

# Recent DEA Rules Every Pharmacist Should Know

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American  
Society for  
Pharmacy  
Law

**DEVELOPMENTS  
IN PHARMACY LAW  
SEMINAR DPL XXXV**



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**HILTON PHOENIX TAPATIO CLIFFS RESORT 2024**

# Conflict of Interest Disclosure

*I declare that neither I nor any immediate family member have a current affiliation or financial arrangement with any potential sponsor and/or organization(s) that may have a direct interest in the subject matter of this presentation.*



# Learning Objectives

At the completion of this activity, the participant will:

Understand how 3 new DEA rules impact your pharmacy practice

Learn about a proposed rule announced by DEA

Understand the status of DEA's proposed rule regarding prescribing CS via telehealth



# Reporting Theft or Significant Loss of Controlled Substances

- DEA Form 106
  - Electronic submission within 45 calendar days after discovery of significant loss or theft of CS
- Still must notify local DEA Field Division Office, in writing, within 1 business day
- Rule discussed:
  - What is a “significant” vs. “normal” loss?
  - What does “discovery” mean?



# Transfer of E-Prescriptions for CII – CV Between Pharmacies for Initial Filling

When is transfer of e-prescriptions for CS permissible:

- ✓ Between retail pharmacies
- ✓ Initial filling
- ✓ One-time basis
- ✓ Upon request from the patient
- ✓ All refills for the CIII – CV are transferred

State law must also allow for such transfer



# Transfer of E-Prescriptions for CII – CV Between Pharmacies for Initial Filling

## Requirements for the transfer:

- ✓ Rx maintained in its electronic form
- ✓ Contents of rx cannot be altered
- ✓ Pharmacist to pharmacist communication
- ✓ Each pharmacist has record keeping requirements
  - e.g., receiving pharmacist add word “transfer” to the e-rx record
- ✓ Maintain records for 2 years

## Other notable comments from DEA



# Partial Filling of CII Prescriptions

- General requirements:
  - Requested by patient (or someone acting on behalf of patient) or by prescriber
  - Total quantity dispensed does not exceed total quantity prescribed
  - Not prohibited by State law
- All partial fills within 30 days of date of prescription



# Partial Filling of CII Prescriptions

## How to request a partial fill:

Prescriber can  
specify on face of  
prescription

Upon request by:

- Patient
- Caregiver named in adult patient's medical POA
- Parent/legal guardian if patient is under 18 y/o

Request can be made in  
person, in writing (signed),  
or telephone

After consultation with  
pharmacist, with pharmacist  
recording on rx:

- "Authorized by Practitioner to Partial Fill"
- Name of prescriber, date/time,  
pharmacist's initials

Must make notation of who  
requested partial fill, date,  
quantity dispensed,  
pharmacist's initials



# CS Destruction Alternatives to Incineration

- DEA does not specify a particular means for destruction of CS
- Render “non-retrievable”
  - A process that permanently alters CS physical or chemical state through irreversible means that renders it unusable
- DEA requested stakeholder responses to 10 questions to identify chemical and technical methods of destruction as alternatives to incineration



# DEA Proposed Rulemaking on Prescribing CS via Telehealth

- Submitted to Office of Management and Budget
- What we know?
  - ✓ CII require an in-person visit
  - ✓ CIII – CVs can be prescribed solely via telehealth
  - ✓ Up to 50% CS prescribing via telehealth
  - ✓ Check all 50 states' PDMP before prescribing
- What is being done?



# DEA Proposed Rulemaking on Prescribing CS via Telehealth



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### Pending EO 12866 Regulatory Review

<b>RIN:</b> <a href="#">1117-ZA06</a>	<b>Received Date:</b> 10/10/2024
<b>Title:</b> Third Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications	
<b>Agency/Subagency:</b> DOJ / DEA	<b>Stage:</b> Final Rule
<b>Legal Deadline:</b> None	<b>Section 3(f)(1) Significant:</b> No
<b>International Impacts:</b> No	<b>Affordable Care Act [Pub. L. 111-148 &amp; 111-152]:</b> No
<b>Pandemic Response:</b> No	<b>Dodd-Frank Wall Street Reform and Consumer Protection Act, [Pub. L. 111-203]:</b> No

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Jonathan Keller is a registered pharmacist and attorney who leverages his health care background to advise health care and life science companies on a wide range of regulatory, compliance and licensure matters.

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[View Jonathan's Full Biography.](#)



2024 ASPL Fall Meeting

*Developments in Pharmacy Law Seminar XXXV*

# Questions?

# Thank you!

