The ABC's of Controlled Substances and Veterinary Medicine in Illinois

WELCOME COLLEAGUES

Session 3 of 3

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Best Practices and Legal Requirements

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Clarification of Position Statement

- This presentation is based on my personal interpretation of the available regulatory information.
- It does not represent legal advice
- It does not represent any stated or assumed position of the Ohio Veterinary Medical Licensing Board

"Knowledge is an antidote to fear“

- **Ralph Waldo Emerson**

Legal Requirements

- DEA
  - Drug schedules
  - Registration rules
  - Veterinary mobility act
  - Transfer of controlled substances
- State Board of Pharmacy
  - PDMP reporting
  - Prescription limitations

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Drug Enforcement Administration

- Enforce the Controlled Substances Act
- Audit documentation for all controlled substance activity from point of origin to end use (AKA cradle to grave).
- Work with state, and local governments, including pharmacy and veterinary boards to enforce law.

Drug Schedules

Schedule I	Schedule II	Schedule III	Schedule IV	Schedule V
Heroin	Astramorph	Beuthanasia	Diazepam	Diphenoxylate
LSD	Codeine	Buprenorphine	Lorazepam	Gabapentin*
Ecstasy	Fentanyl	Ketamine	Phenobarbital	
	Hydromorphone		Tramadol	
	Morphine		Propofol[1]	

Registration Requirements

- Every person who manufactures, distributes, dispenses, imports, or exports any controlled substance
- A separate registration is required for each principal place of business or professional practice
- An individual practitioner who is an agent or employee of another practitioner registered to dispense controlled substances may, when acting in the normal course of business or employment, administer or dispense (other than by issuance of prescription) controlled substances

https://www.deadiversion.usdoj.gov/21cfr/cfr/2101cfrt.htm

Veterinary Mobility Act of 2014

- Ambulatory vehicles
  - Classified as an extension of your building
  - Drug storage security controls
  - Records and documentation of controlled substance inventories available.

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Transfer of Controlled Substances

- A registered practitioner may transfer controlled substances to another registered practitioner, provided that—
  - If the substance is listed in Schedule I or II, an order form (222) is completed and submitted
  - If the substance is listed in Schedule III, IV or V utilizing an invoice of sale as documentation
  - The total number of dosage units of all controlled substances transferred by the practitioner during each year does not exceed 5 percent of the total number of dosage units of all controlled substances distributed and dispensed during the same year.

- Suspicious Orders Report System (SORS)

https://www.deadiversion.usdoj.gov/21cfr/cfr/1307/1307_11.htm

State Actions

- Prescription Drug Monitoring / Reporting Systems
  - 49 states now have a program (Missouri)
    - All have some level of use requirement
      - Report dispensing
      - Info query before prescribing
- Opioid Prescribing Limits
  - Rules vs Guidance (varies by state)
  - Acute prescribing limits
  - Chronic Condition exemptions

Illinois Specific Actions

- Prescription Drug Monitoring / Reporting Systems
  - Veterinarians Exempt
- Opioid Prescribing Limits
  - A prescription for a Schedule II controlled substance shall not be issued for more than a 30 day supply
  - A prescription for Schedule III, IV or V controlled substances shall not be filled or refilled more than 6 months after the date thereof or refilled more than 5 times unless renewed
- Continuing Education Requirement
  - Three (3) hours

Best Practices

- Develop SOPs
- Separation of duties
- All about your records
- Security
- Prepare your team

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Documented Best Practices - SOPs

- Record Keeping
  - Ordering and receiving
  - Logging use and dispensing
  - Inventories and discrepancies
- Storage and Security
  - Paperwork – 222's & script pads
  - Drugs
- Access to controlled substances
- Separation of duties

Drug Records & Documentation

- Cradle to Grave Documentation
  - Purchasing
  - Administration
  - Dispensing
  - Writing Prescriptions
  - Diversion and Inventory control
  - Waste and Destruction
  - Record Retention / Retrievability

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Drug Purchasing Records

- Controlled Substance Purchases
  - Separation of records
    - CII – all records should be files separately
    - CIII – CV – should be filed together
  - C-II controlled substances
    - Paper DEA-222 forms – UPDATED single page
      - Blank forms properly secured
      - POAs current and available
      - DO NOT pre-sign forms
      - Completed forms properly filed and available for review
    - DEA's electronic ordering system (CSOS)
  - CIII – CV controlled substance
    - Receiving invoices completed and available for review

Drug Administration Records

- Medical Record Documentation
  - Drug Name
  - Drug Concentration
  - Volume / Count Administered
  - Route of Administration
  - Acknowledgment of Order / Administration
- Controlled Substance Logs
  - Drug Name
  - Drug Concentration
  - Volume / Count Administered
  - Acknowledgment of Order / Administration or Dispensing
  - Perpetual Inventory
- Witness – Who / Why / When

Client provided controlled substances

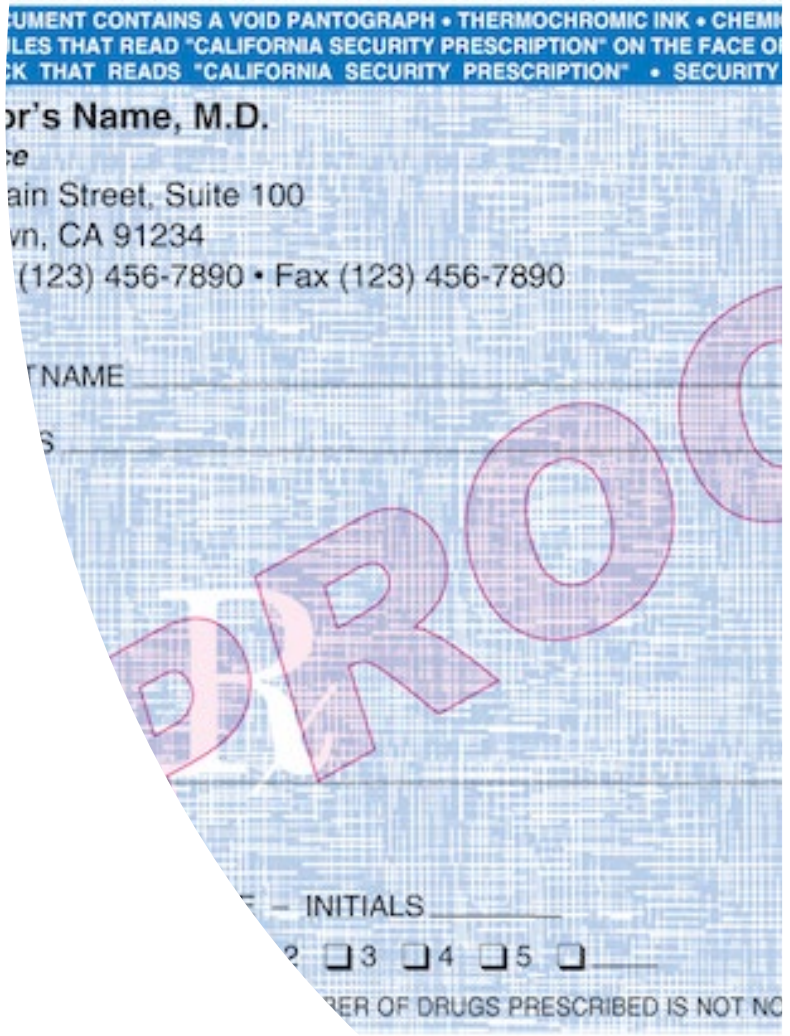
- Acceptable under specific circumstances?
  - Do not stock the controlled drug.
  - Admitting doctor reviews the non-stocked controlled drug.
  - Do not have a suitable alternative.
- Determine your best practice and documentation

Client provided controlled substances

- Recommended Protocol
  - Drug must be in the original pharmacy or referral partner bottle.
  - Follow these handling standards:
    - Generate a distinct log page for each bottle.
    - Bottle contents should be counted in front of the client (client signs log as a witness).
    - Follow controlled drug storage and security practices while in the hospital.
    - At discharge, drugs are counted in front of the client (client signs log).
    - Log page is retained with the patient's medical records and retained per state requirements.

Written Prescription Records

- Script blank security
- Signature – Manual / “wet ink”
- Duration limitations
- Refill limitations
- Medical Record
  - Include all information including # refills allowed



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Facility Drug Security

- Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet.
  - All lock boxes must be secured when not being accessed
  - Key or code access security protocols and documentation
  - Access should be limited to authorized persons only
  - List of those individuals assigned available for review
  - Camera coverage for lock boxes

https://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_75.htm

Drug Diversion / Inventory

- Have protocols and procedures in place to monitor for and determine if a controlled substance diversion has taken place
  - What is the interval for controlled substance inventory counts?
    - The DEA requires every two years (CII vs CIII – CV)
    - Illinois requires an annual controlled substance inventory
    - Is a copy of your latest inventory available for review?
    - Retain inventory records for five (5) years in Illinois
    - Best inventory interval?
  - CII exact count or measure of volume
  - CIII – CV exact counts and estimate volumes

Inventory Documents

Rev. 2019.03.21

Annual Controlled Substance Inventory - DEA Schedule/Class II

Hospital Name:		Wintess #1 (print):				
Address:		Wintess #1 (sign):				
City, State, Zip:		Wintess #2 (print):				
DEA Holder & Reg #:		Wintess #2 (sign):				
Ohio TDDD #:						
Inventory done: (Begin End 24/7) of Businsess	Date:				Time:	am / pm

Product name/(Size/Strength/Form/Container Size)	Schedule/ Class	Container Size	# of Full containers	# of Partial Containers	Total Amount in Partial Containers	Total Quantity

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Drug Diversion / Inventory Discrepancies

- All inventory discrepancies or unusual activities are investigated for possible diversion
  - Protocol / timing / documentation
  - Reconciling Discrepancies
    - Logging errors
    - Invoices not entered correctly
    - Math mistakes
    - Manufacturer over-fill / hub loss

Drug Diversion

- Know the process to report when a drug theft or loss is determined to be significant
  - Prompt reporting required to:
    - DEA via a form 106 (online)
    - SBOP in most states
    - Local law enforcement (per rule or their recommendation)
- How is “significant” defined?

Drug Diversion

- The DEA definition of significant loss.
  - When determining whether a loss is significant, a registrant should consider, among others, the following factors:
    - The actual quantity of controlled substances lost in relation to the type of business;
    - A pattern of such losses, and the results of efforts taken to resolve them; and, if known
    - Local trends and other indicators of the diversion potential of the missing material.

https://www.deadiversion.usdoj.gov/

Outdated Drugs and Drug Destruction

- Determine how you legally destroy controlled or non-controlled drugs at your practice
  - Reverse distributor
    - Licensed by DEA and State
    - Can be used for both controlled and non-controlled drugs
    - Provide documentation of destruction
    - Various Local, State and National Providers
      - Stericycle - Pharmaceutical Dimensions -National Pharmaceutical Returns

Outdated Drugs and Drug Destruction

- Destruction of drugs at your practice
  - Rules associated with controlled vs non-controlled
  - Determine who can complete the process
  - What documentation is required?
  - Always have a documented witness
- Non-retrievable (DEA definition)
  - For the purpose of destruction, the condition or state to which a controlled substance shall be rendered following a process that permanently alters that controlled substance's physical or chemical condition or state through irreversible means and thereby renders the controlled substance unavailable and unusable for all practical purposes.

  - Various products available – be sure to check with your State Board of Pharmacy

Drug Destruction

United States Environmental Protection Agency

- U.S. EPA Rule Update
  - ‘Management Standards for Hazardous Waste Pharmaceuticals’ (aka the “Hazardous Waste Pharmaceuticals Sewer Ban”)
  - Become effective August 21, 2019
  - Applies to all healthcare facilities and reverse distributors

Prepare Your Team

- Develop and utilize your SOPs
- Start training at new hire
- Designate and train a “lead-auditor” and train someone as a back-up
- Rotate roles and responsibilities
- Regularly review receiving / administration and dispensing documentation
- Use consistency in evaluating drug discrepancies
- Document EVERYTHING

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Readily Retrievable Files

- DEA registration
- DVM license
- Controlled Substance registration
- Authorized Persons list
- POA documents
- Initial Controlled Substance Inventory
- Current Annual inventory
- Blank 222 order forms
- Completed 222 order forms
- Invoices for CIII – CV
- Completed Form 41s
- Records for transferred
- Records of administered and dispensed (Logs / HMS)

Thank you!

Questions?

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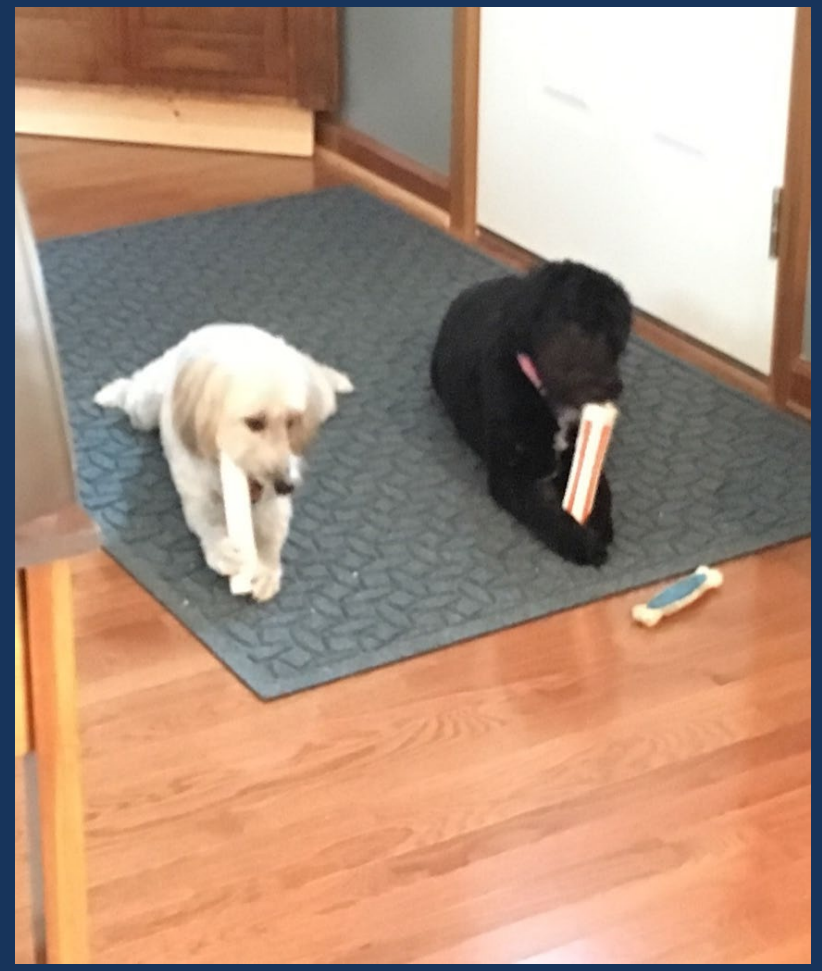

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