Through the Lens of Experts: Meaningful Risk Mitigation and Patient Education in Consideration of COVID-19

Presented by Jennifer Bolen, JD

Ms. Bolen is a Consultant to Paradigm Healthcare

Disclosures

Background

- Those who have been on either side of a courtroom battle on chronic opioid therapy have seen experts and lawyers spend a great deal of time arguing about the extent and nature of risk mitigation and patient education necessary to demonstrate that the prescriber issued a valid controlled substance prescription.
- The focus of expert testimony is on whether the prescriber engaged in meaningful risk evaluation and monitoring practices, and whether the prescriber individualized medical care for the patient, based on specific history and behaviors as treatment went on.
- This course will use published medical expert testimony and common expert reports of illegal and insufficient risk mitigation and patient education.
- The main goal is to facilitate a prescriber's self-audit of risk mitigation practices and to help attendees improve documentation of risk mitigation protocols and patient education efforts.
- In the era of COVID-19, a renewed effort to engage in meaningful risk mitigation is necessary for protecting patient access to quality pain care and creating a framework within which other practitioners may confidently assume care for patients when necessary and demonstrating appropriate prescribing of chronic opioid therapy.

Learning Objectives

- **OBJECTIVE 1** - Examine DEA's current position on controlled substance prescribing and telemedicine during the COVID-19 Public Health Emergency3
- **OBJECTIVE 2** – Review examples of current medical licensing board position statements and rules on risk mitigation for chronic pain management.
- **OBJECTIVE 3** – In a brief case discussion format, review various government and defense medical expert statements made in actions against prescribers (administrative and criminal) regarding the prescriber's duty to take reasonable steps to prevent abuse and diversion.
- **OBJECTIVE 4** - Identify educational concepts and resources for patients and practice staff to facilitate "reasonable steps" to prevent abuse and diversion of, and adverse outcomes associated with, opioids.

DEA’s current position on controlled substance prescribing and telemedicine during the COVID-19 Public Health Emergency

Objective 1

COVID-19 Public Health Emergency and Addition of DEA Guidance on Prescribing

https://www.deadiversion.usdoj.gov

Diversion Control Division

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COVID-19 Information Page

COVID-19 Information Page

Suspicious Orders and Due Diligence | Prescriptions | Registration | Quota |National Drug Supply | EPCS | Telemedicine | Medication Assisted Treatment | Records and Reports | Pseudoephrine & Listed Chemicals | Contacts | Important Federal Links | Important State Links

The mission of Drug Enforcement Administrations (DEA), Diversion Control Division is to prevent, detect, and investigate the diversion of controlled pharmaceuticals and listed chemicals from legitimate sources while ensuring an adequate and uninterrupted supply for legitimate medical, commercial and scientific needs.

During this National Emergency the Diversion Control Division is working with our Federal partners including ASPR, FEMA, HHS, FDA, ONDCP, SAMSHA, and members of the White House Task Force; DEA registrants; and representatives of the medical and health-care

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DEA's COVID-19 Web Page

https://www.deadiversion.usdoj.gov/coronavirus.html.

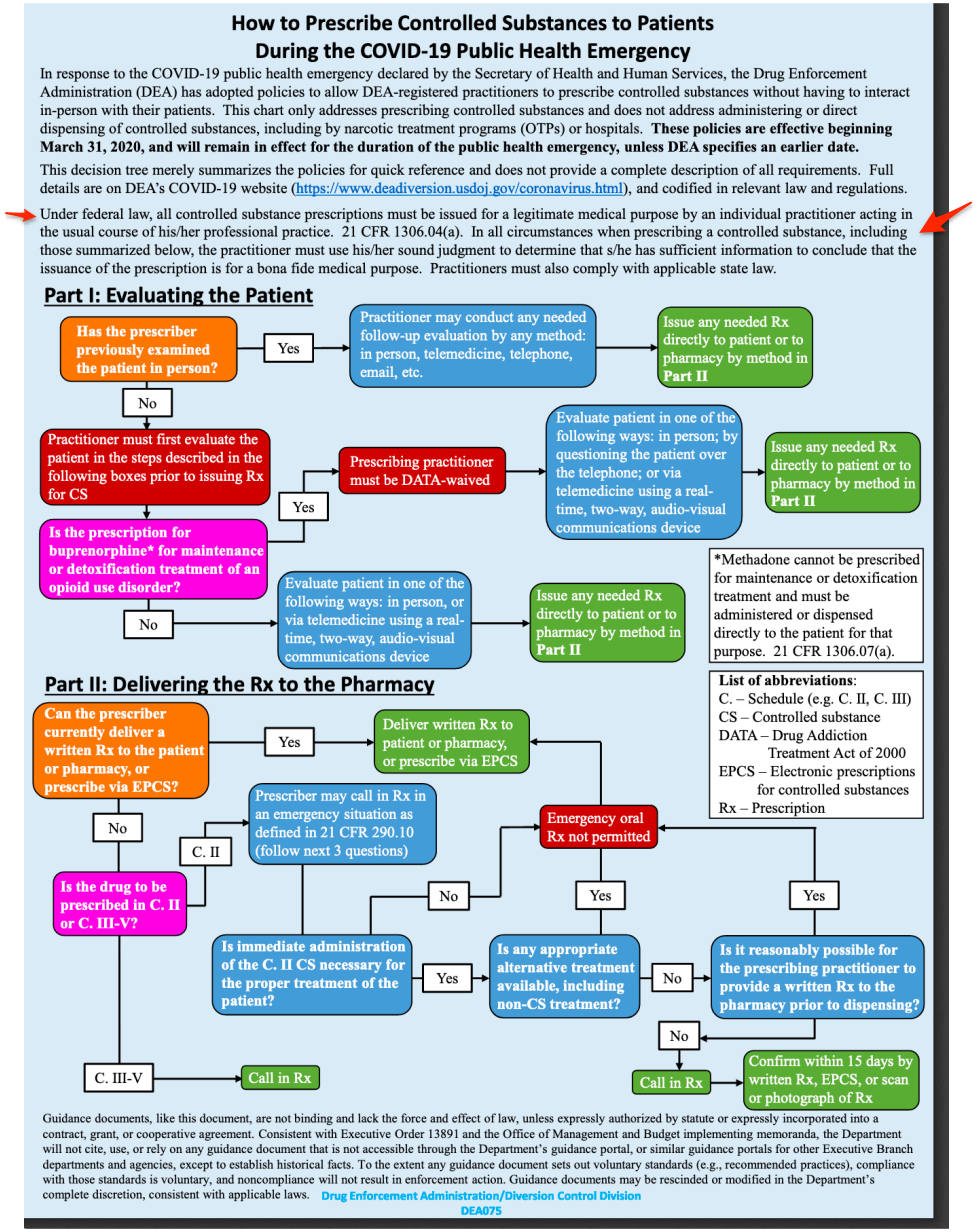
Questions and Answers

Administering

DEA's COVID-19 PRESCRIBING GUIDANCE

(Current as of August 11, 2020)

https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-023)(DEA075)Decision_Tree_(Final)_33120_2007.pdf



How to Prescribe Controlled Substances to Patients During the COVID-19 Public Health Emergency

In response to the COVID-19 public health emergency declared by the Secretary of Health and Human Services, the Drug Enforcement Administration (DEA) has adopted policies to allow DEA-registered practitioners to prescribe controlled substances without having to interact in-person with their patients. This chart only addresses prescribing controlled substances and does not address administering or direct dispensing of controlled substances, including by narcotic treatment programs (OTPs) or hospitals. **These policies are effective beginning March 31, 2020, and will remain in effect for the duration of the public health emergency, unless DEA specifies an earlier date.**

This decision tree merely summarizes the policies for quick reference and does not provide a complete description of all requirements. Full details are on DEA's COVID-19 website (https://www.deadiversion.usdoj.gov/coronavirus.html), and codified in relevant law and regulations.

Under federal law, all controlled substance prescriptions must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his/her professional practice. 21 CFR 1306.04(a). In all circumstances when prescribing a controlled substance, including those summarized below, the practitioner must use his/her sound judgment to determine that s/he has sufficient information to conclude that the issuance of the prescription is for a bona fide medical purpose. Practitioners must also comply with applicable state law.

Part I: Evaluating the Patient

- Has the prescriber previously examined the patient in person?
  - Yes → Practitioner may conduct any needed follow-up evaluation by any method: in person, telemedicine, telephone, email, etc. → Issue any needed Rx directly to patient or to pharmacy by method in **Part II**
  - No → Practitioner must first evaluate the patient in the steps described in the following boxes prior to issuing Rx for CS
- Is the prescription for buprenorphine* for maintenance or detoxification treatment of an opioid use disorder?
  - Yes → Prescribing practitioner must be DATA-waived → Evaluate patient in one of the following ways: in person; by questioning the patient over the telephone; or via telemedicine using a real-time, two-way, audio-visual communications device → Issue any needed Rx directly to patient or to pharmacy by method in **Part II**
  - No → Evaluate patient in one of the following ways: in person, or via telemedicine using a real-time, two-way, audio-visual communications device → Issue any needed Rx directly to patient or to pharmacy by method in **Part II**

*Methadone cannot be prescribed for maintenance or detoxification treatment and must be administered or dispensed directly to the patient for that purpose. 21 CFR 1306.07(a).

Part II: Delivering the Rx to the Pharmacy

- Can the prescriber currently deliver a written Rx to the patient or pharmacy, or prescribe via EPCS?
  - Yes → Deliver written Rx to patient or pharmacy, or prescribe via EPCS
  - No → Is the drug to be prescribed in C. II or C. III-V?
    - C. II → Prescriber may call in Rx in an emergency situation as defined in 21 CFR 290.10 (follow next 3 questions)
      - Is immediate administration of the C. II CS necessary for the proper treatment of the patient?
        - Yes → Is any appropriate alternative treatment available, including non-CS treatment?
          - Yes → Emergency oral Rx not permitted
          - No → Is it reasonably possible for the prescribing practitioner to provide a written Rx to the pharmacy prior to dispensing?
            - Yes → Emergency oral Rx not permitted
            - No → Call in Rx → Confirm within 15 days by written Rx, EPCS, or scan or photograph of Rx
        - No → Emergency oral Rx not permitted
    - C. III-V → Call in Rx

List of abbreviations:
C. – Schedule (e.g. C. II, C. III)
CS – Controlled substance
DATA – Drug Addiction Treatment Act of 2000
EPCS – Electronic prescriptions for controlled substances
Rx – Prescription

Guidance documents, like this document, are not binding and lack the force and effect of law, unless expressly authorized by statute or expressly incorporated into a contract, grant, or cooperative agreement. Consistent with Executive Order 13891 and the Office of Management and Budget implementing memoranda, the Department will not cite, use, or rely on any guidance document that is not accessible through the Department's guidance portal, or similar guidance portals for other Executive Branch departments and agencies, except to establish historical facts. To the extent any guidance document sets out voluntary standards (e.g., recommended practices), compliance with those standards is voluntary, and noncompliance will not result in enforcement action. Guidance documents may be rescinded or modified in the Department's complete discretion, consistent with applicable laws. Drug Enforcement Administration/Diversion Control Division DEA075

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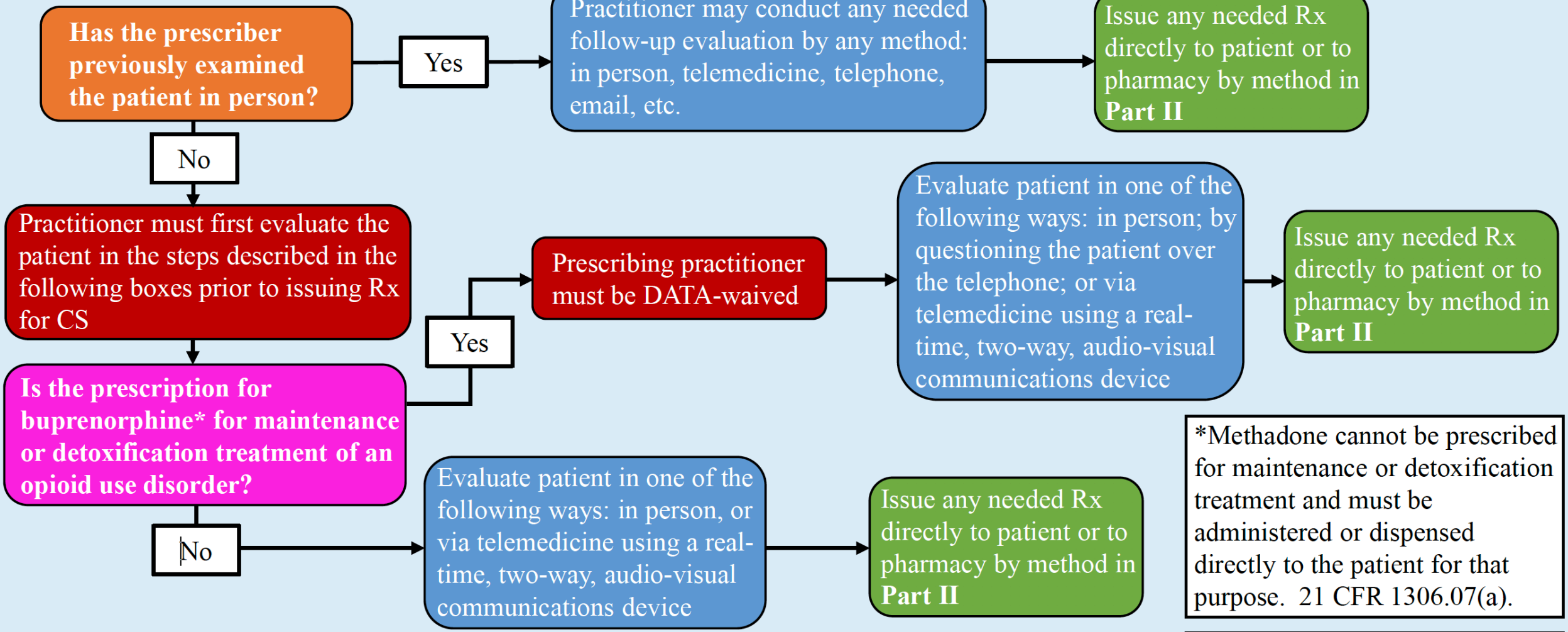
https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-023)(DEA075)Decision_Tree_(Final)_33120_2007.pdf

Part I: Evaluating the Patient



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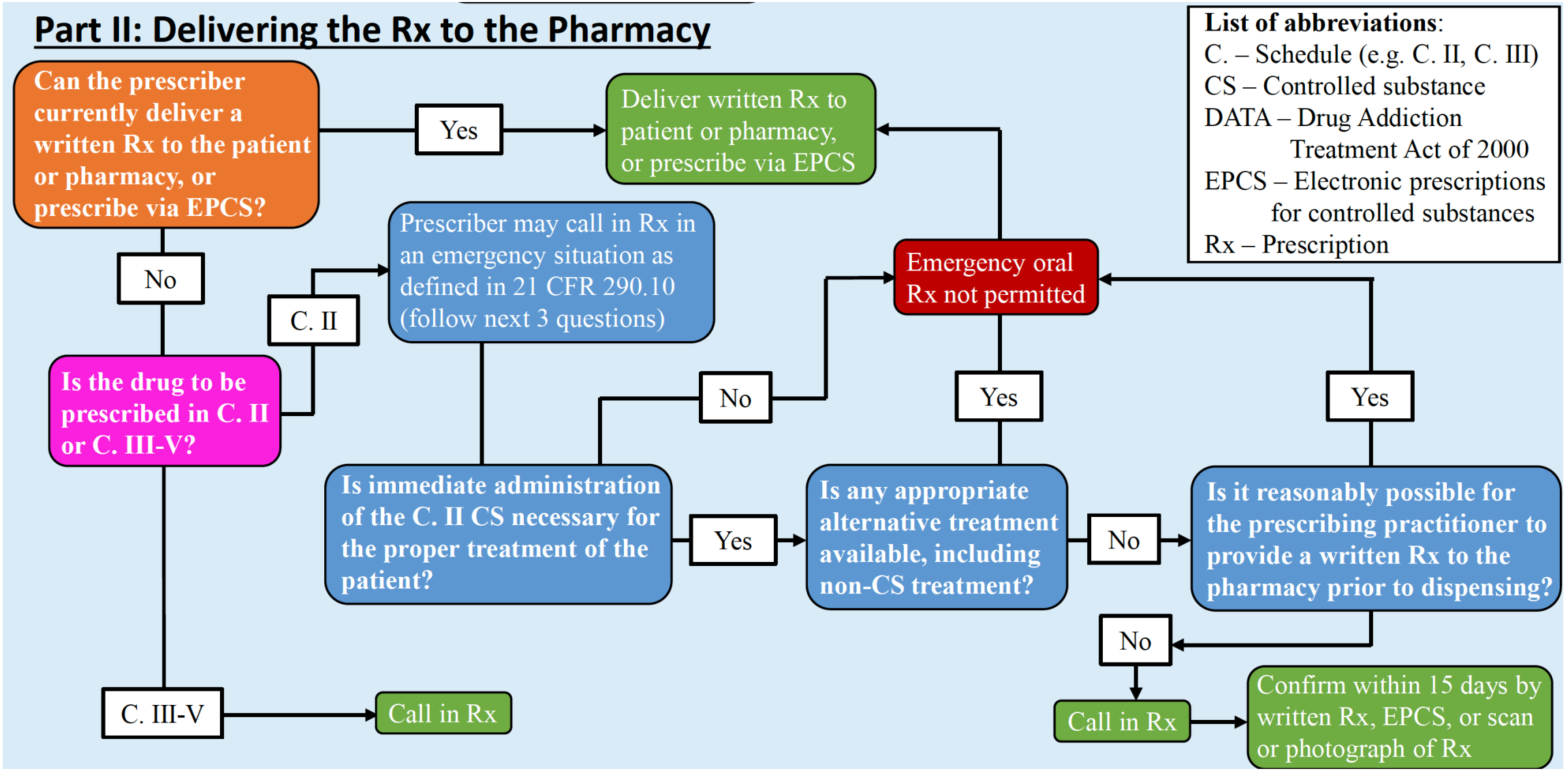


https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-023)(DEA075)Decision_Tree_(Final)_33120_2007.pdf

DEA's COVID-19 TELEHEALTH GUIDANCE

Telemedicine

DEA Policy: **Use of Telephone Evaluations to Initiate Buprenorphine Prescribing** (Effective March 31, 2020)

On January 31, 2020, the Secretary of the Department of Health and Human Services issues a public health emergency (**HHS Public Health Emergency Declaration**).

Question: Can telemedicine now be used under the conditions outlined in Title 21, United States Code (U.S.C.), **Section 802(54)(D)**?

Answer: Yes. While a prescription for a controlled substance issued by means of the Internet (including telemedicine) must generally be predicated on an in-person medical evaluation (**21 U.S.C. 829(e)**), the Controlled Substances Act contains certain exceptions to this requirement. One such exception occurs when the Secretary of Health and Human Services has declared a public health emergency under 42 U.S.C. 247d (section 319 of the Public Health Service Act), as set forth in 21 U.S.C. 802(54)(D). Secretary Azar declared such a public health emergency with regard to COVID-19 on January 31, 2020 (**https://www.hhs.gov/about/news/2020/01/31/secretary-azar-declares-public-health-emergency-us-2019-novel-coronavirus.html**). On March 16, 2020, the Secretary, with the concurrence of the Acting DEA Administrator, designated that the telemedicine allowance under section 802(54)(D) applies to all schedule II-V controlled substances in all areas of the United States. Accordingly, as of March 16, 2020, and continuing for as long as the Secretary's designation of a public health emergency remains in effect, DEA-registered practitioners in all areas of the United States may issue prescriptions for all schedule II-V controlled substances to patients for whom they have not conducted an in-person medical evaluation, provided all of the following conditions are met:

- The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice;
- The telemedicine communication is conducted using an audio-visual, real-time, two-way interactive communication system; and
- The practitioner is acting in accordance with applicable Federal and State laws.

Provided the practitioner satisfies the above requirements, the practitioner may issue the prescription using any of the methods of prescribing currently available and in the manner set forth in the DEA regulations. Thus, the practitioner may issue a prescription either electronically (for schedules II-V) or by calling in an emergency schedule II prescription to the pharmacy, or by calling in a schedule III-V prescription to the pharmacy.

The term "practitioner" in this context includes a physician, dentist, veterinarian, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which s/he practices to prescribe controlled substances in the course of his/her professional practice (**21 U.S.C. 802(21)**).

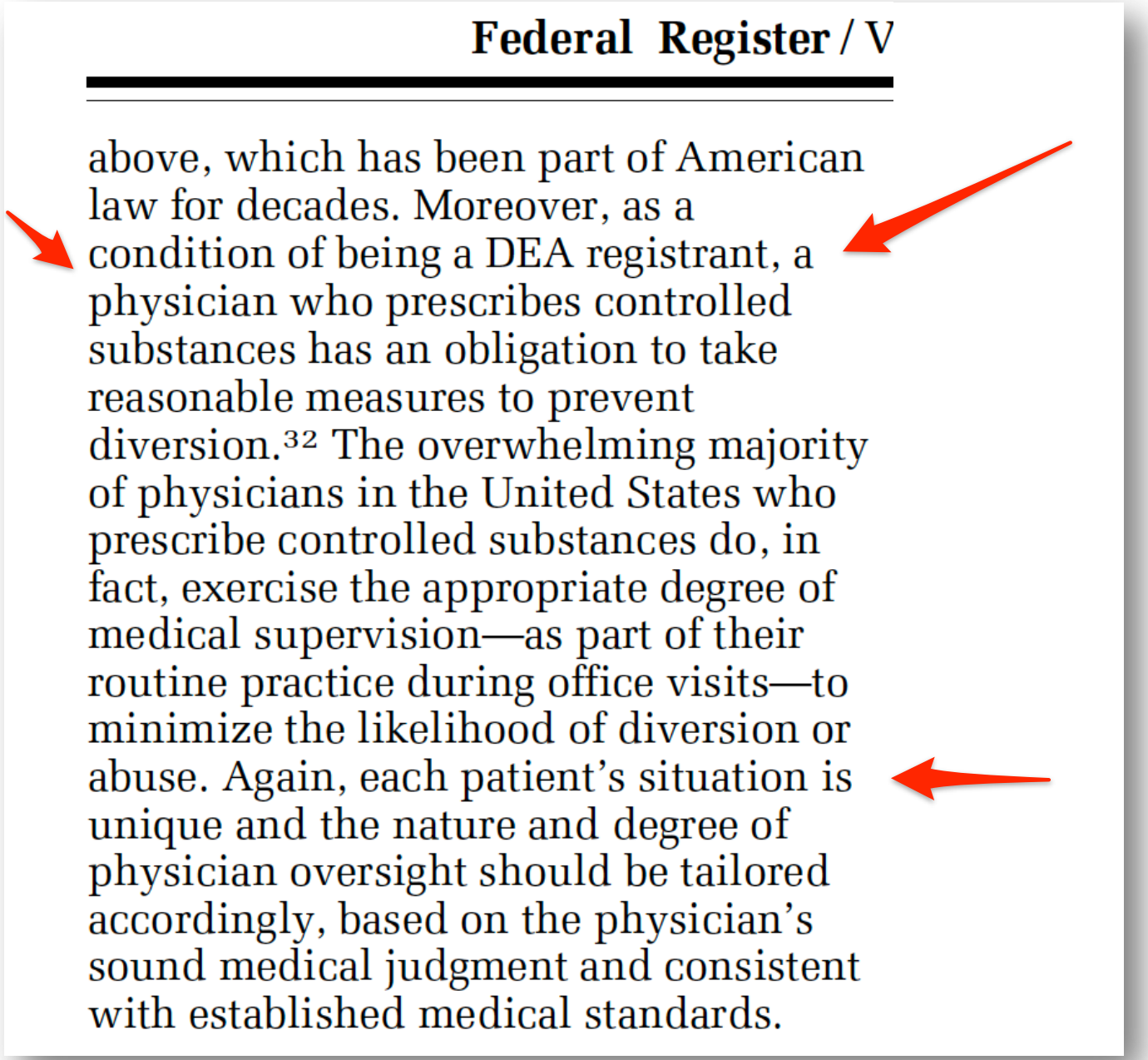
Important note: If the prescribing practitioner has previously conducted an in-person medical evaluation of the patient, the practitioner may issue a prescription for a controlled substance after having communicated with the patient via telemedicine, or any other means, regardless of whether a public health emergency has been declared by the Secretary of Health and Human Services, so long as the prescription is issued for a legitimate medical purpose and the practitioner is acting in the usual course of his/her professional practice. In addition, for the prescription to be valid, the practitioner must comply with applicable Federal and State laws.

- https://www.deadiversion.usdoj.gov/coronavirus.html Scroll down the page to telemedicine

DEA Final Policy Statement on Obligation to "Take Reasonable Steps to Prevent Abuse and Diversion"

- Published on 9/6/2006

- Federal Register link: https://www.govinfo.gov/content/pkg/FR-2006-09-06/pdf/FR-2006-09-06.pdf, accessed on 8/10/2020 (Go to page 52716-52723.



Federal Register / V

above, which has been part of American law for decades. Moreover, as a condition of being a DEA registrant, a physician who prescribes controlled substances has an obligation to take reasonable measures to prevent diversion.[32] The overwhelming majority of physicians in the United States who prescribe controlled substances do, in fact, exercise the appropriate degree of medical supervision—as part of their routine practice during office visits—to minimize the likelihood of diversion or abuse. Again, each patient's situation is unique and the nature and degree of physician oversight should be tailored accordingly, based on the physician's sound medical judgment and consistent with established medical standards.

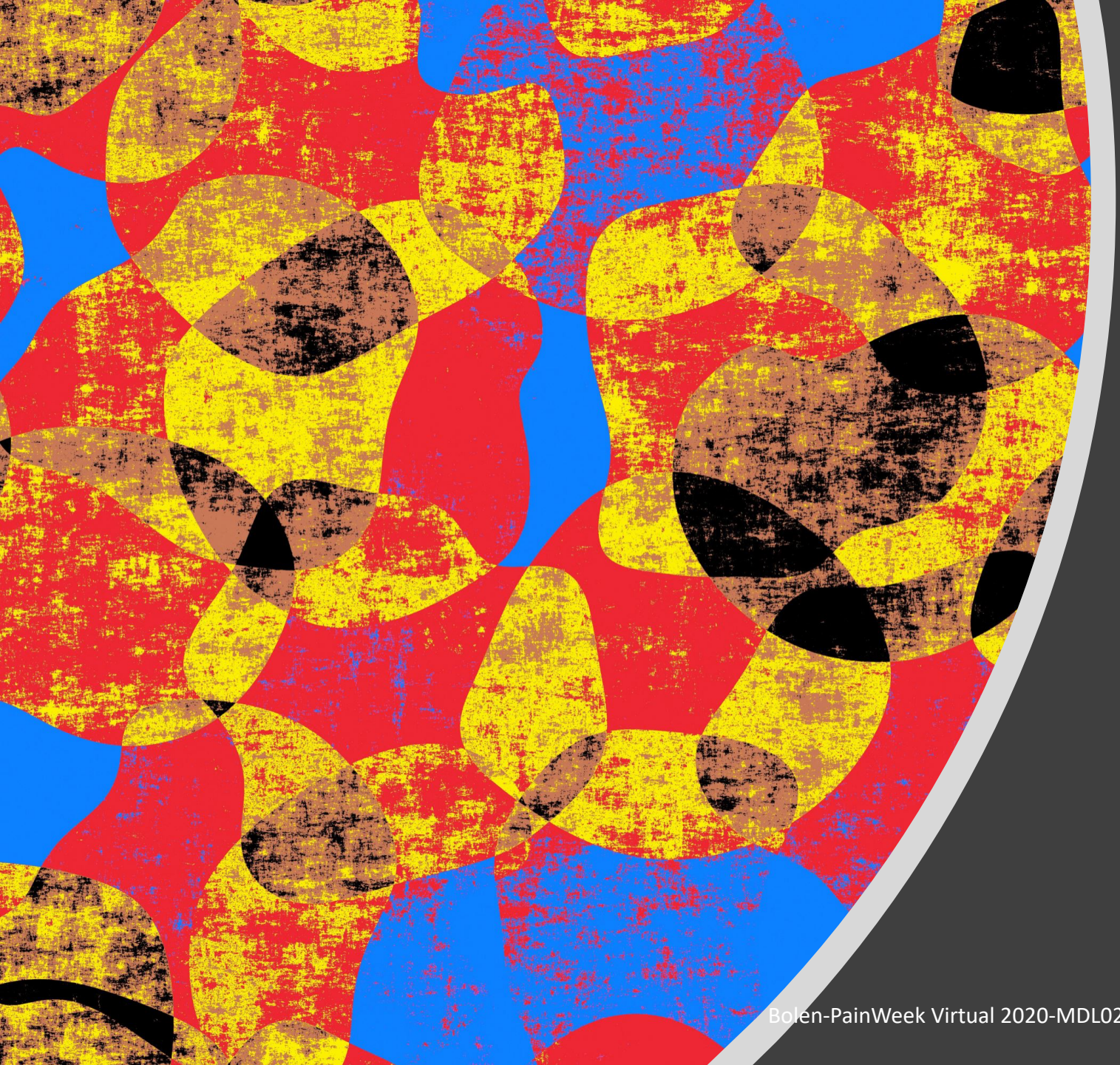
DEA Final Policy Statement

- Published on 9/6/2006

- Federal Register link: https://www.govinfo.gov/content/pkg/FR-2006-09-06/pdf/FR-2006-09-06.pdf, accessed on /10/2020, go to page 52716-52723.

What additional precaution should be taken when a patient has a history of drug abuse?

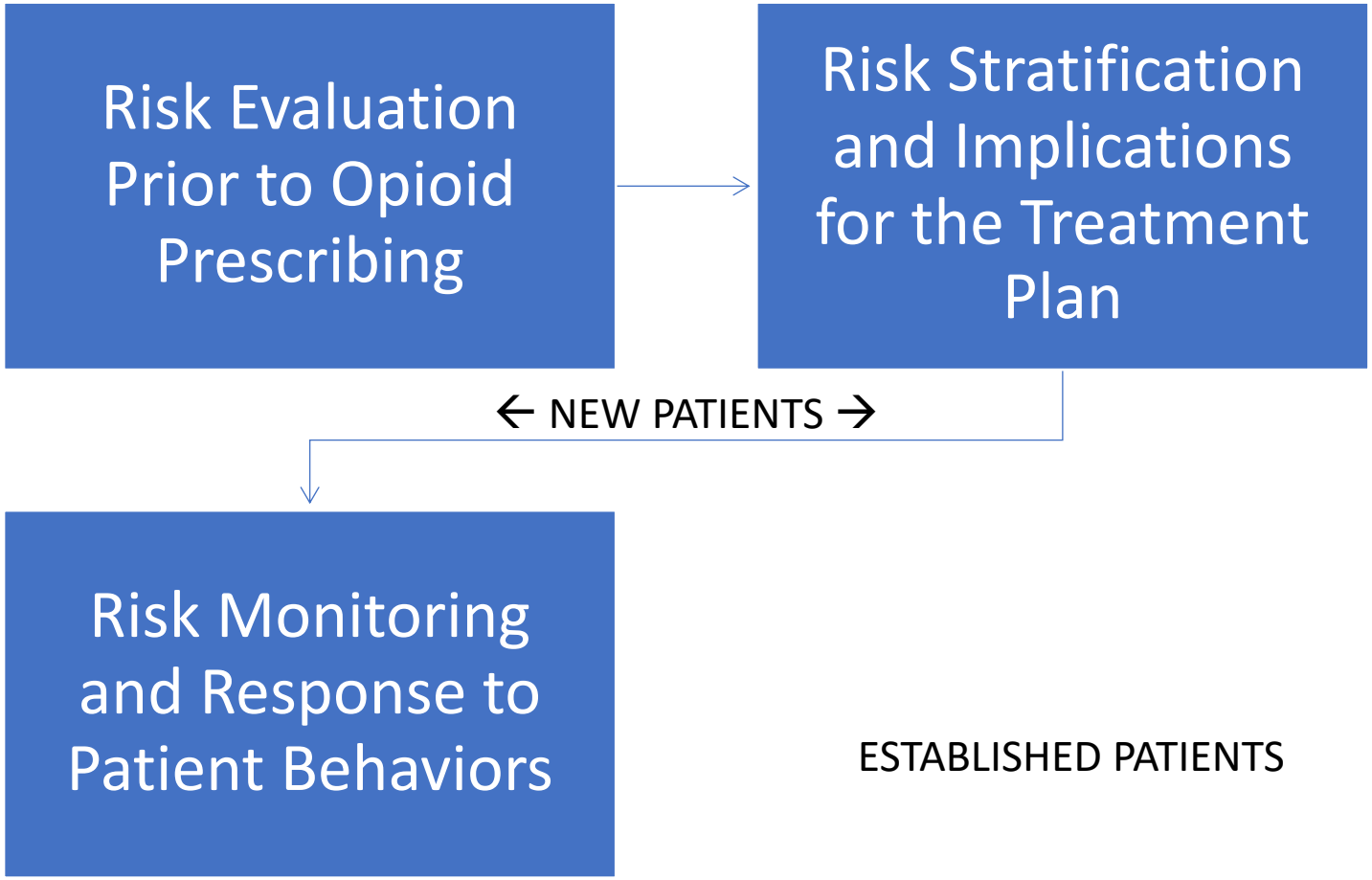
As a DEA registrant, a physician has a responsibility to exercise a much greater degree of oversight to prevent diversion and abuse in the case of a known or suspected addict than in the case of a patient for whom there are no indicators of drug abuse. Under no circumstances may a physician dispense controlled substances with the knowledge they will be used for a nonmedical purpose or that they will be resold by the patient. Some physicians who treat patients having a history of drug abuse require each patient to sign a contract agreeing to certain terms designed to prevent diversion and abuse, such as periodic urinalysis. While such measures are not mandated by the CSA or DEA regulations, they can be very useful.



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

Objective 2

Risk Mitigation in Phases – Begin at the first encounter and continue throughout the practitioner-patient relationship



New Hampshire Medical Board's 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 https://www.oplc.nh.gov/medicine/documents/med502-adopted.pdf. Accessed 8/24/20.

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;

Example Licensing Board Requirement on Risk Evaluation

Checklist for the Prescribing of Opioids for the Management or Treatment of Pain

Excludes cancer and terminal pain and does not apply to the supervised administration of opioids in a health care setting.

_____

Patient name & date

For ALL Pain (Acute and Chronic)

- ☐ Documented history and physical
- ☐ Complete Board approved risk assessment tool to determine patient appropriateness for opioids
- ☐ Treatment Plan that includes consideration of nonpharmacological modalities and non-opioid options for pain
- ☐ Lowest effective dose for fewest number of days
- ☐ Informed Consent outlining risks and benefits of opioid use
- ☐ Query the NH PDMP* (Prescription Drug Monitoring Program) Initial script: _____ (date)
  Prescriber may want to print the PDMP query results/screen shot for the medical record

*Exceptions for PDMP use: Controlled Rx *administered* to patient; PDMP inaccessible due to electronic issue; or ED with high patient volume such that querying the PDMP would create a delay in care.

- New Hampshire Medical Board – Required evaluation and list of board-approved risk assessment tools, available online at https://www.oplc.nh.gov/medicine/opioid-prescribing.htm.

Chronic Pain

- ☐ Written Treatment Agreement **
- ☐ Consideration of pain consultation for patients receiving 100mg morphine equivalent daily dose > 90 days
- ☐ Reevaluate Treatment Plan and use of opioids at least twice per year: _____ (date) _____ (date)
- ☐ Re-check PDMP, at least twice per year: _____ (date) _____ (date)
- ☐ Urine Drug Screens ** at least annually for patients taking opioids > 90 days: _____ (date) _____ (date)

** Not required for patients in long-term, non-rehab facility when opioid is administered **or** for patients with episodic intermittent pain receiving no more than 50 dose units in a 3 month period.

NH RSA 318-B:41 Rulemaking for Prescribing Controlled Drugs

Example Licensing Board Requirement on Risk Evaluation

- New Hampshire Medical Board – Required evaluation and list of board-approved risk assessment tools, available online at https://www.oplc.nh.gov/medicine/opioid-prescribing.htm.

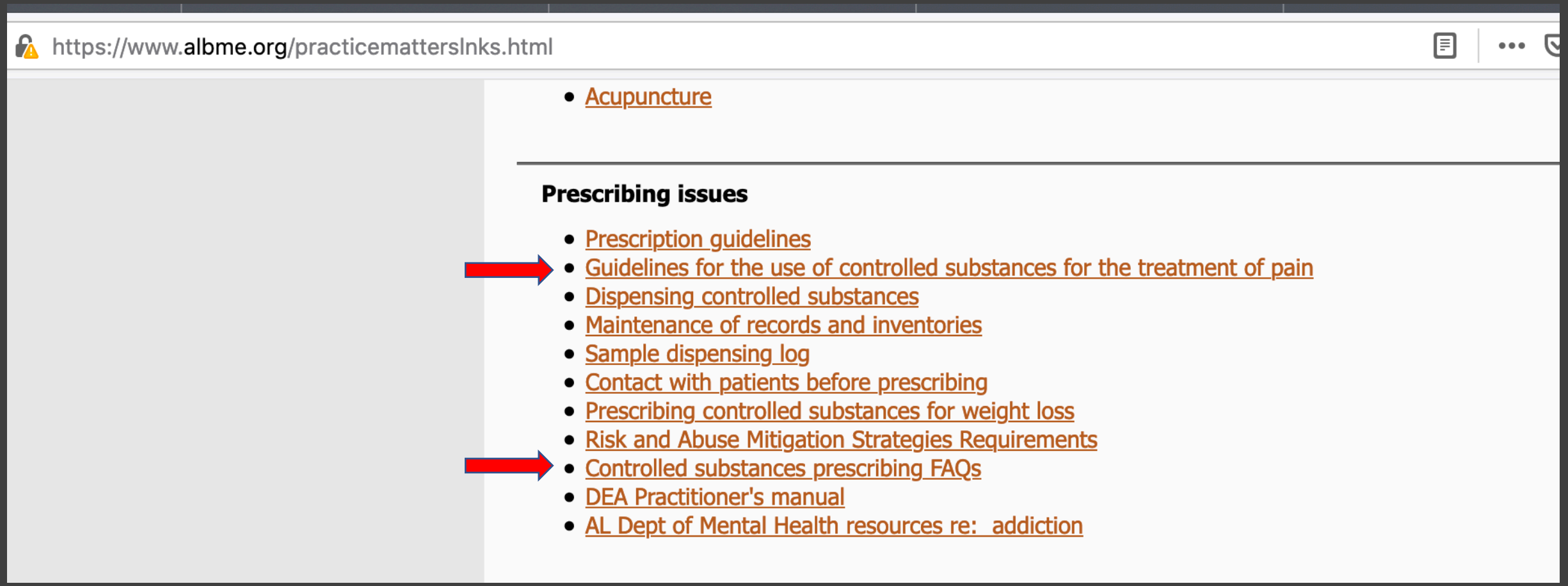
(l) Require random and periodic urine drug testing at least annually for all patients using opioids for longer than 90 days. Unanticipated findings shall be addressed in a manner that supports the health of the patient;

(m) Have clinical coverage available for 24 hours per day, 7 days per week, to assist in the management of patients; and

New Hampshire Medical Board and UDT/Use of Test Results; Coverage to Manage Patients

SOURCE: New Hampshire Medical Board Rules, Rule 502, Opioid Prescribing, Effective 5/3/16, available online at https://www.oplc.nh.gov/medicine/documents/med502-adopted.pdf. Accessed 8/24/20.

Alabama Medical Board's Risk Evaluation & Monitoring Requirements

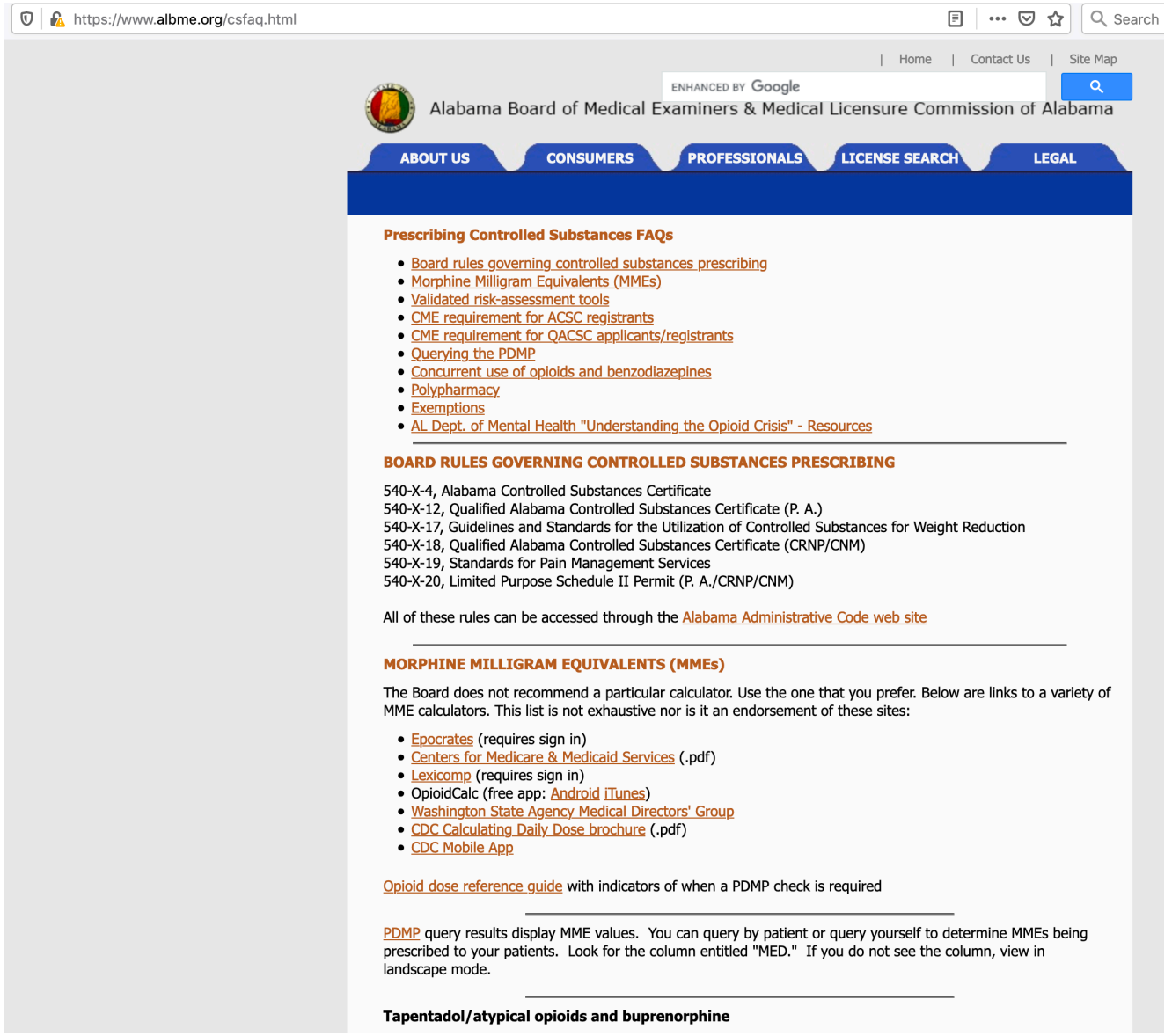


Alabama Medical Board's Material on Prescribing Controlled Medication

- SOURCE: https://www.albme.org (Select tab for professionals and scroll down to "Prescribing Issues")

Alabama Medical Board's Prescribing FAQs and Related Documents

- SOURCE: https://www.albme.org/csfaq.html .



https://www.albme.org/csfaq.html

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Prescribing Controlled Substances FAQs

- Board rules governing controlled substances prescribing
- Morphine Milligram Equivalents (MMEs)
- Validated risk-assessment tools
- CME requirement for ACSC registrants
- CME requirement for QACSC applicants/registrants
- Querying the PDMP
- Concurrent use of opioids and benzodiazepines
- Polypharmacy
- Exemptions
- AL Dept. of Mental Health "Understanding the Opioid Crisis" - Resources

BOARD RULES GOVERNING CONTROLLED SUBSTANCES PRESCRIBING

540-X-4, Alabama Controlled Substances Certificate
540-X-12, Qualified Alabama Controlled Substances Certificate (P. A.)
540-X-17, Guidelines and Standards for the Utilization of Controlled Substances for Weight Reduction
540-X-18, Qualified Alabama Controlled Substances Certificate (CRNP/CNM)
540-X-19, Standards for Pain Management Services
540-X-20, Limited Purpose Schedule II Permit (P. A./CRNP/CNM)

All of these rules can be accessed through the Alabama Administrative Code web site

MORPHINE MILLIGRAM EQUIVALENTS (MMEs)

The Board does not recommend a particular calculator. Use the one that you prefer. Below are links to a variety of MME calculators. This list is not exhaustive nor is it an endorsement of these sites:

- Epocrates (requires sign in)
- Centers for Medicare & Medicaid Services (.pdf)
- Lexicomp (requires sign in)
- OpioidCalc (free app: Android iTunes)
- Washington State Agency Medical Directors' Group
- CDC Calculating Daily Dose brochure (.pdf)
- CDC Mobile App

Opioid dose reference guide with indicators of when a PDMP check is required

PDMP query results display MME values. You can query by patient or query yourself to determine MMEs being prescribed to your patients. Look for the column entitled "MED." If you do not see the column, view in landscape mode.

Tapentadol/atypical opioids and buprenorphine

The use of validated risk assessment tools as a part of your risk and abuse mitigation strategies is a **suggestion** by the Board for best practices. Their use will vary from patient to patient. For some practices, their use may not be appropriate at all.

Not using the validated risk assessment tools is not a violation of the rule; however, failure to incorporate any risk and abuse mitigation strategies could be used to determine a practice pattern and whether it is within the recognized standard of care.

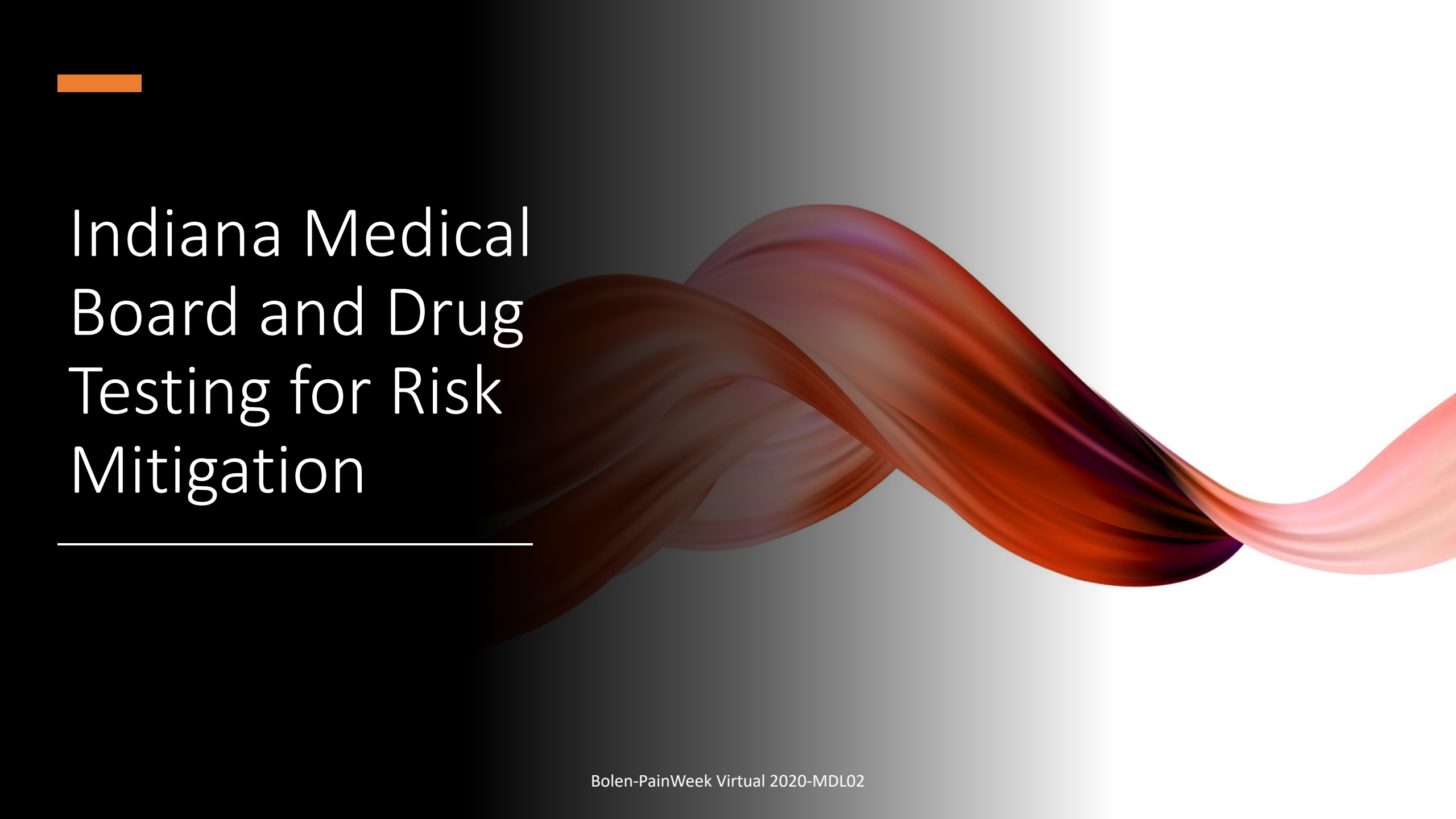
The following are examples of validates risk-assessment tools. This is not an exhaustive list. There may be other validated risk-assessment tools that you prefer.

- BRI - Brief Risk Interview
- DIRE - Diagnosis, Intractability, Risk, Efficacy score
- ORT - Opioid Risk Tool
- PMQ - Pain Medication Questionnaire
- SOAPP - Screener and Opioid Assessment for Patients with Pain
- SOAPP-R - Screener and Opioid Assessment for Patients with Pain - Revised

Alabama Medical Board's Position on Risk Evaluation and Monitoring (Prescribing Standards)

- SOURCE: https://www.albme.org/csfaq.html.

Indiana Medical Board and Drug Testing for Risk Mitigation



Indiana Medical Board on Using UDT in Risk Mitigation

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

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

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

Drug Monitoring Tests (Effective Jan. 1, 2015)

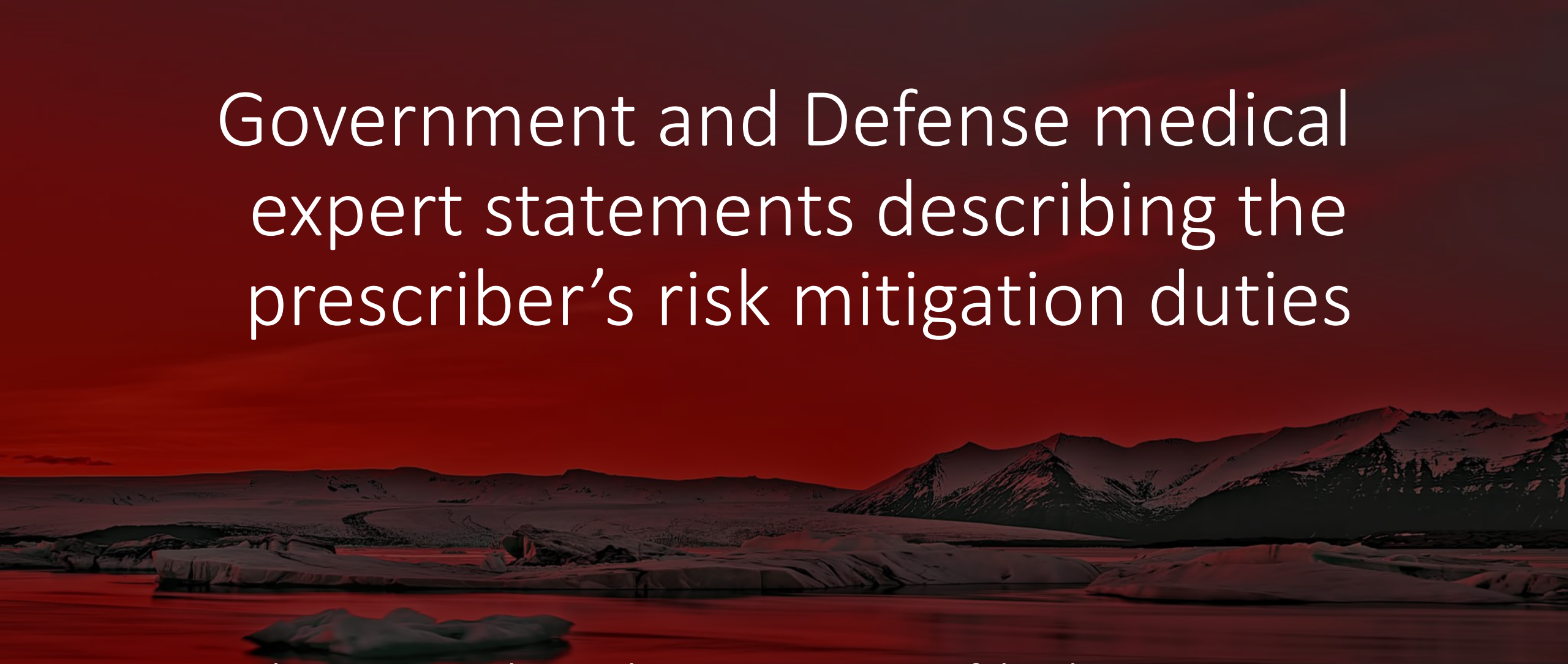
*At any time the physician determines that it is medically necessary, whether at the outset of the treatment plan, or any time thereafter, a prescribing physician shall perform or order a drug monitoring test that must include a confirmatory test using a method selective enough to differentiate individual drugs within a drug class.

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

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

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

Government and Defense medical expert statements describing the prescriber's risk mitigation duties



Objective 3 - Making Risk Mitigation Meaningful and Demonstrating Conduct within the Usual Course of Professional Practice

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

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

In addition to providing expert opinion testimony related to the patient file reviews, Greenberg, Vohra, and Aultman may present testimony on the following general topics base their specialized education, training, and experience:

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

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

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

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

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

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

2

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

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

Risk Mitigation: Balancing Risks and Benefits

GOVERNMENT MEDICAL EXPERT IN US v. STEPHEN SCHNEIDER; District of Kansas; Convicted in 2010.

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

- Trial Testimony of Graves Owen, MD (for the Government) in *US v. Schneider*, 6:07-CR-10234, Doc. 623, Filed 4/4/11 (Convicted in 2010).

Q Now, Dr. Owen, in the treatment of chronic p
there a balance or a weighing that needs to be c
regarding risk and the benefit?
A Yes, there is.
Q Could you explain to the jury what the balar
that a physician treating chronic pain needs to
with regards to such treatment?
A Well, the balance is one of public safety ve
individual needs. If the individual is not impr
therapeutically, making functional improvements,
continuing to prescribe controlled substance is
safety issue.
Q Is it also a risk to that patient's life?
A Yes, it is.

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

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

Defendant?
A Previous medical records were often not obtained that could have been valuable such as history of addiction or unstable mental health conditions. Poorly done physical exams and original histories. Inadequate diagnostic testing. Not referring to psychotherapy or psychiatry, addictionology, physical -- lack of any referrals. And ever escalating doses of opioids with multiple early refills.
Q What did the medical charts reveal to you in general about how the physical examinations and medical histories were being conducted?
A They appeared to be very rushed, poorly documented and partially illegible.
Q What, if any, patterns did you see in the medical records that you reviewed regarding how the treatment over the course of time was documented?
A There was a tendency to just increase pain medications and add other controlled substances like benzodiazepines.

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

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

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

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

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

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

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

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

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

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

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

Q Now, you mentioned something called aberrant behaviors. What's an aberrant behavior?
A An aberrant behavior is when something occurs that was not authorized or is unexpected.
Q And what are some examples of that?
A Increasing your medication without consent from the physician; a urine drug screen that has illegal drugs in it, or has prescribed drugs that shouldn't be there because you don't prescribe them; or the urine drug screen that does not contain the drug you are prescribing.
Q How about early refills, is that an aberrant behavior at times?
A Yes. Because it's one of the few warning signs that somebody is losing control of their drugs. Inability to self-regulate is one of the only clinically detectable signs we have to detect addiction as it's starting.
Q Now, did you see those patterns documented in the medical records you reviewed?
A Yes.
Q And what patterns did you see with regards to taking corrective action based on those aberrant behaviors?
A I never saw any corrective action taken.

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

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

Q Would these aberrant behaviors have put the clinic's providers on notice of anything?
A Yes.
Q And what?
A That she is developing addictive problems.
Q Did you find information that the clinic's providers reacted to these aberrant behaviors in any way?
A No.
Q Can you give us some examples of the aberrant behaviors of the clinic's -- in the clinic's records?
A Early refill request. Aberrant urine drug screens. Those kinds of items.
Q Did she indicate that she was drinking under age?
A I don't remember.
Q Let me hand you your report in the K--------- case and hopefully you can review that real quickly and refresh your recollection on that issue.
(Off-the-record.)
A Yes.
Q And in Lacey's situation when non-euphoric drugs were not effective, what did the clinic do in response to that?
A They gave very euphoric drugs.
Q Is that an appropriate response in your opinion?
A No.

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

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

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

Does it matter if you drug test for THC?

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

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

Does it matter if you perform toxicology tests?

Does it matter if you perform PDMP checks?

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

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

Does it matter if you monitor and address “red flags”?

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

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

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?

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

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

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

Risk Mitigation: 2010 Defense Position on Alcohol and Marijuana

DEFENSE MEDICAL EXPERT IN US v. SHAYGAN, SDFL, Defendant Acquitted in 2009.

A DEFENSE EXPERT'S PERSPECTIVE ON ALCOHOL & MARIJUANA

Carol Warfield, MD in *US v. Shaygan,* 1:08-CR-20112-ASK, Document 324, Warfield Testimony; Defendant was Acquitted in 2009.

09:20:52	1	screenings were positive for drugs that he didn't prescribe.
09:20:57	2	So, in my mind that absolutely shows not only
09:21:00	3	legitimate medical practice, but a true concern for patients
09:21:06	4	who might have become addicted or might have problems with
09:21:09	5	these drugs.
09:21:10	6	Q. Let's talk about that for a second. If a patient tests
09:21:15	7	positive for marijuana in a urine drug screen, should that be
09:21:20	8	an automatic dismissal?
09:21:22	9	A. Not necessarily. It depends on the patient, depends on --
09:21:26	10	you know, every physician has to make their mind up
09:21:29	11	individually. For example, you know, we have patients who we
09:21:32	12	know have a couple of glasses of wine at night and we prescribe
09:21:36	13	medications for them, pain medications. And if I did a toxic
09:21:41	14	screen on that patient and found alcohol, I might not
09:21:44	15	necessarily dismiss that patient.
09:21:46	16	There are physicians out there who feel that alcohol
09:21:48	17	is a more addictive drug than is marijuana and who don't feel
09:21:53	18	that that's a contraindication to prescribing these
09:21:57	19	medications.
09:21:58	20	I think what you need to understand also is that
09:22:00	21	patients who drink alcohol or maybe smoke marijuana
09:22:05	22	occasionally have legitimate pain, too, just like everybody
09:22:09	23	else does. It doesn't necessarily mean that a patient who had
09:22:13	24	had a problem in the past or even currently is using -- taking
09:22:18	25	a couple of glasses of wine at night doesn't have real pain and

A DEFENSE EXPERT'S GENERAL PERSPECTIVE ON ALCOHOL AND MARIJUANA

Carol Warfield, MD in US v. Shaygan (Acquitted)(2009)

10:11:17 14 Q. You've mentioned marijuana. Now, marijuana is an illegal
10:11:23 15 drug, correct?
10:11:25 16 A. Yes, yes.
10:11:26 17 Q. So when a patient tests positive for marijuana --
10:11:30 18 A. Yes.
10:11:30 19 Q. -- while you might not terminate that patient right that
10:11:34 20 second because they've broken the law, you would counsel him
10:11:40 21 that it's, one, against the law; and, two, that it's an illeg
10:11:46 22 medicine being combined with the powerful opioids that are
10:11:50 23 being prescribed, correct?
10:11:52 24 A. It's an interesting question. You know, in my practice,
10:11:54 25 probably would, but, as I said, I think there are physicians

TOTAL ACCESS NETWORK COURTROOM REALTIME TRANSCRIPTION
March 9, 2009

10:12:02 2 of combining it with medications than is alcohol. Is it
10:12:06 3 illegal? Is it an illegal drug? Yes. Would I tell the
10:12:09 4 patient to go out and get an illegal drug? No.
10:12:13 5 But would all pain physicians counsel the patient to
10:12:17 6 stop their opiates because they are also using marijuana? Not
10:12:21 7 necessarily. I mean, I must admit I have patients with cancer,
10:12:24 8 for example, who tell me that they smoke marijuana because it
10:12:27 9 helps them with X, Y and Z symptoms. I mean, do I tell them I
10:12:32 10 won't give them their opiates because of that? No, I still
10:12:37 11 give them their opiates. It depends on the situation, and it
10:12:40 12 depends on the pain physician. I mean, some feel very strongly
10:12:42 13 about that.
10:12:42 14 Q. You would, though, counsel a patient. You wouldn't,
10:12:45 15 though, would you, counsel a patient -- let me rephrase that
10:12:48 16 question since I did it both ways.
10:12:50 17 You wouldn't tell a patient who comes in with their
10:12:53 18 marijuana usage that they should stop using it so their urine

NOTE: TODAY'S EXPERT WITNESS POSITIONS ON ALCOHOL AND MARIJUANA MAY BE DIFFERENT

- 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.*

Licensing Board Example on Medical Record Documentation Guideline

NORTH CAROLINA

NORTH CAROLINA MEDICAL BOARD POSITION STATEMENTS

- Medical Record Documentation

- Illustration of tie to Risk Mitigation in Pain Management; NOTE: Caution about EMR pre-populating certain fields without updating information to reflect the medical record charting requirement of the board.

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

Medical record documentation

The North Carolina Medical Board takes the position that an accurate, current and complete medical record is an essential component of patient care. Licensees should maintain a medical record for each patient to whom they provide care. The medical record should contain an appropriate history and physical examination, results of ancillary studies, diagnoses, and any plan for treatment. The medical record should be legible. When the care giver does not handwrite legibly, notes should be dictated, transcribed, reviewed, and signed within a reasonable time. The Board recognizes and encourages the trend towards the use of electronic medical records ("EMR"). However, the Board cautions against relying upon software that pre-populates particular fields in the EMR without updating those fields in order to create a medical record that accurately reflects the elements delineated in this Position Statement.

The medical record is a chronological document that:

- records pertinent facts about an individual's health and wellness;
- enables the treating care provider to plan and evaluate treatments or interventions;
- enhances communication between professionals, assuring the patient optimum continuity of care;
- assists both patient and physician to communicate to third party participants;
- allows the physician to develop an ongoing quality assurance program;
- provides a legal document to verify the delivery of care; and
- is available as a source of clinical data for research and education.

The following required elements should be present in all medical records:

1. The record reflects the purpose of each patient encounter and appropriate information about the patient's history and examination, and the care and treatment provided are described.
2. The patient's past medical history is easily identified and includes serious accidents, operations, significant illnesses and other appropriate information.
3. Medication and other significant allergies, or a statement of their absence, are prominently noted in the record.
4. When appropriate, informed consent obtained from the patient is clearly documented.
5. All entries are dated.

The following additional elements reflect commonly accepted standards for medical record documentation.

1. Each page in the medical record contains the patient's name or ID number.
2. Personal biographical information such as home address, employer, marital status, and all telephone numbers, including home, work, and mobile phone numbers.
3. All entries in the medical record contain the author's identification. Author identification may be a handwritten signature, initials, or a unique electronic identifier.
4. All drug therapies are listed, including dosage instructions and, when appropriate, indication of refill limits. Prescriptions refilled by phone should be recorded.
5. Encounter notes should include appropriate arrangements and specified times for follow-up care.
6. All consultation, laboratory and imaging reports should be entered into the patient's record, reviewed, and the review documented by the practitioner who ordered them. Abnormal reports should be noted in the record, along with corresponding follow-up plans and actions taken.
7. An appropriate immunization record is evident and kept up to date.
8. Appropriate preventive screening and services are offered in accordance with the accepted practice guidelines.

(Adopted May 1994) (Amended May 1996, May 2009)(Reviewed May 2013)

NORTH CAROLINA MEDICAL BOARD POSITION STATEMENTS

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

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

Suspicious history:

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

Suspicious physical exam:

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

Equivocal compliance:

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

No or equivocal clinical improvement:

- Subjective improvement alone does not count
- Lack of evidence of objective improvement in physical, functional and psychosocial activities,
- Lack of evidence of decreasing use of opioid medications, decreasing visits to emergency rooms, etc.

What you should do when the clinician suspects misuse, abuse or addiction:

- Request picture I.D. or other I.D. and a Social Security number. Photocopy these documents and include in the patient's record.
- Call a previous practitioner, pharmacist or hospital to confirm the patient's story.
- Confirm a telephone number, if provided by the patient.
- Confirm the current address at each visit.
- Investigate suspicions further by presenting and discussing specific concerns with the patient, re-checking NCCSRS information, increase the use of drug screens, talk with family members

NORTH CAROLINA MEDICAL BOARD POSITION STATEMENTS

- Pain Management and Risk Mitigation: Recommendations for Primary Care

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

Recommendations For Primary Care

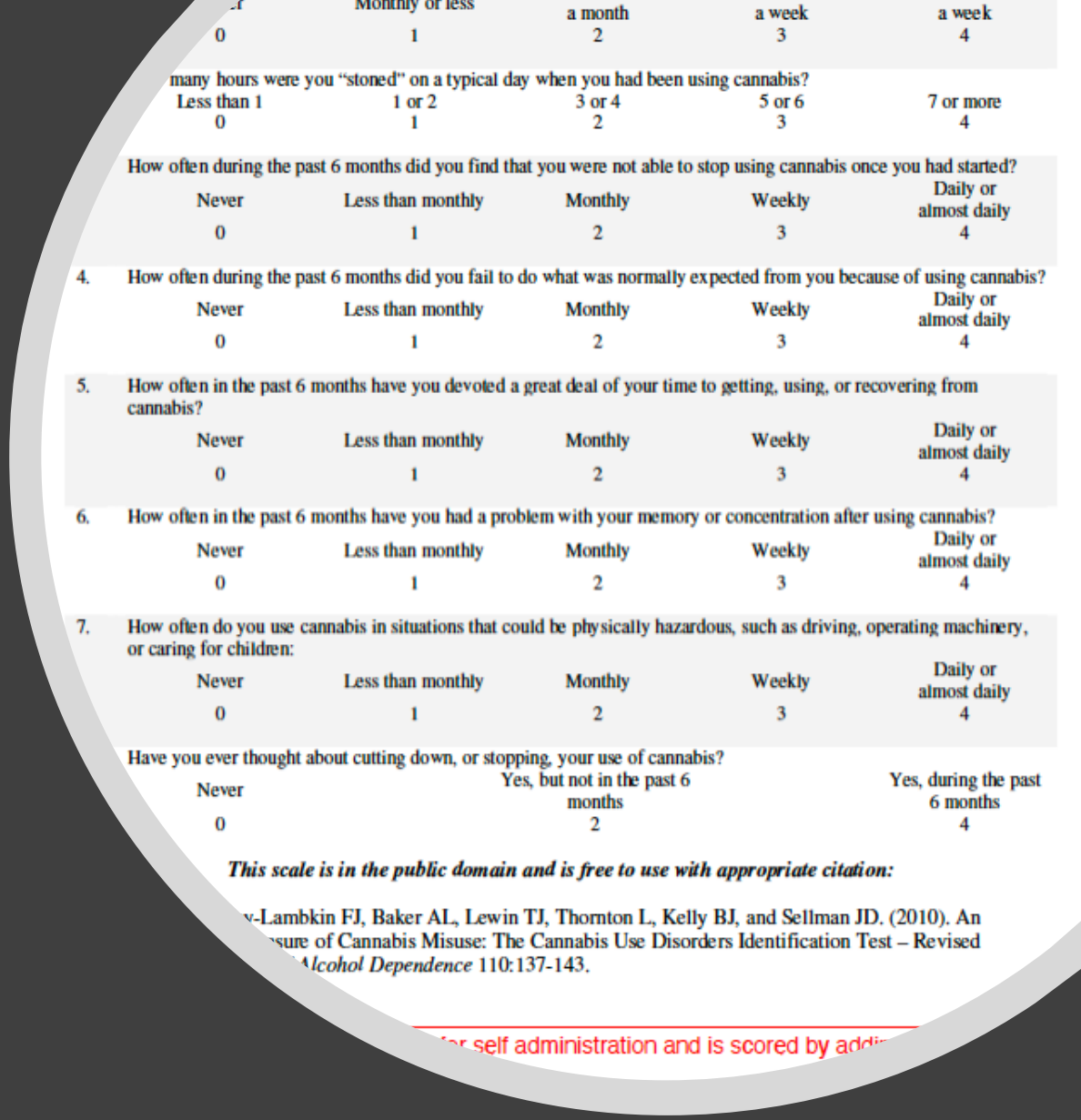
- Develop an office policy for opioid prescribing and have this clearly posted and available for patients.
- Perform a thorough history and physical at the onset.
- Acute pain patients should be frequently evaluated for physical, functional and psychosocial improvement, adjustments to treatment as needed. It is almost always contraindicated to include refills on opioid prescrip for acute pain.
- Educate your patients about pain and analgesia. Explain the underlying diagnosis causing the pain, the na history of the condition, and how your patient can help the healing process.
- If medically possible, exhaust non-opioid medications and collaborate with other professionals, including phy 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 appropriat 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 or their breathing and even lead to death; fractures from falls, especially in patients aged 60 years and c 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 interventions 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.

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]

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

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/.



Monthly or less | a month | a week | a week
0 | 1 | 2 | 3 | 4

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

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

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 | 2 | 4

This scale is in the public domain and is free to use with appropriate citation:

y-Lambkin FJ, Baker AL, Lewin TJ, Thornton L, Kelly BJ, and Sellman JD. (2010). An sure of Cannabis Misuse: The Cannabis Use Disorders Identification Test – Revised *Alcohol Dependence* 110:137-143.

or self administration and is scored by addi

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

PART INFORMED CONSENT; PART RESPONSIBLE PRESCRIBING – IN A NEW REALITY

NEVER FORGET:
Informed Consent for Treatment Involving Controlled Substances
IS A PROCESS – NOT JUST A PIECE OF PAPER

Common Educational Topics to Facilitate Informed Consent for Patients

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.

PRE-COVID: INFORMED CONSENT EDUCATIONAL PROCESS

- Use of an *informed consent process, rather than just a piece of paper, to educate the patient and that is kept updated throughout the practitioner-patient relationship. 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.

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

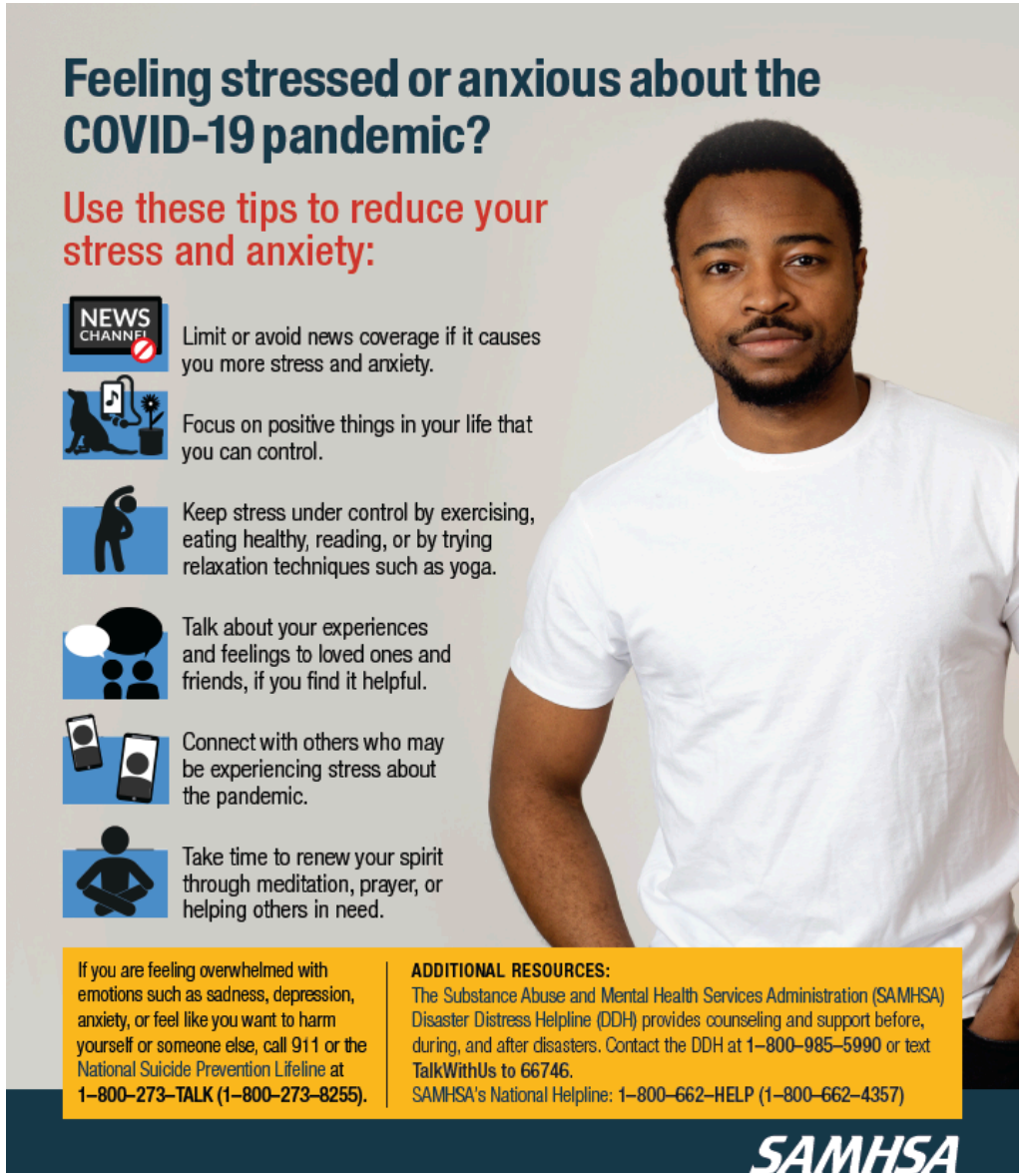
- The complications raised by COVID-19 in terms of risks:
  - If a patient contracts COVID-19, risk of respiratory depression is significant and may be more problematic when patient is using opioids during illness.
  - Anxiety is heightened and the temptation is great to reach for something “to calm the nerves.” Use telemedicine to reeducate the patient and provide coordinated care opportunities.
  - Use telemedicine 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.

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.



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.

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 relevant COVID-19-related disclosures (telemedicine, additional risks if faced with COVID) and educational material.

SUMMARY POINTS & THANK YOU!

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