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1

Drugs, Documentation, and DEA

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

Prepared and Presented by Jen Bolen, JD

2

Disclosures

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

3

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 Koniz F. Khan-Jaffery*, MD (2020) AND in DEA Administrative Case: In re George Pursley, MD (Denial of Application 12/11/20)

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.

4

Review DEA Regulatory Requirements for a Valid Controlled Substance Prescription Issued via Telemedicine During the COVID-19 PHE

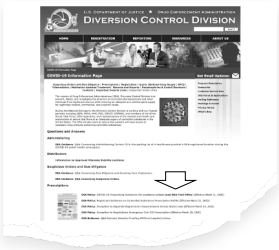
Objective #1

5

https://www.deadiversion.usdoj.gov

DEA Website

6



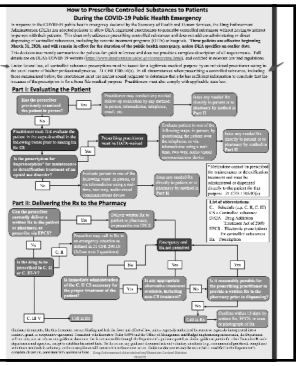
DEA's COVID-19 Information Page

https://www.deadiversion.usdoj.gov/coronavirus.html, accessed 02/04/2021.

7

DEA's COVID-19 PRESCRIBING GUIDANCE (Current as of February 4, 2021)

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



8

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.

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

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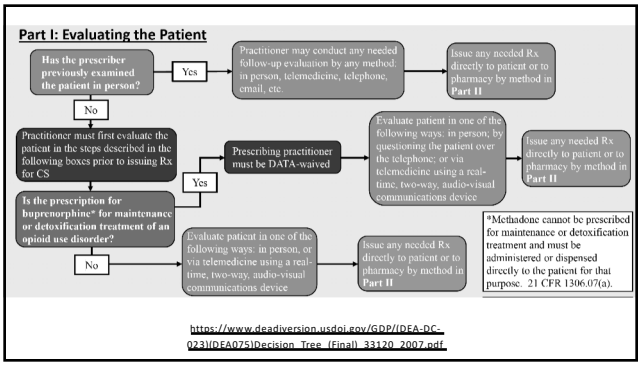

https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-023)(DEA075)Decision_Tree_(Final)_33120_2007.pdf

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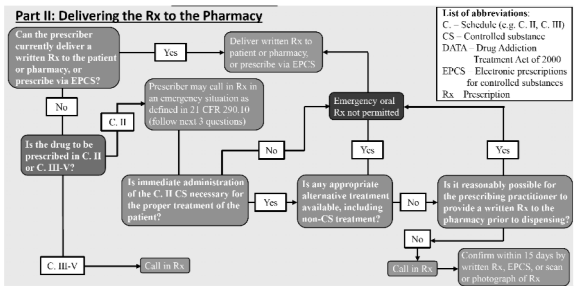
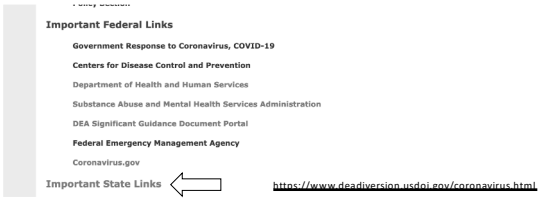


https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-023)(DEA075)Decision_Tree_(Final)_33120_2007.pdf

11

Other Useful Links on the DEA's COVID Information Page



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

12

Question #1

PICK THE MOST COMPLETE ANSWER: When prescribing controlled substances to a PATIENT NOT PREVIOUSLY EVALUTED 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 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

13

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)

In re George Pursley, MD (Georgia)

Objective #2

14

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?

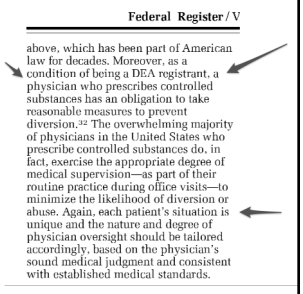
In each instance where a physician issues a prescription for a controlled substance, the physician must properly determine there is a legitimate medical purpose for the patient to be prescribed that controlled substance and the physician must be acting in the usual course of professional practice.[31]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

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

15

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

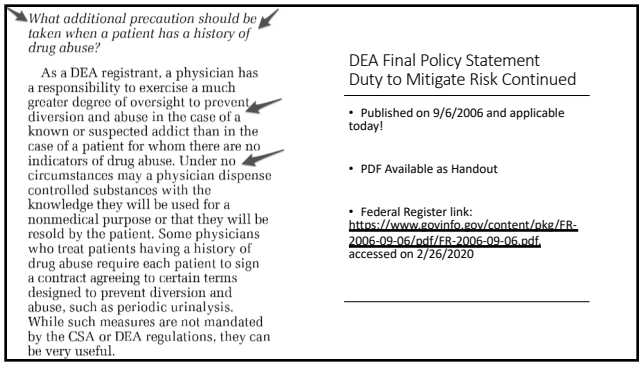
- Published on 9/6/2006 and still part of today's standard!
- PDF Available as Handout
- Federal Register link: https://www.govinfo.gov/content/pkg/FR-2006-09-06/pdf/FR-2006-09-06.pdf, accessed on 2/02/2021



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.

16



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 2/26/2020

17

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,

18

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.

19

Khan-Jaffrey Case Timeline

April 2018
Immediate Suspension Order

September 2018
DEA Administrative Evidentiary Hearing

March 2019
Recommendations & Decision Sent by ALJ to Acting DEA Administrator

July 2020
Acting DEA Administrator's Decision and Order

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.

20

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.

21

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.

22

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.

23

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.

24

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

25

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

26

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

27

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

28

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

29

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

30

In re Pursley

DEA Administrative Case
Georgia Physician
Denial of Application for Registration

SOURCE: https://www.federalregister.gov/documents/2020/12/11/2020-27236/george-pursley-md-denial-of-application, accessed 02/05/2021.

31

Pursley Case Timeline

2015	2017	2018	**Dec. 2020**
Registrant found to be in possession of >300 pre-signed controlled substance prescriptions	Registrant Applies for a New Registration at a Different Location	Hearing	DEA Acting Administrator Rejects ALJ's Recommendations and Denies the Registration
DEA Investigation	DEA Issues an Order to Show Cause and Asked that Application be denied because of Registrant's 2015 behavior	Georgia Composite Medical Board Rule Presented as a Standard	Lack of Registrant's Candor
		ALJ issues Recommendation and Decision; Recommends Registration be Issued	Nothing to show that Registrant can be trusted to adhere to standard given past behavior and evidence regarding Registrant's non-adherence to standard, especially documentation

SOURCE: https://www.federalregister.gov/documents/2020/12/11/2020-27236/george-pursley-md-denial-of-application, accessed 02/05/2021.

32

What led to the DEA's Denial of Dr. Pursley's Application for Registration?

- **Unprofessional Conduct = Failure to maintain records required by licensing board**
  - Not following the requirements of the board's pain management rule and related documentation requirements.
  - Pre-signing prescriptions (what Dr. Pursley did in 2015 at a different address).
  - **Not being candid with the DEA during its initial investigation.**
  - **Not addressing a plan for how he would comply with the controlled substance prescribing standards (federal and state) in the future; Not taking ownership of his responsibilities as a physician and DEA Registrant.**

SOURCE: https://www.federalregister.gov/documents/2020/12/11/2020-27236/george-pursley-md-denial-of-application, accessed 02/05/2021.

33

Expert Witness Testimony in Pursley regarding "minimum standards" and "unprofessional conduct"

- DEA presented expert witness testimony (Dr. Kaufman).
- Dr. Kaufman reviewed the controlled substance prescribing standards in Georgia and referred to the licensing board's pain management related rules.
- Dr. Kaufman testified that a licensing board's pain management rule presents the "minimum standard" a physician should follow when prescribing controlled substances.
  - **Failure to follow the licensing board's rule (minimum standards) is the equivalent of unprofessional conduct [in Georgia].**
- Dr. Kaufman testified that "prescribing controlled substances to a known or suspected habitual drug abuse or other substance misuser in the absence of substantial justification is also unprofessional conduct."

SOURCE: https://www.federalregister.gov/documents/2020/12/11/2020-27236/george-pursley-md-denial-of-application, accessed 02/05/2021.

34

Expert Testimony in Pursley Regarding Risk Monitoring

- Dr. Kaufman testified that **the physician is obligated** to monitor the patient's compliance with therapy and response to treatment.
  - Although the standard of care does not specify exactly how a physician is to monitor compliance, **at the very least the physician is expected to document abnormalities and then provide documented rationale for the physician's treatment decision – to do or not do something.**

SOURCE: https://www.federalregister.gov/documents/2020/12/11/2020-27236/george-pursley-md-denial-of-application, accessed 02/05/2021.

35

Expert Testimony in Pursley Regarding Documentation Efforts

- Dr. Kaufman testified that "complete medical records help prevent a physician from making a mistake due to the difficulty of recalling everything that transpired with the passage of time…Errors or sloppiness are not an 'adequate explanation of the failure to document properly."

SOURCE: https://www.federalregister.gov/documents/2020/12/11/2020-27236/george-pursley-md-denial-of-application, accessed 02/05/2021.

36

DEA Administrative Case

Florida

In re Jeanne E. Germeil, MD

(Nov. 2020)

Usual Course of Professional Practice Area	DEA Findings Based on Evidence & Expert Witness (MD) Testimony
Physical Examination	**Government's Expert MD - "It is the physician's responsibility to examine the patient, to draw his/her own conclusions, and to maintain medical records."** The Florida Rule does not define what constitutes a physical exam and does not necessarily require that a physician conduct a physical examination of the patient each time the patient presents for an appointment. **HOWEVER, the Florida standard of care "requires a physician to perform a physical examination in certain circumstances including**: (a) before first prescribing a controlled substance, (b) when the patient requests a higher dose of controlled substances, (c) when the patient presents with new symptoms or complaints, has a new diagnosis, or has not been seen for a period of months."
Resource	**Federal Register, Vol. 85, No. 224/Thursday, Nov. 19, 2020, at p.73789 at n.14.**

ONLINE SOURCE: https://www.federalregister.gov/documents/2020/11/19/2020-25528/jeanne-e-germeil-md-decision-and-order, accessed 02/05/2021.

37

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.

38

Case-Based Learning Example

Drugs, Documentation & DEA

39

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.

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?

40

Brainstorming Mr. Smith's case

EDUCATE

- Benzodiazepines and Opioids
- Other ways to control anxiety

RISK MITIGATE

- Naloxone
- Supply of Opioid
- Talk with Psychiatrist (get HIPAA consent first)
- Check PDMP
- UDT
- Medication Counts

41

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

42

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

Objective #3

43

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

44

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!

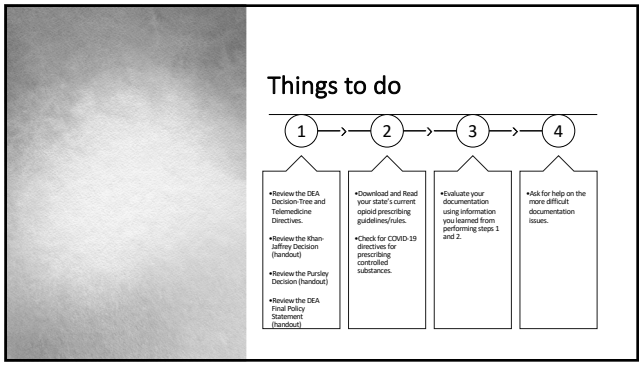
45

Action & Documentation Takeaway Points

DO NOT RELY ON	Update
BOILERPLATE ENTRIES IN EMR FOR CRITICAL CONTROLLED SUBSTANCE PRESCRIBING OBLIGATIONS	RISK ASSESSMENT MATERIAL PRESCRIBING RATIONALE PATIENT EDUCATION

46

Things to do



47

Contact Information

Jen Bolen, JD

865-755-2369 (text first)

jbolen@legalsideofpain.com

THANK YOU!

48

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September 7-11 in Las Vegas

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49