Drugs, Documentation, and DEA

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

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Disclosures

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

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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 Melanie Baker*, NP (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.

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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

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https://www.deadiversion.usdoj.gov

DEA Website

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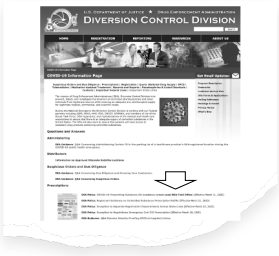

DEA's COVID-19 Information Page

https://www.deadiversion.usdoj.gov/coronavirus.html, accessed 06/01/2021.

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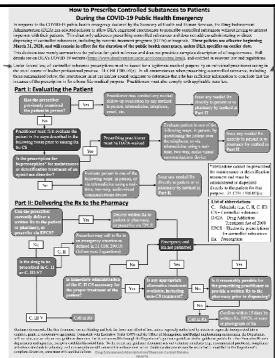
DEA's COVID-19 PRESCRIBING GUIDANCE
(Current as of June 1, 2021)

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



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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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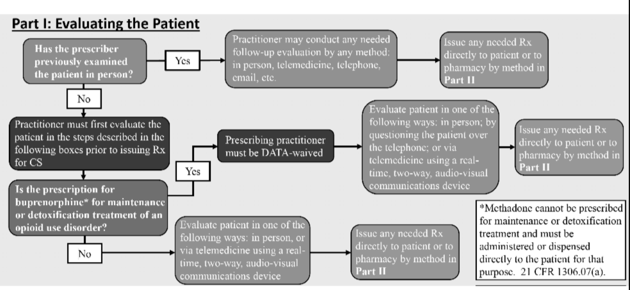

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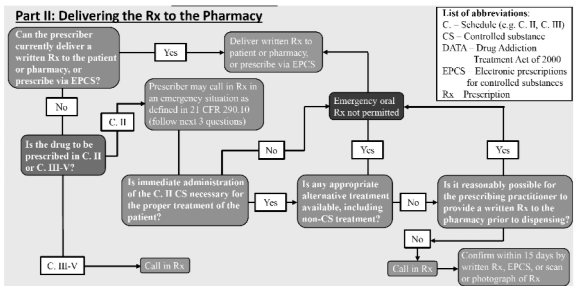

https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-023)(DEA075)Decision_Tree_(Final)_33120_2007.pdf

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Other Useful Links on the DEA's COVID Information Page

Important Federal Links

- Government Response to Coronavirus, COVID-19
- Centers for Disease Control and Prevention
- Department of Health and Human Services
- Substance Abuse and Mental Health Services Administration
- DEA Significant Guidance Document Portal
- Federal Emergency Management Agency
- Coronavirus.gov

Important State Links ⇦

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

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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

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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 Melanie Baker, NP (Louisiana), Decision Published 2021

Objective #2

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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*.

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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 *06/01/2021*

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.

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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.

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 06/01/2021

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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.

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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.

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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

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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.

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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.

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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.

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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.

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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.

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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

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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

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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

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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

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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

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In re Baker

DEA Administrative Case
Louisiana Nurse Practitioner
Registration Revocation

SOURCE: https://www.federalregister.gov/documents/2021/05/05/2021-09463/melanie-baker-np-decision-and-order, accessed 06/01/2021

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Baker Case Timeline

May 2019

Immediate Suspension Order Issued;

Covered an investigative period from May 2017 to May 2019

Jul. – Oct. 2019

Registrant Requests a Hearing

Hearing Held

Nov. 2019

ALJ issues Recommendation and Decision;

Recommends Registration be REVOKED

May 2021

DEA Acting Administrator Agrees with the ALJ

Inappropriate Prescribing to five patients

Violated Federal and State CS Rx Laws

SOURCE: https://www.federalregister.gov/documents/2021/05/05/2021-09463/melanie-baker-np-decision-and-order, accessed 06/01/2021

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What led to the DEA's Revocation of Baker's DEA Registration?

Respondent **consistently failed to**:

(1) Perform adequate psychiatric and cognitive evaluations;

(2) Make appropriate diagnoses based on sufficient clinical evidence, and document [those] diagnoses in [her] medical records;

(3) Document a legitimate medical purpose for the controlled substances that [Respondent] prescribed;

(4) Monitor [her] patients' medication compliance; and

(5) Respond to red flags of drug abuse and diversion.

SOURCE: https://www.federalregister.gov/documents/2021/05/05/2021-09463/melanie-baker-np-decision-and-order, accessed 06/01/2021

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Key Aspects of the Government's Case

- The Government's documentary evidence consisted **primarily of patient files and prescription records for five individuals prescribed controlled substances by Respondent between February 2017 and May 2019.**
- The Government's evidence also contained a copy of the **Louisiana Prescription Drug Monitoring Results** for Respondent from May 23, 2017, to May 23, 2019.
- The Government included the Curriculum Vitae for its **expert witness Dr. Chambers**.
- The Government **called two witnesses** to testify at the hearing: A DEA Diversion Investigator (hereinafter, DI) and the Government's expert Dr. Chambers.

SOURCE: https://www.federalregister.gov/documents/2021/05/05/2021-09463/melanie-baker-np-decision-and-order, accessed 06/01/2021

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Key Aspects of DEA Diversion Investigator's Testimony About the Registrant's Prescribing Patterns

- DEA identified several **"red flags"** in the prescriptions issued by Respondent, **including "patients that were living at the same address, patients that were coming from long distances, patients that were being prescribed high strengths of amphetamines and other dangerous combinations**."
- In July 2018, DI **queried the Louisiana Prescription Monitoring Program for Respondent's prescriptions and discovered the same red flags**.
- DI also testified that she **received statistics from the Louisiana Board of Pharmacy indicating that Respondent was the number one prescriber of controlled substance dosage units among mid-level practitioners in the state**.

SOURCE: https://www.federalregister.gov/documents/2021/05/05/2021-09463/melanie-baker-np-decision-and-order, accessed 06/01/2021

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Key Background of the Government's Medical Expert (Andrew Chambers, MD)

- Licensed physician and a board-certified addiction psychiatrist. In clinical practice since 2000.
- Teaches at various institutions, including as a tenured Associate Professor of Psychiatry and director of the addiction psychiatry specialty at the Indiana University School of Medicine.
- He has had the opportunity to teach nurses and to supervise nurse practitioners, including providing oversight of their prescribing decisions.
- Although licensed in Indiana, Dr. Chambers testified that he was familiar with the standard of care for prescribing controlled substances in Louisiana and had reviewed relevant sections of the Louisiana code.

SOURCE: https://www.federalregister.gov/documents/2021/05/05/2021-09463/melanie-baker-np-decision-and-order, accessed 06/01/2021

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Respondent Baker's Case Summary

- The Respondent's documentary evidence consisted of her CV, Initial Psychiatric Evaluation and Management Forms implemented in Respondent's practice, starting in October 2018, following a quality review from an insurance company, and the practice's discharge policy.
- She also provided eight scholarly articles in defense of her treatment practices.
- She provided limited testimony on her own behalf through her five exhibits.

SOURCE: https://www.federalregister.gov/documents/2021/05/05/2021-09463/melanie-baker-np-decision-and-order, accessed 06/01/2021

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DEA's Findings Regarding Respondent's Case

- Despite being instructed during the hearing that she could not present her case for the first time in closing, Respondent attempted to introduce evidentiary "facts" in her post hearing brief that she presumably believed to be mitigating or to explain the rationale behind her prescribing.
- Some of these "facts" had little-to-no relevance to this case, and other "facts" were blanket statements that Respondent's actions were correct and/or were supported by scientific evidence.
- None of these supposed "facts" were given under oath and none were subject to cross-examination; therefore, DEA found that they were "not part of the evidentiary record."
- Even if Respondent's "facts" had been appropriately submitted through testimonial evidence, they would likely not have outweighed the credible testimony of the Government's expert.
- Moreover, many of these "facts" could not be given significant weight because they were not documented in the patient files, as the Government's expert credibly testified was required to satisfy the standard of care.

SOURCE: https://www.federalregister.gov/documents/2021/05/05/2021-09463/melanie-baker-np-decision-and-order, accessed 06/01/2021

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The Standard of Care Applied in the Case – From the State of Louisiana

Based on the testimony of the Government's Medical Expert, the DEA Administrator applied the following standard of care (generally stated below) used to evaluate Respondent's Prescribing Practices:

(1) Did Respondent make an appropriate assessment and evaluation to make a diagnosis?
(2) Did Respondent use sound rationale for prescribing controlled substances related to that diagnosis?
(3) Did Respondent use ongoing monitoring to ensure that the desired outcome is achieved, and undesirable side effects are not experienced?
(4) Did Respondent create and maintain appropriate documentation?

- Throughout his testimony, Dr. Chambers expanded on the standard of care, explaining in detail what a prescriber must do to satisfy each of these four requirements.

SOURCE: https://www.federalregister.gov/documents/2021/05/05/2021-09463/melanie-baker-np-decision-and-order, accessed 06/01/2021

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Key Learning Points

THE CLINICAL INTERVIEW AND EVALUATION

- A prescriber should conduct "a clinical interview that would cover psychiatric history, addiction history, social history, and demographics, in order to develop a hypothesis as to the correct diagnosis."
- To make a psychiatric diagnosis, "the standard of care is that the physician would evaluate for signs and symptoms that are consistent with that diagnosis and actually write them in the chart."
  "it is actually not sufficient to simply state the diagnosis and not have evidence to support that diagnosis."
- A prescriber should also [use] objective measures testing because "the nature of addictive disease is such that the self-report is often not as reliable as you might find in other areas of health care. . . ."
- Dr. Chambers testified that urine drug screening and evaluation of the prescription drug monitoring program database are two ways to conduct an objective assessment.

SOURCE: https://www.federalregister.gov/documents/2021/05/05/2021-09463/melanie-baker-np-decision-and-order, accessed 06/01/2021

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Key Learning Points

WHAT IS THE PURPOSE OF THE INITIAL EVALUATION?

- Dr. Chambers also explained that *a provider must conduct an appropriate assessment or evaluation to inform the diagnosis even when that provider is sharing in care or taking over care of a patient from a prior prescriber*.

  "There is a responsibility of the second practitioner to look at the information from the prior prescriber, but to also come to their own conclusion and build a treatment plan that would incorporate [the prior] information but also incorporate their own examination, . . . **you owe it to the patient to double-check the prior prescriber**."

- **If a new provider "does not make any changes" and" continues to do exactly what the previous provider did," then the new provider "owns that person's decision."**

SOURCE: https://www.federalregister.gov/documents/2021/05/05/2021-09463/melanie-baker-np-decision-and-order, accessed 06/01/2021

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Key Learning Points

WHAT CONSTITUTES SOUND RATIONALE FOR PRESCRIBING CONTROLLED SUBSTANCES?

- Sound rationale means a **"clear, strong basis and must be justified in the medical records."**
  - **"Clinical decision-making about controlled substances especially is a multi-variable decision" that has to be made within the "whole context" of an individual patient.**
- **Dr. Chambers' opinion is further supported by Louisiana law.**
  - La. Admin. Code states that **"no APRN shall prescribe any controlled substance or other drug having addiction-forming or addiction sustaining liability without a good faith . . . medical indication."**

SOURCE: https://www.federalregister.gov/documents/2021/05/05/2021-09463/melanie-baker-np-decision-and-order, accessed 06/01/2021

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Key Learning Points

WHAT CONSTITUTES SUFFICIENT ONGOING MONITORING OF THE PATIENT'S NEED FOR AND USE OF CS?

- An initial evaluation is comprehensive, **and that at each subsequent visit a physician should "continuously gather new data to:**

  A. Confirm the patient is not running into trouble with the [prescribed medications], but

  A. Confirm whether the medications are working, or whether to discontinue prescribing and your rationale for the same.

SOURCE: https://www.federalregister.gov/documents/2021/05/05/2021-09463/melanie-baker-np-decision-and-order, accessed 06/01/2021

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Key Learning Points

WHAT CONSTITUTES SUFFICIENT ONGOING MONITORING OF THE PATIENT'S NEED FOR AND USE OF CS?

- Dr. Chambers testified that he considers "the potential for diversion" to be an "unfortunate side effect," and that diversion is "more common if a practitioner is not also monitoring the patient or dosing them correctly."
- "Monitoring means urine drug screens, and/or prescription drug monitoring program database inquiries."
- Dr. Chambers also explained that addiction is a negative side effect that a prescriber should monitor for signs of.

SOURCE: https://www.federalregister.gov/documents/2021/05/05/2021-09463/melanie-baker-np-decision-and-order, accessed 06/01/2021

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Key Learning Points

WHAT CONSTITUTES SUFFICIENT ONGOING MONITORING OF THE PATIENT'S NEED FOR AND USE OF CS?

- Dr. Chambers opined that "any time you make a diagnosis, or if you have sufficient evidence that a person has addiction, it is absolutely a standard of care to drug-test them . . . randomly and frequently."
- **According to Dr. Chambers, a prescriber "cannot rely on a patient with mental illness and addiction to self-report . . . it needs confirmation with drug-testing."**
- **Appropriate monitoring also requires investigation and documentation of issues that arise, such as reasons for a missed appointment, potential withdrawal if the patient was without medication, and reports of hospitalization.**

SOURCE: https://www.federalregister.gov/documents/2021/05/05/2021-09463/melanie-baker-np-decision-and-order, accessed 06/01/2021

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Key Learning Points

WHAT CONSTITUTES SUFFICIENT DOCUMENTATION OF THE MEDICAL RECORD?

- The medical record must document a comprehensive evaluation including a mental status or psychiatric exam, and the history including the psychiatric history, substance abuse history, and social history.
- **Appropriate documentation requires the practitioner to "build a narrative that describes real people and events," including what the patient is doing that causes concern, in order to establish "that there really is a cognitive problem."**
- The record must also document objective measures testing, such as urine drug screening or inquiries of the prescription drug monitor database.

SOURCE: https://www.federalregister.gov/documents/2021/05/05/2021-09463/melanie-baker-np-decision-and-order, accessed 06/01/2021

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Key Learning Points

WHAT CONSTITUTES SUFFICIENT DOCUMENTATION OF THE MEDICAL RECORD?

- Moreover, for documentation to be appropriate, anyone who sees a patient must sign their notes in the medical record.
- **A practitioner signing a note written by another practitioner "owns it" despite the ambiguity over "who actually made the decisions."**
- **Dr. Chambers also explained that the standard of care requires that a prescriber act on data obtained from urine drug screening or the prescription drug monitoring program: "you cannot just gather that and put it in the chart."**

SOURCE: https://www.federalregister.gov/documents/2021/05/05/2021-09463/melanie-baker-np-decision-and-order, accessed 06/01/2021

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Controlled Substances Commonly Prescribed by Baker

- Amphetamines
- Benzodiazepines
- Combinations

SOURCE: https://www.federalregister.gov/documents/2021/05/05/2021-09463/melanie-baker-np-decision-and-order, accessed 06/01/2021

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Individual patient case highlights:

Patient FA, a 3-year-old child diagnosed by Baker as having ADD.

- Respondent did not appropriately monitor F.A.'s use of the controlled substances she was prescribed.
- Dr. Chambers explained that you cannot rely on a three-year-old child to accurately report on her compliance with a controlled substance treatment regimen.
- Dr. Chambers testified, "if the parents are using benzos and amphetamines from some source, and there's extreme poverty, and they live really far away, and now the patient's been out of the Adderall for a month, and it is possible they could be selling [the controlled substances, you might get a urine drug screen on the child, or do pill counts, or something to understand what's going on."

SOURCE: https://www.federalregister.gov/documents/2021/05/05/2021-09463/melanie-baker-np-decision-and-order, accessed 06/01/2021

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Individual patient case highlights:

Patient MG, an adult with a bi-polar disorder diagnosis and more.

- **Between February 2017 and May 2019**, Respondent issued **forty-two controlled substance prescriptions** to M.G. **for mixed amphetamine salts, and clonazepam**.
- All of Baker's prescriptions were issued outside the usual course of professional practice and lacked legitimate medical purpose.

SOURCE: https://www.federalregister.gov/documents/2021/05/05/2021-09463/melanie-baker-np-decision-and-order, accessed 06/01/2021

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Individual patient case highlights:

Patient MG, an adult with a bi-polar disorder diagnosis and more.

- **Respondent should have monitored M.G. with drug testing upon receiving the May 27, 2014, report from Dr. L.G., Ph.D. that diagnosed MG with "Cannabis Use Disorder—Mild to Moderate," and "Tobacco Use Disorder—Moderate."**
- **Dr. Chambers explained that where "there [are] substance use issues, you have to start drug-testing. People [do not] have compartmentalized addictions . . . [t]he part of the brain where addiction happens does not care what the source of the drug is."**

SOURCE: https://www.federalregister.gov/documents/2021/05/05/2021-09463/melanie-baker-np-decision-and-order, accessed 06/01/2021

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Individual patient case highlights:

Patient MG, an adult with a bi-polar disorder diagnosis and more.

- On May 22, 2017, MG informed Respondent that he was taking "Norco for back from [primary care physician]" due to "4 herniated disks from a motorcycle accident."
- Dr. Chambers opined that the stimulant and benzodiazepine prescriptions Respondent issued to MG were already outside the standard of care, but they became "super-dangerous both with respect to addiction and worsening of mental illness," when MG started receiving narcotics from his primary care physician.

SOURCE: https://www.federalregister.gov/documents/2021/05/05/2021-09463/melanie-baker-np-decision-and-order, accessed 06/01/2021

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Individual patient case highlights:

Patient MG, an adult with a bi-polar disorder diagnosis and more.

- In addition to not having sound rationale for prescribing, Dr. Chambers noted that **Respondent did not appropriately monitor MG's use of the controlled substances** he was prescribed.
- For example, in May 2017, Dr. Chambers testified, Respondent was aware that MG was taking Norco prescribed by another practitioner and yet she issued to MG three months of prescriptions for Adderall and Klonopin.

SOURCE: https://www.federalregister.gov/documents/2021/05/05/2021-09463/melanie-baker-np-decision-and-order, accessed 06/01/2021

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Individual patient case highlights:

Patient MG, an adult with a bi-polar disorder diagnosis and more.

- Dr. Chambers opined that "you would expect the patient to be back in August, but we did not see that . . . then there was a note for October and the patient was a no-show."
- Dr. Chambers explained that the patient had "been going on for five months on a lethal combination of drugs prescribed by doctors, and Respondent knew this."
- Dr. Chambers explained that, at this point, some investigation was necessary to determine what had happened in the two months during which MG, had he taken the controlled substances as prescribed, would have been out of medication.

SOURCE: https://www.federalregister.gov/documents/2021/05/05/2021-09463/melanie-baker-np-decision-and-order, accessed 06/01/2021

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Individual patient case highlights:

Patient MG, an adult with a bi-polar disorder diagnosis and more.

Dr. Chambers opined that there were three possible scenarios:

1. The controlled substances may not have "actually gotten in his body" as he could have been "selling every bit of it."
2. MG could have run out and gotten the drugs "from street sources."
3. MG was "fine going with these big gaps without controlled substances . . . so MG should not be on them anyway."

Dr. Chambers' testimony made clear that there was "nothing appropriate" going on in any of the three scenarios and that some investigation was required to appropriately monitor MG.

Dr. Chambers opined that "this was not health care."

SOURCE: https://www.federalregister.gov/documents/2021/05/05/2021-09463/melanie-baker-np-decision-and-order, accessed 06/01/2021

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Individual patient case highlights:

Patient MG, an adult with a bi-polar disorder diagnosis and more.

Dr. Chambers testified that for patient MG, "there was not a single drug-screen in the record."

SOURCE: https://www.federalregister.gov/documents/2021/05/05/2021-09463/melanie-baker-np-decision-and-order, accessed 06/01/2021

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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.

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Case-Based Learning Example

Drugs, Documentation & DEA

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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.

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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?

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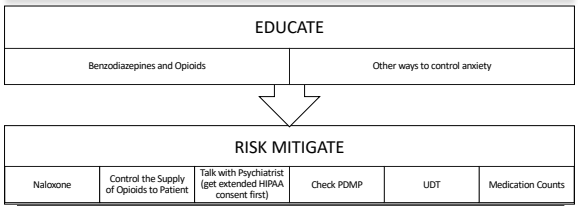
Brainstorming Mr. Smith's case



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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

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

Objective #3

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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 06/01/2021.

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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!

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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

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Things to do

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

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THANK YOU!

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