

**Drugs,
Documentation,
and DEA**

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

Prepared and Presented by Jen Bolen, JD for PainWeek and PainWeekEnd

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Disclosures

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

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Objectives

1. Review DEA Regulatory Requirements for a Valid Controlled Substance Prescription During the COVID-19 PHE and Using Telemedicine.
2. Discuss key questions that practitioners should pose to patients while weighing the risks and benefits of ongoing controlled substance therapy in the face of COVID-19 infection, possible reinfection, and lingering side-effects and changes to the patient's system following recovery from the virus.
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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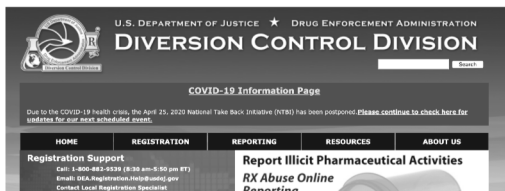
Review DEA Regulatory Requirements
for a Valid Controlled Substance
Prescription Issued via Telemedicine
During the COVID-19 PHE

Objective #1

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DEA and COVID-19 PHE – Website and Guidance

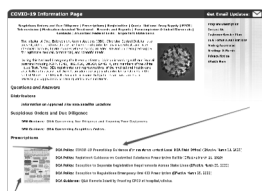
<https://www.deadiversion.usdoj.gov>



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DEA's COVID-19
Web Page

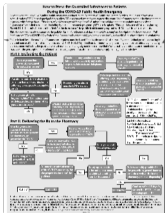
<https://www.deadiversion.usdoj.gov/coronavirus.html>



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**DEA's COVID-19
PRESCRIBING
GUIDANCE**

[https://www.deadiversion.usdoj.gov/GDP/IDEA-DC-0231\(IDEA075\)Decision_Tree_\(Final\)_33120_2007.pdf](https://www.deadiversion.usdoj.gov/GDP/IDEA-DC-0231(IDEA075)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.

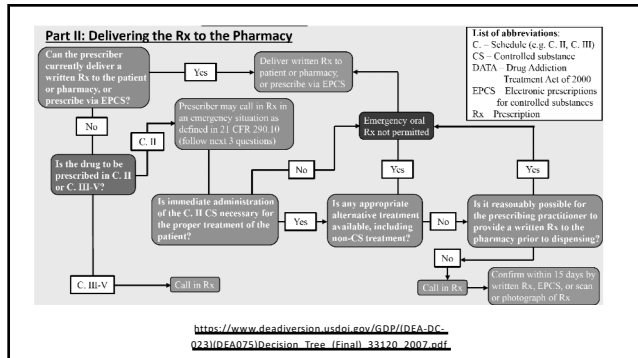
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Part I: Evaluating the Patient

[https://www.deadiversion.usdoj.gov/GDP/IDEA-DC-0231\(IDEA075\)Decision_Tree_\(Final\)_33120_2007.pdf](https://www.deadiversion.usdoj.gov/GDP/IDEA-DC-0231(IDEA075)Decision_Tree_(Final)_33120_2007.pdf)

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DEA's COVID-19 TELEHEALTH GUIDANCE

Telemedicine

DEA Policy: Use of Telehealth Evaluations to Substitute In-person Prescribing (Effective March 31, 2020)

On January 31, 2020, the Secretary of the Department of Health and Human Services issues a public health emergency (PHE) Public Health Emergency Declaration.

Question: Can information use be used under the conditions outlined in Title 21, United States Code (21 U.S.C.), Section 802(a)(10)?

Answer: Yes, while a temporary flex in controlled substance requirements of the Federal Drug Control Administration must generally be predicated on an in-person medical evaluation (21 U.S.C. 802(a)(10)), the Controlled Substances Act contains certain exceptions to this requirement. One such exception exists when the Secretary of Health and Human Services has declared a public health emergency under 42 U.S.C. 262(a)(2) of the Public Health Service Act, as amended (42 U.S.C. 262(a)(2)). Secretary Aarons declared such a public health emergency with regard to COVID-19 on January 31, 2020. **Important:** **Emergency Temporary Order (ETO) for a Temporary Waiver of Certain Requirements for the Administration of Controlled Substances.** On the U.S. State Department website, with the concurrence of the Acting DEA Administrator, announced that the administrative waiver under section 802(a)(10) applies to all Schedule II-V controlled substances in all areas of the United States. Accordingly, as of March 16, 2020, and continuing for as long as the Secretary's declaration of a public health emergency remains in effect, DEA-registered practitioners in all areas of the United States may issue prescriptions for all Schedule II-V controlled substances to patients for whom they have not conducted an in-person medical evaluation, provided all of the following conditions are met:

- The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice;
- The telemedicine communication is conducted using an audio-visual, two-way, real-time, interactive communication system; and
- The practitioner is acting in accordance with applicable Federal and State laws.

Provided the practitioner satisfies the above requirements, the practitioner may issue the prescription using any of the methods of practice currently available and in the manner set forth in the DEA regulations. Thus, the practitioner may issue a prescription either electronically (for Schedules II-V) or by call-in to an emergency schedule II prescription in the pharmacy, or by writing in a Schedule II-V prescription by the practitioner.

The term "practitioner" in this context includes a physician, dentist, veterinarian, or other person licensed, registered, or otherwise permitted by the United States or the jurisdiction in which the practice to prescribe controlled substances in the course of his/her professional practice (21 U.S.C. 802(a)(10)).

Important note: If the prescribing practitioner has previously conducted an in-person medical evaluation of the patient, the practitioner may issue a prescription for a controlled substance after having communicated with this patient via telemedicine, or any other means, independent of whether a public health emergency has been declared by the Secretary of Health and Human Services. As long as the prescription is issued for a legitimate medical purpose and the practitioner is acting in the usual course of his/her professional practice. In addition, for the prescription to be valid, the practitioner must comply with applicable Federal and State laws.

• <https://www.deadiversion.usdoj.gov/coronavirus.html> Scroll down the page to telemedicine

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Key DEA Requirements for Valid CS Rx via Telehealth

- CS Rx must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.
- The telemedicine communication must be *audio-visual, real-time, two-way interactive communication system*.
- The practitioner is acting in accordance with applicable federal and state laws

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Question #1

PICK THE MOST COMPLETE ANSWER: When prescribing controlled substances via telemedicine 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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Legitimate Medical Purpose & Usual Course of Professional Practice

Additional Things to Remember and Elevating Your Risk Mitigation Efforts During COVID-19 PHE and Beyond

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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/06-cfr-1FR-2006-09-06.pdf> accessed on 2/26/2020

817 6. 2006 / Statutes 32717

may only be prescribed, administered, or dispensed for a legitimate medical purpose by a physician acting in the usual course of professional practice. That requirement has been interpreted to mean that the prescription must be "in accordance with a standard of medical practice generally recognized and accepted in the United States."

However, medical practitioners being recognized that it is not possible to expand on the phrase "legitimate medical purpose in the usual course of professional practice," in a way that will generally allow a practitioner the ability to fill the usual obligations of his or her specialty.

As a result, the majority of practitioners have found it difficult to comply with the usual course of professional practice. The courts in response to a number of cases of medical practitioners seeking a declaratory judgment to permit them to obtain controlled substances for their patients.

Significantly, another court stated:

A majority of cases in which physicians were allowed to have dispensed controlled substances to their patients without a prescription were cases in which the physician was acting in the usual course of professional practice. In a number of cases, the courts found that the physician's conduct was in accordance with the standard of medical practice generally recognized and accepted in the United States.

The foregoing question makes a point of noting that the courts have been found to have dispensed controlled substances to their patients without a prescription in a number of cases, but that the majority of courts have found that the physician's conduct was in accordance with the standard of medical practice generally recognized and accepted in the United States.

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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

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- PDF Available as Handout
- Federal Register link: <https://www.govinfo.gov/cont...ent/nke/FR-2006-09-06/pdf/FR-2006-09-06.pdf> accessed on 2/26/2020

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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DEA Final Policy Statement

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

As a DEA registrant, a physician has a responsibility to exercise a much greater degree of oversight to prevent diversion and abuse in the case of a known or suspected addict than in the case of a patient for whom there are no indicators of drug abuse. Under no circumstances may a physician dispense controlled substances with the knowledge they will be used for a nonmedical purpose or that they will be resold by the patient. Some physicians who treat patients having a history of drug abuse require each patient to sign a contract agreeing to certain terms designed to prevent diversion and abuse, such as periodic urinalysis. While such measures are not mandated by the CSA or DEA regulations, they can be very useful.

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Discuss key questions for patients aimed at the risks and benefits of ongoing controlled substance therapy in the face of COVID-19 infection, possible reinfection, and lingering side-effects and changes to the patient's system following recovery from the virus.

Objective #2

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Three Basic (but Critical) Question Areas Regarding COVID-19 and Relevance to Opioid Risk Mitigation



Do you presently have s/s COVID-19?



Have you been treated for COVID-19?



How did COVID-19 affect your breathing and other organs?

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Question #2

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

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

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Case-Based Learning Examples

Drugs, Documentation & DEA

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Case Based Learning Scenario – Mr. Smith

Mr. Smith is an established patient and has been seeing you and your colleagues for more than 5 years.

Mr. Smith is 63 years old, walks with a cane, has a partial disability (all well documented). He is quite functional despite these medical hardships and works part time at a manufacturing plant where he can sit to perform his assigned tasks.

During a recent telemedicine visit for medication renewal, Mr. Smith told you that he wanted to try cannabis and you told him that you would not be able to prescribe/recommend it to him because of potential increased risk associated with his medical breathing conditions (COPD, Asthma).

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

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

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

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Case Based Learning Scenario – Mr. Smith

Your colleagues have encouraged you to cut back on the opioids you prescribe to Mr. Smith.
Is this a good idea? Why?
What are the risk issues here?

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

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CASE-BASED QUESTION – PRESCRIBING
CONTROLLED SUBSTANCES DURING COVID-19 PHE

- You are seeing Jane, an established patient, via telemedicine during the COVID-19 Public Health Emergency.
- Jane saw you in person two months prior to the COVID-19 quarantine.
- Jane was referred by her family physician from another city because Jane is living with her daughter's family in your town for the near future.
- Jane has a valid pain complaint and you've been able to review the records from her family physician.

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CASE-BASED QUESTION – PRESCRIBING
CONTROLLED SUBSTANCES DURING COVID-19 PHE

Which general items should you document (or show you considered/reviewed) prior to prescribing a controlled substance to treat Jane, even though you have not been able to re-examine her in person:

- A. History, Discussion of how pain continues to impact Jane's life, updated Risk Information, to include discussion and education on safe medication storage because of Jane's changed living arrangement, Discussion of How Jane is using her medication in relation to her pain, and any ongoing Coordination of Care issues.
- B. History, Plan, and Monitoring.
- C. History, Physical Examination, Follow-up Care.
- D. History, Physical Examination, Periodic Review, and Consultations/Referrals

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Summary and
Questions



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Takeaway - Point 1

Telemedicine patient encounters and controlled substance prescribing during the COVID-19 public health emergency (COVID-19 PHE) is permitted - for new and established patients - but this legal "allowance" comes with some specific documentation rules and clinical standards.



The paper trail and documentation of support for clinical decision-making is everything.

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Takeaway – Point 2

Informed consent associated with controlled substance prescribing in the face of risks posed by COVID-19 is tricky.

Make sure informed consent documentation is current and educates the patient about the impact COVID-19 may have on the patient's system and how those risks change if the patient continues to use controlled medications.



Update documentation and increase educational efforts to keep patients informed.

By doing so, you will be better prepared to face legal challenges about your controlled substance prescribing decisions.

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Takeaway – Point 3

- As various cities "re-open" for business, exercise caution as you navigate both in person and via telemedicine prescribing platforms.
- No one knows how long the COVID-19 PHE declaration will remain in place; DEA will re-address the legal status of controlled substance prescribing via telemedicine.
- Be prepared for the "new normal" of weighing risks and benefits of controlled substance prescribing in the time of "COVID-19."

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Materials available with your PainWeek/PainWeekEnd Course Registration Link

Prescriptions



- DEA Policy:** COVID-19 Prescribing Guidance (For assistance contact **Local DEA Field Office**) (Effective March 31, 2020)
- DEA Policy:** Registrant Guidance on Controlled Substance Prescription Refills (Effective March 21, 2020)
- DEA Policy:** Exception to Separate Registration Requirements Across State Lines (Effective March 25, 2020)
- DEA Policy:** Exception to Regulations Emergency Oral CII Prescription (Effective March 28, 2020)
- DEA Guidance:** Q&A Remote Identity Proofing EPCS at hospital/clinics.

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Contact Information

- Jen Bolen, JD
- 865-755-2369 (text first)
- jbolen@legalsideofpain.com

THANK YOU!

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