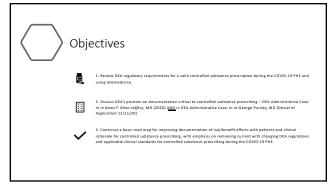
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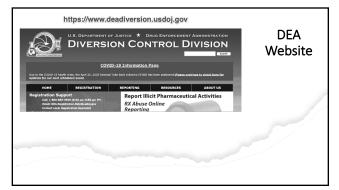


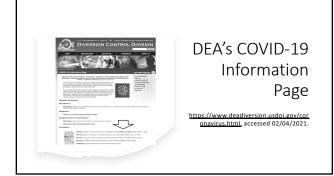


Review DEA Regulatory Requirements for a Valid Controlled Substance Prescription Issued via Telemedicine During the COVID-19 PHE

Objective #1

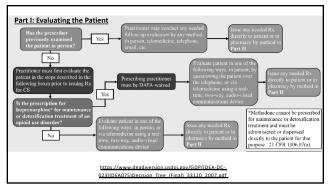
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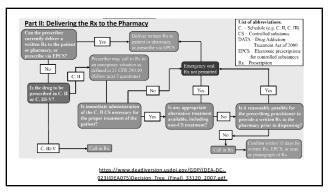


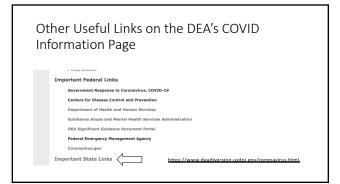


	How to Prescribe Controlled Substances to Patients
DEA's COVID-19 PRESCRIBING GUIDANCE	In segment to the EST OFFICE of the COVID-19 Public Health Emergency is because to the EST OFFICE of the EST OFFICE of the EST OFFICE O
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	CLUV  (LEADER)

## How to Prescribe Controlled Substances to Patients During the COVID-19 Public Health Emergency In response to the COVID-19 Public health caregings declared by the Secretory of Fealth and Human Services, the Drug Enforcement Administration (DEA) has adopted policies to allow DEA/registered practitioners to prescribe controlled substances without having to internal repressive with their patients. The clast early addresses proceedings controlled adoptances and does not address administration of the register. The control of the patients of of the







### 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.

audio piatrorm.

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) In re George Pursley, MD (Georgia)

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
- Federal Register link: https://www.govinfo.gov/content/pkg/FR-2006-09-06/pdf/FR-

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. <sup>31</sup> This is the basic legal requirement discussed

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

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

- Published on 9/6/2006 and still part of today's standard!
- Federal Register link: 2006-09-06/pdf/FR-2006-09-06.pdf. accessed on 2/02/2021

### $\textbf{Federal Register} / \, V$

rederal 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 provent diversion. 22 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 stuation 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 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

Khan-	Physician licensed in New Jersey and Registered to Prescribe CS.
Jaffrey Case	<ul> <li>Pharmacy data showed the physician was high-volume for controlled medication.</li> </ul>
	Physician saw 50-55 patients per day.
Background	<ul> <li>Physician put controls in place, including required referrals and UDT.</li> </ul>
	Government presented a medical expert.
	<ul> <li>Defense presented a medical expert, a medical record documentation expert, and the respondent-physician testified.</li> </ul>
	<ul> <li>Case involved an undercover "patient" and review of other real patient charts.</li> </ul>
	In re Kaniz F. Khan-Jaffery, available online at
	https://www.federalregister.gov/documents/2020/07/29/2020-
	16387/kaniz-f-khan-iaffery-md-decision-and-order.

### Khan-Jaffrey Case Timeline September 2018 March 2019 July 2020 April 2018 Recommendations & Decision Sent by ALJ to Acting DEA Administrator DEA Administrative Evidentiary Hearing 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-

20

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

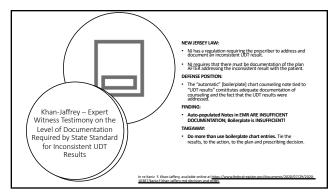
- UDT results that are negative for the prescribed controlled medication are inconsistent with the plan.
- The prescriber must take steps to reconcile the matter with the patient.

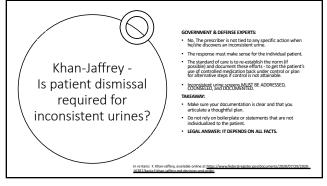
### GOVERNMENT EXPERT:

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.





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## \* 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 upstament plan, including any adjustments and referrals. \*\*NEW JERSY LAUE: NI has a regulation that requires prescribers to: - MSSSS the patient prior to issuing each prescription to determine whether the patient is experiencing problems of document the results of that assessment, prescribers to: - MSSSS the patient prior to issuing each prescription to determine whether the patient is experiencing problems of document the results of that assessment, prescribers of the patient in the patient in the patient and prescribers, and including the patient in the taking drugs, appreciated 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 Incensing borard, DEA, and crimmal cases. - This is a DEA administrative case and it resulted in the registrant's loss of her DEA. \*\*In Examples, valuable colors at time //www.bedratente.eu/document/2000/07/28/0700.\*\* \*\*In Examples of Administrative case and it resulted in the registrant's loss of the Other.eu/document.eu/document.eu/document.eu/document.eu/document.eu/document.eu/document.eu/do

GOVERNMENT EXPERT:

			_		
		ing Controlled Substances to			
	Patients who use Alco	nol			
	counseling/education on the topic is part	e drink may not be problematic, experts are likely to testify that of the standard of care. It is in NJ. sued to one patient were not issued in the usual course of		 	
	professional practice because the prescri patient. Once again, the boilerplate chart	ner never addressed the alcohol positive UDT results with the			
	taking opioid drugs with alcohol' before t states that the [prescriber] shall include a	"a discussion about the risks that shall include the 'danger of he initial prescription and prior to the third prescription. It also note in the patient record that the required discussions took			
	<ul> <li>TAKEAWAY: USE CAUTION WHEN TESTIN problematic. Not testing for it is equally</li> </ul>	G FOR ALCOHOL. Testing for it and ignoring the results is problematic. DO NOT IGNORE ALCOHOL USE.			
	In re Kaniz F. Khan-Jaffery, available online at https://www.fe 16387/kaniz-Ekhan-Jaffery.md-decision-and-order,	deralregister gov/documents/2020/07/29/2020-		 	
25			_		
			1		
		The Administrative Law Judge found:			
	Khan-Jaffrey	<ul> <li>Recommended a sanction short of revocation.</li> <li>DEA ADMINISTRATOR DISAGREED WITH THE ALI and REVOKED THE PHYSICIAN'S REGISTRATION</li> </ul>			
	Case Result	<ul> <li>The Physician issued 23 prescriptions that were found to be beneath the standard of care and outside the usual course of professional practice.</li> </ul>			
		The physician failed to:  • CONDUCT a physical exam in the case of the undercover officer.			
	REGISTRATION REVOKED	<ul> <li>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.</li> </ul>			
		<ul> <li>TAKE RESPONSIBILITY FOR her actions; Administrator found her credibility lacking and that she offered no measure of trust whereby he could accept the ALI's recommendation of a sanction short of revocation and involving monitoring.</li> </ul>			
		In re Kaniz F. Khan-Jaffery, available online at http://www.lederairesister.com/documents/2020/07/29/2020-16387/kaniz-f-khan-jaffery-md- der/don-and-order			
			J		
26					
			,		
	Khan-Jaffrey				
		"Although the evidence of her struggles with her software system is relatable at a basic level to every			
	DEA Administrator's	human being who has experienced technological frustrations, it again shows a passing of blame and an unwillingness to accept responsibility for a legal			
	Comments on Documentation	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."			

	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."	
 28		decision-and-order	
	Khan-Jaffrey  DEA  Administrator's  Comments on  Documentation	"None of the recordkeeping in the Government's evidence demonstrates the rationale behind her prescribing decisions and she demonstrated through her testimony that her memory is not reliable to fill in the gaps."	
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 Pursley

DEA Administrative Case Georgia Physician Denial of Application for Registration

SOURCE: https://www.federalreeister.gov/documents/2020/12/11/2020-27236/george-ourslev-md-denial-of-application\_accessed 02/05/2021.

31

## Pursley Case Timeline 2015 2017 2018 Dec. 2020 Suppose fraction to the parameters of the paramet

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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/seorge-pursley-md

<b>Expert Witness</b>
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: <a href="https://www.federalregister.gov/documents/2020/12/11/2020-27236/george-pursletmd-denial-of-application">https://www.federalregister.gov/documents/2020/12/11/2020-27236/george-pursletmd-denial-of-application</a>, accessed 02/05/2021.

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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 compiliance, 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.

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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/georg pursley-md-denial-of-application, accessed 02/05/2021.

DEA Administrative
Case

Florida

Florida

In re Jeanne E.
Germeil, MD

(Nov. 2020)

Dea Findings Based on Evidence & Expert Witness (MD)
Testimony

Testimony

Testimony

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 examination of the patient greater that a physician conduct a physical examination of the patient greater that a physician conduct a physical examination of the patient greater that a physician in conduct a physical examination of care "requires a physical records of care "requires a physic

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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.

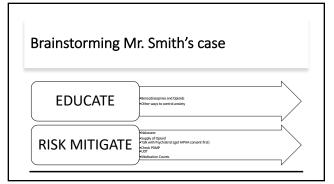
D. A and C, but not B.

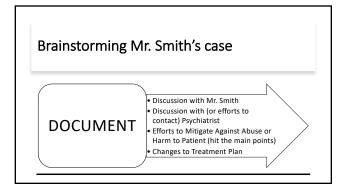
38

Case-Based Learning Example

Drugs, Documentation & DEA

	an established patient and has been seen in your office for more than 5 years.
	63 years old, walks with a cane, has a partial disability (all well documented). He is quite functional despite these medica d works part time at a manufacturing plant where he can sit to perform his assigned tasks.
psychiatrist	ent telemedicine visit for opioid medication renewal, Mr. Smith told you that he received a benzodiazepine from a te saw because he was anoticus about COVID-related matters. He also told you that he DID NOT tell the psychiatrist of opioids because he was concerned that the psychiatrist would not prescribe medication to him.
What are th	e critical education and risk-related items you should take up with Mr. Smith?
Charlet	all the psychiatrist?
Siloulu you	



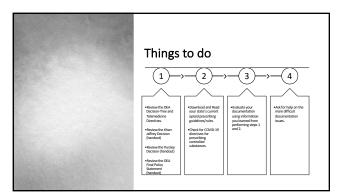


Construct a basic road map documentation of controlle prescriptions in the time of peyond.				
Objective #3				
		_		
	##·.	$\neg$		
Other DEA	Potential Diversion: Practitioners	<b>]</b>		
Educational Publications	Questiones to Consider  Oce the provide provide variety level when providing controlled substances?  One the providence consult curvey resident excess on any resident sector as at ?  Does the providence consult curvey resident excess on any resident sector and at ?  Does the providence consult curvey resident excess on the providence sector for the consultation.			
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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 Guidane Document. Your paper trail and documentation of facts and clinical decision-making is critical!

## 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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