Drugs, Documentation, and DEA

- Improving Your Charting of Prescribing Rationale During the COVID-19 Pandemic and Beyond

- Prepared and Presented by Jen Bolen, JD

Disclosures

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

Objectives

1. Review DEA regulatory requirements for a valid controlled substance prescription as we continue and come out of the COVID-19 Public Health Emergency.

2. Discuss DEA's position on documentation critical to controlled substance prescribing – DEA Administrative Case: *In re Kaniz F. Khan-Jaffery*, MD (2020) AND in DEA Administrative Case *In re Carol Hippenmeyer*, MD (July 2021)

3. Construct a basic road map for improving documentation of risk/benefit efforts with patients and clinical rationale for controlled substance prescribing, with emphasis on remaining current with changing DEA regulations and applicable clinical standards for controlled substance prescribing during the COVID-19 PHE.

Review DEA regulatory requirements for a valid controlled substance prescription as we continue and come out of the COVID-19 Public Health Emergency.

Objective #1

https://www.deadiversion.usdoj.gov

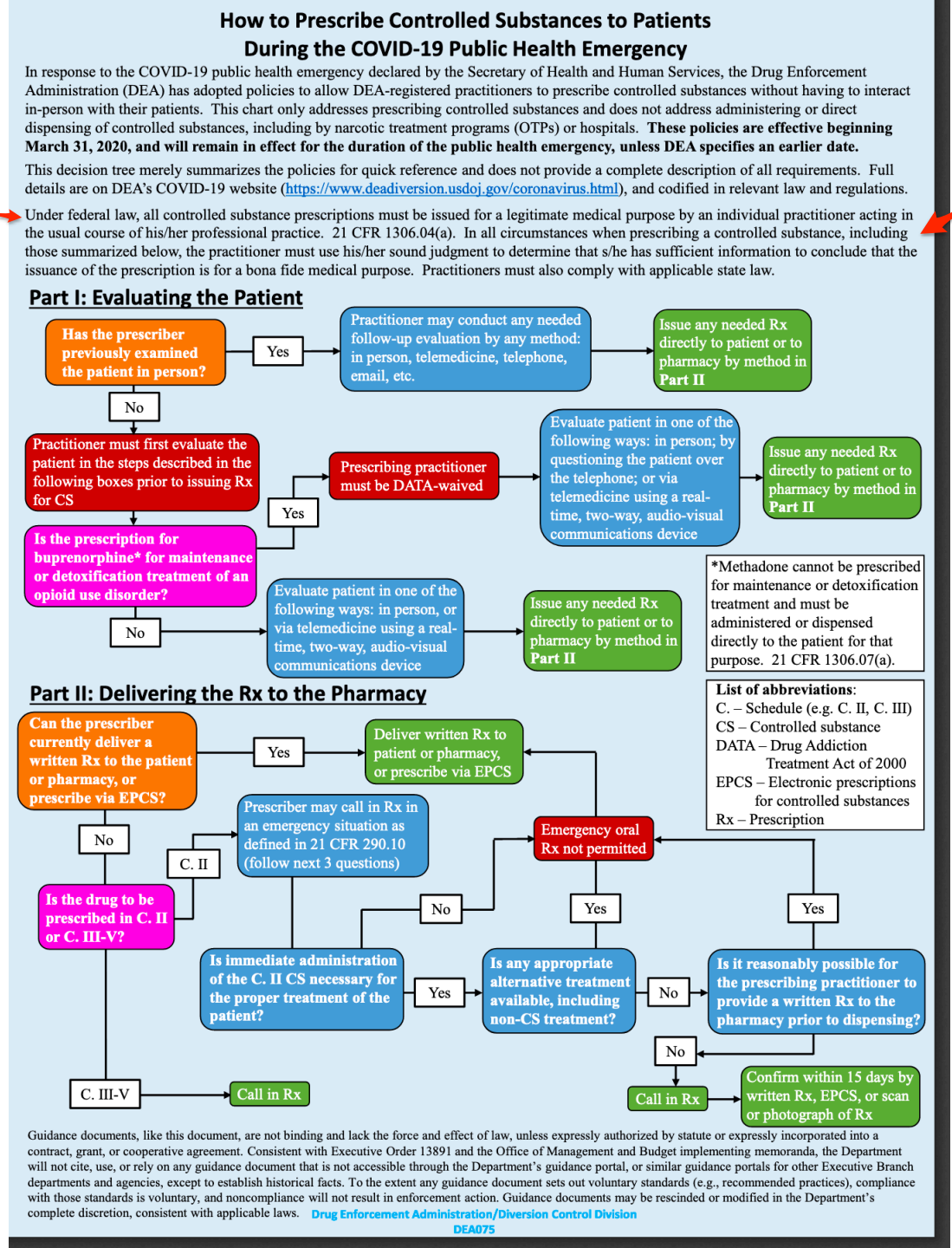
DEA Website

DEA's COVID-19 Information Page

https://www.deadiversion.usdoj.gov/coronavirus.html, accessed 09/20/2021.

DEA's COVID-19 PRESCRIBING GUIDANCE (Current as of Sept. 20, 2021)

HANDOUT:
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

*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

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

 Drug Enforcement Administration/Diversion Control Division
DEA075

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

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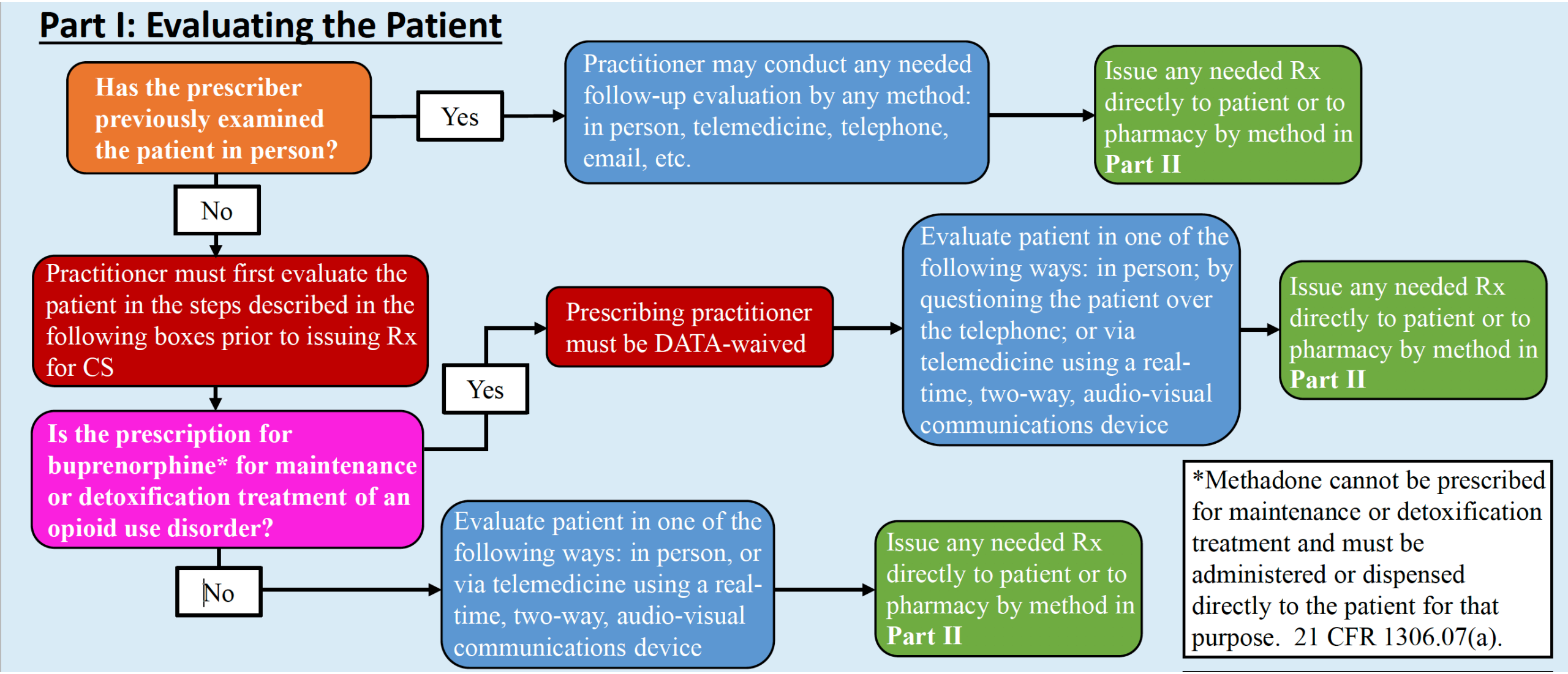
https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-023)(DEA075)Decision_Tree_(Final)_33120_2007.pdf

Part I: Evaluating the Patient



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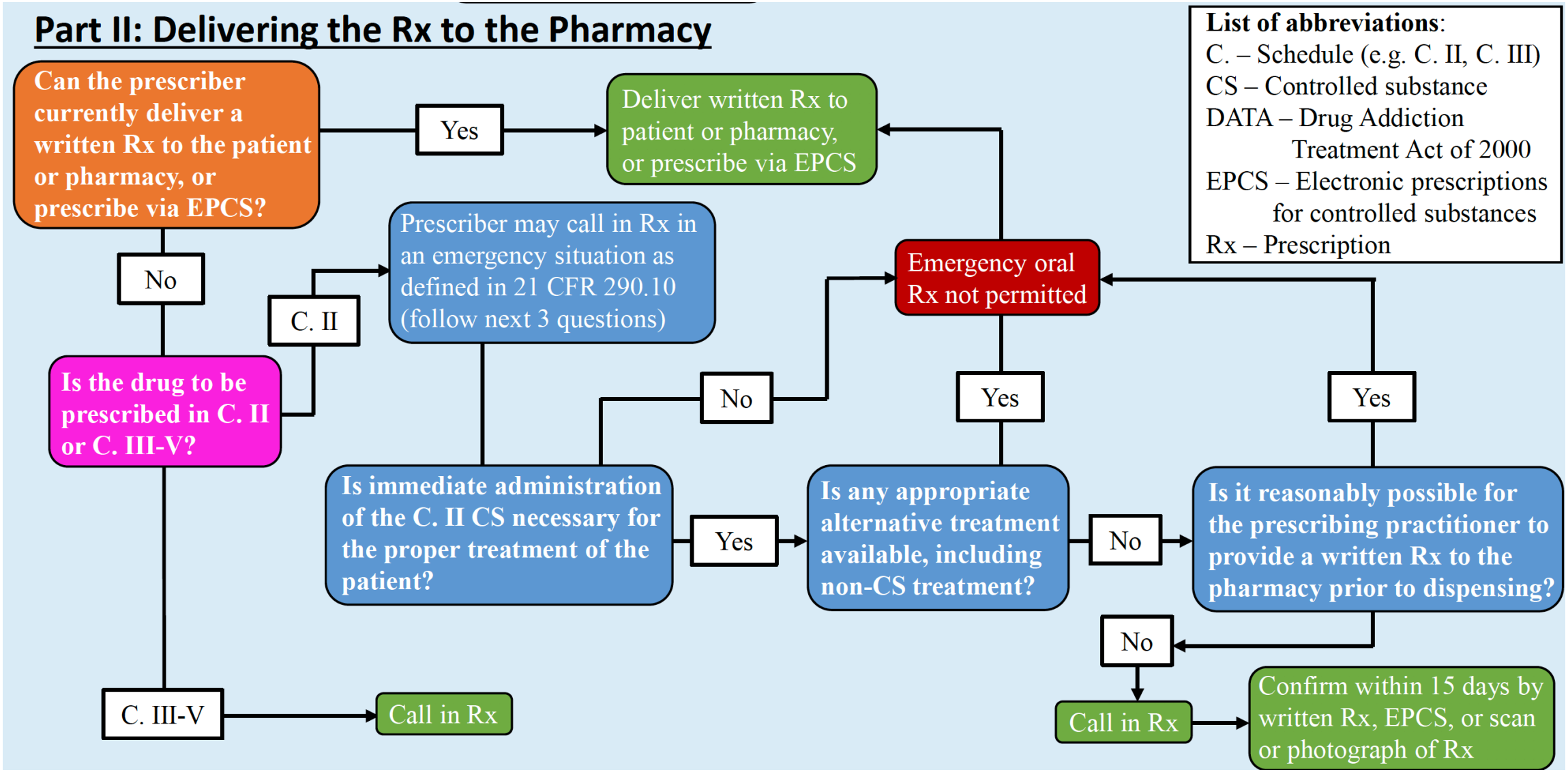
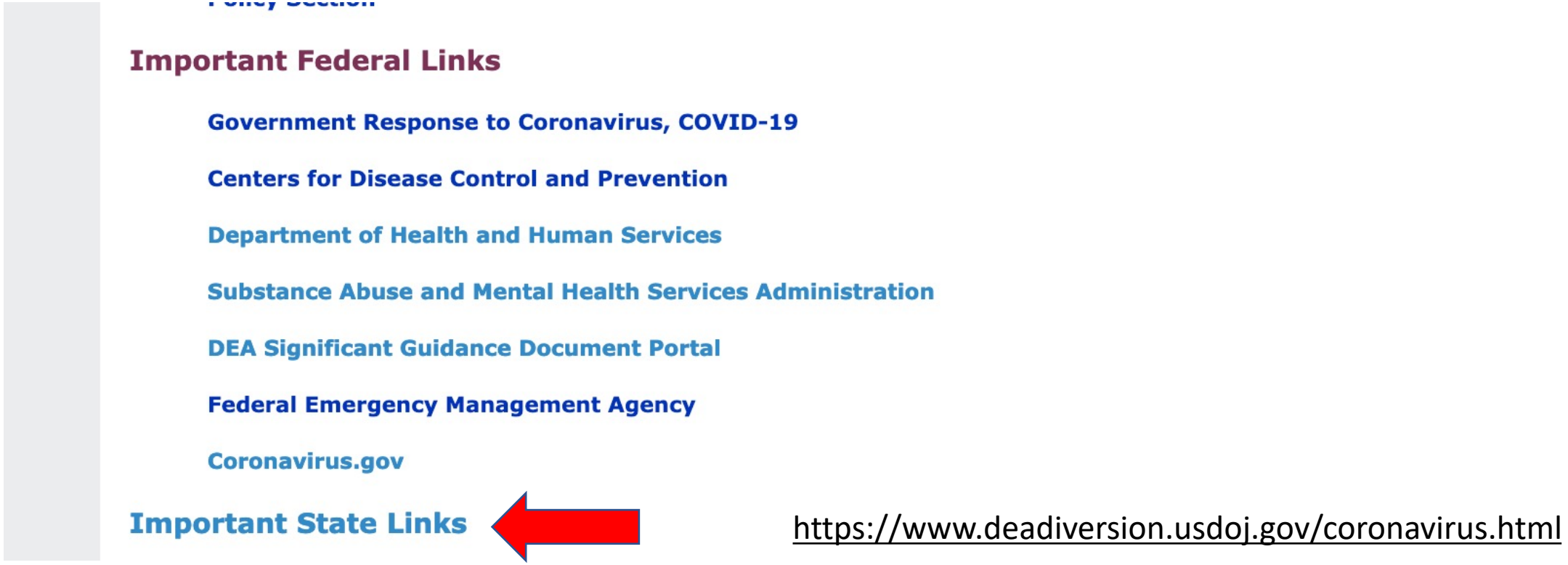


https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-023)(DEA075)Decision_Tree_(Final)_33120_2007.pdf

Other Useful Links on the DEA's COVID Information Page



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

Question #1

PICK THE MOST COMPLETE ANSWER: When prescribing controlled substances to a PATIENT NOT PREVIOUSLY EVALUATED BY YOU during the COVID-19 public health emergency, DEA expects registrants to document information that the prescription was issued:

A. For a legitimate medical purpose by a practitioner acting within their scope of practice over an audio platform.

B. For a legitimate medical purpose by a practitioner who is acting in the usual course of professional practice and either seen in person or through a real-time, two-way interactive, audio-video platform for a telemedicine visit and the prescription is delivered in person or through electronic prescribing of controlled substances.

C. For an accepted medical reason and in-person delivery.

D. By a medical practitioner for legitimate reasons tied to a medical emergency

Usual Course of Professional Practice & Standard of Care

A look at TWO RECENT DEA Administrative Cases

In re Kaniz F. Khan-Jaffery, MD (New Jersey), Decision Published 2020

In re Carol Hippenmeyer, MD (Arizona) Decision Published 2021

Objective #2

REMINDER:
Legitimate Medical Purpose and Usual Course of Professional Practice

- DEA Final Policy Statement Published on 9/6/2006
- PDF Available as Handout
- Federal Register link: https://www.govinfo.gov/content/pkg/FR-2006-09-06/pdf/FR-2006-09-06.pdf, accessed on 09/20/2021.

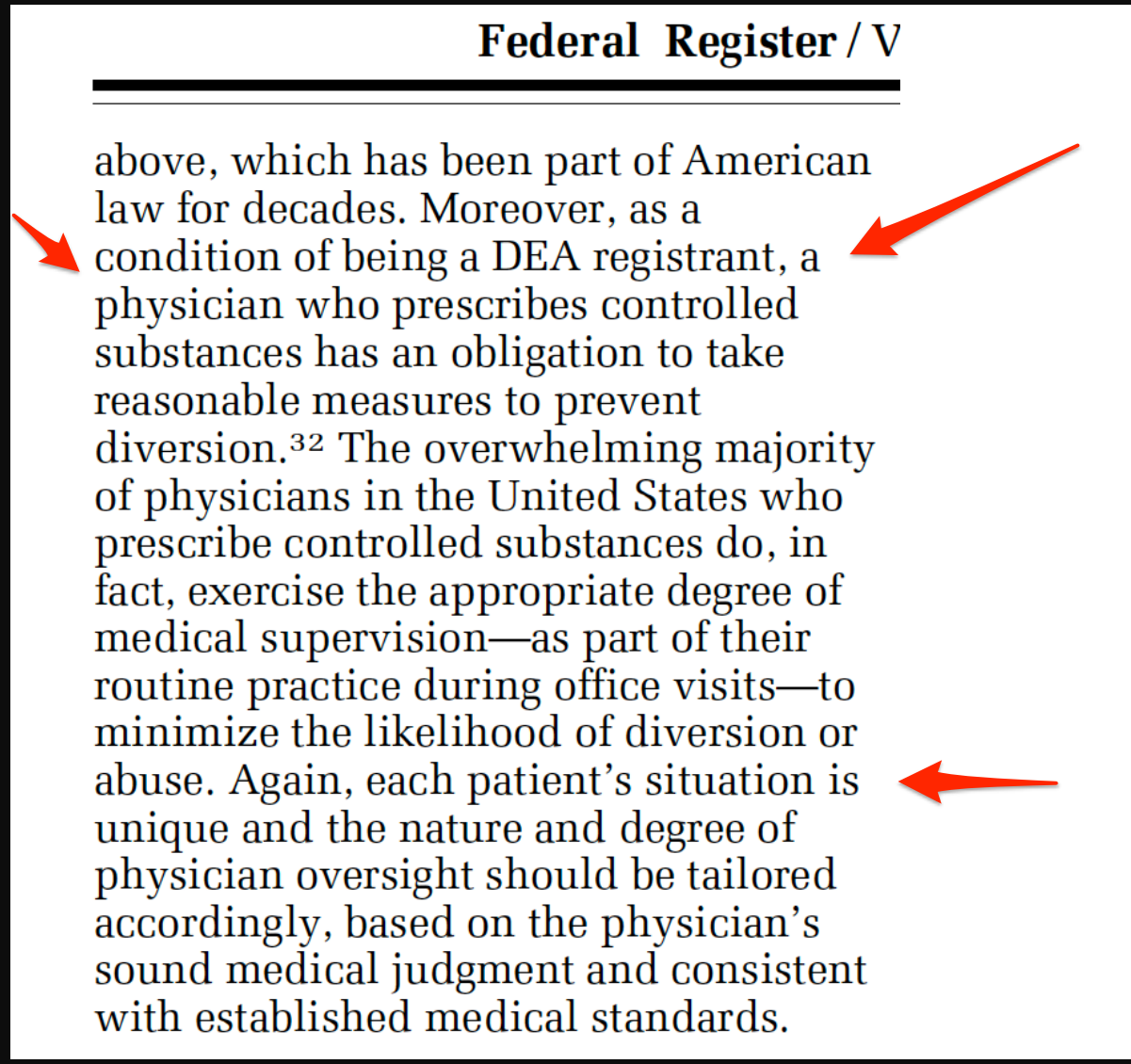
What are the general legal responsibilities of a physician to prevent diversion and abuse when prescribing controlled substances?

In each instance where a physician issues a prescription for a controlled substance, the physician must properly determine there is a legitimate medical purpose for the patient to be prescribed that controlled substance and the physician must be acting in the usual course of professional practice.[31] This is the basic legal requirement discussed

[31] 21 CFR 1306.04(a); *United States* v. *Moore*, *supra*.

DEA Final Policy Statement Reminder: DEA Registrants Have a Duty to Mitigate Risk

- Published on 9/6/2006 and still part of today's standard!
- PDF Available as Handout
- Federal Register link: https://www.govinfo.gov/content/pkg/FR-2006-09-06/pdf/FR-2006-09-06.pdf, accessed on *09/20/2021*



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.

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.

DEA Final Policy Statement
Duty to Mitigate Risk Continued

- Published on 9/6/2006 and applicable today!
- PDF Available as Handout
- Federal Register link: https://www.govinfo.gov/content/pkg/FR-2006-09-06/pdf/FR-2006-09-06.pdf, accessed on 09/20/2021

In re Khan-Jaffrey

DEA Administrative Case

New Jersey Physician

Decision and Order to Revoke

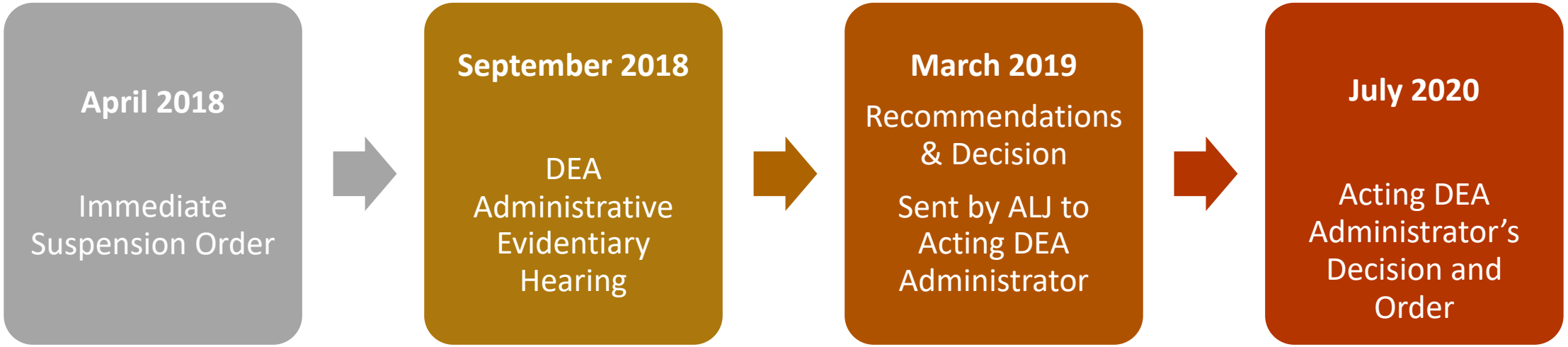
In re Kaniz F. Khan-Jaffery, available online at https://www.federalregister.gov/documents/2020/07/29/2020-16387/kaniz-f-khan-jaffery-md-decision-and-order.

Khan-Jaffrey Case Background

- Physician licensed in New Jersey and Registered to Prescribe CS.
- Pharmacy data showed the physician was high-volume for controlled medication.
- Physician saw 50-55 patients per day.
- Physician put controls in place, including required referrals and UDT.
- Government presented a medical expert.
- Defense presented a medical expert, a medical record documentation expert, and the respondent-physician testified.
- Case involved an undercover “patient” and review of other real patient charts.

In re Kaniz F. Khan-Jaffery, available online at https://www.federalregister.gov/documents/2020/07/29/2020-16387/kaniz-f-khan-jaffery-md-decision-and-order.

Khan-Jaffrey Case Timeline



ALJ = Administrative Law Judge

In re Kaniz F. Khan-Jaffery, available online at https://www.federalregister.gov/documents/2020/07/29/2020-16387/kaniz-f-khan-jaffery-md-decision-and-order.

Khan-Jaffrey Risk Mitigation and Responding to UDT Results Showing Inconsistency with Prescribed Medication

GOVERNMENT EXPERT:

- UDT results that are negative for the prescribed controlled medication are inconsistent with the plan.
- The prescriber must take steps to reconcile the matter with the patient.

GOVERNMENT EXPERT:

- The prescriber should document counseling and their action (reevaluating the patient's situation) and decision-making (prescribe, change the treatment plan, not prescribe or reduce amount of drug) related thereto.

TAKEAWAY: Complete the task.

- Review the UDT results in a timely fashion.
- Counsel or talk to the patient to try to gain more information (when it's missing medication).
- Discuss the information gained in the medical record and take appropriate steps – see the patient, if necessary.
- Decide what you're going to do and document your reasoning.

In re Kaniz F. Khan-Jaffery, available online at https://www.federalregister.gov/documents/2020/07/29/2020-16387/kaniz-f-khan-jaffery-md-decision-and-order.

Khan-Jaffrey – Expert Witness Testimony on the Level of Documentation Required by State Standard for Inconsistent UDT Results

NEW JERSEY LAW:

- NJ has a regulation requiring the prescriber to address and document an inconsistent UDT result.
- NJ requires that there must be documentation of the plan AFTER addressing the inconsistent result with the patient.

DEFENSE POSITION:

- The "automatic" [boilerplate] chart counseling note tied to "UDT results" constitutes adequate documentation of counseling and the fact that the UDT results were addressed.

FINDING:

- **Auto-populated Notes in EMR ARE INSUFFICIENT DOCUMENTATION; Boilerplate is INSUFFICIENT!**

TAKEAWAY:

- **Do more than use boilerplate chart entries.** Tie the results, to the action, to the plan and prescribing decision.

In re Kaniz F. Khan-Jaffery, available online at https://www.federalregister.gov/documents/2020/07/29/2020-16387/kaniz-f-khan-jaffery-md-decision-and-order.

Khan-Jaffrey - Is patient dismissal required for inconsistent urines?

GOVERNMENT & DEFENSE EXPERTS:

- No. The prescriber is not tied to any specific action when he/she discovers an inconsistent urine.
- The response must make sense for the individual patient.
- The standard of care is to re-establish the norm (if possible) and document these efforts - to get the patient's use of controlled medication back under control or plan for alternative steps if control is not attainable.
- Inconsistent urine screens MUST BE ADDRESSED, COUNSELED, and DOCUMENTED.

TAKEAWAY:

- Make sure your documentation is clear and that you articulate a thoughtful plan.
- Do not rely on boilerplate or statements that are not individualized to the patient.
- **LEGAL ANSWER: IT DEPENDS ON ALL FACTS.**

In re Kaniz F. Khan-Jaffery, available online at https://www.federalregister.gov/documents/2020/07/29/2020-16387/kaniz-f-khan-jaffery-md-decision-and-order.

Khan-Jaffrey – What's expected of the Prescriber when UDT Results Show Non-Prescribed Controlled Substances?

GOVERNMENT EXPERT:

- **The standard of care requires the prescriber to address the test results with the patient in a timely fashion and document the conversation and ongoing treatment plan, including any adjustments and referrals.**

NEW JERSEY LAW: NJ has a regulation that requires prescribers to:

- **ASSESS** the patient prior to issuing each prescription to determine whether the patient is experiencing problems associated with physical and psychological dependence and document the results of that assessment,
- **MONITOR** compliance with the treatment agreement . . . ,
- **DISCUSS** with the patient any breaches that reflect that the patient is not taking drugs as prescribed or is taking drugs, illicit or prescribed by other prescribers, AND
- **DOCUMENT** within the patient record the plan after that discussion.

TAKEAWAY:

- Know your state rules! Many states do not spell out requirements the way NJ does, but the same or similar standards are used in licensing board, DEA, and criminal cases.
- This is a DEA administrative case and it resulted in the registrant's loss of her DEA #.

In re Kaniz F. Khan-Jaffery, available online at https://www.federalregister.gov/documents/2020/07/29/2020-16387/kaniz-f-khan-jaffery-md-decision-and-order.

Khan-Jaffrey - Prescribing Controlled Substances to Patients who use Alcohol

- Alcohol and opioids do not mix. While one drink may not be problematic, experts are likely to testify that counseling/education on the topic is part of the standard of care. It is in NJ.
- **GOVERNMENT'S EXPERT:** Prescriptions issued to one patient were not issued in the usual course of professional practice because the prescriber never addressed the alcohol positive UDT results with the patient. Once again, the boilerplate charting hurt the physician.
    - Multiple alcohol metabolite positives [probably] requires the prescriber to discontinue controlled substance therapy.
- **NEW JERSEY LAW:** NJ regulations require "a discussion about the risks that shall include the 'danger of taking opioid drugs with alcohol' before the initial prescription and prior to the third prescription. It also states that the [prescriber] shall include a note in the patient record that the required discussions took place.
- **TAKEAWAY: USE CAUTION WHEN TESTING FOR ALCOHOL. Testing for it and ignoring the results is problematic. Not testing for it is equally problematic. DO NOT IGNORE ALCOHOL USE.**

In re Kaniz F. Khan-Jaffery, available online at https://www.federalregister.gov/documents/2020/07/29/2020-16387/kaniz-f-khan-jaffery-md-decision-and-order.

Khan-Jaffrey

Case Result

REGISTRATION REVOKED

- **The Administrative Law Judge found:**
  - Recommended a sanction short of revocation.
- DEA ADMINISTRATOR DISAGREED WITH THE ALJ and REVOKED THE PHYSICIAN'S REGISTRATION
- The Physician issued 23 prescriptions that were found to be beneath the standard of care and outside the usual course of professional practice.

The physician failed to:

- **CONDUCT** a physical exam in the case of the undercover officer.
- **DOCUMENT** discussions of a plan and assess the risk of abuse, addiction, or diversion after inconsistent urine screens – all in violation of state law/regulations.
- **TAKE RESPONSIBILITY FOR** her actions; Administrator found her credibility lacking and that she offered no measure of trust whereby he could accept the ALJ's recommendation of a sanction short of revocation and involving monitoring.

In re Kaniz F. Khan-Jaffery, available online at https://www.federalregister.gov/documents/2020/07/29/2020-16387/kaniz-f-khan-jaffery-md-decision-and-order.

Khan-Jaffrey

DEA Administrator's Comments on Documentation

"Although the evidence of her struggles with her software system is relatable at a basic level to every human being who has experienced technological frustrations, it again shows a passing of blame and an unwillingness to accept responsibility for a legal requirement and a requirement of the applicable standard of care and the usual course of professional practice in her field *to document her prescribing practices and decisions*."

In re Kaniz F. Khan-Jaffery, available online at https://www.federalregister.gov/documents/2020/07/29/2020-16387/kaniz-f-khan-jaffery-md-decision-and-order.

Khan-Jaffrey

DEA Administrator's Comments on Documentation

"Documentation of the discretion that Respondent had been implementing in her prescribing practices in the face of inconsistent urine screens is similar to accepting responsibility for her actions, because it memorializes her decisions with permanence."

In re Kaniz F. Khan-Jaffery, available online at https://www.federalregister.gov/documents/2020/07/29/2020-16387/kaniz-f-khan-jaffery-md-decision-and-order.

Khan-Jaffrey

DEA Administrator's Comments on Documentation

"None of the recordkeeping in the Government's evidence demonstrates the rationale behind her prescribing decisions and she demonstrated through her testimony that her memory is not reliable to fill in the gaps."

In re Kaniz F. Khan-Jaffery, available online at https://www.federalregister.gov/documents/2020/07/29/2020-16387/kaniz-f-khan-jaffery-md-decision-and-order.

Khan-Jaffrey

DEA Administrator's Comments on Documentation

"Although the [administrative law judge] ultimately recommended a sanction short of revocation, I cannot agree, because there is insufficient evidence in the record to demonstrate that the Respondent can be entrusted with a registration. … Respondent has not given [the Acting DEA Administrator] a reason to extend [his authority] to monitor her compliance."

In re Kaniz F. Khan-Jaffery, available online at https://www.federalregister.gov/documents/2020/07/29/2020-16387/kaniz-f-khan-jaffery-md-decision-and-order.

In re Carol Hippenmeyer, MD

DEA Administrative Case

Arizona Physician

Registration Revocation

SOURCE: Available online at https://www.federalregister.gov/documents/2021/06/25/2021-13526/carol-hippenmeyer-md-decision-and-order (accessed 09/20/21).

Hippenmeyer Case Background

- Physician licensed in Arizona and Registered to Prescribe CS.

MD prescribed to healthcare practitioners who were “friends, intimate partners, or otherwise close associates” and prescribing took place outside the usual course of professional practice.

SOURCE: Available online at https://www.federalregister.gov/documents/2021/06/25/2021-13526/carol-hippenmeyer-md-decision-and-order (accessed 09/20/21).

Hippenmeyer Case Timeline (Basic Summary)

Aug. 2018

Order to Show Cause

Covered an investigative period originating in 2017

Between Aug 2018 and Mar. 2019

Registrant Requests a Hearing

Hearing Held

Mar. 2019

ALJ issues Recommendation and Decision;

Recommends Something Short of Revocation

July 2021

DEA Acting Administrator DISAGREES with the ALJ and ORDERS REVOCATION

More than a record-keeping case with several areas of concern

Violated Federal and State CS Rx Laws and Applicable Standards of Care

SOURCE: Available online at https://www.federalregister.gov/documents/2021/06/25/2021-13526/carol-hippenmeyer-md-decision-and-order (accessed 09/20/21).

Core Issues in Hippenmeyer

There was significant disagreement at the hearing and in the parties' posthearing briefs on a number of issues: (1) Whether a physician must maintain medical records in order to establish a valid doctor-patient relationship, (2) whether the Arizona standard of care requires physicians to conduct urine drug screens and query the Arizona PMP while prescribing controlled substances, and (3) whether it is a violation of the standard of care to prescribe benzodiazepines and opioids concurrently. In accordance with Dr. Lynch's uncontroverted expert testimony and the record as a whole, I make the following findings regarding the applicable standard of care in Arizona.

- SOURCE: Available online at https://www.federalregister.gov/documents/2021/06/25/2021-13526/carol-hippenmeyer-md-decision-and-order (accessed 09/20/21).

Core Issue in Hippenmeyer: Physical Examination and Role in Demonstrating a Valid Physician-Patient Relationship Prior to Controlled Substance Prescribing

- SOURCE: Available online at https://www.federalregister.gov/documents/2021/06/25/2021-13526/carol-hippenmeyer-md-decision-and-order (accessed 09/20/21).

1. The Record Evidence Supports a Finding That the Applicable Standard of Care in Arizona Requires Physicians To Perform a Physical Examination or Otherwise Establish a Valid, Documented Doctor-Patient Relationship Prior to Prescribing Controlled Substances

Dr. Lynch testified that the applicable standard of care in Arizona requires a physician to conduct a physical examination before prescribing controlled substances. Tr. 176–77. Dr. Lynch's opinion is supported by Arizona statute, which states that it is "unprofessional conduct" to "[p]rescrib[e], dispens[e] or furnish[ ] a prescription medication . . . to a person unless the [doctor] first conducts a physical or mental health status examination of that person or has previously established a doctor-patient relationship." [23] Ariz. Rev. Stat. Ann. § 32–1401(27)(ss) (2017).

Core Issue in Hippenmeyer: Physical Examination and Role in Demonstrating a Valid Physician-Patient Relationship Prior to Controlled Substance Prescribing

- SOURCE: Available online at https://www.federalregister.gov/documents/2021/06/25/2021-13526/carol-hippenmeyer-md-decision-and-order (accessed 09/20/21).

Dr. Lynch testified about the requirements for establishing a valid doctor-patient relationship. Dr. Lynch testified that a valid doctor-patient relationship is not established unless the physician documents the treatment of the patient. *Id.* at 233, 379, 381. Dr. Lynch testified that the Arizona Medical Board does not define a doctor-patient relationship, but it "goes to great lengths to define how [doctors] should document." *Id.* at 235. Therefore, he has "always inferred" that documentation and the doctor-patient relationship are "very similar things." *Id.*[24] Dr. Lynch identified additional aspects of a doctor-patient relationship—that the treatment is "done in an office setting" and "in the normal course of medical practice that occurs [ ] in Arizona every day." Tr. 232–35.

Core Issue in Hippenmeyer: Taking a Medical History and Conducting a Review of Past Relevant Medical Records Prior to Prescribing Controlled Substances

- SOURCE: Available online at https://www.federalregister.gov/documents/2021/06/25/2021-13526/carol-hippenmeyer-md-decision-and-order (accessed 09/20/21).

2. The Record Evidence Supports a Finding That the Applicable Standard of Care in Arizona Requires Physicians To Take a Medical History and Conduct a Review of Past Relevant Medical Records Prior to Prescribing Controlled Substances

Dr. Lynch testified that the applicable standard of care in Arizona requires that a physician take a medical history before prescribing controlled substances. Tr. 176, 239–40. The purpose of the medical history is to "define the disease state." *Id.* at 176, 239–40. Dr. Lynch testified that a medical history should explore "when the condition started, what's happened since, what makes it better, what makes it worse, what's been tried, what's failed, [and] what works." *Id.* at 176. Dr. Lynch's testimony is supported by the Arizona DHS Guidelines, which state that physicians should complete an evaluation that includes "a medical, pain-related, and social history." GX 16, at 11. The medical history should be documented in the patient's medical records. GX 14, at 12.

Core Issue in Hippenmeyer: Taking a Medical History and Conducting a Review of Past Relevant Medical Records Prior to Prescribing Controlled Substances

Lynch testified that the minimum standard of care in Arizona requires that the review of past medical records be documented in the medical record. Tr. 196–97 (referencing GX 14). Therefore, based on the unrebutted and credible expert testimony of Dr. Lynch, as supported by Arizona guidance, I find that the standard of care in Arizona requires physicians to take a medical history and document that medical history in the patient's medical record before prescribing controlled substances. I also find that a physician must conduct a review of the patient's past relevant medical records prior to prescribing.

- SOURCE: Available online at https://www.federalregister.gov/documents/2021/06/25/2021-13526/carol-hippenmeyer-md-decision-and-order (accessed 09/20/21).

Core Issue in Hippenmeyer: Periodic Drug Screens and Use of the PDMP + Documentation are part of the Standard of Care (in AZ)

- SOURCE: Available online at https://www.federalregister.gov/documents/2021/06/25/2021-13526/carol-hippenmeyer-md-decision-and-order (accessed 09/20/21).

3. The Record Evidence Supports a Finding That the Applicable Standard of Care in Arizona Requires Physicians To Perform Periodic Urine Drug Screens and Regularly Query the Arizona PMP, and Document Those Results in the Medical Record

Dr. Lynch testified that the applicable standard of care in Arizona requires that a physician query the Arizona PMP on a regular basis and document the results in the medical record. Tr. 181–82. He testified that regular PMP monitoring became "strong standard in care" in 2014 when the Arizona DHS Guidelines were published. *Id.* at 181. Dr. Lynch's testimony is supported by the Arizona DHS Guidelines, which provide that "[a]ppropriate monitoring for [chronic opioid therapy] includes, at a minimum, . . . periodic query of the [Arizona PMP]." GX 16, at 8. Dr. Lynch's testimony is also supported by the Arizona Medical Board Guidelines,

Core Issue in Hippenmeyer: Periodic Drug Screens and Use of the PDMP + Documentation are part of the Standard of Care (in AZ)

- SOURCE: Available online at https://www.federalregister.gov/documents/2021/06/25/2021-13526/carol-hippenmeyer-md-decision-and-order (accessed 09/20/21).

According to the Arizona DHS Guidelines, the frequency with which a practitioner checks the PMP should be based on the patient's risk of misuse. GX 16, at 13–14. The PMP should be checked "yearly or more often as indicated" for low-risk patients, "every [six] months or more often as indicated" for moderate-risk patients, and "every [three] months or more often as indicated" for high-risk patients. GX 16, at 13–14, 16; *see also* Tr. 277–80.[28] Risk factors include a "personal or family history of addiction" and "[a]berrant drug-related behaviors," such as "obtaining opioids from multiple sources." GX 16, at 13.

The Arizona Medical Board states that it will consider the failure to "mak[e] use of available tools for risk mitigation," such as the PMP, as "inappropriate management of pain" and a "departure from best clinical practices." GX 14, at 3–4. The Board also states that "[t]o be within the usual course of professional practice, . . . the prescribing or administration of medications should be . . . accompanied by careful follow-up monitoring of the patient's response to treatment as well as his or her safe use of the prescribed medication." *Id.* at 5.

Core Issue in Hippenmeyer: Periodic Drug Screens and Use of the PDMP + Documentation are part of the Standard of Care (in AZ)

Dr. Lynch testified that if a doctor learns that a patient is receiving controlled substances from other providers, the doctor must discuss it with the patient to understand why the patient is receiving controlled substances from other providers and make sure that the doctor is "okay with it." Tr. 281, 323. The doctor must document those discussions in the record, as well as the patient's reason for receiving controlled substances from multiple providers. *Id.*

- SOURCE: Available online at https://www.federalregister.gov/documents/2021/06/25/2021-13526/carol-hippenmeyer-md-decision-and-order (accessed 09/20/21).

Core Issue in Hippenmeyer: Concurrent Prescribing of Opioids and Benzodiazepines

- SOURCE: Available online at https://www.federalregister.gov/documents/2021/06/25/2021-13526/carol-hippenmeyer-md-decision-and-order (accessed 09/20/21).

4. The Record Evidence Supports a Finding That the Applicable Standard of Care in Arizona Requires Physicians to Document Their Justification for Prescribing Opioids and Benzodiazepines Concurrently, and to Avoid Prescribing This Combination If Possible

Dr. Lynch testified about the applicable standard of care in Arizona for prescribing opioids and benzodiazepines concurrently. Tr. 178–80, 244–45, 275, 299, 300–02, 370–72. He referred to this practice as "co-prescribing." *Id.* at 245. Dr. Lynch testified that "about 1 in 500 patients who take a pain pill will overdose and die every year, which is a very high death rate." *Id.* at 182. When opioids and benzodiazepines are combined, the death rate increases by nine times. *Id.* at 180, 302. Dr. Lynch testified that the "second biggest predictor" of overdose and death is "concomitant benzodiazepine use."[31] *Id.* at 244. In 2014, the Arizona DHS reported that benzodiazepines were involved in thirty to sixty percent of opioid overdose deaths. *Id.*; GX 16, at 19.

Core Issue in Hippenmeyer: Concurrent Prescribing of Opioids and Benzodiazepines

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Dr. Lynch discussed the Arizona DHS's and the CDC's recommendations on co-prescribing. *Id.* at 179. The Arizona DHS recommends that "[c]ombined use of opioids and benzodiazepines should be avoided if possible. If this combination is used, it should be with great caution and informed consent should be obtained." GX 16, at 8. The CDC likewise cautions that "[c]linicians should avoid prescribing opioid pain medication and benzodiazepines concurrently wherever possible." GX 15, at 18. Dr. Lynch testified that the Arizona DHS and the CDC also advise physicians not to prescribe opioids along with carisoprodol,[33] which he described as "a highly diverted and addictive muscle relaxant." Tr. 200; *see*

Core Issue in Hippenmeyer: Concurrent Prescribing of Opioids and Benzodiazepines

Therefore, I conclude that based on the uncontroverted and credible testimony of Dr. Lynch, as supported by Arizona guidance, the applicable standard of care in Arizona requires that: Physicians must get an assessment by an addiction specialist before prescribing opioids to a patient with a history of substance abuse, and they must document the patient's baseline; physicians should not prescribe opioids to individuals who have active substance abuse disorders unless those patients are in active treatment; and, physicians should not prescribe opioids and benzodiazepines concurrently to anyone who is abusing any medication or alcohol.

- SOURCE: Available online at https://www.federalregister.gov/documents/2021/06/25/2021-13526/carol-hippenmeyer-md-decision-and-order (accessed 09/20/21).

Core Issue in Hippenmeyer: Requirement to Maintain Contemporaneous Medical Records of Patient Care and Decision-Making

6. The Record Evidence Supports a Finding That the Applicable Standard of Care in Arizona Requires Physicians To Maintain Contemporaneous Medical Records Documenting the Patient's Treatment

- SOURCE: Available online at https://www.federalregister.gov/documents/2021/06/25/2021-13526/carol-hippenmeyer-md-decision-and-order (accessed 09/20/21).

Core Issue in Hippenmeyer: Requirement to Maintain Contemporaneous Medical Records of Patient Care and Decision-Making

- SOURCE: Available online at https://www.federalregister.gov/documents/2021/06/25/2021-13526/carol-hippenmeyer-md-decision-and-order (accessed 09/20/21).

observed.'' GX 16, at 8, 16. The Arizona Medical Board Guidelines provide that ''[t]he medical record should document the presence of one or more recognized medical indications for prescribing an opioid analgesic and reflect an appropriately detailed patient evaluation.'' GX 14, at 6. They further state that:

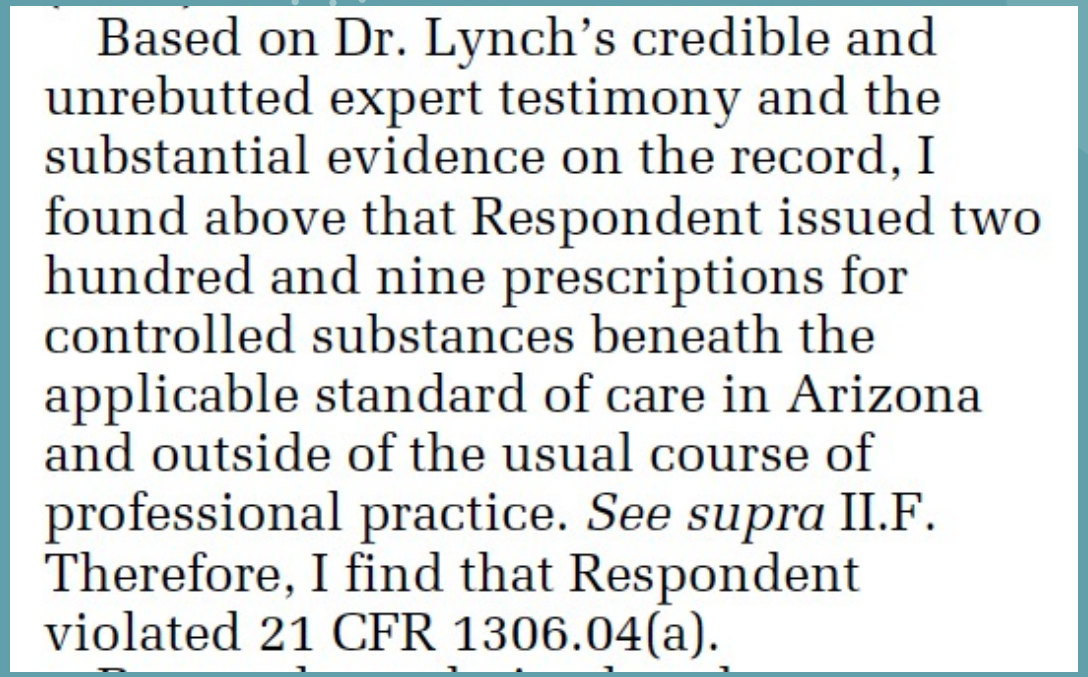
Every physician who treats patients for chronic pain must maintain accurate and complete medical records'' that include the following information:

- Copies of the signed informed consent and treatment agreement.
- The patient's medical history.
- Results of the physical examination and all laboratory tests.
- Results of the risk assessment, including results of any screening instruments used.
- A description of the treatments provided, including all medications prescribed or administered (including the date, type, dose and quantity).
- Instructions to the patient, including discussions of risks and benefits with the patient and any significant others.
- Results of ongoing monitoring of patient progress (or lack of progress) in terms of pain management and functional improvement.
- Notes on evaluations by and consultations with specialists.
- Any other information used to support the initiation, continuation, revision, or termination of treatment and the steps taken in response to any aberrant medication use behaviors. These may include actual copies of, or references to, medical records of past hospitalizations or treatments by other providers.
- Authorization for release of information to other treatment providers.

Id. (internal citations removed). Further, the Arizona Medical Board's ''10

In re Carol Hippenmeyer, MD: DEA ACTING ADMINISTRATOR'S FINAL POSITION

- SOURCE: Available online at https://www.federalregister.gov/documents/2021/06/25/2021-13526/carol-hippenmeyer-md-decision-and-order (accessed 09/20/21).



Based on Dr. Lynch's credible and unrebutted expert testimony and the substantial evidence on the record, I found above that Respondent issued two hundred and nine prescriptions for controlled substances beneath the applicable standard of care in Arizona and outside of the usual course of professional practice. *See supra* II.F. Therefore, I find that Respondent violated 21 CFR 1306.04(a).

In re Carol Hippenmeyer, MD: DEA ACTING ADMINISTRATOR'S FINAL POSITION

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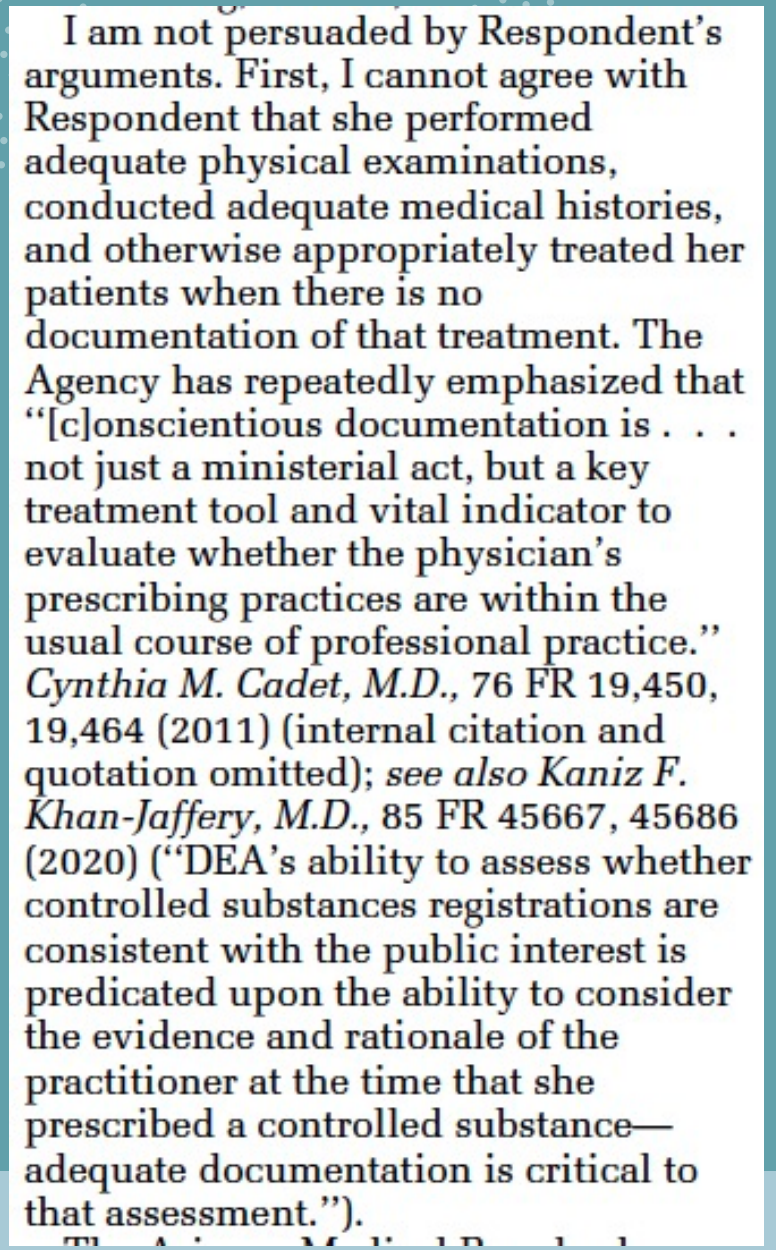

I am not persuaded by Respondent's arguments. First, I cannot agree with Respondent that she performed adequate physical examinations, conducted adequate medical histories, and otherwise appropriately treated her patients when there is no documentation of that treatment. The Agency has repeatedly emphasized that "[c]onscientious documentation is . . . not just a ministerial act, but a key treatment tool and vital indicator to evaluate whether the physician's prescribing practices are within the usual course of professional practice." *Cynthia M. Cadet, M.D.*, 76 FR 19,450, 19,464 (2011) (internal citation and quotation omitted); *see also Kaniz F. Khan-Jaffery, M.D.*, 85 FR 45667, 45686 (2020) ("DEA's ability to assess whether controlled substances registrations are consistent with the public interest is predicated upon the ability to consider the evidence and rationale of the practitioner at the time that she prescribed a controlled substance—adequate documentation is critical to that assessment.").

In re Carol Hippenmeyer, MD: DEA ACTING ADMINISTRATOR'S FINAL POSITION

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Without documentation, there is no way to adequately assess Respondent's treatment of her patients. Witness accounts of treatment that happened years before are not reliable.[55] Respondent's witnesses occasionally acknowledged that their recollection was limited. For example, M.D. and S.P. could not reliably estimate how many times Respondent had physically examined them. M.D. testified, "that's a lot of years. I don't recall." *Id.* at 502. S.P. testified that she "[did not] recall that number" and she could not "give [] an estimate." *Id.* at 598. When pressed, S.P. testified that she was examined "several times" and agreed that it was more than ten. *Id.* at 599. S.P. also could not recall what condition Respondent first treated her for, or when Respondent first prescribed her controlled substances. *Id.* at 536–37. This lack of precision is insufficient to assess Respondent's compliance with the standard of care.

In re Carol Hippenmeyer, MD: DEA ACTING ADMINISTRATOR'S FINAL POSITION

- SOURCE: Available online at https://www.federalregister.gov/documents/2021/06/25/2021-13526/carol-hippenmeyer-md-decision-and-order (accessed 09/20/21).

I am also not persuaded by Respondent's argument that her only violation of the standard of care was her failure to maintain adequate medical records. I found above that the Government's expert credibly testified that Respondent committed numerous violations of the Arizona standard of care in her treatment of H.D., M.D., and S.P. *See supra* II.F. For example, I found that Respondent failed to document adequate medical histories and physical examinations, failed to conduct urine drug screens, failed to check the Arizona PMP, failed to document a justification for co-prescribing opioids and benzodiazepines, and failed to adequately review past medical records—all required by the Arizona standard of care. I also found that Respondent violated the standard of care by prescribing opioids and benzodiazepines to an individual with known substance abuse problems.

In re Carol Hippenmeyer, MD: WHY REVOCATION?

- SOURCE: Available online at https://www.federalregister.gov/documents/2021/06/25/2021-13526/carol-hippenmeyer-md-decision-and-order (accessed 09/20/21).

Regardless, Respondent's admission that she failed to maintain adequate medical records was not a sufficient acceptance of responsibility, because I found above that Respondent's standard of care violations went beyond her failure to maintain adequate medical records. *See supra* II.F, III.A.1. Respondent did not accept responsibility for any of those additional violations. In all, Respondent failed to explain why, in spite of her misconduct, she can be entrusted with a registration. ''The degree of acceptance of responsibility that is required does not hinge on the respondent uttering 'magic words' of repentance, but rather on whether the respondent has credibly and candidly demonstrated that [s]he will not repeat the same behavior and endanger the public in a manner that instills confidence in the Administrator.'' *Jeffrey Stein, M.D.*, 84 FR 46968, 49973 (2019); *see also Singh,*

Question #2

When controlled substances are prescribed, the appropriate standard of care is derived from which two main sources of information?

A. DEA rule on prescribing controlled substances to treat pain.

B. DEA controlled substance prescribing regulations AND state licensing board rule(s)/guideline(s) applicable to controlled substance prescribing.

C. CDC Opioid Guidelines.

D. A and C, but not B.

Case-Based Learning Example

Drugs, Documentation & DEA

Case Based Learning Scenario – Mr. Smith

- Mr. Smith is an established patient and has been seen in your office for more than 5 years.
- Mr. Smith is 63 years old, walks with a cane, has a partial disability (all well documented). He is quite functional despite these medical hardships and works part time at a manufacturing plant where he can sit to perform his assigned tasks.
- During a recent telemedicine visit for opioid medication renewal, Mr. Smith told you that he received a benzodiazepine from a psychiatrist he saw because he was anxious about COVID-related matters. He also told you that he DID NOT tell the psychiatrist about his use of opioids because he was concerned that the psychiatrist would not prescribe medication to him.

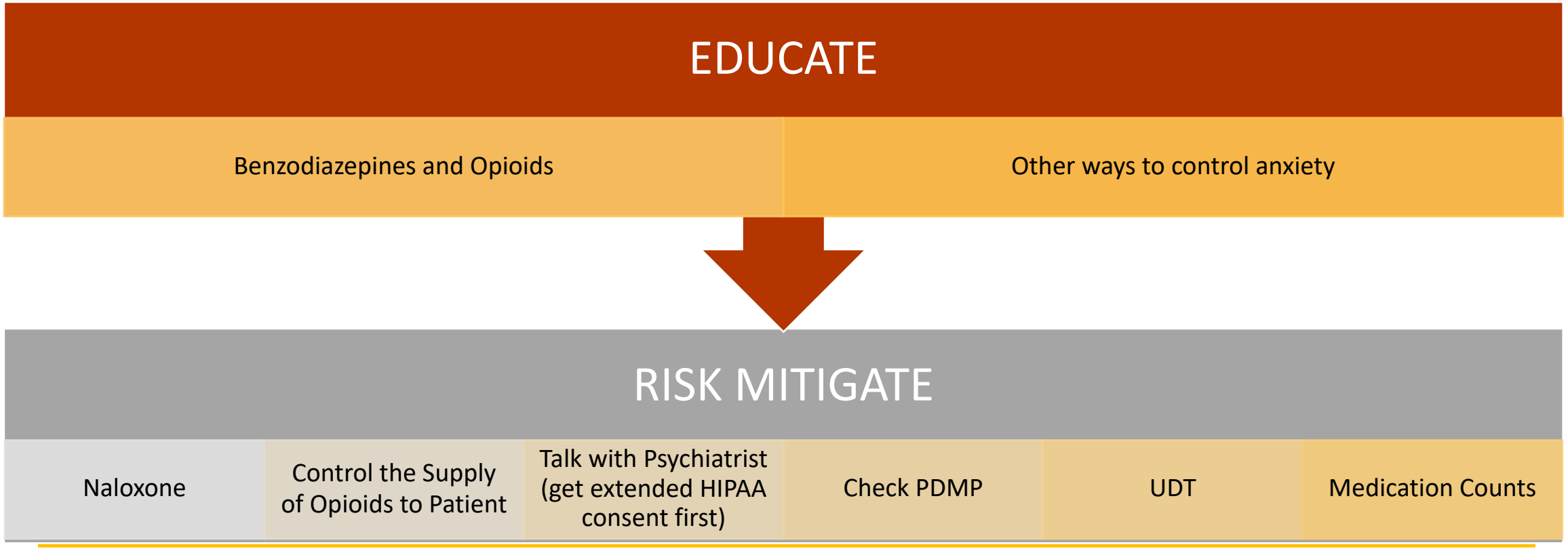
Case Based Learning Scenario – Mr. Smith

What are the critical education and risk-related items you should take up with Mr. Smith?

Should you call the psychiatrist?

What should you do regarding Mr. Smith’s use of opioids with benzodiazepines?

Brainstorming Mr. Smith's case



Brainstorming Mr. Smith's case

DOCUMENT

- Discussion with Mr. Smith
- Discussion with (or efforts to contact) Psychiatrist
- Efforts to Mitigate Against Abuse or Harm to Patient (hit the main points)
- Changes to Treatment Plan

Construct a basic road map for improving documentation of controlled substance prescriptions in the time of COVID-19 PHE and beyond.

Objective #3

Other DEA Educational Publications Revealing DEA's "Mindset" on "Drugs and Documentation"

- **Resource:** https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-13)%20Preventing%20Diversion.pdf, accessed 09/20/2021.

Potential Diversion: Practitioners

Questions to Consider

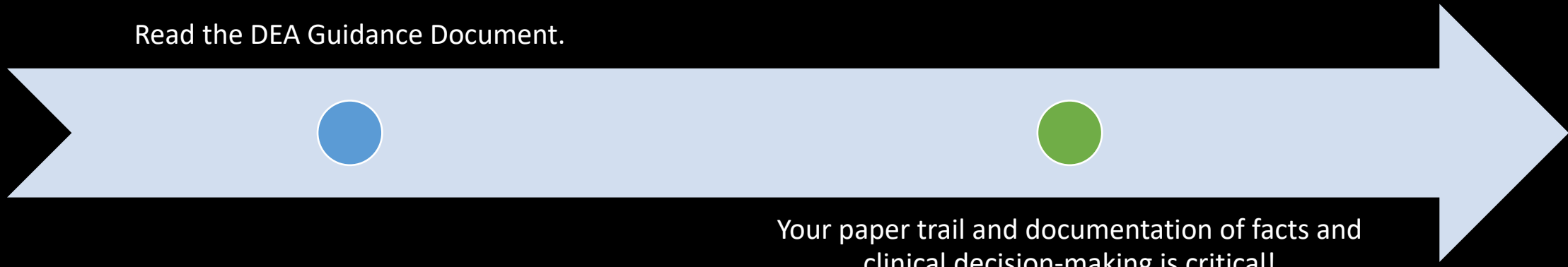
- Does the practitioner follow state laws when prescribing controlled substances?
- Does the practitioner conduct cursory medical exams or any medical exam at all?
- Does the doctor do diagnostic testing or refer patients out for diagnostic testing?
- Is the practitioner referring patients to other specialists (surgery, physical therapy, etc.)?
- Are the initial office visits or follow-up visits brief?
- Does the practitioner prescribe multiple drugs within the same drug category?
- Does the practitioner prescribe excessive quantities of controlled substances relative to the medical condition the prescription is purported to treat?
- Do patients travel a great distance to see the practitioner?
- Does the practitioner ignore signs of abuse?
  - Patient appears to be under the influence
  - Patient asks for the controlled substances he wants
  - Patient is doctor shopping in PDMP
  - Practitioner is warned by family members that the patient is abusing or selling his controlled substances
- Does the practitioner ignore toxicology reports?
- Does the practitioner only treat patients with narcotic controlled substances?
- Does the practitioner start on a low-dose or low-level controlled substance and then over time work up to higher levels, or does the practitioner just start patients on a high-dose narcotic?
- Does the practitioner continue to prescribe controlled substances to patients even though it would be ineffective for treatment purposes?
- Does the practitioner allow the non-medical staff to determine the narcotic to be prescribed, the practitioner just signs the prescription?
- Does the practitioner coach patients on what to say so that patients can get the narcotics that they want?
- Does the practitioner violate his own pain management policies and guidelines?
- Does the practitioner ignore warnings from insurance companies, law enforcement, other practitioners, family members, etc.?
- Does the practitioner receive other compensation for narcotic prescriptions (sex, guns, drugs, etc.)?
- Does the doctor still charge patients for visits if the patients do not receive narcotic prescriptions?
- Are patient deaths attributed to drug abuse or overdose?
- Does the practitioner use inventory for personal use?

DISCLAIMER: Doing one or more of these does not make prescribing illegal. It is the totality of the circumstances. This list is not all-inclusive.

Telemedicine Takeaway Points

Telemedicine patient encounters and controlled substance prescribing during COVID-19 is permitted—for new and established patients—but this legal "allowance" comes with some specific documentation rules and clinical standards.

Read the DEA Guidance Document.



Your paper trail and documentation of facts and clinical decision-making is critical!

Action & Documentation Takeaway Points

DO NOT RELY ON

BOILERPLATE ENTRIES IN EMR FOR CRITICAL CONTROLLED SUBSTANCE PRESCRIBING OBLIGATIONS

Update

RISK ASSESSMENT MATERIAL

PRESCRIBING RATIONALE

PATIENT EDUCATION

Things to do

1

- Review the DEA Decision-Tree and Telemedicine Directives.
- Review the Khan-Jaffrey Decision (handout)
- Review the Hippenmeyer Decision (handout)
- Review the DEA Final Policy Statement (handout)

2

- Download and Read your state's current opioid prescribing guidelines/rules.
- Check for COVID-19 directives for prescribing controlled substances.

3

- Evaluate your documentation using information you learned from performing steps 1 and 2.

4

- Ask for help on the more difficult documentation issues.

Contact Information

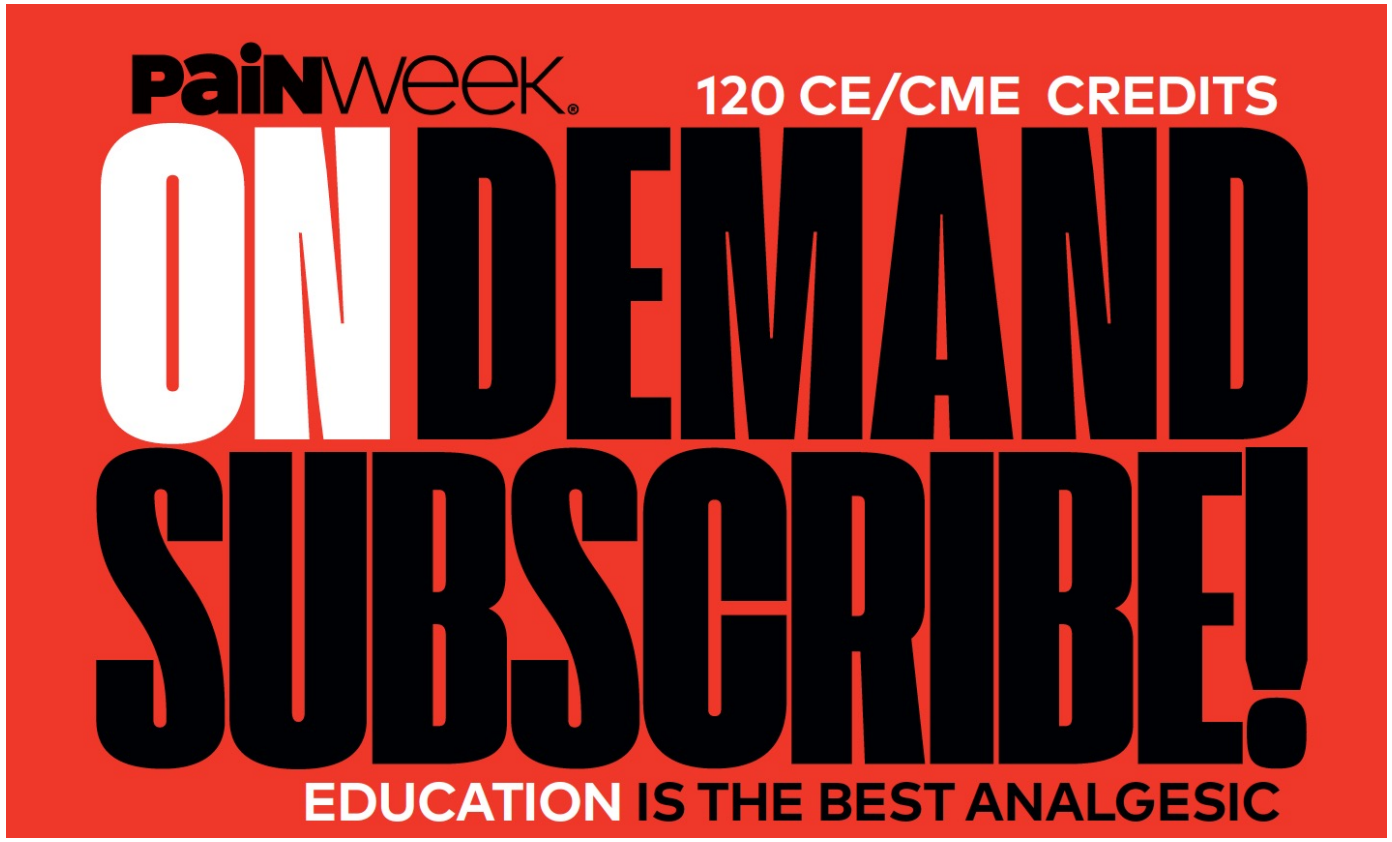
Jen Bolen, JD

865-755-2369 (text first)

jbolen@legalsideofpain.com

THANK YOU!

DIGITAL ALL ACCESS



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