Prescriptions: (Transfers of, Changes to, EPCS)

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Prescriptions

• §1300.01(b)

A *Prescription* means, “an order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user (e.g., an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription).”
Prescriptions

• §1306.03 Persons entitled to issue prescriptions.

• (a) A prescription for a controlled substance may be issued only by an individual practitioner who is:

• (1) authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession and . . .
Prescriptions

• (2) either registered or exempted from registration pursuant to Secs. 1301.22 (c) and 1301.23 of this chapter.
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.
An order purporting to be a prescription issued not in the usual course of professional treatment … is not a prescription…
21 C.F.R. § 1306.04(a)

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.
Prescriptions

• §1306.05 Manner of issuance of prescriptions.
• (a) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the...
Prescriptions

full name and address of the patient, the
drug name, strength, dosage form,
quantity prescribed, directions for use,
and the name, address and registration
number of the practitioner.
Prescriptions

• (b) A prescription issued by an individual practitioner may be communicated to a pharmacist by an employee or agent of the individual practitioner.
Prescriptions

• (d) A practitioner may sign a paper prescription in the same manner as he would sign a check or legal document (e.g., J.H. Smith or John H. Smith). 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.
Prescriptions

• (f) 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.
Prescription Transfers

• Forms of a Prescription

• The DEA’s regulations on Transfers:

• The DEA’s policy on Transferring Original Unfilled Prescriptions
  • What can be Transferred
  • What cannot be Transferred
Changes to a Prescription?

The CSA and current DEA regulations do not provide for a pharmacy to make changes to a written prescription for a schedule II controlled substance.
Electronic Prescriptions for Controlled Substances (EPCS)

• Benefits of EPCS

• Problems with EPCS

• What is not an EPCS
Unique Identification Number (UIN)

• When is it required
• When is it not required
• The practitioner with Multiple DEA registrations
• Impact on Prescription Drug Monitoring Programs
Multiple Prescriptions CII

Individual practitioner may issue multiple prescriptions which authorizes patient to receive a 90-day supply of a C-II

21 CFR § 1306.12(b)
Multiple Prescriptions CII

Each separate prescription is for legitimate medical purpose issued by practitioner acting in usual court of professional practice

Written instructions on each prescription indicating earliest date it can be filled
Addresses on a Prescription

• The Practitioner Address

• The Patient Address
Pre-Populated Prescriptions

An agent may not legally perform duties that must be personally performed by the individual practitioner.
Pre-Populated Prescriptions

The practitioner must first determine that a prescription for a controlled substance is for a legitimate medical purpose; then, the practitioner may authorize an agent to prepare the prescription.
Pre-Populated Prescriptions

A pharmacy cannot provide in whole, or in part, pre-populated information on a document and have that document then become the prescription.
Emergency Oral Schedule II
Prescriptions

• What is an emergency
• Who decides if it is an emergency
• What are the prescribing limits
• What is the responsibility of prescriber & pharmacist
Retail versus Central Fill Pharmacies

- Final Rule
- Who can do central fill
- Limitation on Central Fill dispensing
- Common problems at both the retail and central fill pharmacies
Some Final Notes

Dispelling misconceptions on what the DEA requires regarding prescriptions
Handy Resources

www.DEAdiversion.usdoj.gov

www.dea.gov

www.operationprevention.com

U.S. Drug Enforcement Administration
Diversion Control Division
“Guideline for Prescribing Opioids for Chronic Pain”

“Checklist for Prescribing Opioids for Chronic Pain”

https://www.cdc.gov/drugoverdose/prescribing/trainings.html
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Thank You