

# Drug Dispensation and Opioid Diversion Guidelines Part 1

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## Objectives- Drug inspection and dispensation

- To describe all federal and state regulations for medication used in a veterinary practice.
- To describe DEA licenses and controlled substances security storage and record keeping, reviewing the current opioid diversion guidelines.
- To review all aspects of handling all formulations of drugs from purchasing, ordering, receiving, storage, administration, and disposal in a legal manner.
- To review documentation in medical records of all drug treatments.
- To review any SOP's or protocol that are available .
- To review training records for all personnel handling drugs and medical waste.

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## Center of Veterinary Medicine

- **The Federal Food, Drug, and Cosmetic Act allows the Secretary of Health and Human Services to delegate his or her authority to others, such as the Commissioner of Food and Drugs. The Commissioner has redelegated his or her authority for a number of functions to CVM. Among these redelegated functions are:**
- Authority to approve New Animal Drug Applications (NADA) and their supplements and Abbreviated New Animal Drug Applications (ANADA)(for generic drugs) and 503b Outsourcing Compounding Pharmacies. ( New GFI 256) Compounding from bulk chemicals
- Authority to issue proposals, notices, and orders relating to refusal to approve and withdrawal of approval of New Animal Drug Applications and corresponding new animal drug regulations.
- Authority to approve the use of certain food additives.

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## Office of Surveillance and Compliance

Primary job is protecting and promoting animal and human health. We are strategic and dynamic in our approach to public health challenges. We make informed decisions guided by science and law. We collaborate and leverage relationships with our stakeholders.

- Sign up for the newsletters from the FDA/CVM
- Untitled Letters- minor
- Warning letters- need regulatory action
- FDA expects prompt and adequate correction.

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## Importing Veterinary Drugs and Track animal compounded products that are outsourced.

- Specific requirements for importing drugs, contact the CVM
  - [Importing - Veterinary Drugs | FDA](#)
  - Center for Drug Evaluation and Research- Pre-Approved Safety Review- drugs and biological dashboard.
  - All 503b compounding pharmacies have to report to the CDER
- For all outsourcing of animal medications.

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## Drug Classifications

- ▶ Controlled substances- Federal DEA guidelines for drugs that are addictive or abusive.
- ▶ States can add to the Federal CS classification if there is a harm to the public or diversion.
- ▶ Human OTC drugs are Prescription for animals? Why? Toxic vehicles or inappropriate Prescription drugs (Rx) verification- all must be in date and kept in a secure area away from clients to include veterinary, human and compounded drugs.
- ▶ Dosage or forms of drugs that require a veterinarians knowledge to prohibit use or make treatment adjustments. All Extra-label! (ELDU)
- ▶ Veterinary OTC drugs can be dispensed as they have a OTC label for clients, however if the veterinarian changes the directions, a label is needed.
- ▶ Hazardous Drugs ( Both human and animals) NIOSH
- ▶ Vaccines- Blood products, some biologicals, stored appropriately, USDA
- ▶ Veterinary Stem Cells and Cell Based therapies- FDA? CVM or USDA- CVB- Tissue repair

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### Veterinary Controlled Substance Drugs

► Controlled Substances (CS) Act since 1970 and subsequent amendments enforces Rx meds must be sold by licensed veterinarian with a current DEA number and a state CS number if required (individual state regulations). Each location requires a separate DEA registration. If the home, then the agreement is that the DEA is allowed to have unannounced inspection now called "controlled premise". 21 CFR 13016.01-13. Record keeping required and security storage locked of all drugs, restricted access. Prescription must be written by a veterinarian

- Restricts this drug to use by or order of a licensed veterinarian
- A current log/documentation of all CS that are ordered, received, stored, administered and dispensed. Store in a secure, limited access locked cabinet, or automated dispenser.
- A SOP or written protocol of who is allowed to have access to the CS and RX drugs.
- Ambulatory trucks- locked on the truck and the truck parked on the inside of a brick and mortar building or bring drugs back into the practice. Multiple practices should have sign in and out log if you are checking in and out of the clinic.
- Cameras are one of the best protections of diversion.

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### Opioid Crisis- Veterinary Cautions

- One Health Issue- over 100,000 deaths in 2/2022
- Inspections: Question to ask:
  - Who is the registrant on the DEA certificate?
  - Where are the drugs kept, who has access. Documentation who enters in the CS cabinet.
  - Do not leave Rx pads out with the DEA number on the Rx.
  - Security- locked cabinet, double lock for Schedule II drugs.
  - Separate records for CII from CIII, IV, V. Readily retrievable.
  - CS's require a drivers license to pick up Rx's.
  - Send home proper disposal systems.

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### Security-first step- Facility

- Training of all personnel- No diversion tolerated, discuss addiction.
- Addiction is a disease, have training programs on drug abuse and make sure each employee has the information that is needed. Inspectors can relay all this information to the practice.
- Have Naloxone intranasal kits in your practice and make sure everyone knows where it is kept.
- Review the security of all medications, particularly CS's, but all Rx medications.
- Automated dispensers are an excellent system to prevent diversion. Still have a 2 person check system.
- Do you require drug testing? If so, contact a lawyer to make sure all legal requirements are met. Continuous auditing of the drugs are significant
  - Automated machines for dispensing such as CUBEX, PYXIS, or OMNICELL are excellent options or other controlled electronic cabinets. Also cameras are inexpensive and deter thief. Drug testing, make sure to contact a lawyer, and follow all guidelines for any drug testing.

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Storage of medication

- All drugs have various storage guidelines.
- Make sure the drug is stored at the recommended temperature.
- Room temperature now can be 75-77 degrees.
- Is the drug a single dose unit, do not use, or save, discard in the proper waste system.  
Vaccines and Drugs all have guidelines to follow. Make sure the veterinarian knows these guidelines and they are appropriately stored and disposed legally in the state and local areas of practice.
- Very few items can be thrown away. CS's go to a reverse distributor with a record of their destruction by a bonded company.

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Storage of medication

- Open vials should be dated for multiple dose vials.
- Outdated drugs should NEVER be used.
- A separate location is needed for storage until proper disposal.
- Medical waste should be in proper containers and sharps are for all needle disposal, none in the trash.
- Refrigerators need a temperature controlled thermometer that stores temperature, particularly when the practice is closed and assign someone to check daily. No storage on doors and in meat and veggie drawers.
- If drugs are received hot, they should be replaced from the vendor.
- No OTC veterinary or human drugs out front, in a closed area.
- Do not leave Rx medications in the treatment rooms, lock in the cabinet. Remove all cardboard boxes from the pharmacy.

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Aseptic technique of medications

- An area should be available in a practice to have a quiet safe counter away from traffic for preparation of all sterile injectable products with proper PPE's.  
Oral formulations must be prepared and if crushed, a powder hood is desirable, if not the technical support needs to wear mask.  
Allergies are a huge issue in veterinary medicine.
- Penicillin and Tetracycline are both absorbed by handling if not done properly, and allergies will occur. If a person is allergic to penicillin, an allergic reaction can take place from as little as 10 I.U. A 500 kg horse may receive 20 MU 4 times a day.

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## Controlled Substance Inspection

- Review the inventory, ask to see a copy of all transactions.
- All CS order forms, CII. DEA 222 form, entered into a log, paper or electronic with signatures of the DEA sponsor.
- CIII,CIV,CV- separate file and signature and date by the veterinarian.
- Is there a paper trail? Who orders the controlled drugs? Who has access? How do you handle documentation of CS use from relief veterinarian.
- Ask to look at the SOP for all aspects of handling CS's. Where are the drugs delivered in the practice? Who is allowed to receive these packages?

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## CS Inspection- Paper trail

- Schedule II registrant may also add a person who is tracking the drugs if they are registered. All registration is 1 page with copies as of Oct 2021.
  - [New Single-Sheet Format for U.S. Official Order Form for Schedule I and II Controlled Substances \(DEA Form 222\)](#) ([usdoj.gov](https://www.usdoj.gov))
  - Have you returned your old DEA 222 forms, if not here is the address.
  - All old DEA 222 forms must be returned to the office\* DEA Section/DRP P.O. Box 2639, Springfield, VA. 22152-2739
- Include a note to say, business not closing, just returning forms.
- Ask to review the waste log, make sure there is a witness. Good idea, not always the same person, but have a double check or the DEA registrant needs to sign.

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## Hazardous Drugs Inspection

- USP Chapter 800- Handling of Hazardous Drugs
- Train workers to know what a HD is and make sure you everyone is wearing PPE's.
- No eating, drinking, chewing , gum, applying cosmetics.
- HD's must be stored in a separate are and prepared in a segregate area. A clean counter. Have a spill kit available.
- All men and women of child bearing age must sign a consent form that they have been trained to properly handle HD's.
- Make sure anyone that anyone pregnant has reviewed the safety data sheets of all medications for safe use and how to properly to or not to handle and dispose of these or any medical waste to include fluids, urine and feces. Many drugs are eliminated by feces and urine.
- Need to be in a separate space.
- 21 CFR 1910.120. Clean up or a large spill training.
- [2010-150.pdf](#) ([cdc.gov](https://www.cdc.gov)) Workplace Solution for HDs

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### Examples of Drugs to avoid with during pregnancy

- Prostaglandins such as Lutalyse, Prostamate and Estrumate can lead to the abortion of a sow's pregnancy if there is an accidental exposure; they can also cause abortion in pregnant women. The drug Matrix( progestin) can actually prolong pregnancy if absorbed in both sows and women as well as altrenogest(Regumate)
- Prostaglandins may cause an asthmatic attack.
- Chloramphenicol, Chemotherapy, Cyclosporine, DES, Mitolane and Trilostate ( for Cushing disease) Methimazole, Misoprostol, Emodepside+Praziquantel, a cat topical dewormer, glucocorticoids such as prednisone, dexamethasone may induce labor and radioactive iodine 131

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### Client information sheets

- Does the veterinarian council the patient on safe use of medication? Educate the owner
- Make sure the veterinarian and staff have a copy of the Safety Data Sheets for their medications.
- Tranquillizer such as detomidine, medetomidine, xylazine, and acepromazine may also be harmful, drops BP.
- Antipsychotic drugs, amitriptyline
- Fentanyl Patches- lethal to children, cover the patch with adhesive, keep out of reach of children. Locked cabinet at home.

[www.fda.gov/ForConsumers/ConsumerUpdates/ucm300803.htm](http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm300803.htm)

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### Theft

- Make sure the DEA registrant understands the protocol to report any stolen CS's or other drugs.
- File a police report, call the DEA immediately and fill out the
- DEA Form 106 for theft or loss of CS and disposal receptacles
- DEA Form 107 for theft or loss of Listed Chemicals that may be used for preparing crystal methamphetamine.
- [Significant Theft or Loss Reporting of Controlled Substances \(usdoj.gov\)](http://www.usdoj.gov)
- [2005 - Reports by Registrants of Theft or Significant Loss of Controlled Substances \(usdoj.gov\)](http://www.usdoj.gov) 21 CFR Part 1301 DEA

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## Veterinary CS and Human Extra-label CS Inspection Priority

- **Schedule I** - LSD, illegal drugs with little or no accepted medical use and a high potential for abuse (heroin, drugs)
- **Schedule II** - drugs with a high potential for abuse and potential for physical or severe psychological dependence (e.g. morphine, codeine)
- **Schedule III** - drugs with lower potential for abuse, but with the potential for physical or psychological dependence ketamine, buprenorphine (e.g. combination drugs such as Vicodin® and Tylenol® with codeine, anabolic steroids)
- **Schedule IV** - drugs with lower potential for abuse than Schedule 3 agents (e.g., diazepam, midazolam) use intra nasal for seizures
- **Schedule V** - drugs with lower potential for abuse than Schedule 4 agents - primarily combination products containing limited amounts of codeine (e.g., cough syrup)
- Euthanasia's can be a Schedule II if straight pentobarbital, or Schedule II if Beuthanasia in combination Pentobarbital-Phenytion
- Often used is small animal and particularly large animals, horses butorphanol injection 10mg/ml (an abusive drug, many times from staff) Propofol- not CS in all states, but a problem of abuse.
- [https://www.deadiversion.usdoj.gov/drug\\_chem\\_info/propofol.pdf](https://www.deadiversion.usdoj.gov/drug_chem_info/propofol.pdf)
- Euthanasia and Ketamine - may have overfill

## Websites for approved drugs/devices

- **Animals@FDA**-list of approved drugs for approved species.
- **Legally, what is different OTC vs Rx**
- ▶ **Medical Animal Devices**- Glucometers, vehicles, hydrogels, PLO gels as they are not metabolized or have a chemical action with the body of man or animals, dental appliances, needles, syringes and surgical instruments. Do not require a 510K or any premarket approval for devices intended for animal use.
- ▶ **Different - Radiation admitting devices** such as an MRI must comply with 21 CFR 1000-1050. CDRH regulations is responsible for these products.
- ▶ **Labeling**- OTC are labeled for safe use by the consumer-  
**Rx**- must be labeled by the veterinarian safety to be used by the consumer. No such directions as used as directed.
- ▶ If the medication is too small, place in a Rx vial for adequate directions and place what you can on the drug product such as an eye formulation.

## Extra-label Use in Food-Producing Animals: 21 CFR 530.20

- **Legal Guidelines for Protection of the Food Chain**
- **1. Only use if there is need of a treatment, and no approved labeled food animal drug that is efficacious under a valid VCPN.**
- **2. Requirement of a careful diagnosis and conditions for which the drug may safely be used.**
- **3. Extended withdrawal date of all edible products supported with scientific data ( Call FARAD). If no data available, take measures that the animal products not enter the food chain.**
- [Home I FARAD](#)
- **4. Identify the animal as treated is an appropriate environment tagged.**
- **5. Make sure the producer understands the longer withdrawal period.**
- **6. ELUD not permitted to use a human product if there is a veterinary product on the market.**
- **7. Compounding is extremely rare, check first.**

### Veterinary Feed Directive

A written authorization that allows producers to use animal feed containing restrictive antibiotics in accordance with the FDA approved use. It is required for any species of animal fed medicated feed containing a VFD, livestock, bees only under the supervision of a licensed veterinarian. 3 copies, 1 vendor, 1 farmer, 1 veterinarian

21 CFR 510.514 and 558.

[Veterinary Feed Directive \(VFD\) | FDA](#)

[FACT SHEET: Veterinary Feed Directive Final Rule and Next Steps | FDA](#)

[CVM GFI #120 Veterinary Feed Directive Regulation Questions and Answers | FDA](#)

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### Drugs dispensed

- Animal pictures or stickers assist.



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### Cases of Diversion-Caution

Pharmacists and staff diversion-The DEA registration number is assigned to a pharmacist or clinician. Now at research facilities, they will ask who is responsible for daily control and inventory of all CS's used? If this is not the licensed person that has the DEA registration, then the DEA also has the name of that person.

A double check is extremely important. If an employee has an injury or has a drug addiction problem, discovery is critical and can be done by a double audit. If you have an automated dispenser, then all of the system can program a double signature or finger print or eye identification. Counting daily is critical as well.

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## Examples of employees with addiction problems

1. Frequent questions about drugs, which are the best for pain.
  2. Drugs removed after a person has gone home, signed out in an automated dispenser or from the paper sign-out sheet.
  3. Solutions: Make sure all access is denied once the person walks out the door with the animal. Requires attention to details.
  4. Solutions- be aware of anyone who is hanging around the CS cabinet storage.
  5. Have an audit system of all orders placed for CS's.
- All vendors will send you a separate copy of what you ordered in a letter or request an email. Make sure you look at what was ordered.

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## Strategies for Prevention and Education in Drug Abuse

- ▶ Each Medical Profession is responsible
- ▶ Veterinary Board is working with Task force to develop strategies
- ▶ Veterinary Students and community need to be educated by professionals
- ▶ Concentrate on the youth
- ▶ Regulations must ensure patient care and pain control is available, but with only dosages that are needed.
- ▶ Send home disposal systems for destroying medication.
- ▶ [Drug Disposal: Drug Take Back Locations | FDA](#)
- ▶ [Disposal of Unused Medicines: What You Should Know | FDA](#) teaching video

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## Diversion prevention summary

- Have a proper training to make sure all employees understand that you monitor these CS's and there will be no tolerance of abuse.
- Give all employees access to the programs available for pharmacists and veterinarians and staff who have an addiction problem.
- Discuss the current crisis with illicit street drugs and make sure you educate your employees not to purchase any medications.
- Weed is laced with fentanyl now, and the death from opioids in the US this year has already hit 100,000.

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#### Additional References

- 1. [www.fda.gov](http://www.fda.gov)
- 2. [www.nabp.org](http://www.nabp.org)
- 3. [www.aavp.org](http://www.aavp.org)
- 4. **21 CFR 200**
- 5. [www.fda.gov](http://www.fda.gov)
- 6. [www.nabp.org](http://www.nabp.org)
- 7. [www.fda.gov](http://www.fda.gov)
- 8. [www.fda.gov](http://www.fda.gov)
- 9. [www.fda.gov](http://www.fda.gov)
- 10. [www.fda.gov](http://www.fda.gov)
- 11. [www.fda.gov](http://www.fda.gov)
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- 13. [www.fda.gov](http://www.fda.gov)
- 14. [www.fda.gov](http://www.fda.gov)
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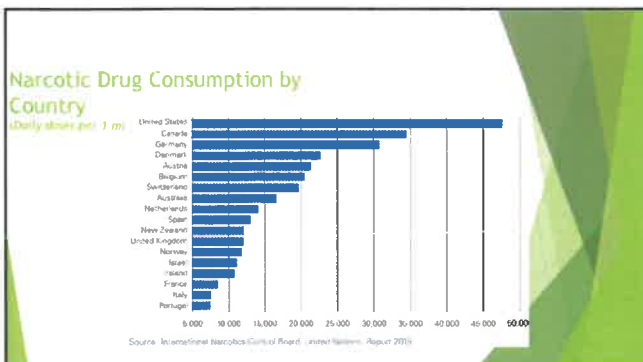
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## U.S. Government Response

- President Trump declares the opioid epidemic a national emergency in 2017
  - Federal Emergency Management Agency (FEMA) funds become available
  - Public health workers redeployed
  - Access to Medication Assisted Treatment is increased
  - Medicaid pays for more treatment
- Centers for Disease Control and Prevention awards \$28.6 million to help states fight opioid overdose epidemic
- FY 2018 budget included nearly \$4 billion in funding
- Trump has proposed \$10 billion for the FY 2019 budget



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## Pain Management

- Healthcare worker including veterinarians are required by law and ethics to help fight the crisis of prescription drug abuse. There is delicate balance between pain management and preventing misuse.
- Veterinarians, currently are not required to report to the State in Alabama, dispensing of controlled substance. However, check with each state for veterinarians. This responsibility for monitoring your practice dispensing to clients is still required for you to keep records, just not electronically through the state. Pharmacists do report to their states through a PMPD program.
- How many of you have PMPD programs in your state?

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## Strategies for Drug Abuse

- Each Medical Profession is responsible
- Veterinary Board is working with Task force to develop strategies
- Veterinary Students and community need to be educated by professionals
- Concentrate on the youth
- Regulations must ensure patient care and pain control is available

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## Opioid resources for AVMA members

- ▶ **State-by-state law chart** - This chart summarizes state laws and regulations, and shows the extent to which veterinarians are required to participate in prescription drug monitoring programs (PDMPs), including requirements for reporting and searching state PDMP databases if applicable.
- ▶ **Veterinary continuing education** - This chart summarizes state laws and regulations defining veterinary continuing education requirements, including specific provisions related to opioids or other controlled substances.
- ▶ **Identify "vet shoppers" and combat drug diversion** - This printable resource can be used in the back office of your clinic to help identify "vet shoppers" and combat drug diversion.
- ▶ **AVMA policy on prescription drug diversion** - This policy spells out the objectives and efforts the AVMA supports to address the national opioid epidemic.
- ▶ **Alternatives to opioids** - White paper published by the American College of Veterinary Anesthesia and Analgesia along with the International Veterinary Academy of Pain Management.
- ▶ **Controlled substance** - VetBloom webinar created in collaboration with the AVMA.
- ▶ **Other resources** - Training video produced by the University of Illinois with contributions from the AVMA.

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## One Health Issue

- ▶ All schools must educate
- ▶ EDUCATION for staff Handling Controls and other Hazardous Drugs
- ▶ What to do????

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## Reversing Overdose



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NALOXONE REVERSAL



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Naloxone



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Naloxone



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### Naloxone



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### Legal Requirements for surrender/disposal of Opioids

- ▶ Reverse distributor identified by the Board of Pharmacy
- ▶ Police/Pharmacy registered disposal collection
- ▶ Drug Deactivation System

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### Vaping Dog



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## Vaping a New Threat to Animals

- ▶ ASPCA reports
- ▶ E cigarettes contains liquid nicotine and if ingested
- ▶ Vomit
- ▶ Agitation
- ▶ Drool
- ▶ Diarrhea
- ▶ HI heartrate
- ▶ Large quantities depressed, low heartrate and low blood pressure

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## Vaping



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## Vaping Products

- ▶ Cause death
- ▶ Severe Pulmonary disease
- ▶ Cannabis, nicotine, flavorings, CBD oil
- ▶ Reuse old cartridge

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## Vaping

- ▶ If chew the vaping device then battery can cause burn
- ▶ If marijuana vaping then toxic ( ataxic, vocalization, rocks back and forth, hypersensitivity to noise, dribbling urine and enlarged pupils
- ▶ Birds are very sensitive to vaping ...respiratory problems
- ▶ Vape out doors

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## Treatment

- ▶ Supportive therapy
- ▶ Activated charcoal
- ▶ Fluid Therapy
- ▶ Seizures may need to manage

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## Vaping




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## Vaping



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## Cautions associated with CBD OIL



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## CBD OIL

- ▶ Considered a Supplement
- ▶ Hemp Based
- ▶ 0.3% THC
- ▶ Make sure you have a certificate of analysis

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### QUESTIONS????

- ▶ Are your controlled substances stored and dispensed in a security tight facility? True or False
- ▶ Is a driver's license required in Florida to pick up controlled substances (CS)?
- ▶ Yes or No
- ▶ Are you required to report any discrepancy in the inventory if a loss has occurred? Yes or No
- ▶ When should you report a theft of CS's?
- ▶ Who is responsible legally for all aspects of handling CS's?

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# **Compounding Animal Drugs from Bulk Drug Substances GFI #256 Draft**

## **Auburn University CVM**

### **Duran and Patton Lectures**

#### **What is a GFI document?**

Guidance for Industry (GFI) and Compliance Policy Guides (CPGs) are similar in that they both state the FDA's interpretation and plan to enforce laws. These documents are not laws and do not have the legal authority of laws; however, they indicate the FDA's current thought process. They are subject to change and frequently do.

**Here is an example:** A stretch of road has a posted speed limit of 60 mph. However, the local police department instructs its officers not to pull anyone over for speeding unless they are going faster than 70 mph. Technically it's illegal to drive faster than 60 mph, but the police department is exercising its regulatory discretion by choosing to not enforce the speed limit for drivers going between 60 and 70 mph.

#### **Why is this document necessary?**

In 1968, the Food, Drug, and Cosmetic (FD&C) Act was modified to include veterinary drugs. This made all extra-label use illegal. Therefore, AMDUCA was finalized in 1994 to allow extra-label use with certain restrictions. Since compounds are not approved medications, they don't have approved labels so are always considered extra-label. AMDUCA specifically permits compounding by using the approved medication as the source of active drug. However, it does not permit compounding by using bulk chemicals as the source of active drug.

Multiple documents (CPG 608.400 and GFI #231 draft) have existed over the years to address compounding from bulk chemicals, but the draft of GFI #231 was withdrawn in November 2017, and we have been without guidance since then.

#### **Why is compounding from bulk chemical concerning?**

Compounded medications in general have a higher inherent risk compared to the use of manufactured products. Manufactured products have been reviewed by the FDA for evidence that they are safe, effective, properly manufactured and accurately labeled. Food animal products are also evaluated for their potential to result in drug residues. Compounded medications are not subject to this level of oversight. However, compounded medications are often necessary to treat our patients.

When compounds are prepared by modifying a commercial product, there is a guarantee that the drug source contains what it is labeled to contain. When bulk chemical is used, there is no guarantee that the power is pure drug. Using bulk chemical also opens the door for unethical compounding where it starts to turn into a backdoor way around drug approval. Due to these risks, the FDA wants to limit compounding from bulk chemical to instances when it is necessary to create a suitable, high-quality product.

#### **What are some reasons when compounding from bulk chemical is necessary?**

There are a number of instances when using a bulk chemical is necessary for producing a suitable compound. These include:

- Dosage forms that create a poor product when crushing commercial tablets due to excipients (i.e. transdermals, and solutions)
- Medications that are not available as approved products (i.e. cisapride and potassium bromide)
- Patient intolerance to an excipient (i.e. allergy to a coloring agent in a commercial product)
- Approved product is on backorder

#### **What are the FDA's main areas of concern?**

The FDA is issuing this guidance because they understand the above cases where bulk chemical is necessary, but they also have concerns with bulk chemicals that meet any of the following criteria:

- Present particular human or animal safety concerns
- Are intended for use in food-producing animals
- Are copies of marketed FDA-approved, conditionally approved, or indexed drugs
- Are compounded without a patient-specific prescription

#### **How does this affect us at the U of I VTH?**

From a clinical standpoint, you likely won't notice much difference for medications prepared in the VTH Pharmacy. We are already largely complying with the proposed requirements of this GFI with just some minor labeling changes required to comply with the draft as written. For example, we prepare our suspensions by utilizing commercial tablets when possible and only use powders when the quality of the suspension is decreased by using commercial tablets.

Where you may see a difference is with obtaining office use compounds from outside pharmacies. Theoretically, the future list of bulk chemicals allowed to be used for preparing office use compounds will cover all necessary drugs to prepare compounds that can't be prepared from commercially available products. However, there may be an adjustment period for many compounding pharmacies that have been compounding solely from bulk chemicals.

#### **Where can I find more information?**

You can download the draft GFI document at <https://www.fda.gov/media/132567/download>.

The comment period is open until February 18, 2020. You can leave comments by going to [www.regulations.gov](http://www.regulations.gov) and search for FDA-2018-N-4626.



## vet shopping and drug diversion **A GUIDE FOR VETERINARIANS**

**“Vet shopping” refers to the practice of soliciting multiple veterinarians under false pretenses to obtain prescriptions for controlled substances. Drug diversion is the illegal distribution or abuse of prescription drugs.**

### **HOW TO RECOGNIZE A VET SHOPPER**

- New clients bringing in seriously injured animals with vague histories
- Old, incomplete, or missing veterinary care records
- Describing clinical signs that are inconsistent with findings on examination of the patient
- Describing clinical signs that require specific medications
- Requesting medications by name (e.g., Tramadol or Xanax)
- Refusing medications as prescribed and suggesting alternatives
- Requesting early refills of medication
- Claiming medications were lost or stolen
- Requesting refills, while missing appointments
- Uncooperative and aggressive behavior

### **WAYS TO MINIMIZE DRUG DIVERSION**

- Be thorough about documentation when using or prescribing narcotics
- Restrict access to prescription pads
- Maintain strict refill policies
- Remind clients to turn in unused portions of medications to a controlled substance disposal location
- Minimize the use of commonly abused drugs, if possible
- Strictly control access, and regularly check inventory
- Look for signs of animal abuse during physical exams
- Contact police if you see suspicious behavior

**For more information visit:**

**[AVMA.org/opioids](https://www.avma.org/opioids)**

## FLORIDA PHARMACY LAW AND RULES- PART 1 AND 2

SUE DURAN

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## REGULATION CHANGES WITH FOOD ANIMALS

- Veterinary Feed Directive- (VFD) Veterinarians can purchase antimicrobial feed additives if they register with as a Vendor for FDA.
- No growth promotion feed or water additives allowed in 2017.
- Producers may use drugs on their farm they already have labeled OTC until the expiration date, however the feed must be mixed and under a VFD with a VCPR.

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## CE REQUIREMENTS

- You are required to take 30 hours every biennium.
- Of the 30 hours one credit must be in drug dispensing and two credits must be in laws and rules governing the practice of veterinary medicine

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## CENTER OF VETERINARY MEDICINE

- The Federal Food, Drug, and Cosmetic Act allows the Secretary of Health and Human Services to delegate his or her authority to others, such as the Commissioner of Food and Drugs. The Commissioner has redelegated his or her authority for a number of functions to CVM. Among these redelegated functions are:
- Authority to approve New Animal Drug Applications (NADA) and their supplements and Abbreviated New Animal Drug Applications (ANADA) for animal drugs and products Outsource Compounding Pharmacies (see 21 CFR 312.61) Compounding from bulk materials
- Authority to issue proposals, notices, and orders relating to refusal to approve and withdrawal of approval of New Animal Drug Applications and outsource drug applications
- Authority to conduct inspection of animal food facilities

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## IMPORTING VETERINARY DRUGS AND TRACK ANIMAL COMPOUNDED PRODUCTS THAT ARE OUTSOURCED.

- Specific requirements for importing drugs, contact the CVM
- [Importing - Veterinary Drugs 1 PDA](#)
- Center for Drug Evaluation and Research- Pre-Approved Safety Review- drugs and biological dashboard.
- All 503b compounding pharmacies have to report to the CDER

For all outsourcing of animal medications.

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## OTC ANTIMICROBIALS TO RX AS OF JUNE 11, 2023

- ANTIMICROBIALS WILL BE RX UNDER THE SUPERVISION OF A LICENSED VETERINARIAN.
- A GRACE PERIOD WILL BE GIVEN UNTIL THE CURRENT PRODUCTS EXPIRE
- STILL OTC VACCINES, IONOPHORES, TEAT SEALANTS,
- ANTHELMINTICS, HORMONE IMPLANTS, FLY CONTROL.
- PLEASE STRESS TO ALL YOUR CLIENTS NOT TO SAVE AND USE OUTDATED PRODUCTS AND DISPOSE OF PROPERLY.

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All expired medication and chemicals must be stored in a locked area and away from all in-date medications. A reverse distributor will have rules to follow as to what they can or cannot dispose. Ask questions before you send the items for disposal.

- Prostaglandins such as Lulaprost, Prostamate and Estrumate can lead to the abortion of a sow's pregnancy if there is an accidental exposure, they can also cause abortion in pregnant women. The drug Mifepristone (RU-486) can actually prolong pregnancy if absorbed in both sows and women as well as afternoons (Regumate). Pergolide: agitation, hallucinations, low BP, irregular blood pressure.

- Prostaglandins may cause an asthmatic attack.
- Chemopreventive: Chemotherapy, Cyclophosphamide, D50 Mitomycin and Triazotam (for Ovarian disease), Mithramycin, Macrogol.
- Endometriosis: Progestins, a 3rd topical oestrogen, glycolytic agents such as ethinodiol, dexamethasone may induce luteal and cardiovascular effects.



### CURRENT XYLAZINE ( VETERINARY DRUG ONLY) INFORMATION

- Xylazine has been listed as an emerging human abuse threat. Also call zombie drug illegal street sales.
- An alpha 2 adrenergic agonist similar to clonidine( human drug), but never approved due to the severe hypotension and CNS depression.
- Currently, if injected to the handler in small quantities may drop the BP drastically to require

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### XYLAZINE TOXICITIES TO HUMAN

- Xylazine causes a severe drop in BP injected in small quantities.
- Always use a closed system when preparing this product. Do not recap needles to prevent slicks.
- Do not leave xylazine in the barns or any areas open to clients.
- Dispensation to owner can produce a liability.
- Cause skin and soft tissue infections anywhere on the skin. Causes non-healing wounds of dying flesh from

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### REFERENCES

- Xylazine Drug Policy Alliance, 2023
- 2023.05.23\_xylazine\_fortified.pdf (drugpolicy.org)
- Congress moves to make xylazine a controlled substance (wzgt.com)
- State and Federal Actions to Respond to Xylazine - National Governors Association (nag.nra)
- Xylazine (vidol.gov) DEA warning
- Bing Videos

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## CLIENT INFORMATION SHEETS

- Does the veterinarian counsel the patient on safe use of medication? Educate the owner
- Make sure the veterinarian and staff have a copy of the Safety Data Sheets for their medications.
- Tranquilizer such as detomidine, medetomidine, xylazine, and acepromazine may also be harmful, drops BP. As of June 2023, xylazine is a Schedule IV CS in West Virginia
- Antipsychotic drugs, amitriptyline
- Fentanyl Patches- lethal to children, cover the patch with adhesive, keep out of reach of children. Locked cabinet at home.

## FDA NON-BINDING RECOMMENDATIONS. COMPOUNDING FROM BULK DRUGS

- FDA recognizes that in some situations a drug compounded from bulk drug substances may be the only appropriate treatment option for a particular animal. On April 22, 2022, FDA finalized Guidance for Industry #256, "[Compounding Animal Drugs from Bulk Drug Substances](#)," which addresses situations in which the FDA does not intend to take action for certain violations of the Food, Drug, & Cosmetic Act when pharmacists and veterinarians compound or oversee the compounding of animal drugs from bulk drug substances:
- Enclosed is the Check list for Veterinarians Prescribing Animal Drugs Compounded from Bulk Drug Substances.
- [For Veterinarians Prescribing Animal Drugs Compounded from Bulk Drug Substances \(fda.gov\)](#)

## WHAT ARE SOME REASONS WHEN COMPOUNDING FROM BULK CHEMICAL IS NECESSARY?

THERE ARE A NUMBER OF INSTANCES WHEN USING A BULK CHEMICAL IS NECESSARY FOR PRODUCING A SUITABLE COMPOUND. THESE INCLUDE:

- DOSAGE FORMS THAT CREATE A POOR PRODUCT WHEN CRUSHING COMMERCIAL TABLETS DUE TO EXCIPIENTS (I.E. TRANSDERMALS, AND SOLUTIONS)
- MEDICATIONS THAT ARE NOT AVAILABLE AS APPROVED PRODUCTS (I.E. CISAPRIDE AND POTASSIUM BROMIDE)
- PATIENT INTOLERANCE TO AN EXCIPIENT (I.E. ALLERGY TO A COLORING AGENT IN A COMMERCIAL PRODUCT)
- APPROVED PRODUCT IS ON BACKORDER

### WHAT ARE THE FDA'S MAIN AREAS OF CONCERN?

THE FDA IS ISSUING THIS GUIDANCE BECAUSE THEY UNDERSTAND THE ABOVE CASES WHERE BULK CHEMICAL IS NECESSARY, BUT THEY ALSO HAVE CONCERNS WITH BULK CHEMICALS THAT MEET ANY OF THE FOLLOWING CRITERIA:

- PRESENT PARTICULAR HUMAN OR ANIMAL SAFETY CONCERNS
- ARE INTENDED FOR USE IN FOOD-PRODUCING ANIMALS
- ARE COPIES OF MARKETED FDA-APPROVED, CONDITIONALLY APPROVED, OR INDEXED DRUGS
- ARE COMPOUNDED WITHOUT A PATIENT-SPECIFIC PRESCRIPTION

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### COMPOUNDING 503A PHARMACY, INDIVIDUAL ANIMAL WITH RX- EFFECTIVE 4.1.23

- To fill patient-specific prescriptions for nonfood-producing animals
- to compound "office stock" (certain drugs kept in veterinarians' supply) for nonfood-producing animals and
  - to compound antidotes for food-producing animals or Sedatives and Anesthetics for Free ranging Wildlife Species.
  - To compound drugs when no other drugs are available using FDA approved APIs ( Active Pharmaceutical Ingredients).
  - Follow USP guidelines for pharmacists.

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### SPECIAL BOARD ISSUES

How long are veterinarians required to keep medical records?

- Rule 61G18-18.002(1), Florida Administrative Code, provides that you must keep records three years from the date of last entry, including X-rays.

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### SHIPPING

I need to send an animal out of the country. Whom do I contact?

- The USDA/APHIS Veterinary Services Area office in Gainesville, at 352-313-3060; or the USDA APHIS Miami Import/Export Center, 305-526-2926.

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### HEALTH CERTIFICATE

I need to order more pet health certificates. Whom do I contact?

- The Florida Department of Agriculture. You may reach them at 850.410.0900 or download the form online at [www.doacs.state.fl.us/onestop/forms/09085.pdf](http://www.doacs.state.fl.us/onestop/forms/09085.pdf).

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### PET LEMON LAW

Whom do I contact regarding the Pet Lemon Law?

- The Florida Department of Agriculture. You may reach them at 850.410.0900.

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### PERMITS

- Whom do I contact regarding the Health Care Clinics Establishment Permits?
- Contact the Department of Business and Professional Regulation, Drugs, Devices, and Cosmetics Program. Please refer to their website [www.myfloridalicense.com](http://www.myfloridalicense.com) or call 850.717-1800 if you have question

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### RX FILLED WITHOUT AUTHORIZATION

Complaint against a prescription company who is filling prescriptions without authorization. Who do I contact?

- The Department of Health, Board of Pharmacy. You may reach them at 850.488.0595.

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### PRESCRIPTION BLANKS

- Effective July 1, 2011, counterfeit-proof prescription blanks must be used by licensed health care practitioners who prescribe controlled substances listed in Chapter 893, Florida Statutes. Section 456.42(2),

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### RX BLANKS

- Florida Statutes, was amended requiring licensed healthcare practitioners purchase counterfeit-proof prescription blanks from vendors approved by the Department of Health.

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### RX PAD REPORTING

- Vendors approved by the Department of Health are required to provide monthly reports to the Department, documenting who purchased the prescription pad or blanks and how many were purchased.

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### FLORIDA 61G18-10.0065

- 61G18-10.0065 Notice to the Department of Mailing Address and Place of Practice of Licensee.

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## CHANGE

- Each licensee and registrant shall provide by certified mail written notification to the department the licensee's current mailing address and place of practice upon change thereof or license renewal. The term "place of practice" means the address of the physical location where the veterinarian practices veterinary medicine

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## G18-10.008 PROBABLE CAUSE PANEL

(1) The determination as to whether probable cause exists to believe that a violation of the provisions of Chapter 455 or 474, F.S., or of the rules promulgated thereunder has occurred, shall be made by a majority vote of the probable cause panel.

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## COMPOSITION

- (2) The probable cause panel shall be composed of no less than two (2) nor more than three (3) members of the Board of Veterinary Medicine. Not more than one (1) member of the panel may be a lay member.

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- The Chairman may appoint a former member of the board to serve on the probable cause panel in lieu of a current member of the Board of Veterinary Medicine.

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### FLORIDA MINIMUM STANDARDS

- 61G18-15.0022 Minimum Standards for Permanent Locations Where Agricultural Veterinary Medicine Is Practiced.

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### PERMANENT LOCATION

- Agricultural veterinary medicine is practiced upon livestock as defined by Section 828.23(3), F.S. Minimum standards for permanent locations where agricultural veterinary medicine is practiced are:

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### EXTERIOR

(a) All establishments where veterinary medicine is practiced must have the following:

- 1. Legible sign to identify location,
- 2. Facility clean and in good repair, and
- 3. Telephone number for emergency veterinary care shall be visible and legible from the exterior.

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### CLEAN AND ORDERLY

• (b) The location where agricultural veterinary medicine is practiced must be clean and orderly.

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### INTERIOR

(a) All locations where agricultural veterinary medicine is practiced must have the following:

- 1. Restroom – clean and orderly.
- 2. Office:
  - a. Clean and orderly,
  - b. Current license displayed.
- 3. 24 hours telephone service a day for emergencies.

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### EXAM AREAS

- a. Clean and orderly,
- b. Lined waste receptacles,
- c. Sink and disposable towels (Sinks located in restrooms may not be used to satisfy this standard), and
- d. Examination table, if present, must be of a material subject to disinfection.

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### PHARMACY

- a. Clean and orderly,
- b. Individual patient or herd/flock records,
- c. If controlled substances are on premises, a locking secure cabinet for storage and an accurate controlled substance log.
- d. Segregated area or container for the storage of expired drugs.
- No Rx drugs can be stored in the front area or in a room where owners are left unsupervised.

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### LABORATORY ACCESS REQUIRED

- 6. Accessibility to a laboratory.

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### HOLDING AREAS

- 7. Holding areas shall be capable of sanitation and shall include proper ventilation, sufficient lighting, and be of a size consistent with the welfare of the animal.

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### GARBAGE AND TRASH DISPOSAL:

- a. Sanitary cans lined with disposable bags,
- b. Effective insect and rodent control.

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- 9. Carcass disposal.

- 10. Emergency lighting which must include at least a functioning rechargeable battery-operated light.

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- 11. Fire extinguisher, with current inspection.
- 12. Refrigeration of stored drugs, biologicals, laboratory samples, and other perishable items.

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### BIOHAZARDOUS WASTE

- 13. Compliance with the requirement of Chapter 64E-16, F.A.C., concerning the handling and disposal of biohazardous waste.
- Compliance with hazardous waste.

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### RADIOLOGY/SURGERY HOSPITALIZATION

All locations must have facilities for radiology, surgery, and long term hospitalization, as described below, or in lieu thereof, written evidence that arrangements have been made with another clinic or hospital to provide the services.

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### SURGERY

- a. Clean and orderly,
- b. Method of sterilization of equipment and instructions,
- c. Well-lighted, and
- d. Surfaces, if applicable, must be made of smooth material subject to disinfection.
- If cleaners become resistant, monitor and change products.

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### HOSPITAL HOLDING AREAS

- shall include proper ventilation, sufficient lighting, and be of a size consistent with the welfare of the animal.

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### VETERINARY CLINICS

Where veterinary medicine is practiced are not required to have the following facilities. However, if they do have them, the facilities must meet the standards set forth.

- 1. Reception area – shall be free from hazards.
- 2. Kitchen or food area – clean and orderly.

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## EXERCISE AREAS

- a. Clean and secure, and
- b. No hazards.

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## VETERINARIANS

- Must furnish a permanent address at which they can be reached by clients in order that clients may obtain veterinary medical records.
- Rulemaking Authority 474.206, 474.215(6) FS. Law Implemented 474.215(6) FS. History—New 7-9-95, Amended 9-18-95, 12-28-95, 9-26-12.

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## PROPOSED RULE

- RULE NO.: RULE TITLE:  
61G18-15.0023: Minimum Standards for Permanent Locations Where Agricultural Veterinary Medicine Is Practiced  
61G18-15.0025: Minimum Standards for a Mobile Veterinary Practice for Agricultural Animals

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**PURPOSE AND EFFECT: RULE 61G18-15.0022, F.A.C.:**

- To ensure that expired drugs are not comingled with current drugs in order to avoid the unintentional administration of said expired product.

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**RULE 61G18-15.0025, F.A.C.:**

- To ensure that practitioners are able to euthanize an animal without unnecessary delay in order to humanely reduce suffering in accordance with minimally accepted practices in the industry and to ensure that expired drugs are not comingled with current drugs in order to avoid the unintentional administration of said expired product.

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**SUMMARY: RULE 61G18-15.0022, F.A.C.:**

- The proposed change specifies that all expired drugs are required to be stored in a designated area or container which is segregated from all other drugs.

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### IF SURGERY PERFORMED

- The following shall be maintained:
  - a. Surgical instruments,
  - b. Access to a means of sterilization,
  - c. Suture material, and
  - d. Intravenous equipment.

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- 6. An American Veterinary Medical Association approved chemical method of euthanasia.

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- 7. Segregated area or container for the storage of expired drugs.
- (2) through (4) No change.
- Rulemaking Authority 474.206, 474.215(6) FS. Law Implemented 474.215(6) FS. History—New 7-4-95, Amended 7-22-10,\_\_\_\_\_.

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### RULE 61G18-15.0025, F.A.C.:

- Adds an approved chemical method of euthanasia to the list of items required to be maintained by a mobile veterinary practice for agricultural animals. The proposed change also specifies that all expired drugs are required to be stored in a designated area or container which is segregated from all other drugs

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### 61G18-15.0025 MINIMUM. STANDARDS FOR MOBILE PRACTICE

- (1) Mobile units utilized by veterinarians:
- (a) Shall be clean and orderly.

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### MOBILE UNITS

- (b) Shall contain the following:
  - 1. Sterile syringes and needles.
  - 2. Properly stored biologics.
  - 3. Antiseptic intravenous equipment.
  - 4. If controlled substances are on the unit, a locking secure cabinet for storage and an accurate controlled substance log.

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**61G18-15.005 PERIODIC INSPECTIONS.**

- (1) The Department shall make inspections of veterinary premises every two (2) years. Such inspection shall include but not be limited to verification of compliance with Rule 61G18-15.002, F.A.C., governing minimum standards for veterinary premises.

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**INSPECTIONS**

- (2) Additionally, the Department shall conduct unannounced routine inspections of one percent (1%) of the veterinary premises each year. The selection of premises to be inspected shall be made by the Department on a random basis.

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**61G18-15.007 MINIMUM STANDARDS FOR LIMITED-SERVICE VETERINARY MEDICAL PRACTICES.**

- (1) The term "limited-service veterinary medical practice" shall mean a privately or publicly supported vaccination clinic where a veterinarian performs for a limited time vaccinations and/or immunizations against disease on multiple animals

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### LIMITED SERVICE

- The veterinarian may also perform preventative procedures for parasitic control, and shall not mean a premise otherwise permitted by the Board.

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### REGISTRATION

- (2) The Limited-Service permittee shall register each clinic with the Board of Veterinary Medicine by name, address, date of clinic, time and duration, at least 28 days prior to offering a limited-service clinic.

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- A copy of the limited-service permit shall be clearly visible at each limited service clinic held during its hours of operation and posted at the main office where the records are stored.

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## Legal Issues in Veterinary Pharmacy

- (3) A veterinarian must remain on site throughout the duration of a limited-service clinic and must maintain autonomy for all medical decisions made. A physical examination and history must be taken for each patient receiving veterinary medical care at a limited-service clinic.

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- Recommendations and preventive medicine protocols must be developed from current accepted veterinary medical practice. The veterinarian is responsible for proper immunization and parasitic procedures and the completeness of recommendations made to the public by the paraprofessional staff that the veterinarian supervises or employs.

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- The veterinarian is responsible for consultation and referral of clients when disease is detected or suspected.

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### ALL LIMITED SERVICE LOCATIONS

- (a) Legible sign to identify permit holder and a legible sign to identify the veterinarian(s) on site by name and license number.

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- (b) A clean safe location which allows for the safety of animals and their owners and which is conducive to the handling of animals and consultations with the public. The location shall utilize a method of visibly segregating the vaccination and examination area to deter public access.

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- (c) Meet local sanitation requirements.
- (d) A copy of the Limited Service clinic premise permit displayed.

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- (e) Shall provide a legible list of the name, address and hours of operation of all facilities that provide or advertise emergency services and when applicable the location of other clinics provided by the same entity on that day, that are located within a 30-minute or 30-mile radius.

- (f) Lined waste receptacle.
- (g) A sink with fresh, clean running water, disposable towels, and soap for cleaning and first aid must be provided within ten (10) feet of the examination area. Sinks located in restrooms may not be used to satisfy this requirement.

- (h) Safe, clean examination work area constructed of a smooth impervious material.
- (i) Storage of supplies and equipment to preclude public access.
- (j) Separate area for clerical work.

- (k) Proper handling of vaccinations, biologics, pharmaceuticals and supplies: Facilities must be provided for proper storage, safekeeping and preparation of pharmaceuticals in accordance with federal, state, and local laws

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- . If controlled substances are on the premises, they must be kept in a locking, secure cabinet for storage and an accurate controlled substance log must be maintained. All pharmaceuticals and biologics shall be maintained at the temperature recommended by the

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- manufacturer in a refrigeration device that is powered by a stable energy source and is capable of maintaining a constant temperature. A thermometer shall be included where the pharmaceuticals are being stored.

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- (l) Equipment must be of the type and quality to provide for the delivery of immunization and parasiticides in the best interest of the patient and with safety to the public.

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- (m) Each limited-service clinic must have the capacity to render emergency care for hypersensitivity reaction, anaphylaxis, and immediate emergency care of injury to the animals in attendance at the clinic.

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- (n) Sanitation equipment and solutions.
- (o) Proper bio-medical waste handling equipment, registration and procedures.

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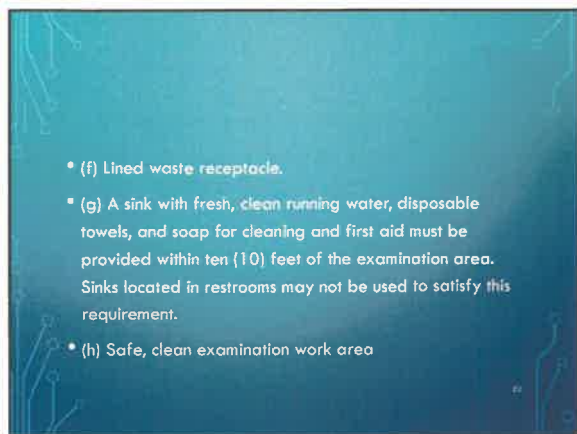
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