

# Controlled Substances: Prescribing, Reporting, Record Keeping, and Diversion Prevention

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# Disclosures



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

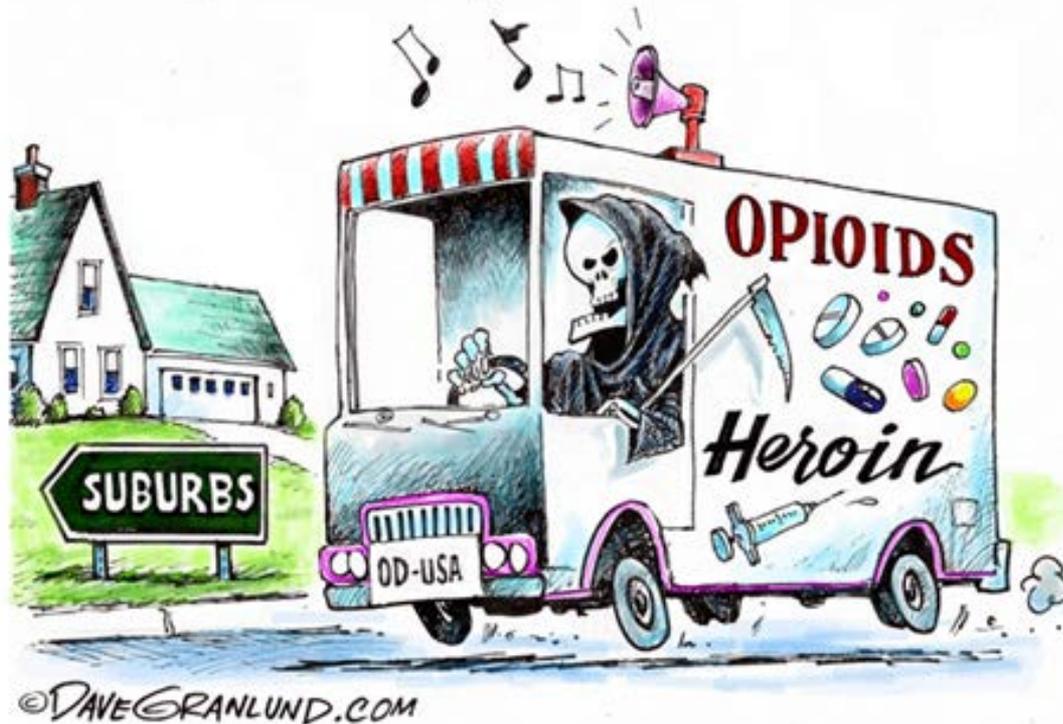
# Objectives

- Drug Diversion, Detection, and Prevention
  
- Classification of Controlled Substances
  
- Federal and State Controlled Substance Regulations
  - Controlled Substance Prescription Writing
  - Controlled Substance Dispensing
  - Reporting-HSC and I-STOP
  - Record Keeping
  - Storage/Destruction/Inventory Requirements
  - Unwanted/Unused Drug Disposal
  
- General Prescribing Guidelines

# Why All the Hype?!

## The Opioid Epidemic.....

What replaced the neighborhood ice cream truck...



# The Opioid Epidemic....

- In September 2017 the New York Times reported drug overdoses killed roughly 64,000 people in the U.S. last year,
  - Drug overdoses now kill more Americans each year than gun violence.<sup>(1)</sup>
  - Is the leading cause of death for Americans under the age of 50.
  - More than the 35,092 motor vehicle deaths in 2015.<sup>(3)</sup>
  - More than AIDS-related deaths in the worst year of the AIDS crisis, when 50,628 people died in 1995.<sup>(3)</sup>
  - More Americans died from drug overdoses in 2016 than the number of American lives lost in the entirety of the Vietnam War.<sup>(3)</sup>
  
- Attorney General Jeff Sessions called drug overdose deaths “the top lethal issue” in the U.S. and urged law enforcement and social workers to “create and foster a culture that’s hostile to drug use.” <sup>(1)</sup>

# Federal Diversion Prevention

- In 2016, Congress passed the 21st Century Cures Act, which allocated \$1 billion over two years to enhance states' response to the epidemic. 80% of the grants have to be devoted to treatment and recovery programs, 5% to administration, and the remaining 15% to what the state sees fit, including prevention such as improving prescription drug monitoring programs (PDMPs).
- In July 2017, Scott Gottlieb, MD, Commissioner of the Food and Drug Administration (FDA), announced new requirements for risk evaluation and mitigation strategy (REMS) programs for opioids, including new training requirements with emphasis on making sure providers understand the current thinking on the dosing and prescribing of opioids.
- In June 2017, the FDA requested that Endo Pharmaceuticals remove its opioid pain medication, reformulated Opana ER (oxymorphone hydrochloride), from the market.

# DEA Diversion Prevention

- The DEA limits the quantity of Schedule I and II controlled substances which may be produced in a given calendar year. 2018 mandates a 20% reduction in the amount of opiate and opioid medication—including oxycodone, hydrocodone, oxymorphone, hydromorphone, morphine, codeine, meperidine, and fentanyl.
- Currently at least 17 states have enacted rules to curb the number of painkillers doctors can prescribe. Some, including Arizona, Connecticut, Delaware, Massachusetts, New Jersey, New York, Indiana, and Ohio, have passed laws limiting the duration of initial opioid prescriptions to five or seven days. <sup>(5)</sup>
- All 50 states have legislation authorizing the creation and operation of a PDMP which can provide a prescriber or pharmacist with information regarding a patient's prescription history, allowing prescribers to identify patients who are potentially abusing medications.

# Not In My World....

- Supply-side interventions that raise the economic costs of supplying legal prescriptions of opioids may have unintended consequences depending on the extent of demand.<sup>(5)</sup>
- The steepest rises in drug overdose deaths were in Delaware, Florida and Maryland. <sup>(11)</sup>
- In 2015 a women in Kentucky received four years in prison after she was convicted of animal torture and fraud for repeatedly cutting her golden retriever with a razor blade in order to get a veterinarian to write a prescription for the animal.<sup>(3)</sup>
- In January a raid outside of Portland, Oregon seized over a 100,000 tramadol pills and 17 dogs were rescued. The four people arrested claimed to be breeding AKC-registered puppies. <sup>(6)</sup>

# Drug Diversion

- Possible types of client diversion:
  - theft of drugs or prescription blanks
  - taking all or part of a patient's ordered dose for self use
  - going to multiple doctors for the same issue
  - distorting the significance of the pain
  - needing early refills or "lost" medication
  
- Possible types of employee diversion:
  - theft of drugs or prescription blanks
  - adding fake patients to use log, or routinely taking extra doses "just in case"
  - Frequently makes "dosing" errors and withdraws too much medication that then needs to be "wasted" without a witness
  - "Throwing out" expired meds instead of putting in outdates for reverse distribution



# Signs of Drug Abuse or Diversion In Co-Workers

- Irritable, antagonistic and even hostile, especially when questioned
- Changes in appearance or attitude/personality
- Financial problems and/or involvement in criminal activity
- A sudden inability to handle their usual responsibilities such as unexplained, or unusual absenteeism
- Frequently volunteering to perform controlled substance inventory, receive orders, or place orders
- Frequently breaking vials/ampoules when no witness present or cleaning up prior to reporting to “witness”
- Offering to throw out waste containers with partially filled syringes or vials
- Coming in early, staying late, preferring to work alone
- Poor or sloppy record keeping
- Frequent, long bathroom breaks



# Schedules



marijuana2go

- 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:** no currently accepted medical use in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse.
  - heroin, lysergic acid diethylamide (LSD), marijuana (cannabis), peyote, methaqualone, and methylenedioxymethamphetamine ("Ecstasy")
  
- **Schedule II:** have a high potential for abuse which may lead to severe psychological or physical dependence.
  - hydromorphone, methadone, meperidine, oxycodone, fentanyl, morphine, opium, codeine, hydrocodone, testosterone, amphetamine, and pentobarbital

# Schedules

- **Schedule III:** have a potential for abuse less than substances in Schedules I or II and abuse may lead to moderate or low physical dependence or high psychological dependence.
  - products containing not more than 90 milligrams of codeine per dosage unit (Tylenol with Codeine®), ketamine, buprenorphine, and euthasol
  
- **Schedule IV:** have a low potential for abuse relative to substances in Schedule III.
  - butorphanol, phenobarbital, tramadol, and *alprazolam*, *clonazepam*, *clorazepate*, *diazepam*, *lorazepam*, *midazolam*
  
- **Schedule V:** have a low potential for abuse relative to substances in Schedule IV, usually antitussive, anti-diarrheal, and analgesic.
  - Lyrica® (pregabalin)

# Controlled Substance Enforcers and Regulators

## ➤ Federal Level:

- Drug Enforcement Agency (DEA)
- Laws are found in Title 21 USC, §801-971
- The regulations, which are more detailed and somewhat more practical are found in Title 21 CFR, §1300
- Overseen by the Department of Justice (DOJ)

## ➤ State Level:

- New York Bureau of Narcotic Enforcement (BNE)
- Public Health Law Article 33 and Title 10 Part 80 Rules & Regulations on Controlled Substances
- Overseen by the Department of Health (DOH)

➤ When federal law or regulations differ from state law or regulations, the practitioner is required to abide by the **more stringent** law or regulation.

# Federal Controlled Substance Laws:

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



- Every practitioner that handles controlled substances **must** be registered with the DEA.
  - To obtain a DEA registration, a practitioner must apply using DEA Form 224
  - Registrations must be renewed every three years
  - Starting January 2017, the DEA will no longer send its second renewal notification by mail. Instead, an electronic reminder to renew will be sent to the email address associated with the DEA registration.
  
- DEA strongly opposes the use of a DEA registration number for any purpose other than the one for which it was intended. The use of DEA registration numbers as an identification number is not an appropriate use and could lead to a weakening of the registration system.
  - NPI numbers

# One DEA number for Clinic versus Individual



➤ Title 21, Code of Federal Regulations, Section 1301.22(b):

- An individual practitioner who is an agent or employee of another practitioner (other than a mid-level 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.**

## What the DEA said 1/12/18:

➤ “As you clearly noted, the individual practitioner who is an agent or employee of the DEA registrant has **no authority to remove these controlled substances from that registered location**, but can administer and dispense controlled substances at that location so long as the DEA registrant ordering those controlled substances agrees. **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.**”

# Additional Federal Controlled Substance Laws

- 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, had a DEA registration revoked, or has surrendered a DEA registration for cause. (*21CFR §1301.76*)
- All registrants must provide effective controls and procedures to guard against theft and diversion of controlled substances.\*
- 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. (DEA Form 106)
  - What is a significant loss?

# Federal Prescription Requirements

- A prescription is an order for medication which is dispensed to or for an ultimate user. To be valid, a prescription for a controlled substance must be issued for a legitimate medical purpose by a registered practitioner acting in the usual course of sound professional practice. **(VCPR)**
- Practitioner's Manual:  
<https://www.deadiversion.usdoj.gov/pubs/manuals/pract/index.html>
- A prescription for a controlled substance must be dated and signed on the date when issued.\*\*
- An individual may be designated by the practitioner to prepare the prescriptions for his/her signature, but must be manually signed by the practitioner. Prescriptions for schedule II controlled substances must be written and be signed by the practitioner.

# Federal Recordkeeping Requirements for Control Drugs

- Must maintain inventories and records of controlled substances listed in Schedules I and II separately from all other records.
  - Invoices and executed 222 forms
- Inventories and records of controlled substances in Schedules III, IV, and V must be maintained separately or in such a form that they are readily retrievable from the ordinary business records.\*
- All records related to controlled substances must be maintained and be available for inspection for a minimum of *two years*.
- Must keep records of controlled substances that are administered if regularly engaged in the dispensing or administering of controlled substances and charges patients, either separately or together with charges for other professional services.
  - Includes all unused or wasted medication during administration.
  - Includes all drugs dispensed to a patient.



# Federal Controlled Substance Inventory Requirements

- A registrant must maintain a complete and accurate record of each substance received, sold, delivered, or otherwise disposed of by the registrant.
- Perpetual or running inventory is the easiest way.

Fentanyl		Injection	50mcg/mL		50mL	
Substance		Form	Strength		Package	
Date	Location	signature	IN	Out	Balance	
1/1/17	Cardinal		10		10	
2/1/17	Henry Schein		5		15	
2/10/17	Surgery			5	10	

- Keep Inventory of Expired Dugs

Date	Drug Name and Strength	Amount Expired	Location	Signature	Date reversed
1/1/17	fentanyl 50mcg	5mL	Surgery		4/30/17
3/3/17	phenobarb 30mg	25 tabs	stock		4/30/17





# Federal Controlled Substance Inventory Requirements

- Each registrant who maintains an inventory of controlled substances must maintain a complete and accurate record of the controlled substances on hand and the date that the inventory was conducted.
- After an initial inventory is taken, the registrant shall take a new inventory of all controlled substances on hand at least every *two years*.\*
- Each inventory must contain the following information:
  - Whether the inventory was taken at the beginning or close of business
  - Names of controlled substances
  - Each finished form of the substances (e.g., 100 milligram tablet)
  - The number of dosage units of each finished form in the commercial container (e.g., 100 tablet bottle)
  - The number of commercial containers of each finished form (e.g., four 100 tablet bottles)
  - Disposition of the controlled substances

# Example of Bi-Annual Inventory Form

Date:		Opening of Business	Close of Business		
Registrant Name:					
Registrant Address:					
DEA Registration #:					
Controlled Substance Name	DEA Schedule	Strength/Dosage form	# of units or volume of each finished form per Container	#of containers	If the substance is not in use
Fentanyl	CII	50mcg/mL	10mL/vial	3 vials	
		Name	Signature	Date	
Inventory performed by:					
Inventory witnessed by:					

- If the container has been opened and the substance is listed in Schedule I or II, make an exact count or measure of the contents.
- If the substance is listed in Schedule III, IV or V, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case make an exact count of the contents.

# Federal Requirements for Ordering Schedule II Substances

- Schedule I and II controlled substances must be ordered by filling out DEA Form 222 or by electronically completing the DEA Controlled Substance Ordering System (CSOS).
  - <https://www.dea diversion.usdoj.gov/webforms/orderFormsRequest.jsp>
- Official DEA order forms for Schedule II controlled substances must be maintained separately from other business records.
- Any sign of alteration on a DEA order form may be enough for a drug supplier to refuse a Schedule II controlled substances order.
  - A distributor may not fill in the "Last Line Completed" area
  - If the product is available in more than one strength, then the strength may not be added
  - if no package size is indicated, and the product comes in various sizes, then the package size may not be added
  - may place the date on the form

# Federal Requirements for Ordering Schedule II Substances

(1) Must write supplier information.



(2) The number of packages, size of the package, and name of the item must be filled out completely on the form.



(4) Must indicate the total number of lines filled out.

See Reverse of PURCHASER'S Copy for Instructions		No order form may be issued for Schedules I and II substances unless a completed application form has been received. (21 CFR 1305.24)		OMB APPROVAL No. 43-R0667		
TO: (Name of Supplier) Alltech Associates, Inc.			STREET ADDRESS 2051 Waukegan Road			
CITY and STATE Deerfield, IL 60015		DATE Today's Date	TO BE FILLED IN BY SUPPLIER			
			SUPPLIER'S DEA REGISTRATION No.			
TO BE FILLED IN BY PURCHASER						
Line No.	No. of Packages	Size of Package	Name of Item	National Drug Code	Packages Shipped	Date Shipped
1	3	25 mg	Benzoylcegonine tetrahydrate			
2	10	25 mg	PCP HCl			
3	5	50 mg	Cocaine HCl			
4	1	10 mg	Lysergic Acid Diethylamide (LSD)			
5						
6						
7						
8						
9						
10						
4		NO. OF LINES COMPLETED		SIGNATURE OF PURCHASER OR HIS ATTORNEY OR AGENT <i>[Signature]</i>		
Date Issued 01/01/08		DEA Registration No. PA0017741		Name and Address of Registrant The ABC Company Main Street Any Town, Any State 99999		
Schedules 1, 2, 3, 3N, 4, 5		Registered as a Analytical Lab		No. of this Order Form K21112988		
DEA Form -- 222 (Aug. 1979)		U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II DRUG ENFORCEMENT ADMINISTRATION SUPPLIER'S COPY 1			16326237	

(3) Must write number of bottles received.



(6) Printed from DEA

(5) Each form must be signed and dated by an authorized individual.

# Practitioner Disposal of Controlled Substances

- Secure and Responsible Drug Disposal Act of 2010
  - Updated 21 CFR 1307 in 2014
  - [https://www.deadiversion.usdoj.gov/drug\\_disposal/dear\\_practitioner\\_pharm\\_waste\\_101714.pdf](https://www.deadiversion.usdoj.gov/drug_disposal/dear_practitioner_pharm_waste_101714.pdf)
  
- A practitioner may 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 (Reverse Distributors)
    - Fee associated with this option
    - Schedule I and II controlled substances should be transferred via the DEA Form 222, Schedule III–V compounds may be transferred via invoice.
  - Request assistance in destruction from the DEA using DEA form 41
  - Promptly destroy in front of an agent or other authorized person using an on-site method of destruction

# Practitioner Disposal of Controlled Substances

- Maintain copies of the records documenting the transfer and disposal of controlled substances for a period of *two years*.
- Controlled substance dispensed for immediate administration that is not fully exhausted, ‘drug wastage’, must be properly recorded, stored, and destroyed in accordance with DEA regulations.
  - The DEA strongly encourages all practitioners to continue to adhere to security controls and procedures that ensure pharmaceutical wastage is not diverted.



# Controlled Substance Disposal-Ultimate User

- Individual members of the public are authorized to voluntarily surrender controlled substances in schedules II-V in a secure manner without identifying themselves.
  - Households are strongly encouraged to dispose of any unused, unwanted, or expired pharmaceuticals through take-back program options.
  
- Disposal sites will be operated by law enforcement agencies, authorized pharmacies, and other DEA authorized collectors.
  
- May call the DEA at 800-882-9539 for collection receptacles
  - [www.deadiversion.usdoj.gov/pubdispsearch/spring/main?execution=e1s](http://www.deadiversion.usdoj.gov/pubdispsearch/spring/main?execution=e1s)
  - <http://1/health.ny.gov/professionals/narcotic/medicationdropboxes>



# New York Controlled Substance Regulations

- Bureau of Narcotic Enforcement (BNE)
  - [www.health.ny.gov/professionals/narcotic/](http://www.health.ny.gov/professionals/narcotic/)
  
- Part 80: Rules and Regulations on Controlled Substances in NYS
  - [www.health.ny.gov/regulations/controlled\\_substance/part/80/docs/80.pdf](http://www.health.ny.gov/regulations/controlled_substance/part/80/docs/80.pdf)
  
- Bureau of Narcotic Enforcement Riverview  
Center 150 Broadway Albany, NY 12204  
Phone: 866-811-7957 Fax: 518-402-0709  
mail: [narcotic@health.ny.gov](mailto:narcotic@health.ny.gov)
  
- Regional Offices
  - NYC (212) 417-4103
  - Buffalo (716) 847-4532
  - Syracuse (315) 477-8459
  - Rochester (585) 423-8043



# NYS Office of the Professions Veterinary Medicine

- NYS Office of the Professions Veterinary Medicine practice guidelines section 5.13:
  - “ May not prescribe, dispense, deliver, or order any controlled substance unless you are currently registered with the Federal Drug Enforcement Administration (DEA). However, if you are not a veterinarian registered by the DEA but you are a DEA unregistered veterinarian employed by a DEA registered veterinarian you may [dispense or] administer controlled substances if the DEA registered veterinarian has designated you to do so and you administer such substances under his or her direction and supervision [knowledge that you are using the drugs in the usual course of your employment].”<sup>(9)</sup>

# What the DOH Narcotics Said...

- The Board of Veterinary Medicine oversees the practice of veterinarian medicine. The guidance provided by the Office of the Professions above is correct. Below is the citation from Public Health Law (PHL) 3331(3):
- 3. A veterinarian, in good faith, and in the course of the practice of veterinary medicine only, may prescribe, administer and dispense substances listed in schedules II, III, IV, and V or he may cause them to be administered by a designated agent under his direction and supervision.



# Official New York Prescription Form

- To prescribe a controlled substance in New York State requires the practitioner to be license in the state and have a DEA registration.
  - There is not a separate state controlled substance license needed for practitioners in New York State.
- Section 21 of the Public Health Law requires all prescriptions (both for controlled substances and non-controlled substances) written in New York State be issued on an Official New York State Prescription form.
- Prescription pads may be used by a practitioner at any location where they practice, but must store the prescriptions at their “shipped to” address.
- Except for the practitioner’s name, the law does not prohibit practitioners from editing practitioner demographic information on the prescription form.

# Official New York Prescription Form

- Unused official NYS prescriptions/EMR paper must be returned to the Bureau of Narcotic Enforcement for destruction.
- Practitioners are required to provide effective safety controls for all prescription pads.
- Lost or stolen Official NYS prescriptions must be reported to the BNE using form DOH-4387, *Notification of Loss/Theft of Official New York State Prescriptions*.

Clinician Name					Pad Number		
Joe Smith					XX#XXX 00-99		
	Date	Patient Name	Owner Name	Drug Name	Quantity	Refills	Initials
00							
01							
02							
03							

# Official New York Prescription Form

- Before a practitioner can order official prescriptions, he/she must register with the Bureau of Narcotic Enforcement on the Official New York State Prescription Registration Form (DOH 4329).
  - [https://www.health.ny.gov/professionals/narcotic/official\\_prescription\\_program/order/instructions\\_for\\_practitioners.htm](https://www.health.ny.gov/professionals/narcotic/official_prescription_program/order/instructions_for_practitioners.htm)
  - Registration is good for two years.
  
- Can order on-line through the Health Commerce System (HCS)
  - Customize with up to 10 practitioners and up to 4 addresses
  - Prescription pads and Electronic Medical Record (EMR) paper
  - Practitioner can designate an alternate who is authorized to order official prescriptions on his or her behalf
  
- Can order snail mail using form DOH-250
  - Only one practitioner and one address
  - Prescription pads only

# Written Prescription Requirements

- A prescription for a controlled substance must include the following information:
  - Practitioner's name, address, and DEA registration number
  - **Date of issue**
  - **Patient's name**; if the ultimate user is an animal, **the species of such animal**, and age or DOB
  - The name and address of the **owner or person** in custody of such animal (no PO box)
  - **Drug name; Drug strength; Dosage form**
  - Quantity prescribed indicated in both numerical and written word form
  - Specific directions for use, including, but not limited to the dosage and frequency of dosage, and the maximum daily dosage allowed
  - Number of refills (if any) authorized;
  - **Manual signature of prescriber.**

# All Controlled Prescriptions

- A practitioner may orally authorize a pharmacist to change/add information on an official New York State prescription form except for:
  - the practitioner's signature
  - date the prescription was signed by the practitioner
  - drug name
  - name of the ultimate user
  
- No additional prescriptions may be filled 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 provided by any previously issued prescription.
  - Include any extra dose potentials in directions.
  - Write on face if change in directions
  
- All written prescriptions for CII-V expire 30 days after date written.

# NY Schedule II Prescription Writing Laws

- No refills may be authorized.
- All benzodiazepines, anabolic steroids and growth hormones are treated as Schedule II prescriptions.
- Maximum of a 30-day supply if the substance were used in accordance with the directions for use.
- A practitioner may issue a prescription for up to a three month supply of a controlled substance treating certain conditions.
  - Such prescription shall specify the condition being treated on the face of the prescription by name of condition or the code.

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

# NY Schedule III-V Prescription Writing Laws

- Rx written requirements the same as Schedule II.
- May write for 30 days supply with up to 5 refills, but refills expire 6 months from the date the prescription is written.
- Number of refills authorized in numerical and written word or check None box.
- May write for more than a 30 days supply for same conditions as schedule II, but may only put 1 refill on the prescription.
- HCG (human chorionic gonadotropin) not controlled federal level but is a schedule III NY.



## One More Thing...

- Effective July 2016, the initial opioid prescribing for acute pain is limited to a 7 day supply.
  - Acute pain is defined as pain, whether resulting from disease, accidental or intentional trauma, or other cause, that the practitioner reasonably expects to last only a short period of time.
- Does not specifically address refill authorizations.
- This rule **SHALL NOT** include prescribing for chronic pain, or pain being treated as a part of cancer care.
- Pharmacists are not required to monitor this.



# Emergency Oral Prescriptions

- Controls must **be called in by the clinician.**
- Need to supply all the information that you would supply on a written prescription.
- Schedule II
  - No oral prescription shall be filled for a quantity which would exceed a five-day supply.
  - Within 72 hours after authorizing an emergency oral prescription, the prescribing practitioner shall cause to be delivered to the pharmacist a written prescription with the words: "**Authorization for emergency dispensing.**"
  - If the pharmacist fails to receive such prescription, he shall notify the department in writing or electronically within seven days from the date of dispensing the substance.
- Can send second script to be filled when emergency supply done.

# Emergency Oral Prescriptions

## ➤ Schedule III and V

- No oral prescription shall be filled for a quantity of controlled substances which would exceed a five-day supply.

## ➤ Schedule IV

- 30-day supply or 100 dosage units whichever is less, if the substances were used in accordance with the directions for use.

## ➤ Schedule III-V

- Within 72 hours after authorizing such an oral prescription, the prescribing practitioner shall cause to be delivered to the pharmacist a written prescription with “**Follow-up prescription to oral order**” written on it.
- If the pharmacist fails to receive such prescription, he shall record on oral prescription "Follow-up prescription not received“.

## ➤ Recommend sending with tracking or signature required.

# BNE Rules that DON'T Apply to Veterinarians

## ➤ Electronic Prescribing

- Mandatory for other health professionals starting March 27, 2016
- Veterinarians who choose to electronically prescribe controlled substances must use an electronic prescribing computer application that meets federal security requirements for EPCS, and must register their certified electronic prescribing application with the Department of Health, Bureau of Narcotic Enforcement.

## ➤ Mandatory requirement to consult the PMP registry when writing prescriptions for Schedule II, III, and IV controlled substances.

## ➤ Mandatory Prescriber Education



- Veterinarians are excluded from the 3 hours of course work or training in eight (8) specific topic areas (pain management, palliative care and addiction) that is mandatory for all prescribers licensed in New York who treat humans and have a DEA registration number to prescribe controlled substances

# Practitioners that Dispense Controlled Substances

- Enclosed within a suitable and durable container (childproof container/packaging) upon which an indelibly typed, printed or otherwise legibly written label is affixed to such container.
  - name, address and telephone number of the clinic/hospital/practitioner
  - the name and address of the owner, patient name and species
  - the date of dispensing
  - name of prescribing veterinarian
  - the manufacturer's trade name of the drug or the generic name, and strength/dosage form (tablet, capsule, solution, etc)
  - specific directions for use, including precautionary info
  - **the maximum daily dosage (controls)**
  - quantity of drug and the expiration date when established by the manufacturer
  - **“CONTROLLED SUBSTANCE, DANGEROUS UNLESS USED AS DIRECTED”**

# Practitioners that Dispense Controlled Substances

- "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian."
- Withdrawal times if necessary.

**Animal Health Hospital  
4140 Tuller Road, Dublin OH 43017  
877-422-8838**

Ty Webb, DVM  
Client: Carl Armstrong  
Patient: DIGGER (CA)

Date: 6/17/3038  
Quantity: 10  
Predrisone 20 mg Tablet  
GIVE ONE TABLET BY MOUTH  
ONCE PER DAY UNTIL GONE.

Exp: 03/01/2011  
Refills: 1

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Veterinary use only. Keep out of children's reach.

**CONTROLLED SUBSTANCE  
DANGEROUS UNLESS  
USED AS DIRECTED**

## Practitioners that Dispense Controlled Substances

- The practitioner shall submit dispensing information, for all controlled substances dispensed, electronically to the department utilizing a transmission format acceptable to the department, not later than 24 hours after the substance was delivered.
  - Must establish an account with the Health Commerce System (HCS)
  - Required to file a zero report, which is a report that no controlled substances were dispensed during the relevant period of time.
  - Zero reports are required to be filed within 14 days of either the most recent previously reported dispensing of a controlled substance, the submission of a prior zero report
  - Must correct errors within 3 days
  - To upload or report dispensing:  
<https://commerce.health.state.ny.us/hcs/index.html>  
or [https://commerce.health.state.ny.us/public/hcs\\_login.html](https://commerce.health.state.ny.us/public/hcs_login.html)

# Health Commerce System (HCS)

- The Health Commerce System (HCS) is the secure website for web-based interactions with the New York State Department of Health.
  - practitioners now order official prescription pads
  - where you need to report control drugs dispensed
  
- To apply for a Health Commerce System (HCS) account go online to fill out the application.
  - <https://hcsteamwork1.health.state.ny.us/pub/top.html>
  - Paperless, all the user needs is a NYS DMV Driver License
  - [https://www.health.ny.gov/professionals/narcotic/docs/hcs\\_licensed\\_professionals.pdf](https://www.health.ny.gov/professionals/narcotic/docs/hcs_licensed_professionals.pdf)
  - Commerce Accounts Management Unit (CAMU) at 1-866-529-1890, option 2
  - remember to have application notarized and send back

# Health Commerce System (HCS)

- Do not need separate account for each veterinarian, one DVM (recommend the DVM whose DEA # is used to purchase controls for the practice) can establish the account for the practice.
  - The HPN Coordinator
  - The coordinator can give other people access.
  
- Any controlled substance administered by a veterinarian and any prescription for a controlled substance written by a veterinarian (and filled at a pharmacy) are not required to be reported by a veterinarian.
  
- FAQ's for Veterinarians:
  - [https://www.health.ny.gov/professionals/narcotic/electronic\\_data\\_transmission/docs/veterinarians\\_faq.pdf](https://www.health.ny.gov/professionals/narcotic/electronic_data_transmission/docs/veterinarians_faq.pdf)

# Practitioners that Dispense Controlled Substances

- If controlled substances are **never dispensed** from your practice to be given by the client/owner to the patient, then you are not considered a dispensing practitioner and do not have to establish an account, file zero reports, or get a waiver.
  - May want account to verify clients use history.
- “Home euthanasia”, as long as the controlled substance remains in the possession of the veterinarian and is administered by the veterinarian, it will be considered administration of the controlled substance and not required to be reported.



## **BNE Record Keeping Requirements**

- Records of all transactions concerning controlled substances shall be kept for a period of **five years** from the date of transaction.
- Records, orders and prescriptions shall be readily available and promptly produced for inspection.
- Records, orders and prescriptions shall be maintained at the premises where the licensed activity is conducted.
- Records of controlled substances received shall include date of receipt, name and address of vendor, type and quantity of such drugs received.
  - A duplicate invoice or separate itemized list furnished by the vendor will be sufficient
  - maintained in a separate file (Schedule II, and Schedules III-V)
  - duplicate copies of Federal order forms for schedule II controlled substances must be retained.

# BNE Record Keeping Requirements

- A separate record, at the main point of supply for controlled substances showing the type and strength of each drug in the form of a running inventory indicating the dates and amounts of such drugs received and their distribution or use (at least one patient identifier if applicable).
- A record in the patient's chart indicating administration of the controlled substance including the name of the administering attendant and the date and hour of administration.
- Records of controlled substances administered shall include date of administration, name of patient, prescriber's signature, signature of person administering, type and quantity of drug.



## **Additional Record Keeping Clinics/Hospitals**

- A medication order, signed by clinician, specifying the controlled substance for an indicated animal
  - verbal orders need to be signed/approved within 48 hours-  
electronic approval can be used in place of a signature.
  - automated drug distribution machines
  
- Record drugs distribution to substations or wards:
  - receipt by the signature of a person authorized to control such substation or ward
  - for Schedule II an administration sheet shall list the type of controlled substances and the number of doses furnished to the substock, date and hour of administration, name of patient, name of prescribing practitioner, quantity of administration, balance on hand after each administration, and signature of person administering

# Substock Transfers and Logs

## ➤ Transfer Log

Date:		Department: <b>Ophthalmology</b>				Section:	
Building: <b>VMC</b>		Room: <b>C2-112</b>				Box #: <b>DBE969</b>	
Requested by:				Phone: <b>3-3194</b>		Acct #	
Item	Route	Strength	Amt/Pk	# Pks	# Sheets	Rx number	Sage
<i><b>One Drug Per Sheet</b></i>							
Recd by:				LVT		Disp'd by:	
				DVM			
Date:				Tech		Date:	
				Other			
				<i>Circle one</i>			

## ➤ Administration Sheet

Methadone 20mg/mL Injection			20mL		
Date/Time	Patient Name/ID	Prescribing DVM	Quantity Ordered	Amount Remaining	Signature of administrator

## **Storage Requirements:**

- Schedule I and II reserve or main stocks shall be kept in one of the following: a GSA class 5 rated steel cabinet or equivalent safe, or a vault. Any cabinet or safe weighing less than 750 pounds shall be bolted or cemented to the floor or wall in such a way that it cannot be removed.
- Schedule III, IV and V reserve or main stocks shall be stored in a securely locked cabinet of substantial construction.
- Schedule I, II, III and IV working stocks shall be kept in stationary, locked double cabinets. Both cabinets, inner and outer, shall have key-locked doors with separate keys.
- Not exceed a 72-hour supply may be stored with the patient's other medications at the patient care unit, provided that they are kept in a securely locked medication cart.

# Mobile Veterinarians



- DEA-registered veterinarians are permitted to transport controlled substances to an unregistered location, such as a client's home or another location where animals need attention, to administer controlled substances on an “as-needed and random basis,” provided the veterinarian does not maintain a principal place of professional business at any of these other locations.
  
- Question: "If a mobile veterinarian is traveling with and administering controlled substances, must they have their own DEA number or can they practice under the DEA license of another member of the practice?"
  - **DEA: The veterinarian must be acting under their own DEA registration, and procuring, administering, dispensing, prescribing, and storing controlled substances under that registration.(1/12/2018)**

# Additional Requirements Reminder

## ➤ Waste Log:

- log should list the date and time, drug name, quantity wasted, patient name, reason for waste, and signature of person wasting and witness

## ➤ Destruction/expired drugs:

- keep a list of drug and quantity of expired drugs
- can get authorization from DEA, must complete Form DEA-41  
[http://www.health.ny.gov/regulations/controlled\\_substance/part/80/docs/80.pdf](http://www.health.ny.gov/regulations/controlled_substance/part/80/docs/80.pdf)
- use a reverse distributor (fee)- keep records together (222 forms too)with your expired log  
[https://www.health.ny.gov/professionals/narcotic/licensing\\_and\\_certification/docs/reverse\\_distributor.pdf](https://www.health.ny.gov/professionals/narcotic/licensing_and_certification/docs/reverse_distributor.pdf)



## ➤ Inventory:

- a biennial inventory (May 1<sup>st</sup>) shall be prepared and **maintained for 5 years.**

# Needles/Syringes

- Prescriptions for any number of needles or syringes may be called into a pharmacy by veterinarian or employee authorized by veterinarian.
  - no longer requires a written prescription.
- Licensed pharmacies register with the New York State Department of Health under the Expanded Syringe Access Program (ESAP) can sell up to 10 hypodermic needles or syringes to persons 18 years of age or older without an Rx.



Syringe Exchange Program

# Drug Disposal for Clients in NY

- Poster must be displayed any facility that dispenses medications.
  - <http://www.dec.ny.gov/chemical/67736.html>
- The DEC recommends that no pharmaceuticals be flushed.
  - add water and then salt, ashes, dirt, cat litter, coffee grounds to the pharmaceuticals, place in an outer container to prevent discovery and removal from the trash, then put in household trash pickup



- Law enforcement agencies that maintain collection receptacles can be found at:  
<http://health.ny.gov/professionals/narcotic/medicationdropboxes>

# Prescriber Diversion Prevention at Work

- Keep all drugs and prescription pads secure, limit access.
- Keep good records-document, document, document.
- Ordering and receiving of medications should be done by different people.
  - Controlled drugs received should have double signatures on invoice and log.
- Spot check administration records with removal records (logs).
  - have witness's for all wastes and log appropriately.
- Do random inventory counts (shift changes).
- Keep a log of all outdated controls and verify with reverse distributor.



# Prescriber Diversion Prevention with Clients

- Avoid prescribing controls for new clients or give limited quantity with no refills.
- Monitor for early refill requests or unusually high usage.
- Use ISTOP (Internet System for Tracking Over Prescribing)– use clients DOB.
  - The PMP Registry provides practitioners with direct, secure access to view dispensed controlled substance prescription histories for their patients.
  - Must have HCS account
- Ask for a “Client Contract for Controlled Substances”
  - [www.drugabuse.gov/sites/default/files/files/SamplePatientAgreementForms.pdf](http://www.drugabuse.gov/sites/default/files/files/SamplePatientAgreementForms.pdf)

# Diversion Reporting

- Report suspected diversion to supervisor or local law enforcement.
  - For non-practitioner reporting: DEA RX Abuse Online Reporting  
[https://www.dea diversion.usdoj.gov/drug\\_disposal/index.html](https://www.dea diversion.usdoj.gov/drug_disposal/index.html)
- The Bureau of Narcotic Enforcement must be notified of missing medication.
  - form DOH-2094 Loss of Controlled Substances Report
  - <https://www.health.ny.gov/forms/doh-4387.pdf>
- If prescription blanks stolen, need to notify local law enforcement and the BNE.
  - form DOH-4387 Notification of Loss/Theft of Official New York State Prescriptions
- Notify the DEA Field Division Office in their area, in writing, of the theft or significant loss of any controlled substance within one business day of discovery of such loss or theft.



# General Prescribing Guidelines

- Non-controlled Rx good for 1 year from date written
- PRN = 1 refill in NYS per pharmacy law
- A prescription for a controlled substance may not be faxed
- Non-controls may be faxed, but must originate from the practice and have an identifier that allows pharmacy to identify where it was faxed from
  - Owner may NOT fax prescriptions
- Dispense as Written box (included on all NYS issued prescription blanks), if DAW written in box, no generic substitution may be made
- One prescription per prescription form – not valid order if write multiple orders on single form

# Question

On August 20th, 2017 Mrs. Smith calls for more tramadol for her 10 year old pit-bull mix “Scrappy”.

You saw him for the first time on July 30<sup>th</sup> 2017 for difficulty in getting up. The prescription you wrote was Tramadol 50mg, 2 tablets every 8 hours, quantity of 60 with no refills.

1. Was the original prescription written correctly?

no- 7 day supply on opioids for acute pain

2. Could you write a new prescription?

yes- the original prescription was a 10 day supply.

3. What should you include on the new prescription?

species, owner and pet info, written and numeric quantity

4. Can you include refills this time?

yes-up to a 30 day supply with 5 refills

5. Can you call the prescription in?

yes-but only a 30 day supply or 100 units and you must mail a cover script

# Question

1. You prescribed Mrs. Smith's dog a new prescription for Tramadol- do you need to report this on the HCS website?

No- only medications you dispense

2. You decide to do rads on Scrappy, but need to sedate him with Butorphanol first. Do you need to report this to the HCS website?

No, but you must "order" this medication and record it in his chart.

3. The butorphanol you gave Scrappy was from the main stock and kept in the imaging room- what kind of records would you need?

Record in the main inventory and the request form. Also on the administration sheet and waste log.

4. You have a DEA license and write for controls, but you never dispense them- Do you need to create a HCS account?

No- but you may want to check control history

# Question



1. Before you write the tramadol prescription for Mrs. Smith do you need to check the PMP website?

no-vets are exempt

2. You decide to check Mrs. Smith on the site anyway-can anyone in your practice check or does it need to be you?

no-anyone that the HCS coordinator gave access to can check for you

3. You notice that some of your prescription pads are missing and 2 vials of fentanyl- you think it may be one of your long term employees. Whom do you need to contact, if anyone?

- BNE for pads and medication, DEA if significant loss, local law enforcement

4. Would administration records help with diversion detection?

-yes-look for witness signatures, real patients, etc.

5. Should you log the missing fentanyl in your records?



# Questions?

**Always stop to smell the flowers...**

# References and Resources

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