



# *Practitioner Diversion Awareness Conference*

## Prescriptions for Controlled Substances

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# Course Objectives

§ Explain the laws and regulations concerning valid controlled substance prescriptions.

21 C.F.R. § 1306

§ Review the basic requirements of controlled substance prescriptions and the importance of each.

21 C.F.R. § 1306.03,04

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

21 C.F.R. § 1306.04(a)



# Course Objectives

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



# 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. 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?**



# Controlled Substance Prescription Requirements





# Dispelling Myth

First, to correct some **misconceptions**:

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





# Dispelling Myth

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

**However, some states and insurance providers may choose to impose such limits.**



# Controlled Substance Prescription Requirements

§ They must be issued by a DEA registered practitioner.

21 C.F.R. § 1306.03(a)

**\*\*The signing of a prescription can not be delegated\*\***

§ Prescriptions must be issued for a legitimate medical purpose.

21 C.F.R. 1306.04(a)



# Controlled Substance Prescription Requirements

§ Prescriptions must be issued in the usual course of professional practice.

[21 C.F.R. 1306.04\(a\)](#)

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

[21 C.F.R. 1306.04\(b\)](#)



# 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. **21 C.F.R. § 1306.05(f)**
- § A pharmacist has no authority to prepare a prescription in whole or in part for the practitioner.



# Schedule II Prescriptions

§ **Must contain the following information:**

**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)**



# Schedule II Prescriptions

§ 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)





# Multiple Schedule II Prescriptions

Individual practitioners may 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 a 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 prescription indicating earliest date it can be filled.**

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

§ **Doesn't cause undue risk of diversion by patient.**

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

§ **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**

## **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 was written."



# Emergency Schedule II Prescription

29 C.F.R. § 290.10

Three criteria for a **practitioner** (not the pharmacy) to determine if the prescription is an emergency:

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



# Emergency 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.**



# Process for Issuing an Emergency 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\(d\)\(1\)](#)



# Process for Issuing an Emergency Prescription

- § **Emergency controlled substances are drawn from emergency kits.**
- § **All prescriptions for patients in long term care facilities must be bona fide prescriptions. LTCFs cannot fill medical orders. These prescriptions must also contain all the required information including the quantity prescribed.**





# Process for Issuing an Emergency Prescription

**Step #1: Patient requires an Emergency  
schedule II prescription.**

**Step #2: Nurse Contacts the Practitioner.**



# Process for Issuing an Emergency Prescription

**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 or anyone else.**



# Process for Issuing an Emergency Prescription

**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.**



# Process for Issuing an Emergency Prescription

Required information on the form that the pharmacist reduced to writing ([21 C.F.R. § 1306.05](#)):

Full Name of Patient	Address of Patient	Drug Name	Strength	Dosage Form
Quantity Prescribed	Directions of Use	Doctors Name	Doctors Address	Doctors DEA Number

The practitioner determines the quantity, not the pharmacy.



# Process for Issuing an Emergency Prescription

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

**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”**



# Process for Issuing an Emergency Prescription

**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.**



# Process for Issuing an Emergency Prescription

**Step #7: The practitioner must fax or mail an original 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)**



# Process for Issuing an Emergency Prescription

**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 below information:

21 C.F.R. § 1306.21(a)

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





# Schedule III-V Prescriptions

6. Dosage Form

7. Quantity Prescribed

8. Directions of Use

9. Name of Practitioner

10. DEA Registered  
Address of Practitioner





# Schedule III-V Prescriptions

11. Practitioner's DEA Registration Number
12. Practitioner's Signature (Unless Called In)
13. Number of Refills

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

**21 C.F.R. § 1306.22(a)**

§ **When a practitioner or his agent calls in a prescription they must provide all the above information to the pharmacist.**

**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

- § You begin by obtaining an application provider.
- § The application provider's system must be audited by qualified third party 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\(d\)](#)





# Electronic Prescriptions

§ A list of third party auditors and certifiers can be found on the DEA's web-site

[https://www.deadiversion.usdoj.gov/ecommm/e\\_rx/thirdparty.htm](https://www.deadiversion.usdoj.gov/ecommm/e_rx/thirdparty.htm)

§ Identity proofing must be conducted by a credential service provider or certification authority approved by the Federal government.

21 C.F.R. § 1311.105



# 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. Practitioners apply to a federally approved Credentialing Service Provider (CSP) or a Certification Authority (CA). Protects practitioners from misuse of credentials and from external threats.**



# Two-Factor Authentication

§ After the practitioner's identity is verified, they will be issued a two-factor authentication credential.



# 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 of 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:

21 C.F.R. § 1311.120(a)(9)

1. Date of issuance
2. Patient name
3. Drug name, strength, form, quantity prescribed, directions for use
4. Name, address, DEA registration number of practitioner
5. Other information as applicable



# 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\(a\)\(3\)](#)

§ Practitioner chooses which prescriptions are ready to be signed.

[21 C.F.R. § 1311.140\(a\)\(2\)](#)



# Signing an EPCS Prescription

§ 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

§ **EPCS prescriptions must be transmitted as soon as possible after signature.**

21 C.F.R. § 1311.170(a)

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

21 C.F.R. § 1311.170(f)



# Transmission

21 C.F.R. 1311.170

§ Prescription may be printed after signature so long as labeled “Copy only - not valid for Dispensing.”

21 C.F.R. § 1311.170(c)

§ Transmitted prescription may be printed for manual signature if practitioner notified that transmission failed; must indicate original was electronic, name of pharmacy, and date/time.

21 C.F.R. § 1311.170(b)



# 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 a user name and password by themselves.**
- § **The use of a biometric or hard token 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, but cannot be dispensed until the pharmacist has the original paper prescription in their possession.





# Long Term Care

- § **There are exceptions for LTCF patients, hospice patients, and terminally ill patients. These written, manually signed prescriptions, when sent by facsimile, and printed out by the pharmacy, serve as original paper prescriptions.**
- § **Schedule II prescriptions for terminally ill patients or LTCF patients can not exceed 60 days from the date of issuance, thus allowing partial fills during that period.**



# 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 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 which 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.





# 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 is a practitioner required to use electronic controlled substance prescriptions?**

**A. Yes**

**B. No**





# Post Questions

**3. Can a Schedule II controlled substance prescription be refilled?**

**A. Yes**

**B. No**





# Post Questions

**4. Can a pharmacist refuse to fill a prescription for a controlled substance for any reason?**

- A. Yes**
- B. No**





# Post Questions

**5. Can a nurse at a long term care facility call in an emergency schedule II prescription for the practitioner?**

- A. Yes**
- B. No**





*Thank You for your time  
and attention !*

