



# 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

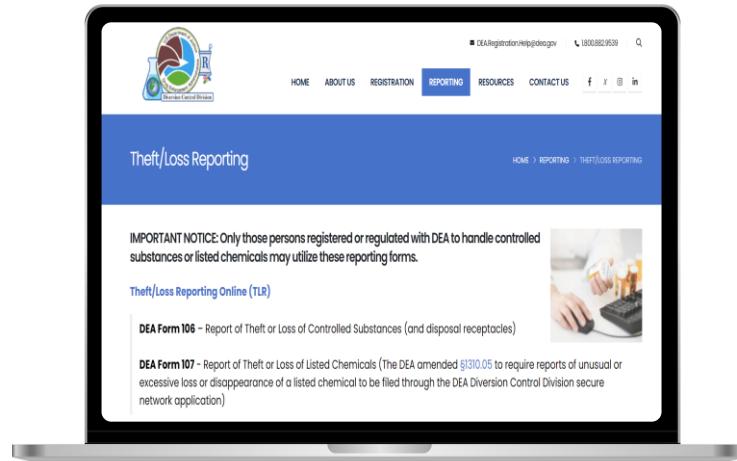
Learn about a proposed rule announced by DEA

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



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

Upon request by:

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?
  - ✓ CIIIs 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

RIN: [1117-ZA06](#)

Received Date: 10/10/2024

Title: Third Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications

Stage: Final Rule

Agency/Subagency: DOJ / DEA

Section 3(f)(1) Significant: No

Legal Deadline: None

Affordable Care Act [Pub. L. 111-148 & 111-152]: No

International Impacts: No

Dodd-Frank Wall Street Reform and Consumer Protection Act, [Pub. L. 111-203]: No

Pandemic Response: No

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*Developments in Pharmacy Law Seminar XXXV*



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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.

As the co-chair of the pharmacy and pharmacy benefit manager (PBM) segment within the health and life sciences industry group, Jonathan regularly counsels hospitals, PBMs, pharmacies, drug manufacturers, wholesalers, 3PLs and telehealth platforms and providers on numerous aspects of their pharmacy-related businesses.

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# Questions?

# Thank you!



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