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### Presenters

**Dr. Peter Weinstein**

**Kelley Detweiler**

SIMPLE SOLUTIONS | CONTROLLED SUBSTANCES 4PDS FOR PROBLEM PREVENTION  
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### NOTE

With every regulatory agency, local, state, or federal, there are documented guidelines under which agents for these organizations work. Much of what is written is subject to interpretation by the representatives when they are reviewing a practice or a registrant. The DEA's guidelines are the Code of Federal Regulations (CFR) Title 21 1308-end.

The information we share are suggested best practices that meet or exceed the guidelines as published. In most cases, we will provide the code from which the best practice was based. It is still up to the DEA registrant to understand the guidelines and implement them appropriately.

**The best practices shared have been determined by experience with investigators and agents in the field and how guidelines are enforced.**

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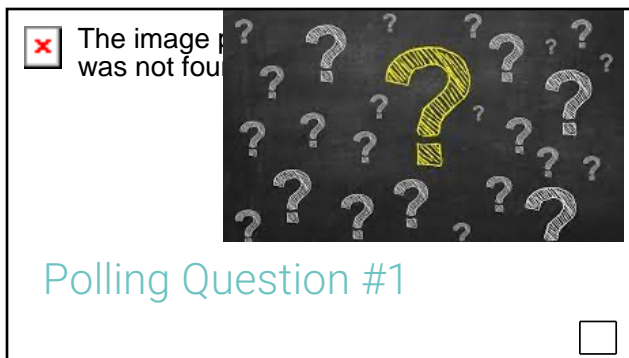
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**Do you know who is working for you?**



**Compliance starts with the hiring process. Employees must be properly vetted prior to working with controlled substances.**

- Perform background checks
- Conduct drug testing
- Execute Employee Screening Statements.

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**Authorized Users**

- An Authorized Personnel List must be created and maintained listing all individuals with authorization.
- A DEA registrant may authorize an individuals on their behalf via Power of Attorney for tasks such as completing DEA Form-222s.

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**Educate, Train & Delegate**



- Train staff on roles, responsibilities and procedures.
- Delegate roles and responsibilities to staff in the form of standard operating procedures
- Use checklists and workflows to promote consistency.

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### Relief & Associate Veterinarians

What you can and cannot do without a DEA registration



You can	You cannot
Administer	Order Prescribe Dispense



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### Witnesses

DEA does not require a witness during receiving or transfers, BUT it is **highly recommended** that you have an authorized witness present for verification purposes.



**Always** implement an authorized witness when conducting inventory (initial and biennial).

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### Products

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**Product**

Do you know what controlled substances are schedules I, II, III, IV and V?

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C1 v C2 v C3 v C4 v C5


C3-5 separate from C2—WHY?

C3-5 separate from C2—HOW?

- Physically
- Paperwork
- Handling

C3-5 separate from C2—WHO?

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Polling Question #2



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Veterinarians have access to a variety of controlled substances which are highly addictive.

**Commonly targeted:**

- Codeine
- Fentanyl
- Hydromorphone
- Buprenorphine
- Morphine
- Oxycodone
- Tramadol
- Ketamine
- Hydrocodone combinations (Vicodin, Lortab and Lorcet)
- Methadone



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## Internal Risks



- Improper wasting/disposal
- Inaccurate logging systems
- Lack of Power of Attorney ("POA")
- Lack of SOP's
- Lack of background checks
- Inadequate storage
- Outdated video surveillance

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## Paperwork

- DEA Registration
- Ordering
- DEA Form-222
- Inventory
- Logging
- DEA Form-106 (Loss, theft)
- Ready & Retrievable

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## DEA Registration – a **privilege** not a right...

How many DEA registrations do you need?

- **If you practice in multiple states:** you need a DEA registration for each state where you practice.
- **If you have multiple clinics/offices in one state and you have supplies of controlled substances to administer or dispense at those locations:** you need a separate DEA registration for each location.
- **If you have only one clinic/office where you practice:** you only need one registration.
- **If you have multiple clinics/offices in one state and you only prescribe at those locations:** you only need one registration.

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Do you also possess **all required** permits, licenses and registrations for working with controlled substances?


Aside from a DEA registration:

- Veterinary practitioner registration (*state-level*)
- State controlled substance license (*as applicable*)
- Veterinary premises permit (*as applicable*)

Are they accurate, active and consistent across all entities?



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## Ordering

Schedule II's are ordered using a paper **DEA Form-222** or via DEA's Controlled Substance Ordering System ("CSOS") using a **DEA Form-222e**.



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## DEA Form-222



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**DEA Form-222 Log**

Track DEA Form-222's in a separate log

DEA Form-222 Serial Number	Facility Name	Date Stored	Date Used	Date Order Received/ Executed	Date Filled
XXXXXXXXXX		XXXXXXXX	XXXXXXXX	XXXXXXXX	XXXXXX

Keep blank DEA Form-222's secured

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**Recordkeeping reminders**

- Schedule II's are ordered using a **DEA Form-222** or via DEA's Controlled Substance Ordering System ("CSOS").
- Ensure schedule II records are **separated out** from other records.
- Remember to properly fill out DEA Form-222, and "close out" 222's with signatures/the date annotated during receiving and attach to all corresponding documents.
- Ensure returns are properly **voided** and documented.

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**Conducting Inventory**

- An initial inventory must be taken prior to the start of operating with controlled substances.
- The DEA requires a biennial inventory to be conducted at least every two years following the initial inventory.

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## Expired Drugs

Expired controlled substances awaiting destruction **must be securely stored** and **included in counts with the rest of controlled substance inventory** until the time of disposal. If expired controlled substances are stored with active controlled substance inventory they must also be clearly separated out in storage.



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## DEA Form-106

If theft or a significant loss of controlled substances is identified, you must notify the DEA within **24 hours**.

A DEA Form 106 is the form used for reporting a theft/loss.

If you suspect potential theft/loss, you may notify the DEA of without initially filing a 106, if the situation is being investigated and after conducting an internal investigation you follow up with the DEA on the outcome and either advise that a 106 was not necessary or determine to file a 106 at that time.



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Are my records compliant?

Compliant records **tell the story** of the lifecycle of controlled substances from the moment of acquisition to the point of dispensing, administration, waste or disposal.



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### Your "ready & retrievable" file

All required documents and records must be available for inspection by the DEA immediately upon request at the location matching your DEA registration. These records should be maintained in a "readily retrievable" file.



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### Your DEA retrievable file

- Initial inventory
- Biennial inventory
- DEA registration & state licenses/certifications
- Executed and unexecuted DEA Form-222s (or electronic equivalent)
- Power of Attorney forms
- Receipts and/or invoices for schedules III-V controlled substances
- Records of controlled substances distributed (transfers)
- Records of controlled substances dispensed
- Reports of Theft or Significant Loss (DEA Form-106), if applicable
- Inventory of Drugs Surrendered for Disposal (DEA Form-41), if applicable
- Records of any transfers of controlled substances
- Authorized Personnel list
- Employee Screening Statements

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## Processes

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**SOP's**

Implement standard operating procedures for **all** aspects of controlled substances processes. Ensure that SOPs are readily retrievable with all other DEA required records.



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**Security processes**

All applicants and registrants shall provide **effective controls and procedures** to guard against theft and diversion of controlled substances.

21 CFR § 1301.71(a)



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**Polling Question #3**

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**Storage processes**  
21 CFR §1301.72

- Controlled substances storage
- Access/Passcodes for storage
- Restocking
- Controlled substances awaiting pickup by clients



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**Prescription Monitoring Programs (PMP/PDMP)**

- The PMPs were created to help mitigate prescription misuse and diversion, as well as to monitor and analyze prescription and dispensing data for controlled substances.
- Requirements for veterinarians vary by state.



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**Wasting processes**

Diversion often takes place during the wasting process when excess drugs are not fully expelled and properly wasted rendering them **“non-retrievable”** therefore proper wasting processes must be put in place.



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## Disposal processes

21 CFR 813.17.05

- Expired controlled substances should be sent to a reverse distributor for disposal. **The reverse distributor will complete all required paperwork for you** and provide with a certificate of destruction as well as all required paperwork for your records.
- Reverse distribution records must be retained for the current two-year period for the DEA (or longer depending on your state).



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## Final Thoughts...

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**Drug diversion** is an increasing concern for veterinarians, and it's not just controlled substances...



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Most drug diversion is an "inside job".

### Internal Theft Risks

- Improper disposal protocols
- Inaccurate logging systems
- Lack of proper Power of Attorney ("POA")
- Out of date video surveillance systems
- Lack of standard operating procedures ("SOP's")
- Lack of employment security/background checks
- Inadequate controlled substance storage

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Stressors such as veterinary compassion fatigue and burnout create a significant layer of drug abuse risk in the veterinary workplace, in addition to those posed by current drug users seeking employment in a workplace where psychoactive drugs are comparatively available.

It takes an average of **18 months** to detect addicted employee theft and misuse of controlled substances

Prattman Drug Diversion Digest February 2018 report: <https://www.prattman.com/blog/diversion-digest>

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## DEA Violations



### \$15,691

Maximum fine per DEA violation

1. **Paperwork:** Poor record-keeping
2. **Processes:** Failure to prevent diversion
3. **Products:** Lack of physical security
4. **People:** Registration issues

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### Best practices




Know your employees



Train your employees




Enhance security



Implement SOP's

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### In Summary...

- People
- Products
- Paperwork
- Processes

} Preparation = Prevention.

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## Thank you

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