# Drugs, Documentation, and DEA

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

Prepared and Presented by Jen Bolen, JD

Updated as of August 11, 2020

# Disclosures

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

# Objectives

1. Review DEA regulatory requirements for a valid controlled substance prescription during the COVID-19 PHE and using telemedicine.

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

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 Issued via Telemedicine During the COVID-19 PHE

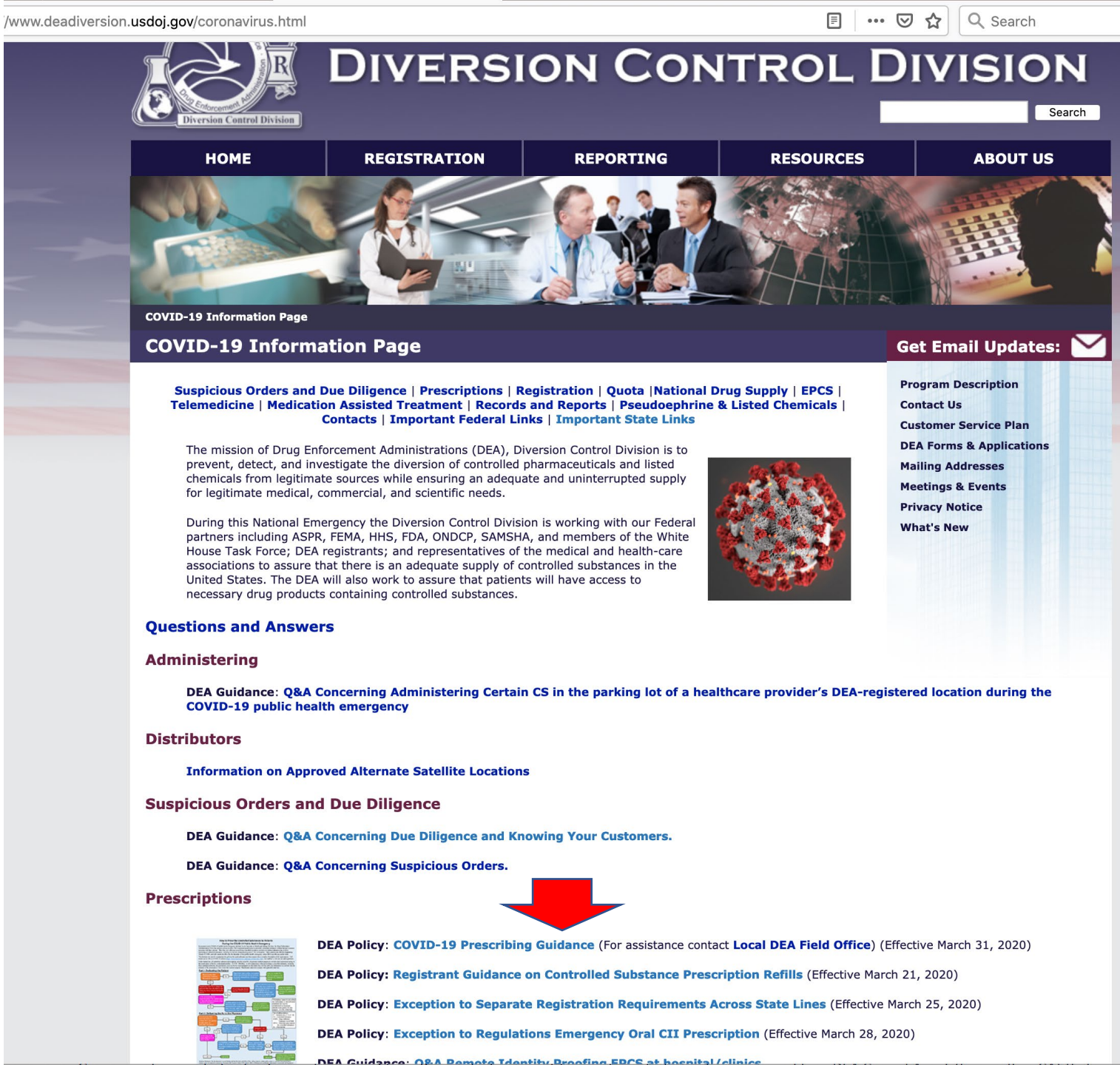
## Objective #1

# DEA Website and Guidance

https://www.deadiversion.usdoj.gov

# DEA's COVID-19 Web Page

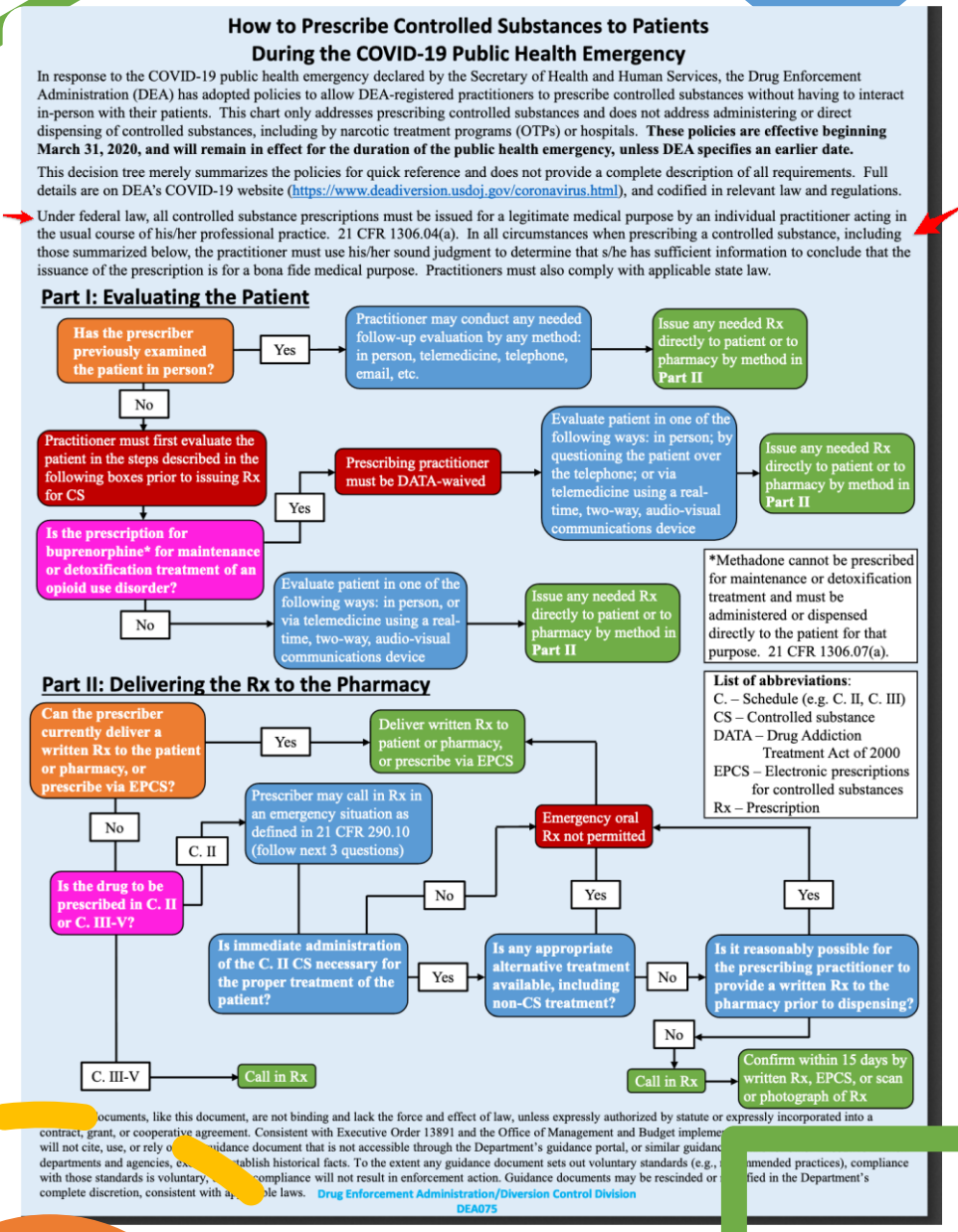
https://www.deadiversion.usdoj.gov/coronavirus.html.



# 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 → Prescriber may call in Rx in an emergency situation as defined in 21 CFR 290.10 (follow next 3 questions)
- Is the drug to be prescribed in C. II or C. III-V?
  - C. II → 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?
      - No → Is it reasonably possible for the prescribing practitioner to provide a written Rx to the pharmacy prior to dispensing?
        - No → Call in Rx → Confirm within 15 days by written Rx, EPCS, or scan or photograph of Rx
        - Yes → Emergency oral Rx not permitted
      - Yes → Emergency oral Rx not permitted
    - 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

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DEA075

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

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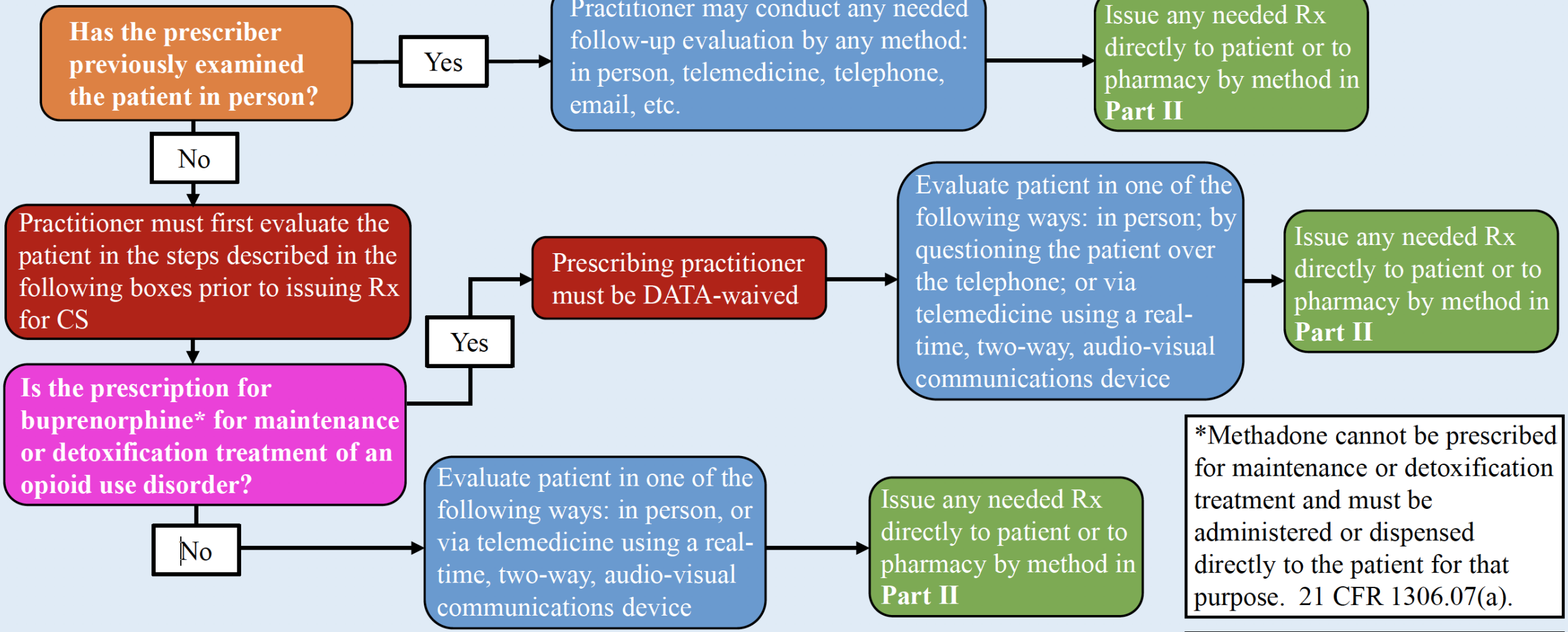
https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-023)(DEA075)Decision_Tree_(Final)_33120_2007.pdf

# Part I: Evaluating the Patient

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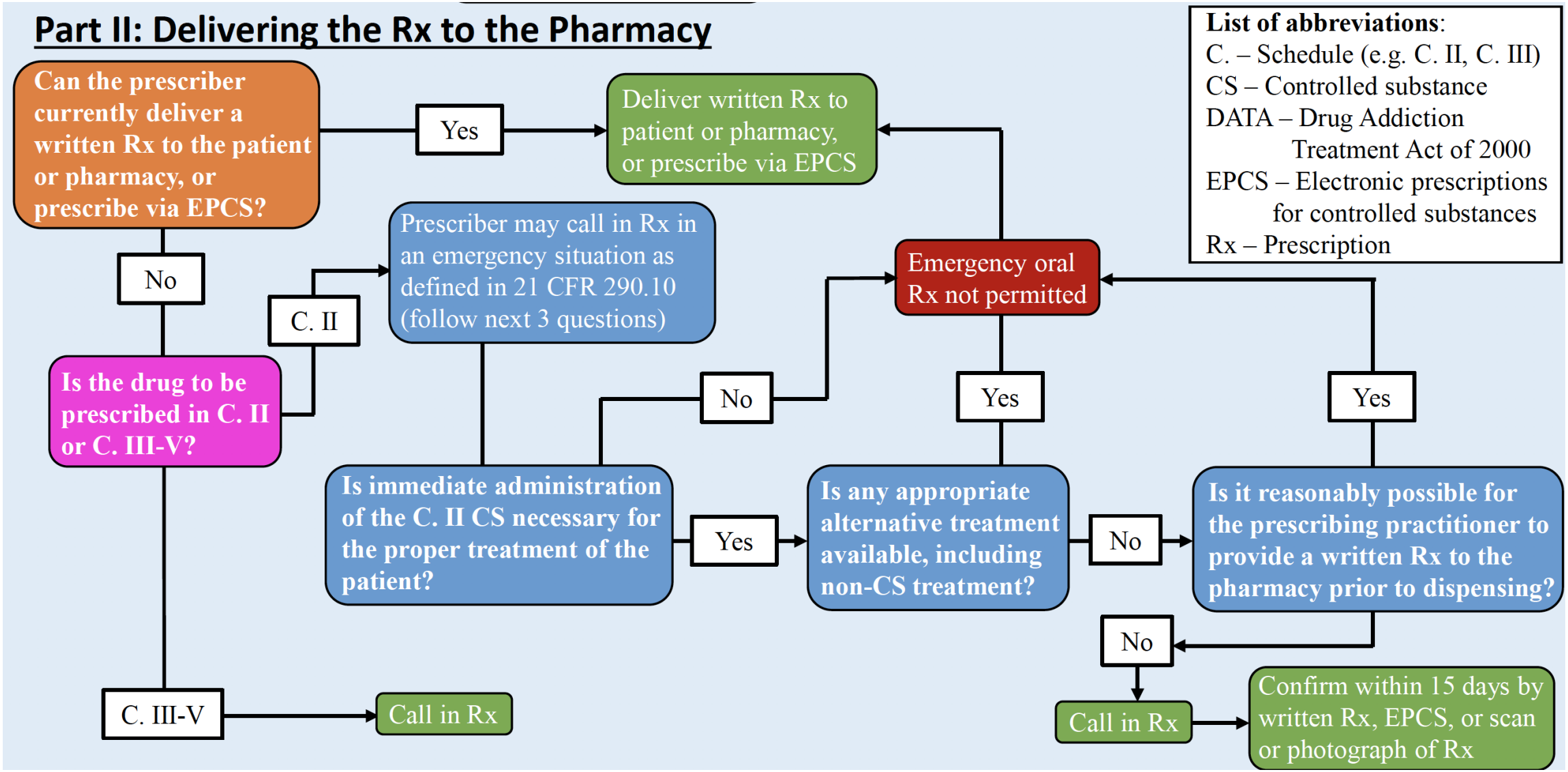


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# DEA &
# Current Telehealth Guidance

**Current as of August 11, 2020**

# 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

# Key DEA Requirements for Valid CS Rx via Telehealth (Not previously evaluated patients)

- CS Rx must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.

- The telemedicine communication must be *audio-visual, real-time, two-way interactive communication system.*

- The practitioner is acting in accordance with applicable federal and state laws

# Key DEA Requirements for Valid CS Rx via Telehealth (Established Patients)

- CS Rx must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.

- Any form of communication (in-person, telephone, email, telemedicine), subject to the requirement below.

- The practitioner is acting in accordance with applicable federal and state laws

# Question #1

**PICK THE MOST COMPLETE ANSWER: When prescribing controlled substances to a NEW PATIENT 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 using 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 a recent DEA Administrative Case against a New Jersey Prescriber: *In re Kaniz F. Khan-Jaffery, MD*

# 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 2/26/2020

*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

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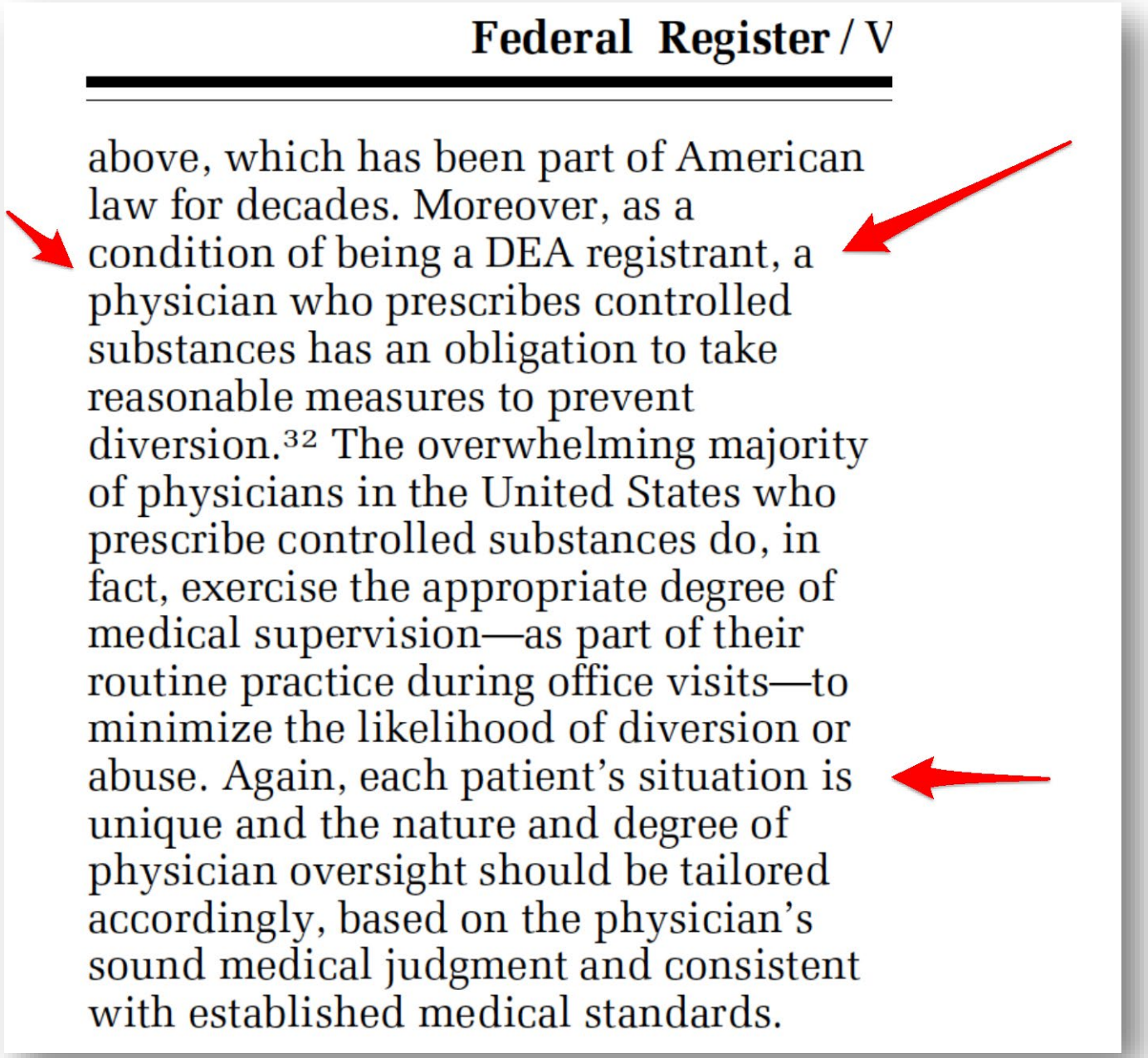

Federal Register / V

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

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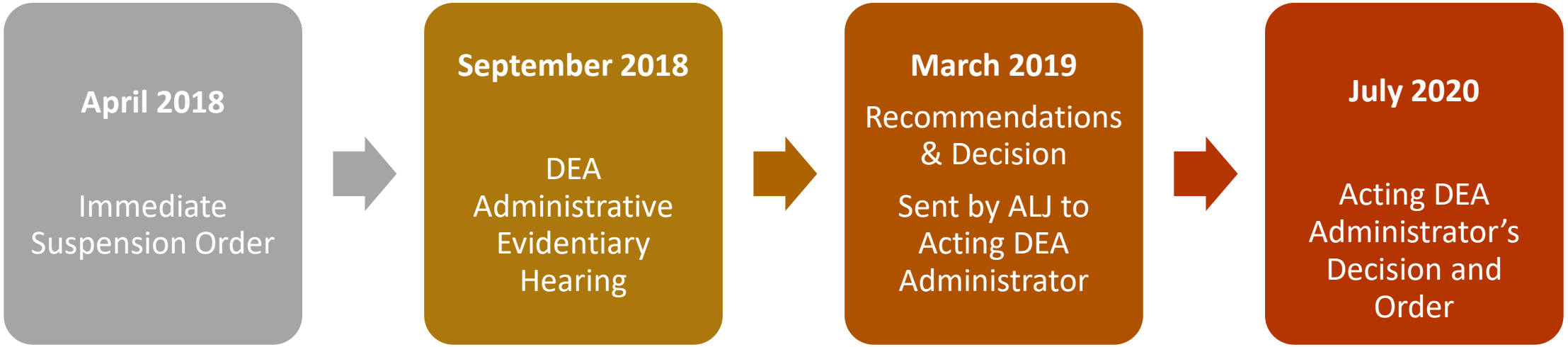
*What additional precaution should be taken when a patient has a history of drug abuse?*

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.

# 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.

# Case Timeline




ALJ = Administrative Law Judge

# Key Issue – Physical Examination and Documentation

- **GOVERNMENT EXPERT:** A physical examination needs to be more than an observation. An observation is not really a physical examination. Observing a patient move does not meet the standard of care.
  - "Could you please move while I watch you and observe you and measure how much you can move your [arm, back, leg]" – this is part of a physical exam.
  - HOWEVER, it is not a physical exam to simply watch the patient's undirected movement.
  - An exception might be when treating a patient for terminal cancer pain.
- **NEW JERSEY LAW:** Applicable regulation requires a physical examination of the patient BEFORE prescribing a Schedule II controlled substance. This also applies to established patients.
- **TAKEAWAY:** Document your requests to the patient to move AND your observations.

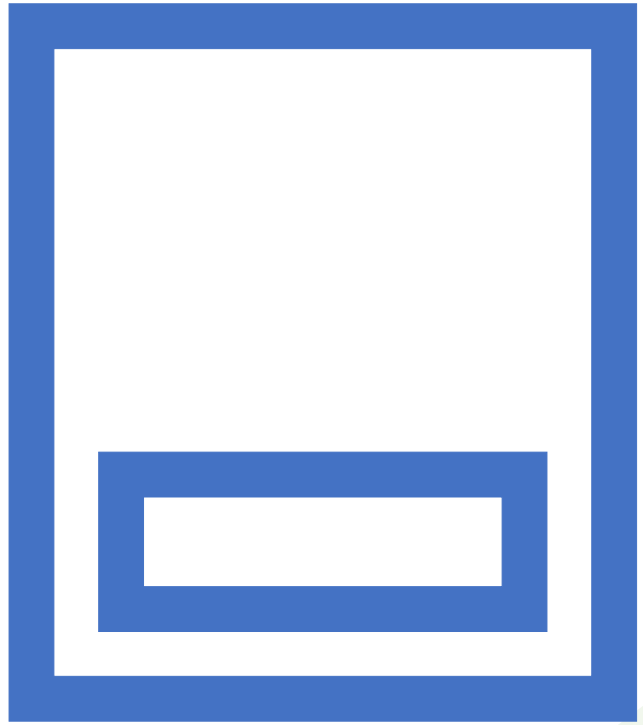
# Key Issue – UDT Results Inconsistent with Prescribed Medication

- **GOVERNMENT EXPERT:** UDT results that are negative for the prescribed controlled medication are inconsistent and the prescriber must take steps to reconcile the matter with the patient. The government's expert referred to the "parent compound" and the "breakdown products" (metabolites).
- **GOVERNMENT EXPERT:** The prescriber should document this counseling and the 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.

# Key Issue – Level of Documentation Required 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.
- **DEFENSE POSITION:** The “automatic” 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 E-Clinical ARE INSUFFICIENT DOCUMENTATION**
- **TAKEAWAY: Do more than use boilerplate chart entries.** Tie the results, to the action, to the plan and prescribing decision.



# Key Issue – Does a Patient Have to Be Dismissed 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.
- 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.

# Key Issue – Action & Documentation Requirements 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
  - 1. “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,”
  - 2. “to monitor compliance with the treatment agreement . . . ,
  - 3. “to 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
  - 4. “to 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 #.

# Key Issue – 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 was 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 positives for alcohol metabolites 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.**

# Case Result

- **The Administrative Law Judge found:**
  - Recommended a sanction short of revocation.
- The ACTING DEA ADMINISTRATOR DISAGREED WITH THE ALJ and REVOKED THE PHYSICIAN'S REGISTRATION
- In the end: 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.
- The physician failed to 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.
- The physician essentially failed to 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.

# ACTING DEA ADMINISTRATOR'S CONCLUSION REGARDING 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. 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. 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."

- "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."

# Question #2

**PICK THE MOST COMPLETE ANSWER: When controlled substances are prescribed, documentation is necessary to show that all generally accepted tasks were accomplished in which of the following categories:**

A. History, Physical Examination, Risk Evaluation, Review of Prior Records, Diagnostic Testing and Review, Diagnosis and Treatment Plan, Informed Consent and Treatment Agreement, Periodic Review and Risk Monitoring, Coordination of Care and Use of Consultations and Referrals.

B. History, Plan, and Monitoring.

C. History, Physical Examination, Follow-up Care.

D. History, Physical Examination, Periodic Review, and Consultations/Referrals.

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 2/26/2020.

## 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.

# Things you should do . . . soon!

1

## Review

- Review the DEA Decision-Tree and Telemedicine Directives.
- Review the Khan-Jaffrey Decision (handout)

2

## Download

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

3

## Evaluate

- Evaluate your documentation efforts.

4

## Ask

- Ask for help on the more difficult documentation issues.

# 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 medication renewal, Mr. Smith told you that he wanted to try cannabis and you told him that you would not be able to prescribe/recommend it to him because of potential increased risk associated with his medical breathing conditions (COPD, asthma).**

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**Fast forward two weeks and you learn from Mr. Smith that he is indeed smoking cannabis regularly, because it helps him remain calm during the COVID-19 crisis.**

**He says he's smoking cannabis and taking the opioids and gabapentin you prescribe to him.**

You have performed three telemedicine visits during the COVID-19 PHE and continue to prescribe him controlled medication.

# Case Based Learning Questions – Mr. Smith

Your colleagues have encouraged you to cut back on the opioids you prescribe to Mr. Smith.

Is this a good idea? Why?

What are the risk issues here?

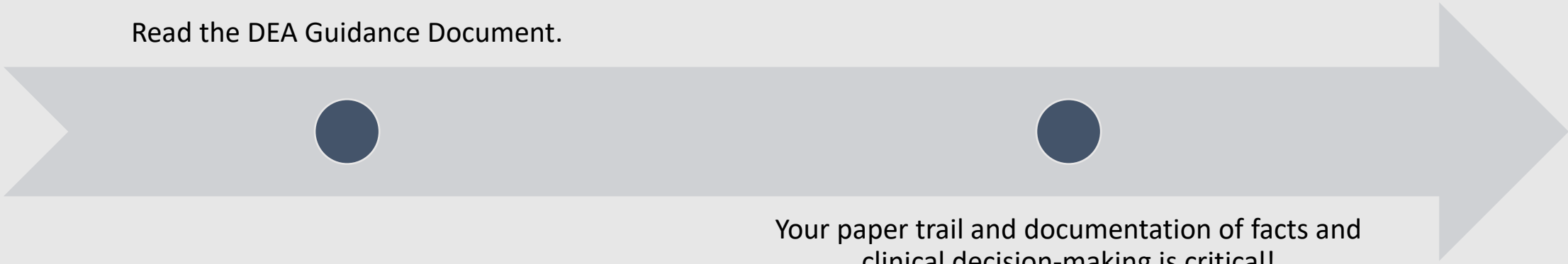
If you are going to continue prescribing opioids to Mr. Smith via telemedicine, what steps should you take to demonstrate and document that your opioid prescribing is still supported by a legitimate medical purpose and that you continue to act in the usual course of professional practice?

# Summary and Questions

# 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!

# Documentation Takeaway Points

## DO NOT RELY ON

DO NOT use boilerplate to document your initial risk evaluation and ongoing risk monitoring

- Address UDT results in a timely fashion.
- Do not ignore UDT results.

## Update

Update documentation and educational efforts to keep patients informed of risks related to opioid use.

- Document counseling, action plan, and thought process.
- Know your state rules.

# Other Takeaway Points

- The baseline requirements are still the same for controlled substance prescribing (legitimate medical purpose while acting in the usual course of professional practice – meaning according to “standards of care”)!
- Follow DEA’s added requirements for controlled substance prescribing during COVID-19.
- Conduct regular checks of the DEA’s website. https://www.deadiversion.usdoj.gov/

# Contact Information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THANK YOU!