

DEA

U.S. DRUG ENFORCEMENT ADMINISTRATION



Practitioner Diversion Awareness Conference

Prescriptions for Controlled Substances

Loren Miller, Section Chief
Policy Section





LEGAL DISCLAIMER

The following presentation was accompanied by an oral presentation on **March 18 & 19, 2019**, and does not purport to establish legal standards that are not contained in statutes, regulations, or other competent law. Statements contained in this presentation that are not embodied in the law are not binding on DEA. Summaries of statutory and regulatory provisions that are summarized in this presentation do not purport to state the full extent of the statutory and regulatory requirements of the cited statutes and regulations. **I have no financial relationships to disclose.**



Fair Use Act Disclaimer

This presentation is for educational purposes only. This presentation may not be further copied or used, with the embedded images and videos, without an independent analysis of the application of the Fair Use doctrine.

Fair Use

Under section 107 of the Copyright Act of 1976, allowance is made for “Fair Use” for purposes such as criticism, comment, news reporting, teaching, scholarship, education and research.

Fair Use is a use permitted by the copyright statute that might otherwise be infringing. Any potentially copyrighted material used in this presentation has been reviewed and found to be used in a manner consistent with Fair Use. A completed Fair Use checklist is attached.



Course Objectives

- § **Acknowledge some common myths and misconceptions about controlled substance prescriptions and the DEA.**

- § **Explain the laws and regulations concerning valid controlled substance prescriptions.**
[21 C.F.R. § 1306](#)

- § **Review the basic elements of controlled substance prescriptions and the importance of each.**
[21 C.F.R. § 1306.03,04](#)



Course Objectives

§ **Review the various forms that prescriptions can take and the limits of each.**

21 C.F.R. § 1306.08, 1311

§ **Note the special circumstances surrounding prescribing controlled substances for hospice patients, LTCF patients, and patients with opioid use disorder.**

§ **Establish the meaning of a pharmacist's corresponding responsibility.**

21 C.F.R. § 1306.04(a)



Questions To Discuss

At the completion of this block of instruction you will be able to answer the following questions:

- 1. How many times can a prescription for a Schedule III-IV controlled substance be refilled?**
- 2. Under federal law is a practitioner required to use electronic controlled substance prescriptions?**



Questions To Discuss

- 3. Can a Schedule II controlled substance prescription be refilled?**
- 4. Federally, can a pharmacist refuse to fill a prescription for a controlled substance for any reason?**
- 5. Can a nurse at a long term care facility (LTCF) call in an emergency schedule II prescription to a pharmacy for the practitioner?**



Dispelling Myth

Common **Myths** and **Misconceptions**:

- § The DEA registration number is **NOT** required on prescriptions for non-controlled substances.
- § DEA does **NOT** define or regulate the practice of medicine.





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.



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.



Controlled Substance Prescription Requirements



Controlled Substance Prescription Requirements

- § A controlled substance prescription must be issued by a DEA registered practitioner. 21 C.F.R. § 1306.03(a)
- § A controlled substance prescription must be issued for a legitimate medical purpose. 21 C.F.R. 1306.04(a)



Controlled Substance Prescription Requirements

§ A controlled substance prescription must be issued in the usual course of professional practice. 21 C.F.R. 1306.04(a)

The signing of a prescription can not be delegated



Preparing a Prescription

“Where an oral order is not permitted, paper prescriptions shall be written with ink or indelible pencil, typewriter, or printed on a computer printer and shall be **manually signed** by the practitioner. A computer-generated prescription that is printed out or faxed by the practitioner **must be manually signed.**” 21 C.F.R. § 1306.(d)

§ A controlled substance prescription cannot be signed by some type of device that generates an electronic signature.



Controlled Substance Prescription Requirements

§ A prescription may not be written to obtain office stock for general dispensing.

21 C.F.R. 1306.04(b)



Controlled Substance Prescription Requirements

§ **A prescription can take three forms:**

§ **1. Paper**

§ **2. Oral**

§ **3. Electronic**

§ **Each have their place, and each have their own restrictions.**



Schedule II Prescriptions

- § Can be written, called in, or faxed to the pharmacy by the practitioner or his/her agent. 21 C.F.R. § 1306.21(a)
- § A prescription must contain all of the following information before a pharmacy can consider filling the prescription.
21 C.F.R. § 1306.05(a)

1. Date
2. Patient's Full Name
3. Patient's Address
4. Drug Name
5. Drug Strength
6. Dosage Form





Schedule II Prescriptions

7. Quantity Prescribed
8. Directions of Use
9. Name of Practitioner
10. DEA Registered Address of Practitioner
11. Practitioner's DEA Registration Number
12. Practitioner's Signature (No Stamps)

§ **No refills** are authorized on Schedule II controlled substance prescriptions.

21 C.F.R. § 1306.12(a)



Multiple Schedule II Prescriptions

In 2007 the DEA published in the Federal Register a Final Rule allowing:

Individual practitioners to issue multiple Schedule II prescriptions which authorize patients to receive up to a 90-day supply providing:

§ Each separate prescription is issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.

21 C.F.R. § 1306.12(b)(1)(i).



Multiple Schedule II Prescriptions

§ **Written instructions on each separate prescription indicate the earliest date it can be filled.**

[21 C.F.R. § 1306.12\(b\)\(1\)\(ii\)](#)

§ **Doing so does not cause undue risk of diversion by patient.**

[21 C.F.R. § 1306.12\(b\)\(1\)\(iii\)](#)

§ **Doing so must be in compliance with all other elements of the CSA and state laws**

[21 C.F.R. § 1306.12\(b\)\(1\)\(iv\)](#)



Partial Filling of Prescriptions for Schedule II controlled substances

The Comprehensive Addiction and Recovery Act of 2016 (CARA), Section 702, titled *Partial Fills of Schedule II Controlled Substances*, amended Title 21, United States Code, Section 829 (21 U.S.C. § 829), by adding subsection (f), which states that a "prescription for a controlled substance in schedule II may be partially filled" at the request of the patient (e.g., ultimate user) or...



Partial Filling of Prescriptions for Schedule II controlled substances

the **prescribing practitioner** if "not prohibited by State law"; if "the prescription is written and filled in accordance with [21 U.S.C. § 829], regulations prescribed by the Attorney General, and State law"; the "total quantity dispensed in all partial fillings does not exceed the total quantity prescribed" and the "remaining portions of a partially filled prescription for a controlled substance in schedule II... shall be filled not later than **30 days** after the **date** on which the prescription is written."



Emergency Oral Schedule II Prescription

29 C.F.R. § 290.10

Three criteria for a **practitioner (not the pharmacy)** to determine if an emergency oral prescription for a Schedule II controlled substance is warranted:

1. That **immediate administration** of the controlled substance **is necessary**, for proper treatment of the intended ultimate user; and



Emergency Oral Schedule II Prescription

29 C.F.R. § 290.10

2. That **no appropriate alternative** treatment is available, including administration of a drug which is not a controlled substance, and
3. That it is **not reasonably possible** for the prescribing practitioner to provide a written prescription to be presented to the person dispensing the substance, prior to the dispensing.



Emergency Oral Schedule II Prescription

Important Note:

§ The prescription is **limited** to the **quantity** adequate to treat the patient during **the emergency period**.

[21 C.F.R. § 1306.11\(d\)\(1\)](#)



Emergency Oral Schedule II Prescription Process

Step #1: Patient requires an Emergency Schedule II prescription.

Step #2: Nurse Contacts the Practitioner.



Emergency Oral Schedule II Prescription Process

Step #3: The **practitioner** contacts the pharmacy.

21 C.F.R. § 1306.11(d) states “...upon receiving oral authorization of a *prescribing individual practitioner...*”

The Practitioner is the **only** person who can make the phone call - not the nurse, secretary, agent, best friend, mother, or anyone else.



Emergency Oral Schedule II Prescription Process

Step #4: The pharmacist reduces the prescription to **writing.**

21 C.F.R. § 1306.11(d)(2)

It must be reduced to writing, not maintained in the computer system, as it represents a paper prescription.



Emergency Oral Schedule II Prescription Process

Required information which the pharmacist must reduced to writing
([21 C.F.R. § 1306.05\(a\)](#)):

Date, Patient Full Name, Address, Drug Name, Strength, Dosage Form,
Quantity Prescribed, Directions of Use, Practitioner name, Address,
Registration number.

The practitioner determines the quantity, **not** the pharmacy.



Emergency Oral Schedule II Prescription Process

Step #5: The pharmacist must verify that he or she is talking to the prescriber.

Title 21 CFR § 1306.11(d)(3) states “If the prescribing individual practitioner is not known to the pharmacist, he must make a reasonable effort to determine that the oral authorization came from a registered individual practitioner, which may include a callback to the prescribing individual practitioner using his phone number as listed in the telephone directory and/or other good faith efforts to insure his identity”



Emergency Oral Schedule II Prescription Process

Step #6: The pharmacy contacts the long term care facility and authorizes the emergency withdrawal from the emergency dispensing kit.

The nurse can then remove the amount needed for the emergency for dispensing to the patient.



Emergency Oral Schedule II Prescription Process

Step #7: The practitioner must fax or mail an original manually signed prescription to the dispensing pharmacy within seven days.

21 CFR § 1306.11(d)(4)

The prescription that is received from the practitioner must have annotated “authorization for emergency dispensing.**”**

21 CFR § 1306.11(d)(4)

The prescription that is received from the practitioner must have annotated “the date of the oral order.**”**

21 CFR § 1306.11(d)(4)



Emergency Oral Schedule II Prescription Process

Step #8: The prescription that was reduced to writing must be attached by the dispensing pharmacist to the original signed prescription.

21 CFR § 1306.11(d)(4)

Step #9: If the practitioner does not provide the original prescriptions the regulations require (Not Optional**) the pharmacist to contact the local DEA office.**

21 CFR § 1306.11(d)(4)



Schedule III-V Prescriptions

Can be written, called in, or faxed to the pharmacy by the practitioner or his/her agent.

[21 C.F.R. § 1306.21\(a\)](#)

Must contain the 12 elements mentioned earlier, plus one additional, refills if applicable.

[21 C.F.R. § 1306.21\(a\)](#)





Schedule III-V Prescriptions

Original plus 5 refills are the maximum that can be authorized.

21 C.F.R. § 1306.22(a)

When a practitioner or the practitioner's agent calls in a prescription they must provide 12 elements to the pharmacist. (excludes the signature)

21 C.F.R. §. 1306.21(a)





Partial Filling of Prescriptions for Schedule III-V controlled substances

The partial filling of a prescription for a controlled substance listed in Schedule III, IV, or V is permissible, provided that:

- a) Each partial filling is recorded in the same manner as a refilling,**
- b) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed, and**
- c) No dispensing occurs after 6 months from the date on which the prescription was issued.**



Electronic Prescriptions

21 C.F.R. § 1311 Subpart C



Electronic Prescriptions

- § Electronic prescriptions for controlled substances are **voluntary** under the DEA's regulations.
- § Manually signed paper prescriptions for controlled substances, and oral prescriptions for controlled substances, are still permitted. However, some insurance carriers and states have now made the use of EPCS mandatory.





EPCS

True electronic prescriptions are transmitted as **electronic data** files to the pharmacy, whose application imports the data file into its database.



Electronic Prescriptions

§ The application provider's system must be audited by qualified independent third part or have the application reviewed and certified by an approved certification body. They will then issue the application provider with a report. The application provider **must provide you a copy of this report.**

21 C.F.R. § 1311.102(d)



Identity Proofing

§ This is critical to the security of EPCS. The ability to sign EPCS can only be granted to individuals whose identity has been confirmed.



Two-Factor Authentication

- § **After the practitioner's identity is verified, they will be issued a two-factor authentication credential.**
- § **Protects practitioners from misuse of credential and from external threats.**



Two-Factor Authentication

21 C.F.R. § 1311.115(a)

§ **Two-factors – two of the following:**

§ **Something you know – password, PIN**

§ **Something you have – separate hard token**

§ **Something you are – a biometric**



Signing an EPCS Prescription

§ A practitioner or agent may prepare the prescription for review and signature by the practitioner.

21 C.F.R. § 1311.135(a)

§ Practitioner accesses a list of prescriptions for a single patient.

21 C.F.R. § 1311.140(a)(1)





Signing an EPCS Prescription

§ List displays the 12 elements for a schedule II controlled substance, and the 13 elements (if refills are to be authorized) for schedule III-V controlled substances.

[21 C.F.R. § 1311.120\(a\)\(9\)](#)



Signing an EPCS Prescription

§ On the same screen is the statement “*by completing the two-factor authentication protocol at this time, you are legally signing prescription(s) and authorizing transmission of the above information to the pharmacy for dispensing.*”

[21 C.F.R. § 1311.140\(a\)\(3\)](#)

§ The practitioner chooses which prescriptions are ready to be signed.

[21 C.F.R. § 1311.140\(a\)\(2\)](#)



Signing an EPCS Prescription

§ The Practitioner is prompted to complete a two-factor authentication protocol.

[21 C.F.R. § 1311.140\(a\)\(4\)](#)

§ Completion of the two-factor authentication protocol is a legal signature.

[21 C.F.R. § 1311.140\(a\)\(5\)](#)





Transmission

21 C.F.R. § 1311.170

§ Each prescription must be transmitted as soon as possible after signature.

21 C.F.R. § 1311.170(a)

§ Each prescription must remain electronic; conversion to a fax is **NOT** permitted.

21 C.F.R. § 1311.170(f)



What is not EPCS

- § **A faxed prescription**
- § **A prescription sent via email**
- § **An electronically transmitted picture of a prescription**



What is also not EPCS

- § **A system that allows the prescriber to “sign” his/her name, or in some way attached a copy of their signature.**
- § **A text message containing prescription information.**



What's NOT Acceptable

The use of any one of the three authentication tools by itself.





Prescriptions for Hospice and Long Term Care (LTCF) Patients



Long Term Care

§ Title 21 C.F.R. § 1300.01(b)(25) states “Long Term Care Facility (LTCF) means a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients.

§ **Important Note:**

Jails and correctional institutions are not long term care facilities.



Long Term Care

§ Written, manually signed prescriptions for Schedule II controlled substances can be sent by facsimile to the pharmacy, but cannot be dispensed until the pharmacist has the original manually signed paper prescription in their possession; however . . .

21 C.F.R. § 1306.11(a)



Long Term Care

§ **There are exceptions** for LTCF patients, hospice patients, and terminally ill patients. These written, manually signed prescriptions, when sent by facsimile, serve as originals.

21 C.F.R. § 1306.11(e)(f) & (g)

§ Schedule II prescriptions for terminally ill patients or LTCF patients can not exceed 60 days from the date of issuance, and allows partial fills during that entire period up to the limit of the quantity authorized.



Prescriptions Issued by Qualified Practitioners and Other Qualified Practitioners



Opioid Treatment

§ **Must contain all of the information as required on prescriptions for schedule III-V controlled substances.**

21 C.F.R. § 1306.05(a).

§ **A prescription for a Schedule III, IV or V narcotic drug approved by FDA specifically for “detoxification treatment” or “maintenance treatment” must also include the unique identification number (X number) issued by the DEA **in addition to the DEA registration.****

21 C.F.R. § 1306.05(b).



Opioid Treatment

§ Practitioners must keep records of all prescriptions issued for maintenance and detoxification. These are required records, and all required records must be kept at the practitioner's DEA registered location for a minimum of two years.





Pharmacist's Corresponding Responsibility



Pharmacist's Corresponding Responsibility

§ Corresponding responsibility rests with the pharmacist who fills the prescription.

21 C.F.R. § 1306.04 (a)

§ Pharmacists **can refuse** to fill a prescription for a controlled substance for any reason.





Controlled Substance Prescription Requirements

§ 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. [21 C.F.R. 1306.04\(a\)](#)



Preparing a Prescription

- § A prescription may be prepared by the secretary or agent for the **signature of a practitioner**, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. **A corresponding liability rests upon the pharmacist, . .** who fills a prescription not prepared in the form prescribed by DEA regulations. 21 C.F.R. § 1306.05(f)
- § A pharmacist has **no authority** to prepare a prescription in whole or in part for the practitioner.



Course Review

We reviewed:

Some common myths and misconceptions

The laws and regulations concerning valid controlled substance prescriptions

The basic elements of controlled substance prescriptions and their importance

The various forms that prescriptions can take and the limits of each

The special circumstances surrounding prescribing controlled substances for hospice patients, LTCF patients, and patients with opioid use disorder

The meaning of a pharmacist's corresponding responsibility



Post Questions

- 1. Schedule III-IV controlled substance prescriptions can be refilled a maximum of how many times?**
 - A. 10 times**
 - B. 5 times**
 - C. 8 times**
 - D. 3 times**



Post Questions

2. Under federal law a practitioner is required to use electronic controlled substance prescriptions.

- A. True**
- B. False**



Post Questions

3. A Schedule II controlled substance prescription can be refilled.

- A. True**
- B. False**





Post Questions

4. Federally, a Pharmacist can refuse to fill a prescription for a controlled substance for any reason.

- A. True**
- B. False**





Post Questions

5. A nurse at a long term care facility can call in an emergency oral schedule II prescription for the practitioner.

- A. True**
- B. False**





*Thank You for your time
and attention !*

