

Drugs, Documentation, and DEA



Improving your Charting of Prescribing Rationale in 2020 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.



2. Discuss DEA Administrative Cases and relevance to the steps a DEA Registrant should take to ensure a valid controlled substance prescription.



3. Construct a basic road map for improving documentation of controlled substance prescriptions.

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Review DEA
Regulatory
Requirements for a
Valid Controlled
Substance
Prescription

Objective #1

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What makes a Controlled Substance Prescription Valid?
How are these requirements relevant to documentation?



DEA Administrative Handbook and Federal Regulation

Legitimate Medical Purpose
Usual Course of Professional Practice



DEA Policy Statements

Legitimate Medical Purpose
Usual Course of Professional Practice
"Reasonable Steps to Prevent Abuse and Diversion"

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Controlled Substances Security Manual

Application of State and Federal Law

Nothing in this manual shall be construed as authorizing or permitting any person to do any act which is not authorized of permitted under other Federal or state laws. In addition, none of the policy and information in this manual may be construed as authorizing or permitting any person to do any act in violation of Title 21, Chapter II of the Code of Federal Regulations: (21 CFR Part 1306 to End). Printed copies of the complete regulations implementing the Controlled Substance Act of 1970 may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20540. Proposed and finalized amendments to the regulations are published in the Federal Register.

In many cases state law is more stringent than Federal law and must be complied with in addition to Federal law. This manual is an informational outline of Federal law covering specific security situations as set forth in the Federal Regulations.

When it comes to controlled substance prescribing (and documentation), the formula is . . .

- FEDERAL LAW + STATE LAW = Compliance
- Must meet both requirements
- States may adopt more stringent requirements, which must be followed



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DEA Regulations 21 Code of Federal Regulations 1306.04

RESOURCES > Title 21 Code of Federal Regulations > Part 1306 > 1306.04

Title 21 Code of Federal Regulations

PART 1306 — PRESCRIPTIONS

GENERAL INFORMATION

§1306.04 Purpose of issue of prescription.

(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act. **21 U.S.C. § 829** and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

(b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

(c) A prescription may not be issued for "detoxification treatment" or "maintenance treatment," unless the prescription is for a Schedule III, IV, or V narcotic drug approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment and the practitioner is in compliance with requirements in **§1301.18** of this chapter.

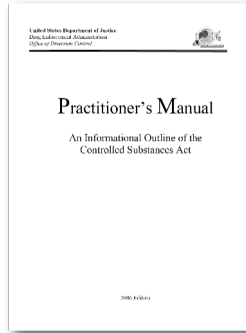
[36 FR 3799, Apr. 24, 1971; Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 39 FR 37986, Oct. 25, 1974; 70 FR 36343, June 21, 2005]

NOTICE: This is an unofficial version. An official version of this publication may be obtained directly from the Government Publishing Office (GPO).

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DEA Administrative Practitioner's Handbook

Resource:
<https://www.deadiversion.usdoj.gov/pubs/manuals/pract/section5.htm>, accessed on 2/26/2020.



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Resource:
<https://www.deadiversion.usdoj.gov/pubs/manuals/pract/section5.htm>, accessed on 2/26/2020.

DEA Administrative Practitioner's Handbook

Drug Enforcement Administration
Practitioner's Manual

Purpose of Issue

To be valid, a prescription for a controlled substance must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act. **21 U.S.C. § 829** and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

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2006 Edition
Page 17

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Resource:
<https://www.dea/diversion.usdoj.gov/pubs/m-schedule-ii-exceptions.htm>, accessed on 2/26/2020.

DEA Administrative Practitioner's Handbook

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DEA Final Policy Statement
 Published on 9/6/2006

Not on DEA website at this time.
 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

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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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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.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 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.

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Can a physician be investigated solely on the basis of the number of tablets prescribed for an individual patient?

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- PDF Available as Handout

• Federal Register link: <https://www.ecvinfo.gov/content/ake/FR-2006-09-06/pdf/FR-2006-09-06.pdf> accessed on 2/26/2020



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DEA Final Policy Statement

- Published on 9/6/2006
- PDF Available as Handout

• Federal Register link: <https://www.ecvinfo.gov/content/ake/FR-2006-09-06/pdf/FR-2006-09-06.pdf> accessed on 2/26/2020

has broad investigative authority¹⁹ and courts have recognized that prescribing an "unusually large quantity of controlled substances,"²⁰ is evidence of a violation of the CSA.²¹ DEA, as the agency responsible for administering the CSA, has the legal authority to investigate a suspicious prescription of any quantity.

Nevertheless, the amount of dosage units per prescription will never be a basis for investigation for the overwhelming majority of physicians, as with every other profession.

However, among the hundreds of thousands of physicians who practice medicine in this country in a manner that excites no government scrutiny are a handful who engage in criminal behavior. For rare cases, it is possible that an aberrant physician could prescribe such an excessive quantity of controlled substances to a given patient that this alone will be a valid basis for investigation. For example, if a physician were to prescribe 1,000 (a thousand) tablets per day of a schedule II opioid to a single patient, this would certainly warrant investigation as there is no reasonable medical basis for anyone to ingest that quantity of such a powerful narcotic in a single day. Again, however, such cases are extremely rare. The overwhelming majority of physicians who conclude that use of a particular controlled substance is medically appropriate for a given patient should generate the amount of that controlled substance which is consistent with their sound medical judgment and accepted medical standards without concern that doing so will subject them to DEA scrutiny.


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Question #1

PICK THE MOST COMPLETE ANSWER: When prescribing of controlled substances is part of the treatment plan, licensing boards and DEA expect providers to document information that the prescription was issued:

- A. For a legitimate medical purpose by a practitioner acting within their scope of practice.
- B. For a legitimate medical purpose by a practitioner who is acting in the usual course of professional practice and taking reasonable steps to prevent abuse and diversion.
- C. For an accepted medical reason.
- D. By a medical practitioner for legitimate reasons.

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DEA Presentations
Addressing "Myths"
Regarding DEA's
Jurisdiction Over
Medical Providers

Materials used under
the "FAIR USE ACT" Per DEA

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DEA Public
Presentation –
June 2019

Resource:
https://www.deadiversion.usdoj.gov/mtes/pract_awareness/conf/2019/june_2019/miller.pdf#search=Final%20Policy%20Statements%20Use%20of%20Controlled%20 accessed 2/26/2020 and used under the "Fair Use Act"

Dispelling Myth

- The DEA does NOT instruct practitioners on what type, or what strength of a Schedule II-V controlled substance they can or must prescribe.
- The DEA does NOT dictate how frequently a practitioner must see a patient.

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DEA Public
Presentation –
June 2019

Resource:
https://www.deadiversion.usdoj.gov/mtes/pract_awareness/conf/2019/june_2019/miller.pdf#search=Final%20Policy%20State%20Use%20of%20Controlled%20 accessed 2/26/2020 and used under the "Fair Use Act"

Dispelling Myth

- The DEA does NOT dictate what tests a practitioner must conduct.
- The DEA does NOT require that a practitioner record diagnosis codes on prescription for a controlled substance.
- However some States and insurance providers may choose to impose such requirements.




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Discuss DEA Administrative Cases and Relevance to the steps a DEA Registrant should take to ensure a valid controlled substance prescription

Objective #2

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Three Basic (but Critical) Periods in DEA Cases Against DEA Registrants

	Pre-2005	<ul style="list-style-type: none"> •Some policy •Some cases
	2005–2007	<ul style="list-style-type: none"> •More Policy •Significant Administrative •A Few Significant Criminal Cases
	2008 and on	<ul style="list-style-type: none"> •Evolution of DEA Public Materials •Many DEA Administrative Cases and Some Longer Criminal Cases

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Lessons Learned: Aycock (2009)

Resource: https://www.deadiversion.usdoj.gov/fed_regs/actions/2009/fr04157.htm, accessed 2/26/2020.


Registrant Actions - 2009

FR Doc E9-8624[Federal Register: April 15, 2009 (Volume 74, Number 71)] [Notices] [Page 17529-17544] From the Fed- [wais.access.gpo.gov] [DOCID:fr15ap09-119]


DEPARTMENT OF JUSTICE
Drug Enforcement Administration
[Docket No. 08-52]
George C. Aycock, M.D.; Revocation of Registration

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Lessons Learned in Aycock (DEA Revocation of Registration 2009)




BACKGROUND




GOVERNMENT
ALLEGATIONS AND
PROOF



DEFENSE PROOF



RESULT: DEA
REGISTRATION
REVOKED



LESSONS LEARNED

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**Lessons Learned:
Mackay (2010)**

- Documentation Checklist

• Resource:
https://www.deadiversion.usdoj.gov/fed_regs/actions/2010/fr0816_4.htm, accessed 2/26/2020.

Registrant Actions - 2010

[Federal Register: August 16, 2010 (Volume 75, Number 157)]
[Notices]
[Page 49956-49978]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr16au10-100]


DEPARTMENT OF JUSTICE
Drug Enforcement Administration

[Docket No. 09-28]


Dewey C. Mackay, M.D.; Revocation of Registration

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Lessons Learned in Mackay (DEA Revocation of Registration 2010)




BACKGROUND




GOVERNMENT
ALLEGATIONS AND
PROOF



DEFENSE PROOF



RESULT: DEA
REGISTRATION
REVOKED



LESSONS LEARNED

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Registrant Actions - 2012

[Federal Register Volume 77, Number 148 (Wednesday, August 1, 2012)]
 [Notice]
 [Pages 45663-45675]
 From the Federal Register Online via the Government Printing Office (www.gpo.gov)
 [FR Doc No: 2012-18747]


DEPARTMENT OF JUSTICE
 Drug Enforcement Administration

[Docket No. 12-27]

James William Eisenberg, M.D.; Decision and Order

On April 5, 2012, Administrative Law Judge Timothy D. Wing issued the attached recommended decision.¹ Neither party filed exceptions to the ALJ's decision.






Lessons Learned:
 Eisenberg (2012)
 (ARIZONA CASE)



* Resource:
https://www.dea.gov/enforcement/registration/fed_reg/actions/2012/fr0801_7.htm, accessed 2/16/2020.

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**Lessons Learned in Eisenberg
 (DEA Revocation of Registration 2012)**

BACKGROUND GOVERNMENT ALLEGATIONS AND PROOF DEFENSE PROOF RESULT: DEA REGISTRATION REVOKED LESSONS LEARNED

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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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Construct a basic road map for improving documentation of controlled substance prescriptions.

Objective #3

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Insight on Drugs and Documentation from DEA Educational Resources

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Drugs, Documentation & DEA Educational Material

Resource: <https://www.dea.gov/press/releases/2018/08/18080701.html> accessed on 2/16/2020.

The purpose of this guide is to inform and educate you, the healthcare practitioner, to ensure that controlled substances continue to be available for legitimate medical and scientific purposes while preventing their diversion into the illicit market. It is the intent of this publication to reduce or deny the use of controlled substances where multiple indicators. Nothing in this guide should be construed as authorizing or permitting any person to conduct any act that is not authorized or permitted under federal or state laws.

Your Responsibilities

The terms of prescription drugs, especially controlled substances, are a critical aspect of public health. It is your responsibility as a healthcare practitioner to ensure responsible use of these drugs. You have a legal and ethical responsibility to provide the best care and to help protect society from drug abuse.


Recognizing the Drug Abuser

It is your responsibility to identify and report signs of diversion and misuse. This includes monitoring for changes in behavior, such as increased requests for prescriptions or early refills. You should also be aware of common characteristics of drug abusers, such as loss of interest in work or social activities.

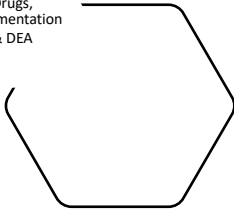
Common Characteristics of the Drug Abuser

- Loss of interest in work or social activities.
- Increased requests for prescriptions or early refills.
- Changes in behavior, such as increased requests for prescriptions or early refills.

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 Drugs,
 Documentation
 & DEA

Case Study Question




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Case Based Learning Scenario – The Scenario

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

Mr. Smith recently 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 you have not registered to engage in medical cannabis recommendations. Fast forward three months, and you learn that Mr. Smith went out of state to get a medical cannabis use card and that he is indeed smoking cannabis on a regular basis, while at the same time using the opioids and other medications you prescribe to him. Mr. Smith is also prescribed Gabapentin and drinks socially.




Nothing about Mr. Smith's use of cannabis impacts his diagnosis and medical purpose for using opioids. 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.

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Case Based Learning Scenario – The Scenario

Your colleagues have encouraged you to drop THC from Mr. Smith's drug test profile. After all, he's low risk and has otherwise been a compliant patient.



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 when prescribing opioids and other controlled medication to Mr. Smith?

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Case Based Learning Question



- Which answer most completely reflects the steps you should take to preserve your DEA Registration and to demonstrate compliance with federal law on prescribing controlled medications, including the documentation of your efforts?
 - A. Remove THC from Mr. Smith's drug test profile and document that Mr. Smith does in fact have a Cannabis card from a state where it is lawful to obtain and use cannabis for medical purposes.
 - B. Reevaluate Mr. Smith's overall medical situation and "risk profile" and document rationale for continued use (or not) of opioids now that he is using medical cannabis. Obtain a copy of the cannabis card and leave THC on Mr. Smith's drug test profile. Consider educating Mr. Smith about the risks associated with using cannabis together with opioids, alcohol, and gabapentin; caution him about the possible impact his combination drug use might have on many aspects of his life. Refer Mr. Smith for a more complete psychological profile to support your ongoing treatment decisions; reevaluate the situation after hearing from the psychologist and decide whether you will change Mr. Smith's opioid dose, type, use, etc. Document these efforts and increase patient monitoring during this reevaluation period.
 - C. Give Mr. Smith a new risk assessment form, talk to him about Cannabis use, and tell him that alcohol and opioids do not mix. See Mr. Smith back on a monthly basis and recheck his urine for alcohol. Drop THC from his drug test profile.
 - D. Cannabis use is proper with a medical cannabis card and it does not impact your prescribing of controlled medication; Make no changes.
 - E. None of the above.

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Summary and Questions

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In general, DEA Actions against a DEA Registration . . .

 <p>Can happen for procedural/technical reasons</p> <p>Failure to renew on time In connection with licensing board suspensions (you need an active medical/nursing license to maintain a DEA Registration to prescribe controlled medications License and/or registration suspension for pending matters</p>	 <p>Can happen for substantive reasons</p> <p>Undercover officers (rare in number when compared to the # of DEA Registrants), but they happen Other law enforcement investigations tied to controlled substance prescribing and related fraud crimes</p>
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Things you should do . . . soon!



1. Download the DEA Practitioner's Manual and Educational Items



2. Download your state's current opioid prescribing guidelines/rules



3. Consider the points raised in the DEA case examples (Administrative)



4. Evaluate the current status of your documentation efforts:

A. To show the patient's legitimate medical purpose for the use of a controlled substance, have you carefully evaluated and documented one or more generally recognized indications for the use of a controlled substance? Have you gone beyond the boilerplate?

B. To show you are acting in the usual course of professional practice, are you making a good faith effort (objectively, not your subjective opinion) to follow licensing board and general standards of care? Does your paper show your rationale or is it a bunch of boilerplate/window dressing?



5. Ask for help on the more difficult issues:

- A. Risk assessment and risk evaluation tools
- B. Use of consultations and referrals when a patient exceeds your scope of practice or needs additional professional support
- C. Boundary setting and opioid trial and treatment success measurements
- D. True individualization of care
- E. Handling alcohol and cannabis issues
- F. Updates to care plans based on patient behavior and compliance with the treatment plan
- G. Use of non-drug treatments and documentation of patient participation or well-documented reasons for not doing so

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THANK YOU!

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