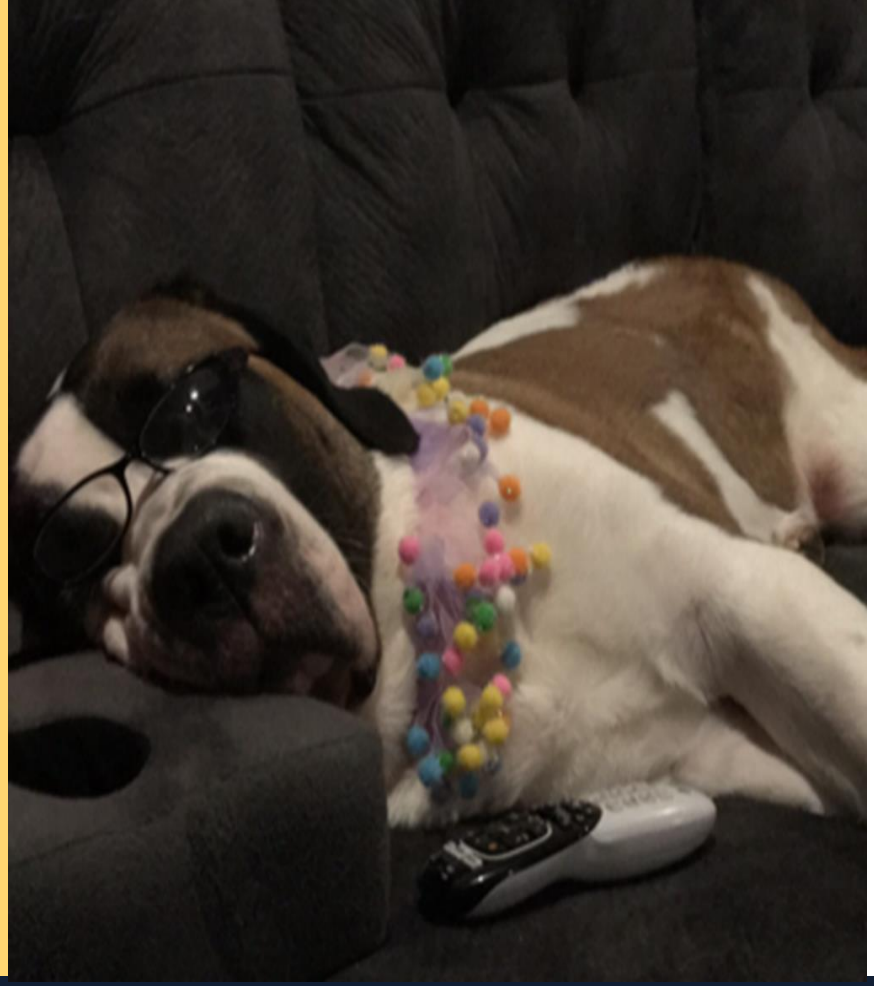
Long Island Veterinary Medical Association
CE Event 2023

Managing Controlled Substances: What Veterinary Professionals Need to Know!

Lisa Penny RPh
Chief Compliance Officer for VIP

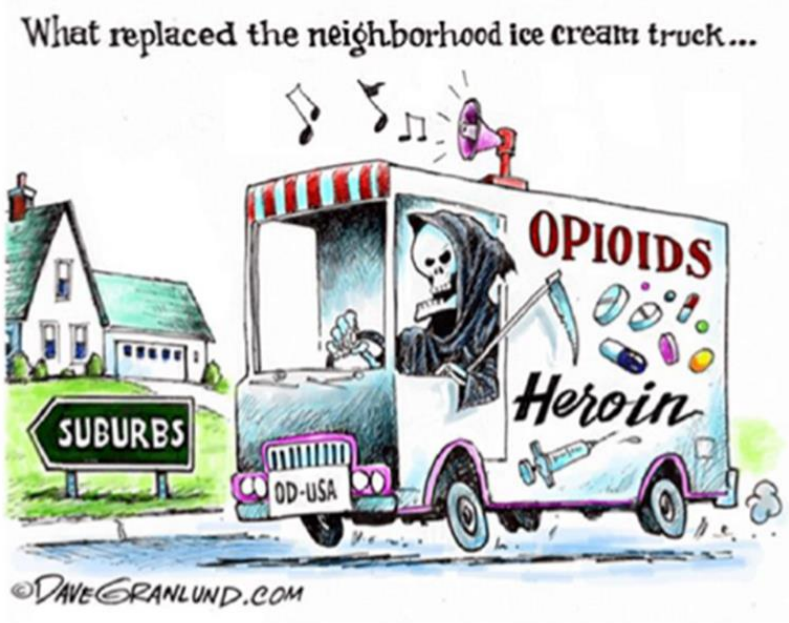


Financial Interest Disclosure

Lisa Penny “declare(s) no conflicts of interest, real or apparent, and no financial interest in any company, service, or product mentioned in this presentation, including grants, employment, gifts, stock holdings, or honoraria.

Objectives

- The DEA's Mission and it's impact on Veterinarians
- Requirements to Avoid the Top DEA Violations:
  - Registrations
  - Security
  - Record Keeping
  - Inventories
- Dispensing and Prescribing Regulations
- Drug Diversion Monitoring



DEA's Mission…

- The mission of DEA is to **ensure compliance with regulations** to support the prevention of drug diversion through a "***Closed System of Drug Distribution***".

- "It is essential that all prescribers—including veterinarians—**keep accurate records of controlled substances** so that we can identify and prevent any diversion, especially in the midst of a rampant and destructive opioid epidemic," said United States Attorney Rachael S. Rollins. "We will enforce compliance of these important safeguards." (9/22)

Veterinarians in the News

FOR IMMEDIATE RELEASE
Wednesday, September 21, 2022

Dedham Veterinarian Agrees to Pay $15,000 Settlement to Resolve Allegations of Inadequate Recordkeeping of Controlled Substances

BOSTON – A Dedham veterinarian has agreed to resolve allegations that he maintained inadequate records of controlled substances, improperly stored controlled substances at his office and residence, ordered controlled substances without a Drug Enforcement Administration (DEA) registration, and failed to report he was on probation on his DEA registration forms.

FOR IMMEDIATE RELEASE Thursday, August 19, 2021

Tooele Veterinarian Ordered to Pay $78,455 and Limit Prescribing for Failing to Properly Track and Control Opioids

SALT LAKE CITY – Dr. Joe Roundy, a licensed veterinarian and the owner of the Tooele Veterinary Clinic in Tooele, Utah, has been ordered to pay the United States $78,455 and restrict his prescribing of opioids and other controlled substances for violations of multiple provisions of the Controlled Substances Act ("CSA").

The Who, Why, and What Happens

The Enforcers

- Federal
  - Drug Enforcement Agency (DEA)
    - **Overseen by the Department of Justice.
  - Laws are found in Title 21 USC, §801-971,
  - Regulations are found in Title 21 CFR §1300 to the end.
- State
  - New York Bureau of Narcotic Enforcement (BNE)
    - **Overseen by the Department of Health.
  - Public Health Law Article 33 and Title 10 Part 80 Rules & Regulations on Controlled Substances.

Reasons for a Visit

- Random on-site inspection
- Reports from suppliers
- Complaints
- Diversion events

Consequences

- Common violations are:
  - Registration issues,
  - Security violations,
  - Record keeping issues,
  - Missing or incomplete inventories.
- Fines are now over **$15,000** per violation.
- Can lead to loss of DEA Registration.

DEA Registrations

Title 21 CRF §1301.11:

- Every practitioner that handles controlled substances must be registered with the DEA, and this is based on a state license, it cannot authorize controlled substance activity outside that state.
  - Registrations must be renewed every three years.
- The DEA Certificate of Registration (DEA Form 223) must be maintained at the registered location in a readily retrievable manner and available for official inspection.
- A separate registration must be obtained for each principal place of business or professional practice where controlled substances are distributed or dispensed.

Title 21 CRF § 1301.22:

- 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 if and to the extent that such individual practitioner is authorized or permitted to do so by the jurisdiction in which he or she practices, under the registration of the employer or principal practitioner in lieu of being registered him/herself.
  - 2018 DEA response for clarification: If a practitioner at the practice location permits another practitioner to act as his or her agent, the primary practitioner must ensure that his or her agents administer and dispense these controlled substances lawfully by **exercising direct, continuous, and active oversight** of these controlled substances.

DEA Registration- Mobile and Relief Vets

Title 21 §822:

- A registrant who is a veterinarian shall not be required to have a separate registration in order to transport and dispense controlled substances in the usual course of veterinary practice at a site other than the registrant's registered principal place of business or professional practice, so long as the site of transporting and dispensing is in a State where the veterinarian is licensed to practice veterinary medicine.

- Transportation/ security and record keeping requirements are all the same as “practice sites”.

- Must have individual DEA Registrations and report dispensing controlled substances.

Relief vets …..

- DEA registration recommended but is still limited by the address on the registration.

- In New York cannot prescribe or dispense without a DEA registration.

- New York it is very difficult to figure out how to handle the prescription pad issue…

Title: Section 80.64:

- A prescription for a controlled substance may be issued only by a practitioner who is registered under the Federal Controlled Substances Act and in possession of a registration number from the DEA or exempt.
  - NY Prescription Monitoring Program (PMP) requirements for dispensing controlled substances: the DEA number of the veterinarian who dispensed the controlled substance must be reported to BNE PMP portal.

- The Consolidated Appropriations Act of 2023 requirement for all practitioners to completed a one time 8-hour training on the treatment and management of patients with opioid or other substance use disorders does **NOT** apply to Doctors of Veterinary Medicine for new applications or renewals.

- NY requires during each triennial registration period, **at least two hours** of the required continuing education credits shall focus on the use, misuse, documentation, safeguarding and prescribing of controlled substances.

The FDA determines what schedule drugs will be placed in. Substances are divided into five schedules based on whether they have a currently accepted medical use in treatment in the United States, their relative abuse potential, and likelihood of causing dependence when abused.

Schedule I
- Marijuana and its derivatives are **ILLEGAL** at a Federal level and still a Schedule 1 narcotic.

Schedule II (CII)
- Fentanyl, codeine, Hycodan, hydromorphone,
- Methadone, morphine, oxycodone.

Schedule III (CIII)
- Buprenorphine, ketamine, Telazol,
- Euthasol, Simbadol, Zorbium.

Schedule IV (CIV)
- Tramadol, *diazepam, midazolam*,
- Torbugesic, Alfaxan.

Schedule V (CV)
- Pregabalin, Lomotil,
- *Gabapentin, Proin, ephedrine.*

Security Requirements-Employees

Employee Self-Attestation

1. Within the past five years, have you been convicted of a felony, or within the past two years, of any misdemeanor or are you presently formally charged with committing a criminal offense?

2. In the past three years, have you ever knowingly used any narcotics, amphetamines or barbiturates, other than those prescribed to you by a physician?

_____signature

_____date

Title 21CFR §1301.76

- The registrant **shall not** employ someone who **has access** to controlled substances that has been convicted of a felony offense relating to controlled substances, or who, at any time, had an application for registration with the DEA denied, revoked, or has surrendered a DEA registration for cause.

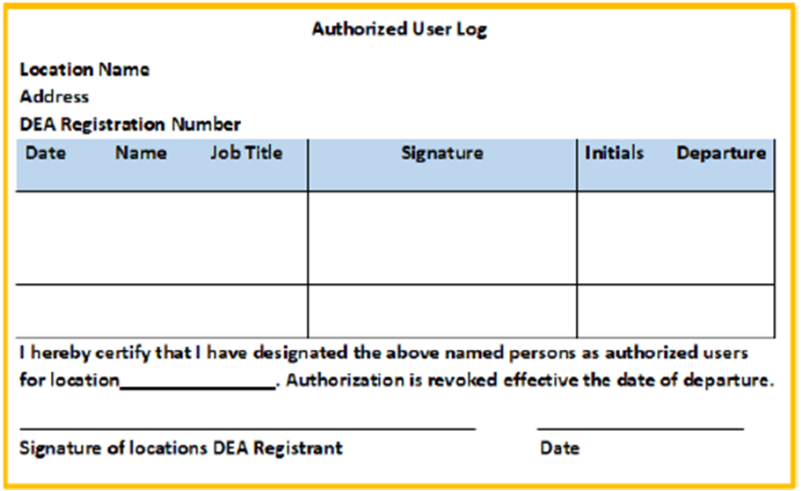
Title 21 CFR §1301.90

- It is the position of DEA that the obtaining of certain information is vital to fairly assess the likelihood of an employee committing a drug security breach. The need to know this information is a matter of business necessity, essential to overall controlled substances security. It is, therefore, assumed that the following questions will become a part of an employer's comprehensive employee screening program.

- Drug Tests? Background Checks?

Authorized User List

- Statement certifying above listed people can handle DEA Registrant's controlled substances.
- Statement saying above people have been properly training to handle controlled substances.*
- Job Title, Department, Date Given and Revoked, etc.
- Review yearly when inventory completed.



Authorized User Log

Location Name
Address
DEA Registration Number

Date	Name	Job Title	Signature	Initials	Departure

I hereby certify that I have designated the above named persons as authorized users for location_____. Authorization is revoked effective the date of departure.

_____ _____
Signature of locations DEA Registrant Date

Security Requirements-Storage

Title 21 CFR §1301.75:

- Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet.
- Schedule II drugs must be separated from Schedule III-V drugs in the safe, and non-controlled drugs cannot be stored in the safe with controlled drugs.
- Suppliers will only ship to address listed on DEA Registration.
- Cameras?
- Drugs of concern?

Part 80: Rules and Regulations NY

- Controlled substances shall always be properly safeguarded and securely kept at the address on file with the DEA and which is used in the ordering of the controlled substances.
- Access to controlled substances stocks shall be limited to the minimum number of employees required to efficiently handle the controlled substances.
- Double Locks and Secured to the Wall?

DEA 222 Form- Mistakes and Reminders

Ordering

- Must complete a DEA 222 Form or
- Use DEA Controlled Substance Ordering System (CSOS)

DO NOT

- Pre-Sign 222 Forms- Get Power of Attorney to sign
- Share CSOS Login info- each user must have own account

Title 21 CFR §1305.16:

- Lost or stolen DEA 222 Forms must be reported to DEA
- Recommend keeping a log to track 222 forms recieved and used

Ordering

- No mistakes or cross-outs
- Make a copy and keep!!

Receiving

- Complete Part 5
- Staple to invoice/packing slip

Backorders

- Form good for 60 days
- Complete Part 5 when order comes in

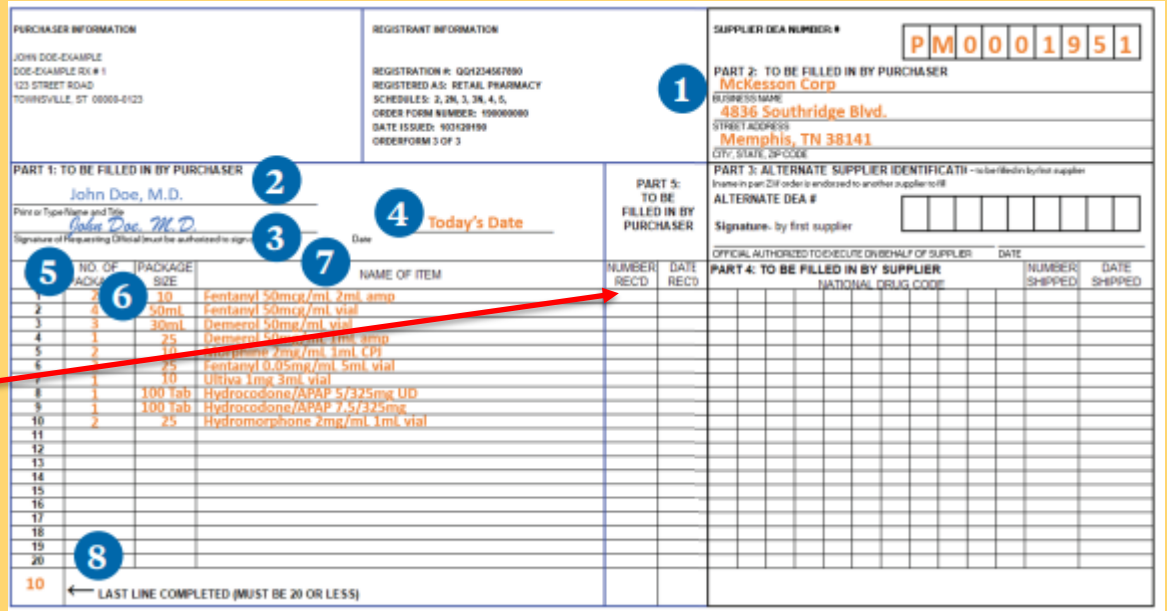
Errors

- Mark 222 Form as "Void"
- Attach any communication from Vendor to Form.

Site Name:			DEA #				
Date Ordered	Date Issued by DEA	Date Received	Form Number	Date Issued to Supplier	Issued To	Date Received	Authorized Initials
			1/3				
			2/3				
			3/3				
			1/3				
			2/3				
			3/3				

DEA POA Link:
https://www.deaecom.gov/poa_letter.html

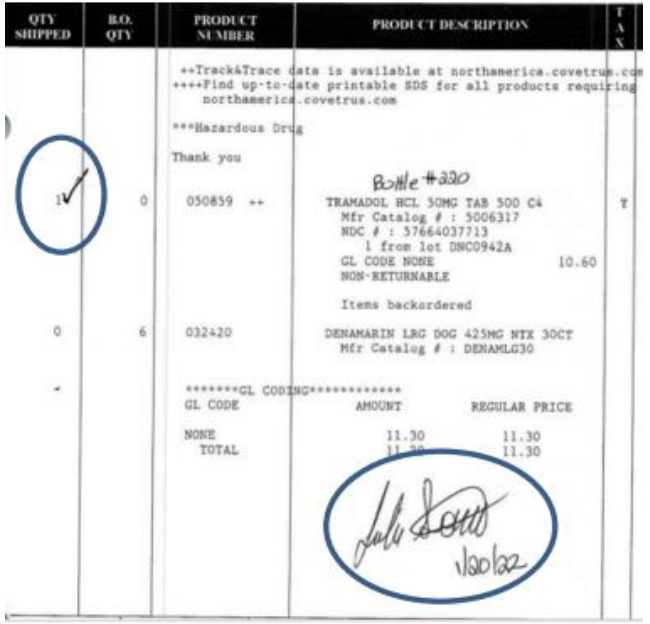
Complete this part when order comes in.



Record Keeping- Packing Slips/Invoices

Title 21 CRF §1304.4 and §1305.14:

- All original controlled substance packing slips/invoices must be **signed and be dated** for the date received by at least one individual.
- All records for Schedule II drugs must be maintained **separately** form Schedule III-V, and Schedules III-V must be maintained separately from Schedule II and from the ordinary business records or clearly identifiable.
- Packing slip/invoice should also be marked to indicate verification of the quantity received matches the quantity on the invoice.
- Best practice recommendation is to have 2 individuals validate quantity received, sign, and date packing slip/invoice.
- Best practice recommendation is to have a different person receiving the order than the person that ordered.



QTY SHIPPED	B.O. QTY	PRODUCT NUMBER	PRODUCT DESCRIPTION	T A X
			++Track&Trace data is available at northamerica.covetrus.com ++++Find up-to-date printable SDS for all products requiring northamerica.covetrus.com	
			***Hazardous Drug	
			Thank you	
1✓	0	050859 ++	Bottle #230 TRAMADOL HCL 50MG TAB 500 C4 Mfr Catalog # : 5006317 NDC # : 57664037713 1 from lot DNC0942A GL CODE NONE 10.60 NON-RETURNABLE	Y
			Items backordered	
0	6	032420	DENAMARIN LRG DOG 425MG NTX 30CT Mfr Catalog # : DENAMLG30	
			********GL CODING**********	
			GL CODE AMOUNT REGULAR PRICE	
			NONE 11.30 11.30 TOTAL 11.30 11.30	
			1/30/22	

Record Keeping- Required Logs

Title 21 CFR §1304.21:

- Every Registrant shall maintain, on a current basis, a complete and accurate record of each substance **received**, sold, delivered, or otherwise **disposed** of by him/her.

Section 80.105 Practitioners:

- Every authorized practitioner shall keep a record of all controlled substances purchased by him and a record of all such drugs **dispensed** or **administered** by him out of his own stock of such drugs.

Title 21 CFR §1304.04:

- Every inventory and other records required to be kept must be kept by the registrant and be available, for **at least 2 years** from the date of such inventory or records.

Section 80.100 Records:

- Records of all transactions concerning controlled substances required to be kept practitioners shall be kept for a **period of five years** from the date of transaction.
- Records shall be maintained at the premises where the licensed activity is conducted.

Record Keeping- Administration Logs

DEA does not define what must be in logbook!

- Each drug needs its own sheet/book
- CII records separate from CIII-CV
- Date
- Pet and Owner information- 2 identifiers
- Ordering Veterinarian
- Amount removed/wasted
- Who removed drug
- Amount remaining
- Witness if needed
- Track by bottle numbers
- Don’t carry over bad math!!

Section 80.105 – Practitioners:

- Records of disposition of controlled substances shall include date of dispensing or administering of such drug, name and address of patient, and type and quantity of drug.

Section 80.48-Administration Records:

- An **order**, signed by a person authorized to prescribe/order the drug.
- A record in the patient's chart **indicating administration** of the controlled substance including the name of the administering attendant and the date of administration.
- Administration Log:
  date of administration,
  name of patient;
  name of prescribing veterinarian;
  quantity of administration;
  balance on hand after each administration; and
  signature of administering nurse.

Midazolam 5mg/mL Injection CIV *(CII NY)*

Drug Name			Strength		Size		Beginning Count	
Midazolam			5mg/mL		10mL vial		**11.2mL** *(7 previous removals from Bottle 22-3 on previous page)*	
Date	**Transaction Information** (Patient/Client Information, Vendor & Invoice #, Inventory)	**Veterinarian Prescribing or Bottle Number(s) & Expiration Date**	**Quantity IN**	**Quantity OUT**	**Signature of User**	**Quantity Remaining**	**Waste Amount**	**Witness Signature**
5/30/2023	Fred: Susie Chapstick Client #54321	Bottle #22-3 Dr. Grumpy		0.5mL	S. Smith	10.7mL	-	
5/31/2023	Kujo: Ralph Meijer Client # 6897 *(needs 1.1mL so you will need to document removal from 2 vials- document **actual amount** removed from each vial)*	Bottle #22-3 Dr. Happy *You can only get **0.2mL** from the vial, not the 0.7mL that is listed on the log. So document actual amount taken from vial and on the next line document the missing amount as out for hub loss to "zero" out the bottle*	-	**0.2mL**	S. Smith	10.5mL	-	
5/31/2023	Adjustment -hub loss for #22-3- *You must show the math for hub loss which is the number of "hits" on the vial times 0.05mL. If the total is close to the missing volume this is an acceptable hub loss.*	Bottle #22-3 ***9hitsx0.05=0.45mL*** *If hub loss math is greater than actual loss that is fine, but if loss math is way off always go back and check all math for errors or errors in documentation.*	-	**0.5mL**	S. Smith	10mL		
5/31/2023	Kujo; Ralph Meijer Client # 6897 *(Document actual amount removed from the new vial to complete the order)*	Bottle #23-1 Dr. Happy	-	0.9mL	S. Smith	9.1mL		
6/1/2023	Received MWI Invoice#1234 *Receives should always have a witness sign.*	Bottle #23-2 exp 1/25 Bottle #23-3 exp 1/25	20mL	-	S. Smith	29.1mL	-	**B. Jones**
6/1/2023	Fluffy; Bob Hines Client # 3245 *Waste must always have a witness sign.*	Bottle #23-1 Dr. Grumpy	-	0.38mL	S. Smith	28.72mL	0.2mL	**B. Jones**

Record Keeping- Other Dispositions

Section 80.48:

- A record of authorized requisitions for backstock controlled drugs to substock.
- Such records shall show receipt by the signature of a person authorized to control such substation or ward.

Title 21 CRF §1317.90:

- The method of destruction shall be consistent with the purpose of rendering all controlled substances to a non-retrievable state in order to prevent diversion of any such substance to illicit purposes and to protect the public health and safety.
- **Waste** must be properly recorded in the administration log and have a witness signature.

Title 21 CFR §1317.05:

- Secure and Responsible Drug Disposal Act of 2010 allows a practitioner to dispose of out-of-date, damaged, or otherwise unusable or unwanted controlled substances in their inventory by:
  - Transferring them to a registrant who is authorized to receive such materials – a **Reverse Distributor**.
    - They will create a DEA 222 form for any CII drugs collected, and a DEA form 41 for the destroyed CII-CV drugs.
  - Request assistance in destruction from the DEA using DEA form 41 to destroy in front of an agent or other authorized person using an on-site method of destruction.
- These records must be maintained for a minimum of 2 years (5 for NY).

Drug Name			Strength		Size	Beginning Count		
Alprazolam			0.5mg		100 count bottle	2		
Date	**Transaction Information** *(Vendor & Invoice#, Location, Inventory, Transfer)*	**Bottle Numbers(s), exp. Date(s)**	**Quantity IN**	**Quantity OUT**	**Signature of User**	**Quantity Remaining**	**Witness Signature**	**Empty Bottle Returned**
1/1/21	*Active stock*	*21-01*		*1*	*t. smith*	*1*	*k. watts*	*yes*
1/10/21	*MWI 1234*	*21-02*	*1*		*t. smith*	*2*	*d. long*	

Expired Drug Log

Date	Drug Name	Location	Amount	Signature	Reverse Date	Signature

- Outdated controlled substances must be stored securely but segregated until destroyed or reverse distributed.
- **DO NOT** use Drug Take Back Days!
- **DO NOT** take controlled substances back from clients!
- Will use a DEA form 41 to document when a controlled substance vial is broken.

https://www.deadiversion.usdoj.gov/21cfr_reports/surrend/41_form.pdf

Record Keeping- Biennial Inventory

Title 21 CFR §1304.11:

- **Biennial Inventory:** The registrant shall take a new inventory of all stocks of controlled substances on hand **at least every two years.**
  - Taken either as of opening or closing of business.
  - Schedules I or II, make an exact count, III-V can estimate.
  - Newly added controlled substances must be counted and then added to biennial moving forward.

- ***Section 80.111-80.112:*** This inventory must be completed on **May 1st** every 2 years (odd years).

- **Initial Inventory:** Must be taken on the date he/she first engages in the ordering, distribution or dispensing of controlled substances.

Date:			**Opening of Business** ☐ **Close of Business** ☐			
Registrant Name:						
Registrant Address:						
DEA Registration Number:			**State Veterinary /Controlled Substance License Number**			
Inventory Performed By:		**Signature:**			**Date:**	
Witness:		**Signature:**			**Date:**	
Drug Name	**DEA Schedule**	**Finished form of the substance**	**The number of units or volume of each finished form in each commercial container**	**The number of units on hand of each such finished form**	**Additional number of units awaiting destruction**	**Total**
Oxycodone IR	II	*10mg*	*100 tablets*	*203*	*10*	*213 tabs*

- ❖ Remember to inventory expired inventory.
- ❖ Do not include inventory that has been dispensed and is awaiting client pick-up.

Record Keeping- Theft and Significant Loss

Theft Example

Dear DEA:
I am writing on behalf of [DEA Registrants Name] to inform you about the discovery on [insert date] of a potential theft of a controlled substance(s). Specifically, [DEA Registrants Name] has discovered that [insert issue, for example, at least 10 Tramadol pills] were potentially diverted by an [insert position] employed by [Name of Company. A DEA Form 106, if warranted, will be submitted once the investigation is complete. We are submitting this notification within one business day of discovery of the theft as required by 21 C.F.R. § 1301.76. Please let me know if you have any questions.
Regards,
[DEA Registrant]

Significant Loss Example

Dear DEA:
I am writing on behalf of [Name of DEA Registrant] to inform you about the discovery on [insert date] of a potentially significant loss of a controlled substance(s). Specifically, [Name of DEA Registrant] has discovered that [insert issue, for example, two bottles of fentanyl were ordered and received into pharmacy inventory] but are now unaccounted for. A DEA Form 106, if warranted, will be submitted once our investigation is complete. We are submitting this notification within one business day of discovery of the significant loss as required by 21
C.F.R. § 1301.76. Please let me know if you have any questions. Regards,
[Name of DEA Registrant]

https://apps.deadiversion.usdoj.gov/TLR/
https://www.health.ny.gov/forms/doh-2094.pdf

Title 21 CFR §1301.76:

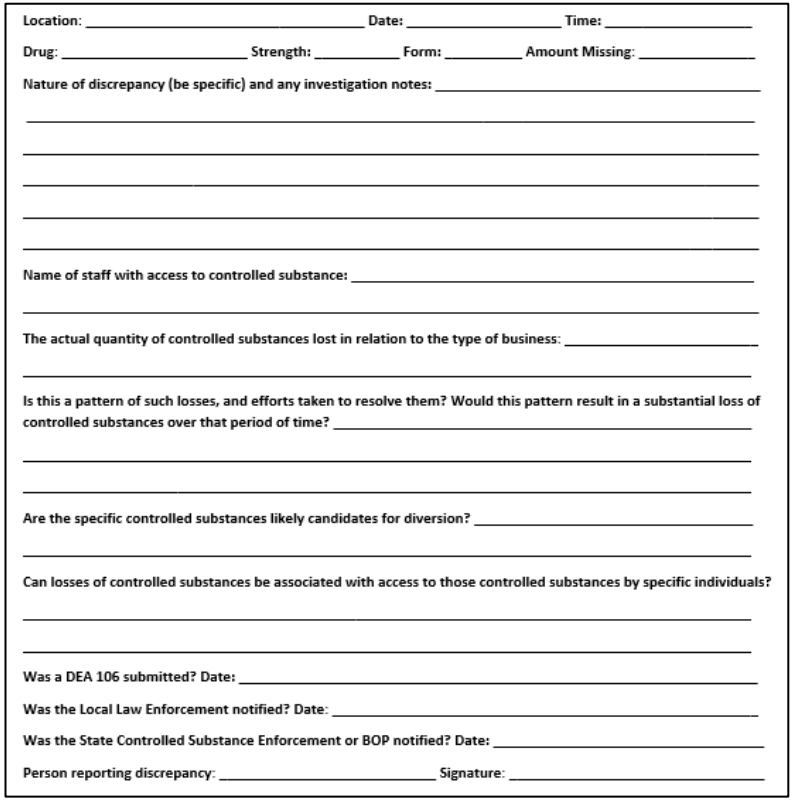
- The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances **within one business** day of discovery of such loss or theft.
  - Initial notification can be sent via email notification to local DEA office.
  - Recommend follow-up notice be sent if no theft or significant loss is determined or if investigation takes more than 2 months.
  - DEA 106 MUST be submitted once investigation is completed if theft or significant loss is determined.
  - Always print and save a copy of DEA 106 submission and attach to any investigation notes.
  - Keep all records for a minimum of 2 years (5 years NY).

Section 80.20:

- The licensee shall promptly notify the department of any theft or loss of any controlled substance on **form DOH-2094**, whether the controlled substances are subsequently recovered, the responsible parties identified, or action taken against them.

Significant Loss and Investigation Documentation

- DEA recognizes there is no single objective standard that can be applied to all registrants--what constitutes a significant loss for one registrant may be construed as comparatively insignificant for another.
- Any unexplained loss or discrepancy must be reviewed within the context of a registrant's business activity and environment.
- Use a Discrepancy form to document investigation and determination.



Location: _____ Date: _____ Time: _____

Drug: _____ Strength: _____ Form: _____ Amount Missing: _____

Nature of discrepancy (be specific) and any investigation notes: _____

_____

_____

_____

_____

_____

Name of staff with access to controlled substance: _____

_____

The actual quantity of controlled substances lost in relation to the type of business: _____

_____

Is this a pattern of such losses, and efforts taken to resolve them? Would this pattern result in a substantial loss of controlled substances over that period of time? _____

_____

_____

Are the specific controlled substances likely candidates for diversion? _____

_____

Can losses of controlled substances be associated with access to those controlled substances by specific individuals?

_____

_____

Was a DEA 106 submitted? Date: _____

Was the Local Law Enforcement notified? Date: _____

Was the State Controlled Substance Enforcement or BOP notified? Date: _____

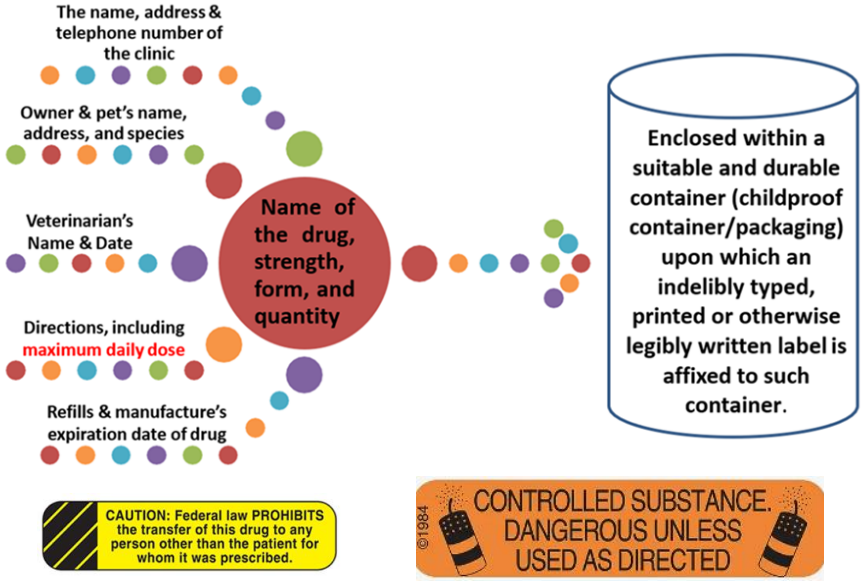
Person reporting discrepancy: _____ Signature: _____

Are You Ready for DEA or NY BNE?

- Policies and SOPs?
- Registrations:
  - Are all DEA Registrations on-site with the correct address and not expired?
- Security:
  - Authorized User List current with minimal individuals accessing controls?
  - Does the safe meet minimum requirements and is access secure?
  - How are drugs kept in the safe (CII separate from CIII-CV), are there non-controls in the safe?
- Records:
  - Are all invoices/packing slips signed and dated by at least one individual?
  - Are CII invoices/packing slips separate from CIII-CV invoices/packing slips?

- Records-cont.:
  - Is Part 5 completed on all DEA 222 forms/CSOS orders and stapled to invoices/packing slips?
  - Are all drugs received logged into logbook as received?
  - Does each drug have its own administration page, and are CII pages separate from CIII-CV?
  - Is waste and overage being properly documented on the log sheets-is the math correct for the usage?
  - Are your expired drugs properly recorded and disposed of?
  - Do you have a biennial inventory within the last 2 years on May 1st?
  - Do you have any thefts or losses?

Dispensing Controlled Substances



Title 21 CFR § 290.5:

- The label of any drug listed in schedule II, III, or IV when dispensed to a patient must contain the following warning: "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."

Section 80.71:

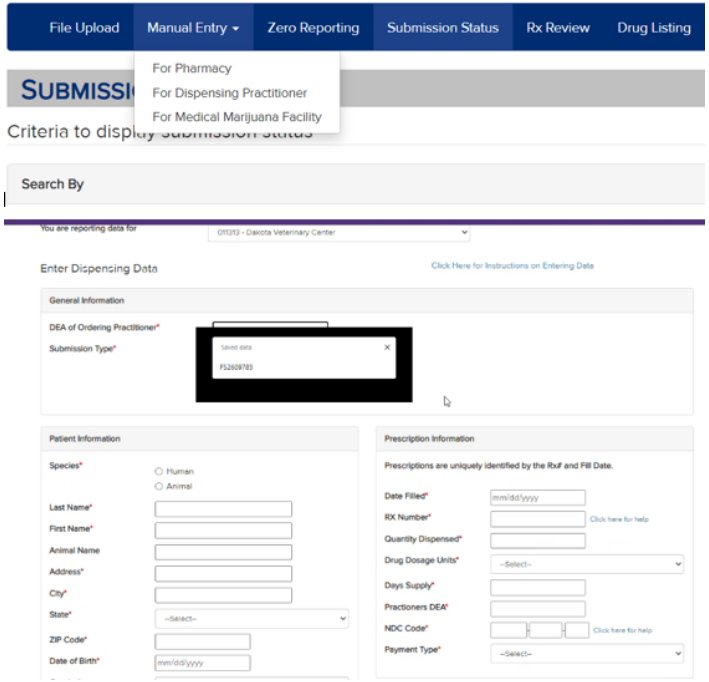
- Prominently marked or printed in either boldface or upper-case lettering: "**CONTROLLED SUBSTANCE, DANGEROUS UNLESS USED AS DIRECTED**".

- Initial prescribing/dispensing for opioids for acute pain is a 7-day supply.

- **Cannot** dispense prescriptions written by another DVM- must have VCPR!

Reporting Dispensed Controlled Substances-FAQs

- All controlled substances dispensed must be reported to the New York State Department of Health (NYSDOH) **no later than 24 hours after the prescription is filled**.
  - Can have one Health Commerce account established for the clinic, but report under the ordering veterinarian's DEA number.
  - Watch the days supply on refills- In NY, no additional prescriptions may be dispensed within 30 days of the date of any prescription previously issued until the ultimate user has exhausted all but a seven days' supply of that controlled substance.
  - Must submit a zero report at least every 14 days.
  - Each user MUST have their own login and password- do not use one clinic login under the Dr.'s account.



Prescribing Controlled Substances

Section 80.63:

- No controlled substance prescription shall be issued prior to the examination of the patient by the practitioner except:
  - either for the same acute or chronic condition as needed;
  - In an emergency the prescription does not exceed a 5-day supply.

- In the temporary absence of the initial prescriber, an authorized practitioner may issue a controlled substance prescription as part of a continuing therapy if the practitioner:
  - had direct access to the patient's medical records;
  - had direct and adequate consultation with the initial prescriber.

Prescribing Regulations

Section 80.67-80.68:

- Exempt from electronic prescribing but must use Official NYS prescription forms including:
  - name, sex, address and, for an animal, the species and the name and address of the person in custody of animal;
  - specific directions for use, including, the dosage and frequency of dosage and the **maximum daily dosage**;
  - the prescription shall be dated as of, and signed on, the date it is issued by the prescriber;
  - the quantity of dosage units prescribed indicated in both numerical and written word form.
- Pharmacist may add to the prescription missing information after speaking to the prescriber except for the following:
  - unsigned or undated prescriptions;
  - where the name and/or quantity of the controlled substance is not specified;
  - where the name of the ultimate user is missing.

Section 80.77:

- Adequate safeguards shall be taken to assure against the loss, destruction, theft or unauthorized use of the official Rx forms.
- Practitioners shall maintain a record of the disposition of all forms, including destruction and cancellations.
- Practitioners shall immediately notify the department of the loss, destruction, theft or unauthorized use of any official NYS Rx forms issued to them, or forms not received.

Prescribing Regulations

Section 80.67: Schedule II Drugs:

- No such prescription shall be made for a quantity of substances which would exceed a 30-day supply.
- No refills can be authorized.

Section 80.68: Emergency Oral Prescriptions CII

- Maximum may not exceed a 5-day supply.
- Within 72 hours the practitioner shall cause to be delivered to the pharmacist the official NYS Rx from with "Authorization for emergency dispensing" written on it.

Section 80.69 - Schedule III, IV and V substances;

- 30-day supply and up to 5 refills.
- If more than 30 days supply, no more than 1 refill.

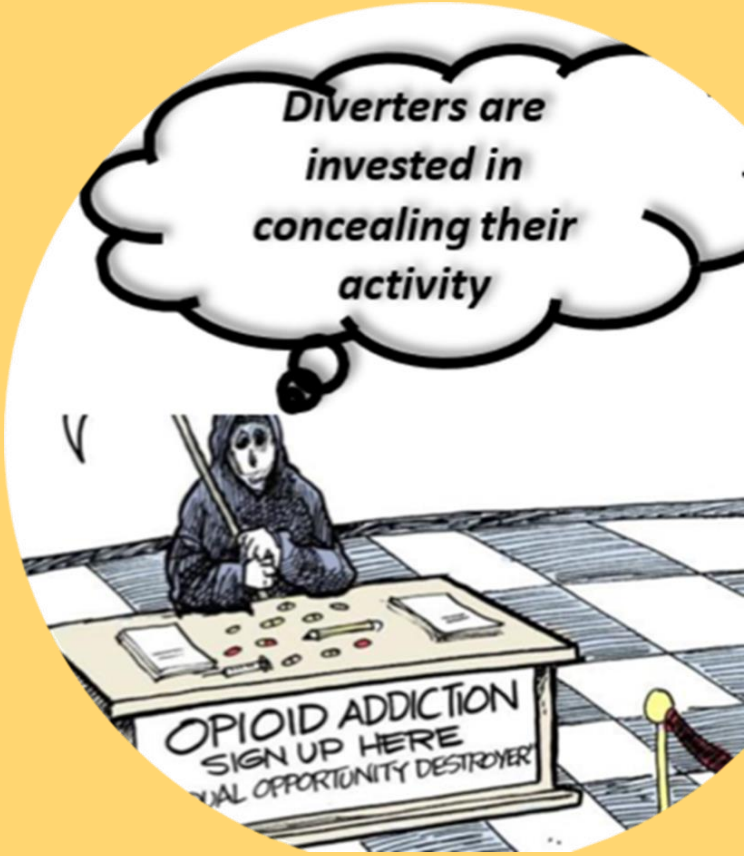
Section 80.70: Emergency Oral Prescriptions CIII-CV

- CIII, and CV: Max may not exceed a five-day supply.
- CIV: Maximum may not exceed a 30-day supply or 100 dosage units whichever is less.
- Within 72 hours after authorizing such an oral prescription, the prescribing practitioner shall cause to be delivered to the pharmacist the official NYS Rx form.

- A 3-month supply can be issued for specific codes written on the face of the prescription:

panic disorders	code A
chronic debilitating neurological conditions characterized as a movement disorder or exhibiting seizure, convulsive or spasm activity,	code C
relief of pain in patients suffering from conditions or diseases known to be chronic or incurable	code D

Drug Diversion in the Veterinary Industry



Signs of Drug Abuse or a Substance Use Disorder

- Changes in appearance, attitude, or personality (agitated or depressed)
- A sudden inability to handle usual responsibilities
- Unexplained, or unusual absenteeism
- Irritable, antagonistic and even hostile, especially when questioned
- Coming in early, staying late, preferring to work alone
- Poor or sloppy record keeping
- Frequently volunteering to perform CS inventory, receive orders, or place orders

Possible Ways for Diversion to Occur

Client Diversion

- Theft of drugs or prescription blanks.
- Taking all or part of pet's dose for self use.
- Going to multiple veterinarians for the same issue.
- Distorting the significance of the pet's pain.
- Needing early refills or "lost" medication.

Employee/Co-Worker Diversion

- Theft of drugs or prescription blanks.
- Adding fake patients to use log.
- Routinely removing extra doses 'just in case" and then not returning dose.
- Frequently making "dosing" errors or withdrawing too much medication that then needs to be "wasted".
- "Padding" the order from suppliers and not adding to the inventory.
- Adding refills to their own pet's-controlled substance medications without authorization.

What Can be Done- Realistically?

- Clear lines of accountability and expectations for following the regulations.
- Don’t let the fox in the hen house in the first place.
- Limit who has access to controlled substances.
- Rotate duties- a system of checks and balances.
- Do routine inventory checks.
- Spot check logs against PM software.
- Drug test for cause.

Questions?

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