

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

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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 clinical trials of animal food and feed

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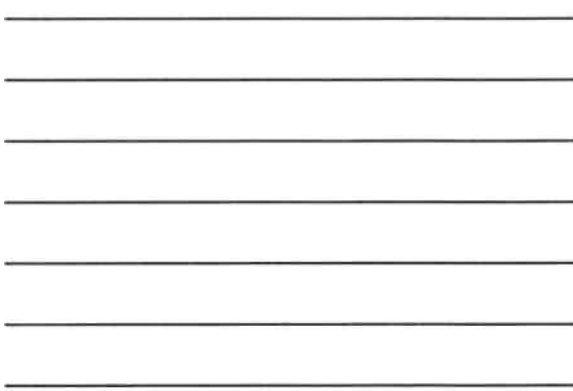
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All expired medications and chemicals must be stored in a restricted area and away from all in-date medications. A licensed distributor will have rules to follow as to what they can or cannot dispose. Ask questions before you send the items for disposal.

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

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### 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\\_forbidden.pdf \(drugpolicy.org\)](#)
- [Congress moves to make xylazine a controlled substance \(wtop.com\)](#)
- [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.

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## 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 \(fda.gov\)](#)

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## 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

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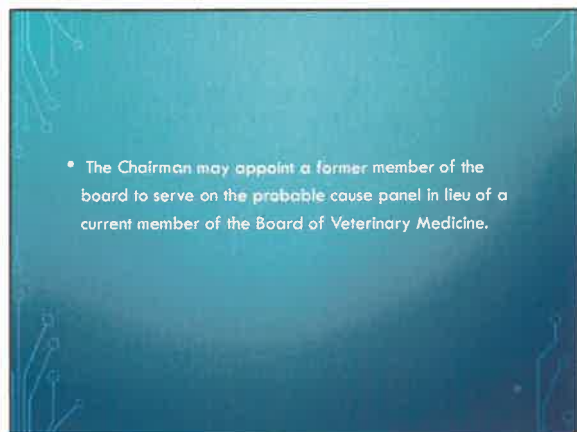
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- The Chairman may appoint a former member of the board to serve on the probable cause panel in lieu of a current member of the Board of Veterinary Medicine.

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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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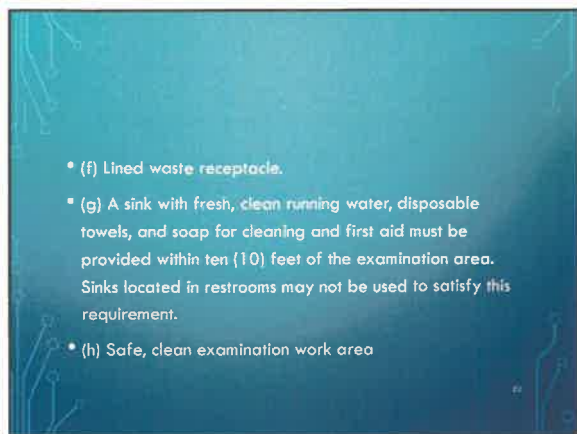
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