
DEA DIVERSION CONTROL UNIT – Administrative and Criminal Cases Against Doctors


RESOURCES > Cases Against Doctors

Cases Against Doctors

Criminal Cases Against Doctors

This is a listing of investigations of physician registrants in which DEA was involved that resulted in the arrest and prosecution of the registrant. DEA is in the process of adding to this site cases against DEA physician registrants since 2003 which have resulted in arrests and prosecutions.

Registrant Actions - Administrative Actions Against Registrants

2019, 2018, 2017, **2016**, **2015**, **2014**, **2013**, **2012**, **2011**, **2010**, **2009**, **2008**, **2007**, **2006**, **2005**, **2004**, **2003**, **2002**, **2001**, **2000**

- SOURCE: https://www.deadiversion.usdoj.gov/crim_admin_actions/index.html

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POSITION OF TRUST

AT THE HEART OF THE MATTER:

The way it is argued in court or through medical experts in inappropriate prescribing cases:

Did you recklessly disregard your duties of care?

The way it is argued in court or through medical experts in <u>fraud cases:</u>

Do your actions and documents show you are putting money before reasonably prudent medical decision-making?

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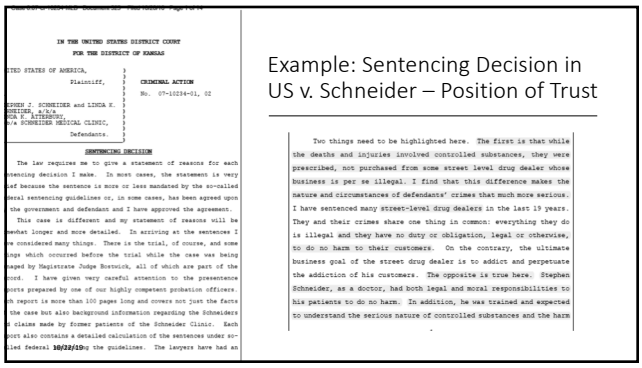
IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

TED STATES OF AMERICA, Plaintiff, vs. CRIMINAL ACTION No. 07-10294-01, 02

EPHEN J. SCHNEIDER and LINDA K. HNEIDER, a/k/a NDA K. ATTERBURY, b/a SCHNEIDER MEDICAL CLINIC, Defendants.

SENTENCING DECISION

The law requires me to give a statement of reasons for each ntencing decision I make. In most cases, the statement is very ief because the sentence is more or less mandated by the so-called deral sentencing guidelines or, in some cases, has been agreed upon the government and defendant and I have approved the agreement.

This case is different and my statement of reasons will be mewhat longer and more detailed. In arriving at the sentences I ve considered many things. There is the trial, of course, and some ings which occurred before the trial while the case was being naged by Magistrate Judge Rostwick, all of which are part of the cord. I have given very careful attention to the presentence ports prepared by one of our highly competent probation officers. ch report is more than 100 pages long and covers not just the facts the case but also background information regarding the Schneiders d claims made by former patients of the Schneider Clinic. Each port also contains a detailed calculation of the sentences under so- lled federal guidelines. The lawyers have had an

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Example: Sentencing Decision in US v. Schneider – Position of Trust

Two things need to be highlighted here. The first is that while the deaths and injuries involved controlled substances, they were prescribed, not purchased from some street level drug dealer whose business is per se illegal. I find that this difference makes the nature and circumstances of defendants' crimes that much more serious. I have sentenced many street-level drug dealers in the last 19 years. They and their crimes share one thing in common: everything they do is illegal and they have no duty or obligation, legal or otherwise, to do no harm to their customers. On the contrary, the ultimate business goal of the street drug dealer is to addict and perpetuate the addiction of his customers. The opposite is true here. Stephen Schneider, as a doctor, had both legal and moral responsibilities to his patients to do no harm. In addition, he was trained and expected to understand the serious nature of controlled substances and the harm

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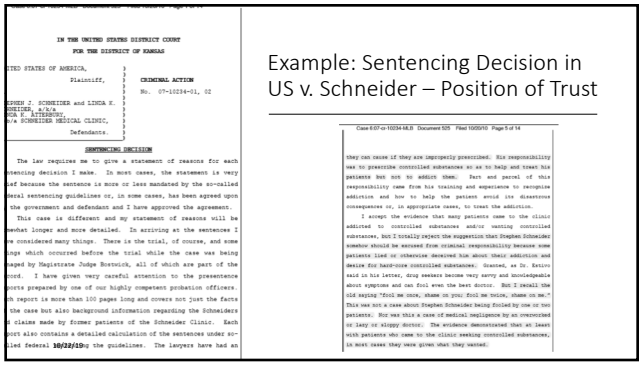

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

TED STATES OF AMERICA, Plaintiff, CRIMINAL ACTION No. 07-10234-01, 02

PHEN J. SCHNEIDER and LINDA K. NEIDER, a/k/a YDA K. ATTERBURY, b/a SCHNEIDER MEDICAL CLINIC, Defendants.

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Example: Sentencing Decision in US v. Schneider – Position of Trust

Case 6:07-cr-10234-MLB Document 525 Filed 10/05/10 Page 5 of 14

they can cause if they are improperly prescribed. His responsibility was to prescribe controlled substances so as to help and treat his patients but not to addict them. Part and parcel of this responsibility came from his training and experience to recognize addiction and how to help the patient avoid its disastrous consequences or, in appropriate cases, to treat the addiction.

I accept the evidence that many patients came to the clinic addicted to controlled substances and/or wanting controlled substances, but I totally reject the suggestion that Stephen Schneider somehow should be excused from criminal responsibility because some patients lied or otherwise deceived him about their addiction and desire for hard-core controlled substances. Granted, as Dr. Estivo said in his letter, drug seekers become very savvy and knowledgeable about symptoms and can fool even the best doctor. But I recall the old saying "fool me once, shame on you; fool me twice, shame on me." This was not a case about Stephen Schneider being fooled by one or two patients. Nor was this a case of medical negligence by an overworked or lazy or sloppy doctor. The evidence demonstrated that at least with patients who came to the clinic seeking controlled substances, in most cases they were given what they wanted.

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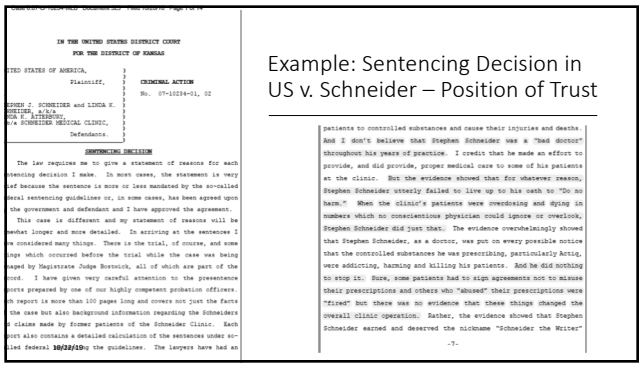

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Example: Sentencing Decision in US v. Schneider – Position of Trust

patients to controlled substances and cause their injuries and deaths. And I don't believe that Stephen Schneider was a "bad doctor" throughout his years of practice. I credit that he made an effort to provide, and did provide, proper medical care to some of his patients at the clinic. But the evidence showed that for whatever reason, Stephen Schneider utterly failed to live up to his oath to "Do no harm." When the clinic's patients were overdosing and dying in numbers which no conscientious physician could ignore or overlook, Stephen Schneider did just that. The evidence overwhelmingly showed that Stephen Schneider, as a doctor, was put on every possible notice that the controlled substances he was prescribing, particularly Actiq, were addicting, harming and killing his patients. And he did nothing to stop it. Sure, some patients had to sign agreements not to misuse their prescriptions and others who "abused" their prescriptions were "fired" but there was no evidence that these things changed the overall clinic operation. Rather, the evidence showed that Stephen Schneider earned and deserved the nickname "Schneider the Writer"

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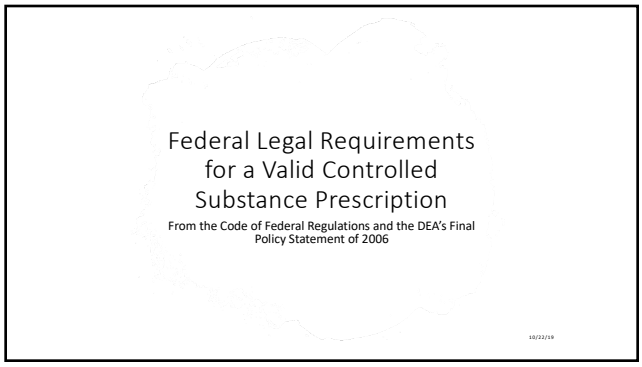

Federal Legal Requirements for a Valid Controlled Substance Prescription

From the Code of Federal Regulations and the DEA's Final Policy Statement of 2006

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Three Federal Resources on "Valid" Controlled Substance Prescriptions

DEA Diversion Website – https://www.deadiversion.usdoj.gov/

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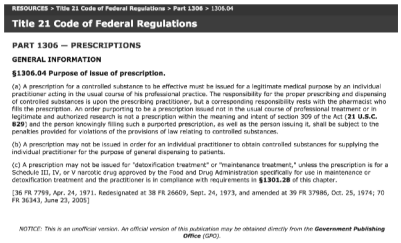
Code of Federal Regulations – Purpose of Issue – Valid Controlled Substance Prescription


RESOURCES > Title 21 Code of Federal Regulations > Part 1306 > 1306.04

Title 21 Code of Federal Regulations

PART 1306 — PRESCRIPTIONS

GENERAL INFORMATION

§1306.04 Purpose of issue of prescription.

(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (**21 U.S.C. 829**) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

(b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

(c) A prescription may not be issued for "detoxification treatment" or "maintenance treatment," unless the prescription is for a Schedule III, IV, or V narcotic drug approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment and the practitioner is in compliance with requirements in **§1301.28** of this chapter.

[36 FR 7799, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 39 FR 37986, Oct. 25, 1974; 70 FR 36143, June 23, 2005]

NOTICE: This is an unofficial version. An official version of this publication may be obtained directly from the ***Government Publishing Office*** *(GPO).*

- SOURCE: DEA Diversion Website, Code of Federal Regulations, available online at https://www.deadiversion.usdoj.gov/21cfr/cfr/1306/1306_04.htm

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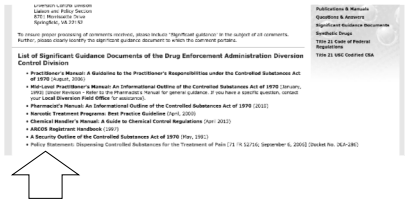
DEA DIVERSION CONTROL UNIT – Significant Guidance Documents

- Accessed 8/22/19; Available online at https://www.deadiversion.usdoj.gov/guide_docs/index.html


List of Significant Guidance Documents of the Drug Enforcement Administration Diversion Control Division

- **Practitioner's Manual: A Guideline to the Practitioner's Responsibilities under the Controlled Substances Act of 1970** (August, 2006)
- **Mid-Level Practitioner's Manual: An Informational Outline of the Controlled Substances Act of 1970** (January, 1992) (Under Revision - Refer to the Pharmacist's Manual for general guidance. If you have a specific question, contact your **Local Diversion Field Office** for assistance).
- **Pharmacist's Manual: An Informational Outline of the Controlled Substances Act of 1970** (2013)
- **Narcotic Treatment Programs: Best Practice Guideline** (April, 2003)
- **Chemical Handler's Manual: A Guide to Chemical Control Regulations** (Apr. 2013)
- **ARCOS Registrant Handbook** (1997)
- **A Security Outline of the Controlled Substances Act of 1970** (May, 1982)
- Policy Statement: Dispensing Controlled Substances for the Treatment of Pain [71 FR 52716; September 6, 2006] [Docket No. DEA-286]

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Legitimate Medical Purpose

- One or more generally recognized medical indication for the use of the controlled substance

Usual Course of Professional Practice

- According to licensing and professional standards, including consideration of licensing board material;
- Steps of a "Reasonably Prudent" Practitioner

Reasonable Steps to Prevent Abuse and Diversion

- Proper Risk Evaluation, Stratification, and Monitoring Protocols, including overdose risk evaluation
- PDMP , UDT, NALOXONE, OPIOID TRIAL, VISIT FREQUENCY,
- Many other "reasonable steps"

Process Visual for "Valid" Controlled Substance Prescription – CFR + DEA Policy Statement of 2006, available online at
https://www.deadiversion.usdoj.gov/fed_regs/notices/2006/fr09062.htm

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DEA Diversion Website – Resource Page on Manuals (Accessed 8/22/19)

https://www.deadiversion.usdoj.gov/pubs/manuals/index.html

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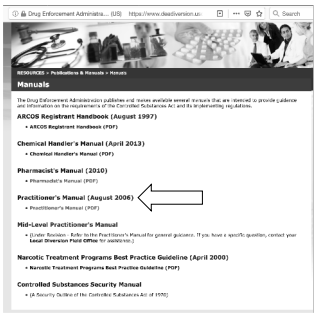

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United States Department of Justice
Drug Enforcement Administration
Office of Diversion Control

Practitioner's Manual

An Informational Outline of the Controlled Substances Act

2006 Edition

DEA Resource on "Valid" Controlled Substance Prescriptions

- DEA Practitioners Manual
- DEA hasn't updated this manual since 2006!
- Resource accessed online 8/22/19, available online at https://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf

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Drug Enforcement Administration
Practitioner's Manual

Table of Contents (continued)

Section V – Valid Prescription Requirements

Resource accessed online 8/22/19, available online at
https://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf

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OBJECTIVE 2

List three common weaknesses associated with documentation of risk assessment of patients for chronic opioid therapy, and describe how they can contribute to bad legal outcomes.

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LEGAL PERSPECTIVE:

Three common risk mitigation weaknesses – chronic opioid therapy

1. Poor Risk Assessment/Mitigation Process and Follow Through.
2. Untimely Use of Information gathered through Risk Assessment/Evaluation and Patient Encounters.
3. Failure to Coordinate Care with Other Healthcare Providers and Lack of Patient Education Related to Coordination of Care Issues.

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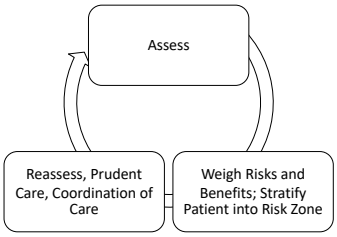
Legal Perspective: Basic Risk Mitigation Process



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Medical Expert Testimony on Common Expectations and Weaknesses

Just a few examples out of many

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EXAMPLES OF RISK MITIGATION FAILURES COMMONLY IDENTIFIED IN LITIGATION

Examples: (The list is much more in-depth and outside the scope of this course)
Unsupported diagnosis or use of "chronic pain" label
Failure to obtain, review, and consider past medical records and pain treatment
Failure to perform targeted physical exam
Failure to write a treatment plan that demonstrates use of reasonably prudent medical decision-making ⇦
Failure to obtain a psychiatric consultation. Failure to consider the weight of the patient's psych history: PTSD, Panic Attacks, Anxiety, etc. ⇦
Failure to consider the overall "weight" of the patient's substance use history: DUI Hx, loss of license, History THC abuse, cocaine use, crack, heroin, ETOH.
Failure to consider all domains of risk when determining the potential for harm to the patient if the treatment plan involves opioids. Failure to provide a meaningful assessment of the risks and benefits – given only in boilerplate paper as "informed consent" or as a "Narcotic Contract" – Paper over process ⇦
Failure to address the Naloxone issue.
Failure to reassess and redirect; Failure to obtain input from others in the patient's circle of medical care. ⇦

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Failure Testified To by Medical Expert	Government Expert	Case and Trial Testimony Year
Failure to obtain, review, and build a "database" of the patient's individual case	L. Douglas Kennedy, MD	US v. Volkman, 2011 (Convicted)
Failure to consider the patient's behavioral health history and relationship with BH medication	L. Douglas Kennedy, MD	US v. Volkman, 2011 (Convicted)
Failure to appreciate medical risks (respiratory-related)	Ted Parran, MD	US v. Schneider, 2010 (Convicted)
Failure to Properly Supervise Physician-Extenders; Failure of MD to be involved with patient	Ted Parran, MD	US v. Schneider, 2010 (Convicted)
Failure to consider Aberrant, Drug-Related Behaviors	Ted Parran, MD	US v. Schneider, 2010 (Convicted)
Failure to Coordinate Care in the Complex Patient	L. Douglas Kennedy, MD	US v. Volkman, 2011 (Convicted)
Failure to Re-Evaluate the Treatment Plan based on Risk/Benefit Analysis, Patient Response, and patient Behavior	Christopher J. Gilligan, MD	US v. Zolot, 2013-2014 (Defendants Acquitted)
Failure to Consider Common Risk Factors	Christopher J. Gilligan, MD	US v. Zolot, 2013-2014 (Defendants Acquitted)

EXAMPLES OF RISK MITIGATION FAILURES – Through the Eyes of Medical Experts

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12. As discussed previously, a physician has an obligation to periodically review both the diagnosis and regimen of treatment (including the use of controlled substances) in order to ensure that they both remain appropriate for the particular circumstances of the specific patient.[9] A physician receiving information about potential misuse/abuse and/or diversion of a controlled substance by a patient is required to reevaluate his/her diagnosis and/or regimen of treatment for that particular patient, including whether and under what circumstances controlled substances will continue to be prescribed to that particular patient.[10] While physicians may differ on what an appropriate response to such information may be in the particular circumstances, there is no dispute in the medical community that a physician cannot ignore such information and simply continue to prescribe controlled substances.[11] Based upon my training and experience, this basic tenet of practicing medicine was controlling at the time of the time of the prescriptions at issue in this case.

Failure to Re-Evaluate the Treatment Plan in Light of Patient Response and Compliance

—

Government Expert Christopher Gilligan, MD, US v. Zolot and Pliner (Both Acquitted);

Affidavit Produced in US v. Zolot, 12/9/2013, D.Mass., 11-CR-10070

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Failure to Consider Common Risk Factors (Part 1)

—

Government Expert Christopher Gilligan, MD, US v. Zolot and Pliner (Both Acquitted);

Affidavit Produced in US v. Zolot, 12/9/2013, D.Mass., 11-CR-10070

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30. Based upon my training and experience some other common indicators or warning signs of potential aberrant behavior or diversion include:

a. Drug-screen results showing that a patient took a drug that was not prescribed, including street drugs such as cocaine;

b. Drug screen results that are negative for controlled substances which are prescribed for the patient and which the patient should be taking;

c. Dubious or repeated claims of lost, destroyed or stolen medications or prescriptions;

d. Patients requesting early refills of narcotic prescriptions;

e. Forged or altered prescriptions;

f. Information that the patient obtains controlled substances from non-medical sources, such as from the "street";

g. Patients receiving controlled substances from multiple medical providers (which is sometimes referred to as "doctor shopping");

h. Patient admissions of present or prior addiction/abuse problems related to controlled substances or alcohol (including admissions or prior narcotic detoxification or drug treatment programs);

i. Patients using multiple pharmacies to fill their prescriptions;

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Failure to Consider Common Risk Factors (Part 2)

–

Government Expert Christopher Gilligan, MD, US v. Zolot and Pliner (Both Acquitted);

Affidavit Produced in US v. Zolot, 12/9/2013, D.Mass., 11-CR-10070

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j. Information that the patient may be diverting (including selling or trading) controlled substances;

k. Information from other sources (such as other medical providers or family members) that the patient is misusing or addicted to controlled substances or has misused or been addicted to controlled substances in the past;

l. Patients who steal medical goods, including prescription pads;

m. Drug-related deterioration in work performance, family relationships, or other social dynamics;

n. Patients who do not take their prescribed controlled substances as directed, including taking too much of the controlled substance;

o. Patients who provide false information regarding their present or prior use of controlled substances;

p. Patients who claim to be allergic or intolerant of every other class of relevant medications besides the directly or indirectly requested controlled substance;

q. Patients who have an unusual amount of knowledge about the controlled medication in question or who request a particular controlled substance;

r. Patients who have little interest in their diagnosis or alternative treatments;

s. Patients who fail to keep appointments with other providers, who are necessary for referral or continuity of care, or who fail to keep appointments for necessary tests and/or alternative treatments;

t. Patients who use controlled substances for purposes other than for which the controlled substances were prescribed (for example, a patient who uses an opioid to overcome anxiety);

u. Patients who have had other healthcare professionals terminate their care of the patient due to concerns of misuse/abuse and/or diversion of controlled substances;

v. Patients who become confrontational regarding the circumstances of the prescription of controlled substances to those patients (for example, becoming confrontational when the dosage or type of controlled substances is changed, or a refill is denied);

w. Patients who refuse to take drug screens or attempt to circumvent drug screens;

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Failure of MD to Consider Developing Patient Risks (Aberrant, Drug-Related Risks) and Continuing to Prescribe Despite these Risks:

Ted Parran, MD, in US v. Schneider (2010 Trial Testimony);

Case 6:07-cr-10234-MLB Document 627 Filed 04/04/11.

were stolen?
A Yes.
Q Were there multiple occasions where she presented withdrawing from medications?
A Yes.
Q And what would that mean, Dr. Parran?
It would mean that she wasn't able to control her use of the medicines. She would go through it too quickly and then she would present to the office in withdrawal.
Did Toni have a prior crack cocaine addiction?
Yes. And had had prison treatment and a court case hanger.
Nevertheless, were her prescriptions continued?
Yes.
Did Toni repeatedly fail drug screens?
Yes.
Was there evidence in the chart of doctor shopping?
A Yes. Evidence of going to see other doctors and getting prescriptions at the same time that she was receiving prescriptions from the Schneider Medical Clinic.
Q Was there evidence of going to multiple pharmacies
A Yes.

- **ENUMERATED ADRBs**
- Repeated stolen medication
- In withdrawal at office visits
- Prior crack cocaine addiction
- Repeated drug screen failures
- Evidence of doctor-shopping
- Evidence of multiple pharmacies

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Failure of MD to Properly Consider Medical Risks (Respiratory) while Prescribing Opioids:

Ted Parran, MD, in US v. Schneider (2010 Trial Testimony);

Case 6:07-cr-10234-MLB Document 627 Filed 04/04/11.

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Q And what is the relationship with the pneumonia and the controlled substances she is being prescribed?
A Well, again, if a person already has COPD, or emphysema, even a little bit of pneumonia can be life-threatening and controlled substances which tend to decrease breathing can increase the risk of pneumonia.
Q And did the chart indicate that the Schneider Medical Clinic received notice that she had been in the hospital with pneumonia?
A Yes.
Q And after being out of the hospital for one week, does she show up at the Schneider Medical Clinic?
A Yes.

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Failure of MD to Properly Supervise Physician-Extenders and Be Involved in Patient Care: Ted Parran, MD, in US v. Schneider (2010 Trial Testimony); Case 6:07-cr-10234-MLB Document 627 Filed 04/04/11.

Q Nevertheless, do you let your physician's assistants start a patient and continue their treatment without your involvement?
A No. The very nature of physician extender or a mid level practitioner is that they're functioning under the supervision of a physician and the licensed physician under who they function is the person who is expected to supervise all of the care that's provided.
Q And if a physician assistant should make a mistake, do you bear the responsibility for that mistake?
A Absolutely. Absolutely.

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Failure of MD to Evaluate Risk (in General)

Government Expert

Doug Kennedy, MD, in US v. Volkman (2011 Trial Testimony);

Case: 1:07-cr-00060-SSB Doc #: 293 Filed: 04/06/11 Page: 2 of 106 PAGEID #: 3188

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KENNEDY - DIRECT 39

A Well, each case is different. So you look to build the database, as we were talking about, history, past surgical history, on down the line and see what diagnostic tests have been done, but also see what therapeutic measures have been done, as we talked about in a multidisciplinary fashion with physical therapy, not just oral medication, but other things.
Q And do you look for signs of noncompliance or drug abuse?
A Yes, and also look for signs of compliance. Just whatever is there.
Q And would a psychiatric history, would you pay attention to something like that?
A Very much so.
Q And what about if the file indicated the risk of suicide?
A Then I would talk to the source and make sure that there was an ongoing investigation and disposition on that.
Q Is that another situation where family members would be helpful?
A Absolutely.

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Failure of MD to Consider Behavioral Health History and Behavioral Health Medication Compliance

Government Expert

Doug Kennedy, MD, in US v. Volkman (2011 Trial Testimony);

Case: 1:07-cr-00060-SSB Doc #: 285 Filed: 04/04/11 Page: 6 of 74 PAGEID #: 2650

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institutional, and they don't -- and they don't practice very good judgment, as you would expect.
Q. Well, how would that affect compliance with the motivation in taking the medication?
A. It -- with mood swings, when things are going up and down like a yo-yo, it indeed they are or were, then that can be a big problem with compliance.
Q. Okay. Now, about five lines down, beginning in the middle of the paragraph, is there a notation about addiction?
A. Yes. He says he got addicted to oxycontin, but already had problems with substance abuse in the past. And he was admitted to the psychiatric unit twice, once in Florida, and the second time was Pathway in Charlotte.
Q. Now, would the fact that these indicate overdoses and addiction, would that be something you would want to know as a treating pain physician?
A. Yeah. They were, in fact, unintentional overdoses. He also has been on the ventilator twice. That is the ventilator had to assist the breathing because of the drug overdose.
And he had actually cut his wrists, making at least a suicidal attempt. So, yeah, you'd want to know all those things.
Q. Now, the next line down, does it describe the medication that he took?
A. Oh, yeah. The lithium, but he had not been taking it as a

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LEGAL PERSPECTIVE:

What is Risk Assessment?

• The identification of INDIVIDUAL AND OTHER KNOW OR READILY ASSESSED FACTORS that MAY lead to adverse outcomes.

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LEGAL PERSPECTIVE:

Commonly described (and readily assessable) Risk Factors

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- Factors include:
  - Patient and family history of substance use (drugs including prescription medications, alcohol, and marijuana)
  - History of opioid use (patient Hx and current PDMP Evaluation)
  - Overdose history
  - Patient medication use history
    - Opioids now
    - Opioids recent (last 3 to 6 months)
    - Others now and recent past (last 3 to 6 months)
- Risk Factors Continued:
  - Mental health/psychological conditions and history
  - Insomnia or other sleep disorders
  - Abuse history including physical, emotional, or sexual abuse.
  - Pregnancy or planning one
  - Health conditions that may increase potential for adverse outcomes (hepatic, renal, respiratory, obesity, age <18 or >65, sleep apnea)
  - Aberrant Drug-Related Behaviors as shown in prior medical records, communications with prior treating providers, or current risk monitoring tools

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LEGAL PERSPECTIVE:

What is Risk Monitoring?

How is it Accomplished?

• Risk monitoring is the ongoing evaluation of the patient and examination of risk/benefit for the patient

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LEGAL PERSPECTIVE: How is Risk Monitoring Accomplished (Basic Tools)

- Use of a treatment agreement outlining boundaries and tools used for monitoring risk.
- Periodic risk monitoring questionnaires and updates
- Functional status review and other medical progress/lack of it reviews
- Coordination of care communication with other providers who see/treat patient
- UDT
- Prescription Drug Monitoring Database Use
- Office visit frequency and required MD office visit
- Medication counts
- Restriction on ETOH and Illicit Drug Use (including recreational THC)
- Safe storage, disposal, and diversion education and precautions
- Opioid trials and exit strategies
- NALOXONE
- EDUCATION TO PATIENT AND FAMILY/CAREGIVERS/SIGNIFICANT OTHERS

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Current Positions on Risk Mitigation in Opioid Therapy

CDC, US Dept. of Health and Human Services, and American Academy of Pain Medicine Consensus Recommendations on UDT in Chronic Pain Management

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CDC Says Risk Assessment is . . .

https://www.cdc.gov/drugoverdose/pdf/Guidelines_Factsheet-a.pdf.

ASSESSING RISK AND ADDRESSING HARMS OF OPIOID USE

8. Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use, are present.
9. Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months.
10. When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.
11. Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.

CLINICAL REMINDERS

- Evaluate risk factors for opioid-related harms
- Check PDMP for high dosages and prescriptions from other providers
- Use urine drug testing to identify prescribed substances and undisclosed use
- Avoid concurrent benzodiazepine and opioid prescribing
- Arrange treatment for opioid use disorder if needed

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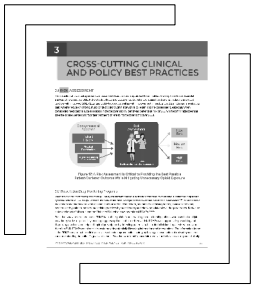

PAIN MANAGEMENT BEST PRACTICES, 2019 INTER-AGENCY TASK FORCE REPORT: US Department of Health & Human Services

- **Section 3, Risk Assessment, pgs. 53-67,**
- available online at https://www.hhs.gov/sites/default/files/pain-mgmt-best-practices-draft-final-report-05062019.pdf

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PAIN MANAGEMENT BEST PRACTICES, 2019 INTER-AGENCY TASK FORCE REPORT: US Department of Health & Human Services

- Pg. 2, Executive Summary, available online at https://www.hhs.gov/sites/default/files/pain-mgmt-best-practices-draft-final-report-05062019.pdf

- **Risk assessment** is one of the four cross-cutting policy approaches necessary for best practices in providing individualized, patient-centered care. A thorough patient assessment and evaluation for treatment that includes a risk-benefit analysis are important considerations when developing patient-centered treatment. Risk assessment involves identifying risk factors from patient history; family history; current biopsychosocial factors; and screening and diagnostic tools, including prescription drug monitoring programs, laboratory data, and other measures. Risk stratification for a particular patient can aid in determining appropriate treatments for the best clinical outcomes for that patient. The final report and this section in particular emphasize safe opioid stewardship, with regular reevaluation of the patient.

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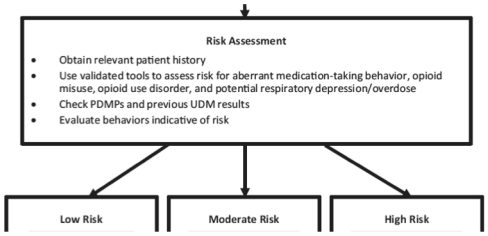
American Academy of Pain Medicine Says Risk Assessment is . . .



Charles E Argoff, et al; Rational Urine Drug Monitoring in Patients Receiving Opioids for Chronic Pain: Consensus Recommendations, Pain Medicine, Volume 19, Issue 1, 1 January 2018, Pages 97–117, https://doi.org/10.1093/pm/pnx285

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American Academy of Pain Medicine Says Risk Factors of Opioid Misuse and Opioid Use Disorder Include . . .

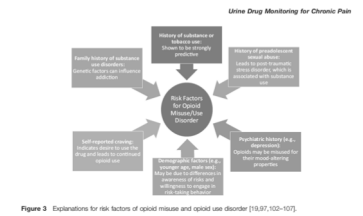

Figure 3 Explanations for risk factors of opioid misuse and opioid use disorder [19,97,102–107].

Charles E Argoff, Daniel P Alford, Jeffrey Fudin, Jeremy A Adler, Matthew J Bair, Richard C Dart, Roy Gandolfi, Bill H McCarberg, Steven P Stanos, Jeffrey A Gudin, Rosemary C Polomano, Lynn R Webster; Rational Urine Drug Monitoring in Patients Receiving Opioids for Chronic Pain: Consensus Recommendations, *Pain Medicine*, Volume 19, Issue 1, 1 January 2018, Pages 97–117, https://doi.org/10.1093/pm/pnx285

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State Examples –
Risk Mitigation in 2019

CALIFORNIA
COLORADO
MINNESOTA
ARIZONA

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Medical Board of California – Risk Mitigation for Opioid Prescribing and Medical Cannabis Recommendations

California Opioid Prescribing Guidelines AND Medical Cannabis Recommendation Guidelines

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Medical Board of California – Key Guideline Resources

MBC Opioid Prescribing Guidelines (2014) –

http://www.mbc.ca.gov/Licensees/Prescribing/Pain_Guidelines.pdf

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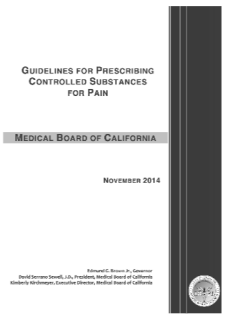
GUIDELINES FOR PRESCRIBING CONTROLLED SUBSTANCES FOR PAIN

MEDICAL BOARD OF CALIFORNIA

NOVEMBER 2014

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California & Cannabis Recommendation Guidelines

FOCUS ON

Risk Assessment

http://www.mbc.ca.gov/Publications/guidelines_cannabis_recommendation.pdf

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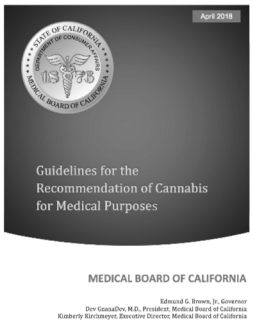

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California Cannabis Recommendation Guidelines:
A VALID PHYSICIAN-PATIENT RELATIONSHIP;
NO DRIVE-BY RECOMMENDATIONS

GUIDELINES
The Board has adopted the following guidelines for the recommendation of cannabis for medical purposes.

Physician-Patient Relationship: The health and well-being of patients depends upon a collaborative effort between the physician and the patient. The relationship between a patient and a physician is complex and based on the mutual understanding of the shared responsibility for the patient's health care. The physician-patient relationship is fundamental to the provision of acceptable medical care. Therefore, physicians should document that an appropriate physician-patient relationship has been established, prior to providing a recommendation, attestation, or authorization for cannabis to the patient. Consistent with the prevailing standard of care, physicians should not recommend, attest, or otherwise authorize cannabis for themselves or family members.

Pursuant to Business and Professions (B&P) Code section 2525.2, a physician shall not recommend cannabis for medical purposes to a patient, unless the physician is the patient's attending physician. Health and Safety (H&S) Code section 11362.7(a) defines an "attending physician" as a physician who has taken responsibility for an aspect of the medical care, treatment, diagnosis, counseling, or referral of a patient. The physician must also have conducted a medical examination of the patient before recording in the patient's medical record the physician's assessment of whether the patient has a serious medical condition and whether the use of cannabis for medical purposes is appropriate.

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California Cannabis Recommendation Guidelines: PATIENT EVALUATION (INCLUDES RISK ISSUES)

Patient Evaluation: A documented medical examination and collection of relevant clinical history commensurate with the presentation of the patient must be obtained before a decision is made as to whether to recommend cannabis for a medical purpose. The examination must be an appropriate prior examination, and at minimum, should include the patient's history of present illness; social history; past medical and surgical history; alcohol and substance use history; family history with emphasis on addiction, psychotic disorders, or mental illness; documentation of therapies with inadequate response; and diagnosis requiring the cannabis recommendation. At this time, there is a paucity of evidence for the efficacy of cannabis in treating certain medical conditions. Recommending cannabis for any medical conditions, however, is at the professional discretion of the physician acting within the standard of care. The indication, appropriateness, and safety of the recommendation should be evaluated in accordance with standards of practice as they evolve over time.

The initial evaluation for the condition that cannabis is being recommended must meet the standard of care; accepted standards are the same as any reasonable and prudent physician would follow when recommending or approving any other medication.

It is important to note that B&P Code section 2525.3 states that physicians recommending cannabis to a patient for a medical purpose without an appropriate prior examination and a medical indication, constitutes unprofessional conduct. The use of telehealth in compliance with B&P Code section 2290.5, and used in a manner consistent with the standard of care is permissible.

FOCUS ON THE WORD "MUST"

LITTLE EVIDENCE NOW, SO FOCUS ON INDICATION, APPROPRIATENESS, AND SAFETY IN ACCORDANCE WITH STANDARDS of "REASONABLE PRUDENCE"

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The CA Medical Board, Cannabis "MUST DO LIST" for PHYSICIANS - EVALUATION

- The physician MUST:
  - Obtain patient's medical history commensurate with presentation BEFORE deciding on MM.
  - **Perform an appropriate examination and at a minimum include:**
    - Patient's history of present illness
    - Social history
    - Past medical and surgical history
    - ETOH and Substance Use History
    - Family history with emphasis on addiction, psychotic disorders, or mental illness
    - Documentation of therapies with inadequate response
    - Diagnosis requiring cannabis recommendation

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California Cannabis Recommendation Guidelines: INFORMED & SHARED DECISION-MAKING

Informed and Shared Decision Making: The decision to recommend cannabis should be a shared decision between the physician and the patient. The physician should discuss the risks and benefits of the use of cannabis with the patient. (See Decision Tree in Appendix 1) Patients should be advised of the variability and lack of standardization of cannabis preparations, as well as the issue that it affects individuals differently. Patients should be reminded that cannabis use may result in cognitive changes that affect function, including driving, and that they should not drive, operate heavy machinery, or engage in any hazardous activity while under the influence of cannabis. As with any medication, patients may be charged with driving under the influence of drugs if they drive while impaired by the substance. If the patient is a minor or without decision-making capacity, the physician should ensure that the patient's parent, guardian or surrogate is fully informed of the risks and benefits of cannabis use, is involved in the treatment plan, and consents to the patient's use of cannabis.

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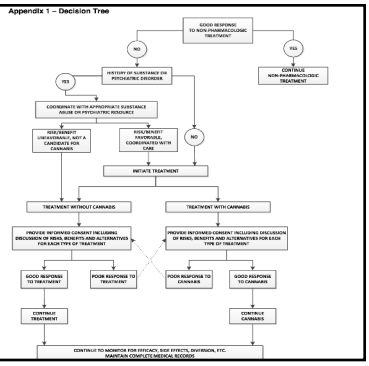
California Cannabis Recommendation Guidelines

APPENDIX 1
DECISION TREE
(as of 4/2018)
Re-evaluate quarterly for changes post 4/6/19



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California's Cannabis Recommendation Guidelines: QUALIFYING CONDITIONS; LACK OF EVIDENCE ISSUES

Qualifying Conditions: At this time, there is a lack of evidence for the efficacy of cannabis in treating certain medical conditions. Recommending cannabis for medical purposes is at the professional discretion of the physician. The indication, appropriateness, and safety of the recommendation should be evaluated in accordance with current standards of practice and in compliance with state laws, rules and regulations which specify qualifying conditions for which a patient may qualify for cannabis for medical purposes.

The Compassionate Use Act names certain medical conditions for which cannabis may be useful, although physicians are not limited in their recommendations to those specific conditions (cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, and migraine). In all cases, the physician should base his or her determination on the results of clinical trials, if available, medical literature and reports, or on experience of that physician or other physicians, or on credible patient reports. In all cases, the physician must determine that the risk/benefit ratio of cannabis is as good, or better, than other treatment options that could be used for that individual patient. A patient need not have failed on all standard medications in order for a physician to recommend or approve the use of cannabis for medical purposes.

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California Cannabis Recommendation Guidelines: ONGOING MONITORING AND ADAPTING TX PLAN

Ongoing Monitoring and Adapting the Treatment Plan: The physician should regularly assess the patient's response to the use of cannabis and overall health and level of function. This assessment should include any change in the overall medical condition, any change in the physical and psychosocial function, the efficacy of the treatment to the patient, the goals of the treatment, and the progress of those goals. Recommendations should be limited to the time necessary to appropriately monitor the patient. There should be a periodic review documented at least annually or more frequently as warranted.

When a trial of cannabis for medical use is successful and the physician and patient decide to continue the use of cannabis, regular review and monitoring should be undertaken for the duration of treatment. Continuation, modification or termination of cannabis for medical use should be contingent on the physician's evaluation of (1) evidence or the patient's progress toward treatment objectives and (2) the absence of substantial risks or adverse events, such as diversion. A satisfactory response to treatment would be indicated by an increased level of

NO ONE AND DONE RECOMMENDATIONS

[1] Please be aware that the risks of cannabis use on a fetus or breast-feeding infant are unknown. The American College of Obstetricians and Gynecologists (ACOG) Committee Opinion (Number 722 - October 2017) states physicians should be discouraged from recommending cannabis for medicinal purposes during pregnancy and lactation.

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California Cannabis Recommendation Guidelines: CONSULTATION & REFERRAL

function and/or improved quality of life. The physician should regularly assess the patient's response to the use of cannabis.

Consultation and Referral: A patient who has a history of substance use disorder or a co-occurring mental health disorder may require specialized assessment and treatment. The physician should seek a consultation with, or refer the patient to, a pain management physician, psychiatrist, psychologist, and/or addiction or mental health specialist as needed. The physician should determine that cannabis use is not masking symptoms of another condition requiring further assessment and treatment (e.g., substances use disorder, or other psychiatric or medical condition) or that such use will lead to a worsening of the patient's condition.

EVALUATE MASKING

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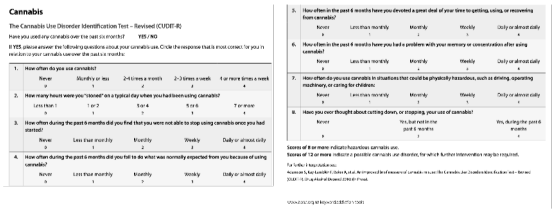
Cannabis Use Disorder Identification Test - Revised (CUDIT-R)

https://bnac.org.nz/BPJ/2010/June/docs/addiction_CUDIT-R.pdf; paper available online at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5531365/



Cannabis

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

Have you used any cannabis over the past 6 months? YES / NO

If YES, please answer the following questions about your cannabis use. Circle the response that is most correct for you in relation to your cannabis use over the past 6 months.

1.	How often do you use cannabis?	Never	Monthly or less	2–4 times a month	2–3 times a week	4 or more times a week
		0	1	2	3	4
2.	How many hours were you "stoned" on a typical day when you had been using cannabis?	Less than 1	1 or 2	3 or 4	5 or 6	7 or more
		0	1	2	3	4
3.	How often during the past 6 months did you find that you were not able to stop using cannabis once you had started?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
		0	1	2	3	4
4.	How often during the past 6 months did you fail to do what was normally expected from you because of using cannabis?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
		0	1	2	3	4

5.	How often in the past 6 months have you devoted a great deal of your time to getting, using, or recovering from cannabis?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
		0	1	2	3	4
6.	How often in the past 6 months have you had a problem with your memory or concentration after using cannabis?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
		0	1	2	3	4
7.	How often do you use cannabis in situations that could be physically hazardous, such as driving, operating machinery, or caring for children?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
		0	1	2	3	4
8.	Have you ever thought about cutting down, or stopping, your use of cannabis?	Never		Yes, but not in the past 6 months		Yes, during the past 6 months
		0		1		2

Scores of 8 or more indicate hazardous cannabis use.
Scores of 12 or more indicate a possible cannabis use disorder, for which further intervention may be required.

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Colorado Medical Board and 2019 Opioid Prescribing Guidelines and Risk Mitigation

RISK ASSESSMENT, EVALUATION, AND MONITORING TO PREVENT ABUSE, DIVERSION, AND OVERDOSE

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Colorado – 2019 - Opioid Prescribing Guidelines

- **Sources:**
- Opioid Guidelines Web Page - https://www.colorado.gov/pacific/dora/opioid_guidelines
- Opioid Guidelines (Full Document as of 3/14/19) - https://drive.google.com/file/d/19xrPqsCbaHHA9nTD1Fl3NeCn5kwK60zR/view

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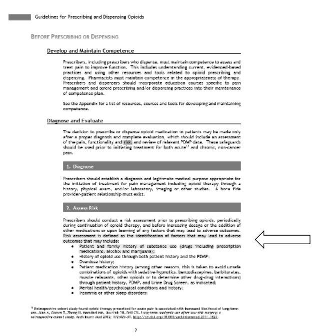
Colorado Medical Board 201 GUIDELINES – Risk Assessment & Evaluation

- ASSESS RISK PRIOR TO PRESCRIBING OPIOIDS AND DURING TREATMENT.
- ASSESS RISK PRIOR TO INCREASING DOSE OR ADDING IN OTHER MEDICATION
- ASSESS RISK UPON LEARNING OF OTHER FACTORS THAT MAY LEAD TO ADVERSE OUTCOMES



Guidelines for Prescribing and Dispensing Opioids

BEFORE PRESCRIBING OR DISPENSING

Develop and Maintain Competence

Prescribers, including prescribers who dispense, must maintain competence to assess and treat pain to improve function. This includes understanding current, evidenced-based practices and using other resources and tools related to opioid prescribing and dispensing. Pharmacists must maintain competence in the appropriateness of therapy. Prescribers and dispensers should incorporate education courses specific to pain management and opioid prescribing and/or dispensing practices into their maintenance of competence plan.

See the Appendix for a list of resources, courses and tools for developing and maintaining competence.

Diagnose and Evaluate

The decision to prescribe or dispense opioid medication to patients may be made only after a proper diagnosis and complete evaluation, which should include an assessment of the pain, functionality and risk, and review of relevant PDMP data. These safeguards should be used prior to initiating treatment for both acute[17] and chronic, non-cancer pain.

1. Diagnose

Prescribers should establish a diagnosis and legitimate medical purpose appropriate for the initiation of treatment for pain management including opioid therapy through a history, physical exam, and/or laboratory, imaging or other studies. A bona fide provider-patient relationship must exist.

2. Assess Risk

Prescribers should conduct a risk assessment prior to prescribing opioids, periodically during continuation of opioid therapy, and before increasing dosage or the addition of other medications or upon learning of any factors that may lead to adverse outcomes. Risk assessment is defined as the identification of factors that may lead to adverse outcomes that may include:

- Patient and family history of substance use (drugs including prescription medications, alcohol and marijuana);
- History of opioid use through both patient history and the PDMP;
- Overdose history;
- Patient medication history (among other reasons, this is taken to avoid unsafe combinations of opioids with sedative-hypnotics, benzodiazepines, barbiturates, muscle relaxants, other opioids or to determine other drug-drug interactions) through patient history, PDMP, and Urine Drug Screen, as indicated;
- Mental health/psychological conditions and history;
- Insomnia or other sleep disorders;

[17] Retrospective cohort study found opioid therapy prescribed for acute pain is associated with increased likelihood of long-term use. Alam A, Gomes T, Zheng H, Mamdani MM, Juurlink DN, Bell CM. Long-term analgesic use after low-risk surgery: a retrospective cohort study. Arch Intern Med 2012; 172:425-30.

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Colorado Medical Board 201 GUIDELINES – Risk Assessment & Evaluation

Consider referral when psychological issues are identified

Guidelines for Prescribing and Dispensing Opioids

5. Psychological Assessment

In instances where the risk assessment identifies a mental health or psychological condition, the prescriber should consider referring the patient to a mental health provider for a psychological or cognitive behavioral assessment.

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Minnesota Opioid Prescribing Guidelines (2018-2019) and Risk Mitigation

RISK ASSESSMENT, EVALUATION, AND MONITORING TO PREVENT ABUSE, DIVERSION, AND OVERDOSE

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Minnesota Opioid Prescribing Guidelines – Resources

Sources:

Opioid Guidelines (Full Document) - https://mn.gov/dhs/assets/mn-opioid-prescribing-guidelines_tcm1053-337012.pdf

Opioid Guidelines (Summary by pain phase) – chronic pain https://mn.gov/dhs/opip/opioid-guidelines/pain-phase/chronic-pain.jsp

Minnesota calls it "Flip the Script" - https://mn.gov/dhs/opip/

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Minnesota Opioid Prescribing Guidelines – Risk Mitigation Strategies

Risk mitigation strategies

14. Monitor reproductive health in all women of childbearing age who receive COAT or MAT. Provide family planning services and counsel women on using effective contraception while on COAT or MAT. Effective contraception is the primary way to prevent unintended pregnancy and risk of delivering a baby with Neonatal Abstinence Syndrome (NAS) or Neonatal Opioid Withdrawal Syndrome (NOWS).

15. Complete a urine drug screen (UDS) prior to initiating or continuing COAT in a new patient and consider a random UDS at least twice a year. Complete a UDS when patients come to the clinic for a pill count. Standardize UDS policies at the clinic or health system level in order to destigmatize their use. Use the UDS results to guide treatment decisions, improve patient-clinician communication and monitor patient safety. Consider ordering a confirmatory test for positive results to confirm substance identification. Clinicians should not dismiss patients from care solely based on UDS results that contradict the patient's self-reported adherence to therapy.

16. Consider pill count callbacks for high risk patients. Callbacks generally require patients to come to the clinic to count remaining opioid pills within 24 hours of being notified. If the pill count results in fewer or greater pills than expected, schedule a visit with the patient to discuss the results.

17. Monitor patients receiving COAT for the presence of opioid use disorder (OUD). Clinicians who are unable to diagnose OUD using the DSM-5 criteria can use a brief, standardized screening tool and make a referral as appropriate.

18. Offer or arrange evidence-based treatment for patients with OUD. Clinicians who are not authorized to provide evidence-based treatment should work with their practice group to build capacity for treatment and/or build a referral network of treatment providers.

19. Consider consulting specialists trained in pain, addiction or mental health conditions when initiating COAT. Early consultation may help identify the potential for increased risk, even in patients at low risk of adverse events, if opioid therapy continues. Refer patients receiving COAT to addiction and mental health specialists when there is a significant risk for opioid-related harm, as appropriate for the patient's needs. The referring clinician should continue to treat the patient until a successful transfer of care has occurred, or until the patient fails to follow through on the referral and continues to be at risk.

Opioid Guidelines (Full Document) - https://mn.gov/dhs/assets/mn-opioid-prescribing-guidelines_tcm1053-337012.pdf

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Minnesota Risk Mitigation Duties and Concomitant Use of Opioids and Benzodiazepines

3. Address concomitant use of benzodiazepines and other sedative hypnotics for patients receiving COAT. Patients receiving potentially dangerous drug combinations require care coordination and medication management. Obtain a patient release of information and contact the relevant prescribers. Consider prescribing naloxone to patients with concomitant use.

Page 19, Minnesota Opioid Prescribing Guidelines (2018 version)

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Minnesota Risk Mitigation Duties and Prescribing Opioids to Patients with Certain Medical Risks (Co-Morbidities)

5. Use extreme caution when prescribing opioids to patients with comorbid conditions that may increase risk of adverse outcomes. Comorbid conditions associated with elevated risk include Chronic Obstructive Pulmonary Disease, Congestive Heart Failure, obstructive sleep apnea, history of alcohol or substance use disorder, advanced age, or renal or hepatic dysfunction.

Page 19, Minnesota Opioid Prescribing Guidelines (2018 version)

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Minnesota Risk Mitigation and Naloxone

Consider prescribing naloxone to the following populations at high-risk of opioid overdose:

1. Individuals with substance use disorder;
2. Individuals concomitantly using benzodiazepines;
3. Individuals on chronic opioid analgesic therapy with an acute injury;
4. Individuals with a past overdose;
5. Individuals with respiratory insufficiency, especially sleep apnea; and
6. Individuals who were recently incarcerated with a history of substance abuse.

Other patient populations who are at elevated risk of opioid-related harm, especially when prescribed long-term opioid therapy, include:

1. Pediatric patients;
2. Geriatric patients;
3. Individuals referred to addiction specialists, pain medicine specialists or mental health providers. These patients may be at risk for overdose during care transitions; and
4. All patients receiving chronic opioid analgesic therapy (COAT).

Page 23, Minnesota Opioid Prescribing Guidelines (2018 version)

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Minnesota Risk Mitigation and Critical Behavioral Health Assessments

4. Screen patients for depression and anxiety using a brief, validated tool at each follow-up visit for pain management.
   - If screening tools indicate an active mental health condition, provide aggressive treatment concomitant to analgesia strategies. *[Post-Acute Pain]*
   - Refer patients with depression or anxiety that has not been previously treated or successfully treated for appropriate psychotherapy. *[Chronic Pain]*
5. Assess and document suicidality in every setting for every initial opioid prescription. Reassess suicidality in patients receiving chronic opioid analgesic therapy at least once a year. *[Acute Pain; Chronic Pain]*
6. Screen patients for substance use disorder using a brief, validated tool. Conduct a structured interviewing using the current Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria when the patient screens positive, or refer to a specialist for diagnosis.
   - Screen patient for substance use disorders one week after the acute event, or at the first opioid refill request. If assessment indicates elevated risk for substance abuse, review and determine tapering strategy. *[Post-Acute Pain]*
   - Assess patients for substance use prior to initiating chronic opioid analgesic therapy. If assessment indicates an active substance use disorder, provide the patient evidence-based treatment or refer to a specialist. Continue to screen for substance use disorders for the duration of the opioid therapy. *[Chronic Pain]*

Minnesota Opioid Prescribing Guidelines, Online List of Risk Mitigation Areas, Opioid Guidelines (Summary by pain phase) – chronic pain https://mn.gov/dhs/opip/opioid-guidelines/pain-phase/chronic-pain.jsp

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ARIZONA and Risk Mitigation through Exit Strategies

Arizona Opioid Prescribing Position 2018-2019

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ARIZONA 2018 – Opioid Prescribing Guidelines and Risk Mitigation Checklist

SOURCE: pg. 3, https://azdhs.gov/documents/audiences/clinicians/clinical-guidelines-recommendations/prescribing-guidelines/az-opioid-prescribing-guidelines.pdf

RISK MITIGATION	
7	For patients on long-term opioid therapy, document informed consent which includes the risks of opioid use, options for alternative therapies and therapeutic boundaries.
8	Do not use long-term opioid therapy in patients with untreated substance use disorders.
9	Avoid concurrent use of opioids and benzodiazepines. If patients are currently prescribed both agents, evaluate tapering or an exit strategy for one or both medications.
10	Check the Arizona Controlled Substances Prescription Monitoring Program before initiating an opioid or benzodiazepine, and then at least quarterly.
11	Discuss reproductive plans and the risk of neonatal abstinence syndrome and other adverse neonatal outcomes prior to prescribing opioids to women of reproductive age.
12	If opioids are used to treat chronic pain, prescribe at the lowest possible dose and for the shortest possible time. Reassess the treatment regimen if prescribing doses ≥50 MEDs.
13	Counsel patients who are taking opioids on safety, including safe storage and disposal of medications, not driving if sedated or confused while using opioids and not sharing opioids with others.
14	Reevaluate patients on long-term opioid therapy at least every 90 days for functional improvements, substance use, high-risk behaviors and psychiatric comorbidities through face-to-face visits, PDMP checks and urine drug tests.
15	Assess patients on long-term opioid therapy on a regular basis for opioid use disorder and offer or arrange for medication-assisted therapy (e.g. methadone and buprenorphine) to those diagnosed.
16	Offer naloxone and provide overdose education for all patients at risk for opioid overdose.
17	Individualize an exit strategy from the use of long-term opioid therapy for chronic pain, while carefully monitoring for risks.

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ARIZONA 2018 Opioid Guidelines
Appendix E: How to Approach an Exit Strategy from Long Term Opioid Therapy

Guideline	Patient Category	Exit Strategy to "Consider"
17	Patients on lower MEDs, lower pain-related dysfunction, and lower psychiatric and substance use disorder comorbidities	Consider opioid tapering (Strategy A, which includes rotation to buprenorphine.
	Patients with prescriptions for higher MEDs, higher pain-related dysfunction, and higher psychiatric and substance use disorder comorbidities	Consider rotation to buprenorphine (Strategy B) with subsequent gradual reduction in buprenorphine dose.
	Patients with opioid use disorder	Offer or arrange for medication assisted treatment (Strategy C).

SOURCE: pgs. 26-28 https://azdhs.gov/documents/audiences/clinicians/clinical-guidelines-recommendations/prescribing-guidelines/az-opioid-prescribing-guidelines.pdf

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ARIZONA 2018 Opioid Guidelines **Appendix E:** How to Approach an Exit Strategy from Long Term Opioid Therapy **(Risks to Consider)**

Opioid Tapering and Risks to be Taken into Account by the Provider* (Patients with multiple risk factors indicate larger, cumulative risk)
No pain reduction, no improvement on opioid regimen
Severe, unmanageable adverse effects (drowsiness, constipation)
High Risk Dosage (>90 MED)
Non-adherence to treatment plans
Concerns related to an increased risk of substance use disorder
Overdose event involving opioids
Medical comorbidities that can increase risk (lung disease, sleep apnea, liver disease, renal disease, fall risk, advanced age)
Concomitant use of medications that increase risk (benzodiazepines, sedative hypnotics)
Mental health comorbidities that can worsen opioid therapy (PTSD, depression, anxiety)

SOURCE: pgs. 26-28 https://azdhs.gov/documents/audiences/clinicians/clinical-guidelines-recommendations/prescribing-guidelines/az-opioid-prescribing-guidelines.pdf

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OBJECTIVE 3

Explain how to create a risk mitigation action plan and use it in daily practice.

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What does risk assessment and monitoring mean to you?

Audience Discussion

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Creating and Using a Risk Mitigation Action Plan:

Basic Steps

Read	Read Licensing Board Rules/Guidelines
Review	Online Review of State Opioid Prescribing Initiatives (if any)
Create	Create a Checklist of Directives…The Physician Shall…The Physician Should
Create	Create a Risk Domain Criteria List
Create	Create a Risk Mitigation Plan for Each

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Thinking about Risk:

The Legal Perspective

Medical Conditions

Medication Situation (Present and Recent Past/Pain Treatment Past)

Behavioral Health

- Diagnosed
- Risk-Questionnaire Evaluated
- Substance Use History (ETOH, THC, Other)(Patient and 1st Degree Relative)
- Observed and Reported (many methods)

Other Indicators and Observations

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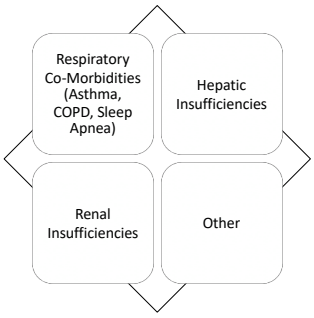
Legal Perspective:

Commonly Referenced Medical Co-Morbidities that Enhance Risk of Overdose



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Legal Perspective:

Common Dosing Boundaries Used WHEN Creating a Risk Mitigation Program and Workflow

50mg MME or less **(Low Risk)**; No "risky" combinations or readily available solutions.

50mg to 90mg MME **(Moderate Risk);** May have "risky combination" but adjustable or substitutions are workable.

>90mg MME **(High Medical Risk)** or combination Opioid + Benzodiazepines (and some status using other CNS depressants); Opioids + Other Medication where Drug-Drug Interaction may be an issue (drugs that induce or inhibit opioid metabolism and may impact patient risks of adverse events)

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Legal Perspective:

Commonly Referenced Psycho-Social Factors and Risk
–

Decide whether the data requires classification of any of these risks into what might be fairly labeled as High Behavioral Risk Classification

Behavioral Health History – Major BH/MH Diagnoses? Use of Multiple BH Medications? Access to BH Treatment and Ability to Coordinate Care?

Aberrant, Drug Related Behaviors (PDMP-Doctor-shopping, Prior discharge for drug-related behavior or inappropriate behaviors)

Smoking, Drinking, THC Use - Personal and First Degree Relative History; Substance Use Disorder, Treatment, Etc.

Aberrant Drug-Related Behavior, Abuse/Diversion Risk Assessment Tools (BRI, BRQ, ORT, SOAPP-R/COMM, and others)

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PATIENT INDIVIDUAL FACTS + ASSESSABLE DOMAINS OF RISK = RISK LEVEL OR PROFILE

- Low Risk
- Moderate Risk
- High Medical Risk
- High Behavioral Risk

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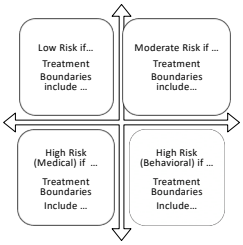
Create your own checklist for Evaluation and Risk Mitigation Decision-Making



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Audience Input & How-To Exercise: Naming Possible Risk Factors by Category; Building a Checklist Framework (Table as an Example for Brainstorming)

Area of Assessment	Potential Risk Factor 1	Potential Risk Factor 2	Potential Risk Factor 3
General Medical History	Respiratory	Cardiac	Renal/Hepatic
Physical Exam	No diagnostics	Unable to Correlate Pain Complaint with Pain Generator	Everything seems normal except for patient reported pain levels
Behavioral	Major BH Diagnosis	Use of Multiple BH Medications	Risk Factors derived from Validated Risk Assessment Questionnaires
Medication-Related	Current Long-Acting Opioid Use	Current Methadone Use	Current Fentanyl Use
	Combination Opioids	Combination Opioids + Benzodiazepines	Combination Opioids + Other CNS Depressants
Other Drug Use and Other Potential Factors	Use of THC	Use of ETOH	No Naloxone or Repeated Refusal to Fill

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Legal Perspective:

Critical Risk Monitoring Considerations

- Frequency of visit AND Frequency of re-evaluation with MD
- Frequency of PDMP check if state does not require specific frequency
- Frequency of Drug Testing and Nature of Drug Testing Menu
- Type of medications that will be allowed
- Dose and Combination of medications that will be allowed without additional monitoring and provider support, including consults/referrals
- Issuance and Confirmation of Naloxone Prescription
- Exit or Additional Provider Support Strategies

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Key is TIMELY Assessment and Evaluation for use in treatment of patient and Physician Involvement

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Coordination of Care

Addressing the Weaknesses

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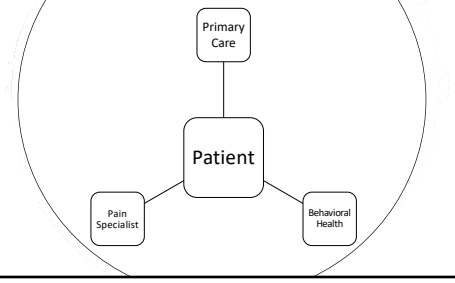
CONSULTATION & COORDINATION OF CARE



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

⇨

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

How do you handle John Smith's report?

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Addressing Adverse Patient Events in a Timely Fashion

With your staff

In your practice processes and work flows

In your documentation practices

REMINDER- STATE REPORTING REQUIREMENTS

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If you learn of a patient overdose, create and activate a risk triage plan

- Learn of Event and Take Immediate Steps to Understand Required and Optional Steps*** Reporting Requirements in some states
- Preserve Chart and Understand Events Regarding Specific Patient
- Obtain Legal Input Regarding Status of Specific Patient and Practice Improvements
- Internal Education to Staff and Necessary Practice Updates
- External Education to Patients and Family Members
- Ongoing Monitoring with Legal Counsel

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Review Charts with Directives List in Mind;

Ask: Where am I vulnerable?

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REMINDER

Individualized Patient Care:

1. Looks backwards and constantly reevaluates the data points
2. And moves forward with the patient's best interests in mind, carefully balancing risks and benefits

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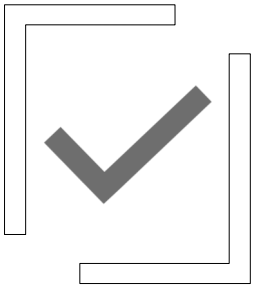

Questions?

- Thank you!
- **Jennifer Bolen, JD**
- 865-755-2369
- jbolen@legalsideofpain.com

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ADDITIONAL RESOURCES

Read the fine print

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Medical Board of California (MBC) – Opioid Guideline Resources and Related Items

- MBC Opioid Prescribing Guidelines (2014) – http://www.mbc.ca.gov/Licensees/Prescribing/Pain_Guidelines.pdf
- MBC Medical Cannabis Recommendation Guidelines (2018) –
- http://www.mbc.ca.gov/Publications/guidelines_cannabis_recommendation.pdf
- http://www.mbc.ca.gov/Licensees/Prescribing/Cannabis.aspx
- MBC Website - http://www.mbc.ca.gov/

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Colorado – 2019 - Opioid Prescribing Guidelines

- **Sources:**
- Opioid Guidelines Web Page - https://www.colorado.gov/pacific/dora/opioid_guidelines
- Opioid Guidelines (Full Document as of 3/14/19) - https://drive.google.com/file/d/19xrPqsCbaHHA9nTD1Fl3NeCn5kwK60zR/view

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Minnesota Opioid Prescribing Guidelines – Resources

Sources:

Opioid Guidelines (Full Document) - https://mn.gov/dhs/assets/mn-opioid-prescribing-guidelines_tcm1053-337012.pdf

Opioid Guidelines (Summary by pain phase) – chronic pain https://mn.gov/dhs/opip/opioid-guidelines/pain-phase/chronic-pain.jsp

Minnesota calls it "Flip the Script" - https://mn.gov/dhs/opip/

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General Resources for Tools - Medication and Medical Risks

CDC - https://www.cdc.gov/opioids/

SAMHSA - https://www.samhsa.gov/

FSMB - http://www.fsmb.org/

State Licensing Boards – google state board or go to state website

Local Medical Associations

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US Department of Health & Human Services

- SOURCES:
- https://www.hhs.gov/opioids/sites/default/files/2018-12/naloxone-coprescribing-guidance.pdf
- https://www.hhs.gov/opioids/prevention/safe-opioid-prescribing/index.html
- https://www.hhs.gov/opioids/

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SAMHSA Opioid Overdose TOOLKIT:

Information for Prescribers

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SAMHSA Original Toolkit and Link to 2016 Kit

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

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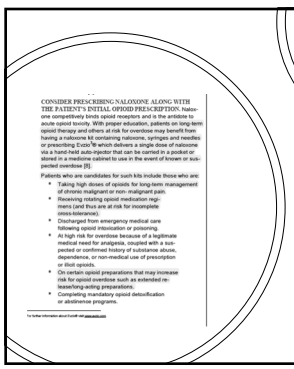
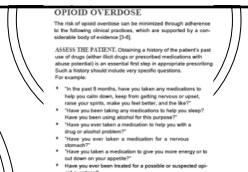


CONSIDER PRESCRIBING NALOXONE ALONG WITH THE PATIENT'S INITIAL OPIOID PRESCRIPTION. Naloxone competitively binds opioid receptors and is the antidote to acute opioid toxicity. With proper education, patients on long-term opioid therapy and others at risk for overdose may benefit from having a naloxone kit containing naloxone, syringes and needles or prescribing Evzio® which delivers a single dose of naloxone via a hand-held auto-injector that can be carried in a pocket or stored in a medicine cabinet to use in the event of known or suspected overdose [6].

Patients who are candidates for such kits include those who are:

- Taking high doses of opioids for long-term management of chronic malignant or non- malignant pain.
- Receiving rotating opioid medication regimens (and thus are at risk for incomplete cross-tolerance).
- Discharged from emergency medical care following opioid intoxication or poisoning.
- At high risk for overdose because of a legitimate medical need for analgesia, coupled with a suspected or confirmed history of substance abuse, dependence, or non-medical use of prescription or illicit opioids.
- On certain opioid preparations that may increase risk for opioid overdose such as extended release/long-acting preparations.
- Completing mandatory opioid detoxification or abstinence programs.



OPIOID OVERDOSE

The risk of opioid overdose can be minimized through adherence to the following clinical practices, which are supported by a considerable body of evidence [3-5].

ASSESS THE PATIENT. Obtaining a history of the patient's past use of drugs (either illicit drugs or prescribed medications with abuse potential) is an essential first step in appropriate prescribing. Such a history should include very specific questions. For example:

- "In the past 6 months, have you taken any medications to help you calm down, keep from getting nervous or upset, raise your spirits, make you feel better, and the like?"
- "Have you been taking any medications to help you sleep? Have you been using alcohol for this purpose?"
- "Have you ever taken a medication to help you with a drug or alcohol problem?"
- "Have you ever taken a medication for a nervous stomach?"
- "Have you taken a medication to give you more energy or to cut down on your appetite?"
- Have you ever been treated for a possible or suspected opioid overdose?

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SAMHSA Opioid Overdose Toolkit

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

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SAMHSA (Substance Abuse and Mental Health Services Administration)

"REDUCE THE RISK"

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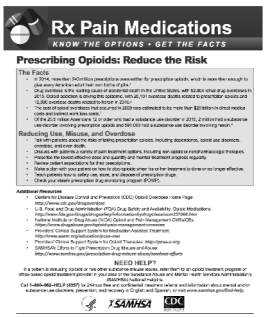

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SAMHSA (Substance Abuse and Mental Health Services Administration)

- Medication and Substance Use Risks
- Dangerous Drug Interactions

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SAMHSA (Substance Abuse and Mental Health Services Administration)

A simple treatment agreement

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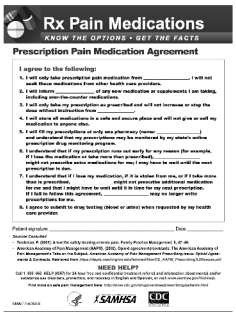

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SAMHSA Medication List

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Rx Pain Medications

KNOW THE OPTIONS • GET THE FACTS

My Medications

Medication	How much?	How often?	Reason?	Prescribed by:

NEED HELP?

SAMHSA CDC

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