THE LAWS & RULES GOVERNING THE PRACTICE OF VETERINARY MEDICINE & DISPENSING LEGEND DRUGS

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THE CHALLENGE:

- How to cover all this material in 3 hours.
- How to do so in a way that will not put you to sleep.
- How to encourage you to undertake additional efforts to become more proficient in these areas.

THE SOLUTION:

- Make you understand the benefit to YOU!!
- Keep it interesting (easier said than done).
- Provide you with specific suggestions and resources to assist your self-study.

WHY ARE YOU HERE?

Section 1

61G18-16.002 CONTINUING EDUCATION REQUIREMENTS FOR ACTIVE STATUS LICENSE RENEWAL

(2) Licensed veterinarians shall complete a minimum of thirty (30) hours of continuing professional education in veterinary medicine every biennium. Beginning on June 1, 2012, no less than one (1) hour of continuing education shall be in the area of dispensing legend drugs and no less than two (2) hours of continuing education shall be in the area of the laws and rules governing the practice of veterinary medicine. For the purposes of this rule, the laws and rules governing the practice of veterinary medicine are Chapters 455 and 474, F.S. and Rule Title 61G18, F.A.C.

(a) One (1) hour equals a minimum of fifty (50) minutes and a maximum of sixty (60) minutes. Total hours of lecture time cannot be added up and divided into 50-minute intervals to obtain 1 hour credit for each 50-minute interval.

(b) Not more than fifteen (15) hours shall be non-interactive, correspondence courses. Interactive Distance Education Courses are not correspondence courses.

(d) Five (5) hours of continuing education in laws and rules may be obtained once per biennium by attending one full day or eight (8) hours of a Board meeting (whichever is shorter) at which disciplinary hearings are conducted by the Board of Veterinary Medicine . . . .

(e) Not more than five (5) hours in complementary and alternative medicine modalities shall be credited toward the required number of continuing professional education hours referenced above.

NEW STATUTE 2024: §455. 2124, F.S. PRORATION OF OR NOT REQUIRING CONTINUING EDUCATION

CS/SB 382 amends §455.2124, F.S.

- Provides that individuals meeting certain criteria are exempt from the obligation to complete any continuing education.
  - Must be a licensee renewing an **active** license with the DBPR that has been held continuously for **at least 10 years**.
  - No disciplinary action has been imposed on the license.

TOPICS OF THIS PRESENTATION

- Disciplinary process and guidelines,
- Recordkeeping requirements,
- Permit requirements,
- Common Pitfalls in veterinary medicine and how to avoid them,
- Recent statutory, regulatory, and case law developments, and
- Risk management tips

WHERE ARE ALL OF THESE LAWS & RULES?

Section 2

LAWS & RULES

- Board of Veterinary Medicine Rules Chapter 61G18, F.A.C.
- Chapter 120, F.S. Administrative Procedure Act
- Chapter 455, F.S. DBPR General Statute.
- Chapter 474, F.S. Veterinary Medicine Practice Act.
- Chapter 499, F.S. Drugs, Devices & Cosmetics.
- Chapter 465, F.S. Florida Pharmacy Act.
- Chapter 585, F.S. Animal Industry
- Section 705.19, F.S. Abandonment of animals by owner; procedure for handling.
- Section 713.655, F.S. Liens for professional services of veterinarians.
- Chapter 828, F.S. Animals: Cruelty; Sales; Animal Enterprise Protection
- Chapter 893, F.S. Controlled Substances Act.

CHAPTER 474, FLORIDA STATUTES

- Veterinary Medical Practice Act:
  - Provides the requirements for licensure as a veterinarian.
  - Provides the grounds for disciplinary action against a licensed veterinarian.
  - Creates the Board of Veterinary Medicine.
  - Grants the Board the authority to promulgate rules, including standards of practice.

RULE 61G18, FL ADMINISTRATIVE CODE

Contains all the rules promulgated by the Board of Veterinary Medicine, including:

- Education, minimum standards of practice, minimum standards for premises where veterinary medicine is practiced, and record requirements.
- Grounds for disciplinary proceedings and disciplinary guidelines.

CHAPTER 455, FLORIDA STATUTES

Contains a number of laws applicable to all practitioners under the umbrella of DBPR including:

- §455.225, F.S., establishes the authority and procedures to conduct an investigation and disciplinary action.
- §455.227, F.S., provides general grounds for disciplinary action against all DBPR licensees.

CHAPTER 455, FLORIDA STATUTES

- **455.24 Advertisement by a veterinarian of free or discounted services; required statement.**—In any advertisement for a free, discounted fee, or reduced fee service, examination, or treatment by a person licensed under chapter 474, the following statement shall appear in capital letters clearly distinguishable from the rest of the text: THE PERSON RESPONSIBLE FOR PAYMENT HAS A RIGHT TO REFUSE TO PAY, CANCEL PAYMENT, OR BE REIMBURSED FOR PAYMENT FOR ANY OTHER SERVICE, EXAMINATION, OR TREATMENT THAT IS PERFORMED AS A RESULT OF AND WITHIN 72 HOURS OF RESPONDING TO THE ADVERTISEMENT FOR THE FREE, DISCOUNTED FEE, OR REDUCED FEE SERVICE, EXAMINATION, OR TREATMENT. However, the required statement shall not be necessary as an accompaniment to an advertisement of a licensed health care provider defined by this section if the advertisement appears in a classified directory the primary purpose of which is to provide products and services at free, reduced, or discounted prices to consumers and in which the statement prominently appears in at least one place.

CHAPTER 455, FLORIDA STATUTES

- **455.243 Authority to inspect.**—Duly authorized agents and employees of the department shall have the power to inspect in a lawful manner at all reasonable hours any establishment at which the services of a licensee authorized to prescribe controlled substances specified in chapter 893 are offered, for the purpose of determining if any of the provisions of this chapter or any practice act of a profession or any rule adopted thereunder is being violated; or for the purpose of securing such other evidence as may be needed for prosecution.

- **455.245 Veterinarians; immediate suspension of license.**—The department shall issue an emergency order suspending the license of any person licensed under chapter 474 who pleads guilty to, is convicted or found guilty of, or who enters a plea of nolo contendere to, regardless of adjudication, a felony under chapter 409 or chapter

CHAPTER 455, FLORIDA STATUTES

455.275 Address of record.—(1) Each licensee of the department is solely responsible for notifying the department in writing of the licensee's current mailing address, e-mail address, and place of practice, as defined by rule of the board or the department when there is no board. A licensee's failure to notify the department of a change of address constitutes a violation of this section, and the licensee may be disciplined by the board or the department when there is no board.

(2) Notwithstanding any other provision of law, service by regular mail or e-mail to a licensee's last known mailing address or e-mail address of record with the department constitutes adequate and sufficient notice to the licensee for any official communication to the licensee by the board or the department except when other service is required pursuant to s. 455.225.

(3)(a) Notwithstanding any provision of law, when an administrative complaint is served on a licensee of the department, the department shall provide service by regular mail to the licensee's last known address of record, by certified mail to the last known address of record, and, if possible, by e-mail.

(b) If service, as provided in paragraph (a), does not provide the department with proof of service, the department shall call the last known telephone number of record and cause a short, plain notice to the licensee to be posted on the front page of the department's website and shall send notice via e-mail to all newspapers of general circulation and all news departments of broadcast network affiliates in the county of the licensee's last known address of record.

COPIES OF THE STATUTES AND RULES

- Show of hands: Who has copies of Chapters 455 & 474, as well as the Board's Rules 61G18?
- Download and keep copies of those statutes and rules!!!
- Google:
  - Chapter 455, Florida Statutes
  - Chapter 474, Florida Statutes
  - Chapter 61G18, Florida Administrative Code

VETERINARY MEDICINE DEFINED

- "**Practice of veterinary medicine**" means diagnosing the medical condition of animals and prescribing, dispensing, or administering drugs, medicine, appliances, applications, or treatment of whatever nature for the prevention, cure, or relief of a wound, fracture, bodily injury, or disease thereof; performing any manual procedure for the diagnosis of or treatment for pregnancy or fertility or infertility of animals; or representing oneself by the use of titles or words, or undertaking, offering, or holding oneself out, as performing any of these functions. The term includes the determination of the health, fitness, or soundness of an animal.
- "**Veterinary medicine**" includes, with respect to animals, surgery, acupuncture, obstetrics, dentistry, physical therapy, radiology, theriogenology, and other branches or specialties of veterinary medicine.

VETERINARY MEDICINE DEFINED

- The definition of the term "**practice of veterinary medicine**" is very important, because the Board can only discipline a veterinarian for negligence "in the practice of veterinary medicine." For example, if the veterinarian runs a red light and is involved in an accident, and a patient in the vehicle is injured, the veterinarian should not be disciplined for negligence in the practice of veterinary medicine because transporting patients is not included in the definition.
- Some chiropractors are offering "animal chiropractic treatment," but they lack the authority to do so under the law because the definition of the term "practice of chiropractic medicine" in §460.403(9), F.S., is defined by reference to "the human body." However, if a chiropractor treats an animal pursuant to the order and direction of a veterinarian, then the chiropractor may be considered to be acting as a veterinary aide.

EXEMPTIONS

- Faculty Members.
- Interns or Residents.
- Enrolled students under immediate supervision of a licensed veterinarian.
- A DVM employed by a State or Federal Agency.
- Any person, or the regular employee of such person administering to the ills or injuries of her or his own animals.
- Part-time or independent contractors hired by the owner to assist with herd management and animal husbandry tasks, including farriery and manual hand floating of teeth on equines.

EXEMPTIONS

- Board Certified Specialist Veterinarian licensed in another state that responds to the request of a veterinarian licensed in this state to assist with treatment on a specific case or the animals of a single owner.
- An employee, an agent, or a contractor of a public or private animal shelter, humane organization, or animal control agency operated by a humane organization or by a county, a municipality, or another incorporated political subdivision whose work is confined solely to the implantation of a radio frequency identification device microchip for dogs and cats in accordance with s. 823.15.
- A paramedic or an emergency medical technician providing emergency medical care to a police canine injured in the line of duty as authorized under s. 401.254. (2020-119)

EXEMPTIONS – NEW

474.203 Exemptions.—This chapter does not apply to:

(11) A veterinarian who holds an active license to practice veterinary medicine in another jurisdiction in the United States and is in good standing in such jurisdiction and who performs dog or cat sterilization services or routine preventative health services at the time of sterilization as an unpaid volunteer under the responsible supervision, as defined in s. 474.202, of a veterinarian licensed in this state. The supervising licensed veterinarian is responsible for all acts performed under this subsection by an out-of-state veterinarian acting under her or his responsible supervision. An out-of-state veterinarian practicing pursuant to this subsection is not eligible to apply for a premises permit under s. 474.215.

CHAPTER 828, F.S.: ANIMALS: CRUELTY, SALES, ANIMAL ENTERPRISE PROTECTION

- §828.05: Killing an injured or diseased domestic animal. A veterinarian acting in good faith and with due care is immune from civil or criminal liability.
- §828.055: Controlled substances and legend drugs; permits for use– Animal Control Agencies or Humane Societies can obtain a permit for possessing certain drugs.
- §828.12: Cruelty to Animals. A veterinarian is immune from a lawsuit for his or her part in an investigation of cruelty to animals.

CHAPTER 828, FLORIDA STATUTES

- §828.29 Dogs and cats transported or offered for sale; health requirements; consumer guarantee.– Official Certificates of Veterinary Inspection.
- Very important that these OCVI's be properly completed. If you do not administer a specific vaccination for a medical reason, "not in the best medical interest" or something similar should be noted.

§705.19, F.S. ABANDONMENT OF ANIMALS BY OWNER; PROCEDURE FOR HANDLING.—

(1) Any animal placed in the custody of a licensed veterinarian or bona fide boarding kennel for treatment, boarding, or other care, which shall be abandoned by its owner or the owner's agent for a period of more than 10 days after written notice is given to the owner or the owner's agent at her or his last known address may be turned over to the custody of the nearest humane society or dog pound in the area for disposal as such custodian may deem proper.

(2) The giving of notice to the owner, or the agent of the owner, of such animal by the licensed veterinarian or kennel operator as provided in subsection (1) shall relieve the veterinarian or kennel operator and any custodian to whom such animal may be given of any further liability for disposal. Such procedure by a licensed veterinarian shall not constitute grounds for disciplinary procedure under chapter 474.

(3) For the purpose of this section, the term "abandonment" means to forsake entirely or to neglect or refuse to provide or perform the legal obligations for care and support of an animal by its owner or the owner's agent. Such abandonment shall constitute the relinquishment of all rights and claim by the owner to such animal.

§713.655, F.S. LIENS FOR PROFESSIONAL SERVICES OF VETERINARIANS.—

In favor of any veterinarian who renders professional services to an animal at the request of the owner of the animal, the owner's agent, or a bailee, lessee, or custodian of the animal, for the unpaid portion of the fees for such professional services, upon the animal to which such services were rendered. Such lien shall remain valid and enforceable for a period of 1 year from the date the professional services were rendered, and such lien is to be enforced in the manner provided for the enforcement of other liens on personal property in this state.

CHAPTER 120, FLORIDA STATUTES (APA)

- Defines what a rule is.
- Provides requirements for promulgation of rules including notices, opportunities to provide comment or objections, and applicable timelines.
- Provides a definition of "invalid exercise of delegated legislative authority," which means the various grounds a rule can be challenged, including that the rule exceeds the authority of the Board; enlarges modifies or contravenes the law implemented; or is vague, arbitrary or capricious.

§286.011, F.S. GOVERNMENT IN THE SUNSHINE LAW

- All meetings of any board or commission at which official acts are to be taken are open to the public at all times and no formal action shall be valid unless taken at such a meeting.
- The board must provide reasonable notice of all such meetings.
- The minutes shall be promptly recorded and shall be open for public inspection.

CH. 119. F.S. PUBLIC RECORDS LAW

"Public records" means all documents, papers, letters, maps, books, tapes, photographs, films, sound recordings, data processing software, or other material, regardless of the physical form, characteristics, or means of transmission, made or received pursuant to law or ordinance or in connection with the transaction of official business by any agency.

It is the policy of this state that all state, county, and municipal records are open for personal inspection and copying by any person. Providing access to public records is a duty of each agency.

THE BOARD OF VETERINARY MEDICINE

Section 3

BOARD OF VETERINARY MEDICINE

Consists of 7 members:

- Five Licensed Veterinarians
- Two Consumer Members

Serve 4-year terms.

No member may serve for more than the remaining portion of a previous member's unexpired term, plus two consecutive 4-year terms.

Appointed by the Governor of Florida, subject to confirmation by the Senate.

THE BOARD OF VETERINARY MEDICINE

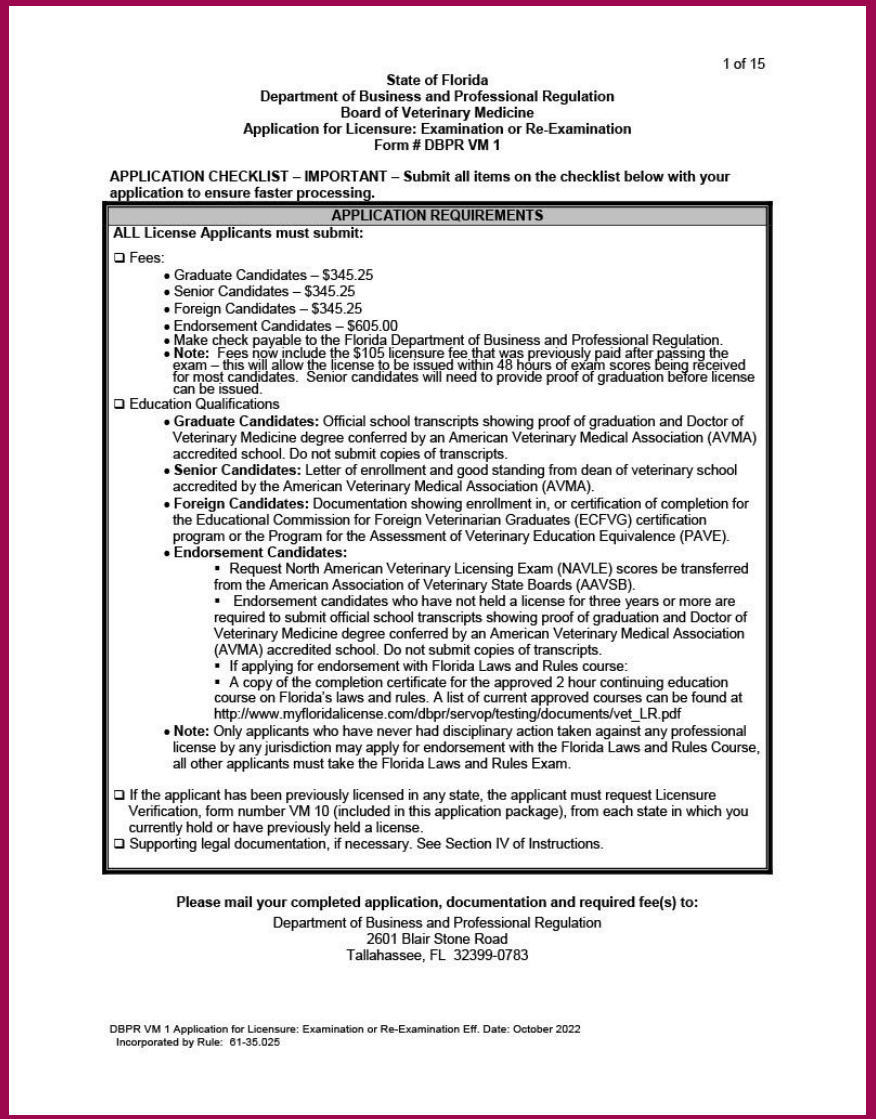
- The Board meets approximately four times a year for one day, plus teleconferences, as necessary.
- The Board of Veterinary Medicine members work with the Department of Business and Professional Regulation in meeting its mission to, "License Efficiently. Regulate Fairly."
- The Board's headquarters are located in Tallahassee, FL.
- Website: http://www.myfloridalicense.com/DBPR/veterinary-medicine/

LICENSURE AND CONTINUING EDUCATION

Section 4

LICENSURE

- License Categories:
  - Veterinarian
  - Limited-Service Permit
  - Premises Permit
- Methods of Licensure:
  - By Examination – Yes
  - By Endorsement – Yes
  - By Reciprocity – No



State of Florida
Department of Business and Professional Regulation
Board of Veterinary Medicine
Application for Licensure: Examination or Re-Examination
Form # DBPR VM 1

APPLICATION CHECKLIST – IMPORTANT – Submit all items on the checklist below with your application to ensure faster processing.

APPLICATION REQUIREMENTS

ALL License Applicants must submit:

❑ Fees:
- Graduate Candidates – $345.25
- Senior Candidates – $345.25
- Foreign Candidates – $345.25
- Endorsement Candidates – $605.00
- Make check payable to the Florida Department of Business and Professional Regulation.
- **Note:** Fees now include the $105 licensure fee that was previously paid after passing the exam – this will allow the license to be issued within 48 hours of exam scores being received for most candidates. Senior candidates will need to provide proof of graduation before license can be issued.

❑ Education Qualifications
- **Graduate Candidates:** Official school transcripts showing proof of graduation and Doctor of Veterinary Medicine degree conferred by an American Veterinary Medical Association (AVMA) accredited school. Do not submit copies of transcripts.
- **Senior Candidates:** Letter of enrollment and good standing from dean of veterinary school accredited by the American Veterinary Medical Association (AVMA).
- **Foreign Candidates:** Documentation showing enrollment in, or certification of completion for the Educational Commission for Foreign Veterinarian Graduates (ECFVG) certification program or the Program for the Assessment of Veterinary Education Equivalence (PAVE).
- **Endorsement Candidates:**
  - Request North American Veterinary Licensing Exam (NAVLE) scores be transferred from the American Association of Veterinary State Boards (AAVSB).
  - Endorsement candidates who have not held a license for three years or more are required to submit official school transcripts showing proof of graduation and Doctor of Veterinary Medicine degree conferred by an American Veterinary Medical Association (AVMA) accredited school. Do not submit copies of transcripts.
  - If applying for endorsement with Florida Laws and Rules course:
  - A copy of the completion certificate for the approved 2 hour continuing education course on Florida's laws and rules. A list of current approved courses can be found at http://www.myfloridalicense.com/dbpr/servop/testing/documents/vet_LR.pdf
- **Note:** Only applicants who have never had disciplinary action taken against any professional license by any jurisdiction may apply for endorsement with the Florida Laws and Rules Course, all other applicants must take the Florida Laws and Rules Exam.

❑ If the applicant has been previously licensed in any state, the applicant must request Licensure Verification, form number VM 10 (included in this application package), from each state in which you currently hold or have previously held a license.
❑ Supporting legal documentation, if necessary. See Section IV of Instructions.

Please mail your completed application, documentation and required fee(s) to:
Department of Business and Professional Regulation
2601 Blair Stone Road
Tallahassee, FL 32399-0783

LICENSURE BY EXAMINATION

- Graduated from a college of veterinary medicine accredited by the AVMA Council on Education.
- Graduated from a college of veterinary medicine listed in the AVMA Roster of Veterinary Colleges of the World and obtained a ECFVG certificate.
- An unlicensed doctor that has completed all parts of the examination and is waiting for the results can practice under the immediate supervision of a licensed veterinarian.

LICENSURE BY ENDORSEMENT

474.217 Licensure by endorsement.—

(1) The department shall issue a license by endorsement to any applicant who, upon applying to the department and remitting a fee set by the board, demonstrates to the board that she or he:

(a) Has demonstrated, in a manner designated by rule of the board, knowledge of the laws and rules governing the practice of veterinary medicine in this state; and

(b) 1. Holds, and has held for the 3 years immediately preceding the application for licensure, a valid, active license to practice veterinary medicine in another state of the United States, the District of Columbia, or a territory of the United States, provided that the applicant has successfully completed a state, regional, national, or other examination that is equivalent to or more stringent than the examination required by the board; or

2. Meets the qualifications of s. 474.207(2)(b) and has successfully completed a state, regional, national, or other examination which is equivalent to or more stringent than the examination given by the department and has passed the board's clinical competency examination or another clinical competency examination specified by rule of the board.

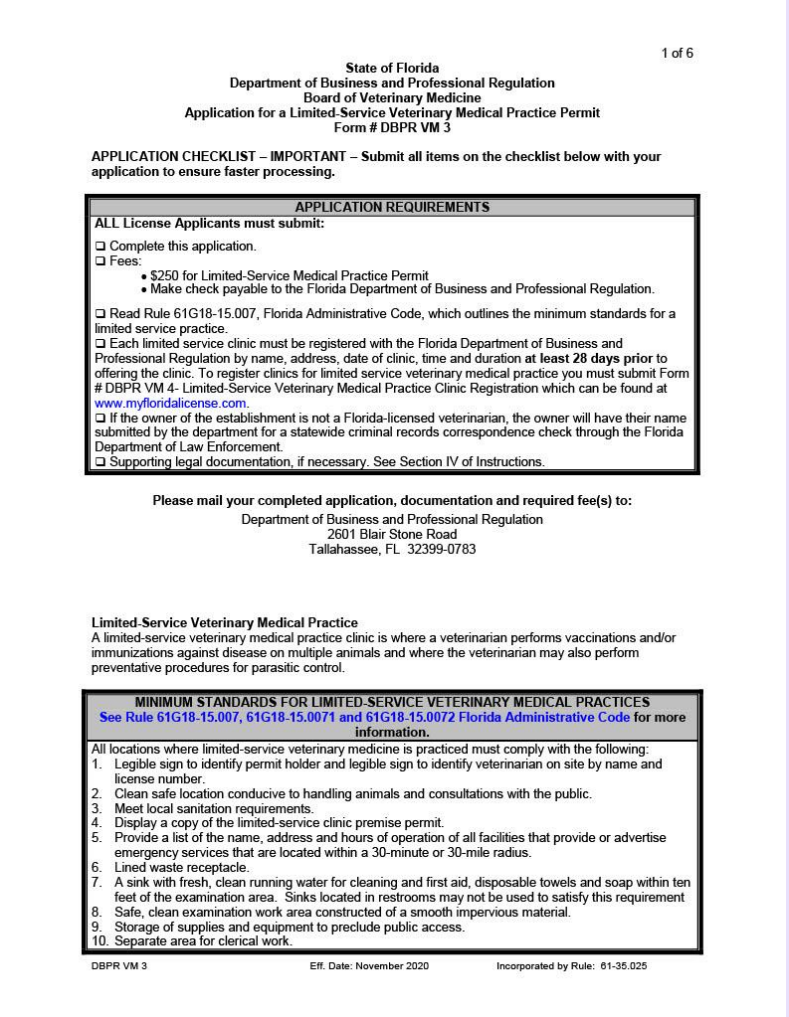
(2) The department shall not issue a license by endorsement to any applicant who is under investigation in any state, territory, or the District of Columbia for an act which would constitute a violation of this chapter until the investigation is complete and disciplinary proceedings have been terminated, at which time the provisions of s. 474.214 shall apply.

PERMITS & REQUIREMENTS

Section 5

LIMITED-SERVICE PERMIT:

- Veterinarians offering limited-service clinics perform vaccinations and/or immunizations against disease on multiple animals, and veterinarians may also perform preventative procedures for parasitic control. Limited-service clinics cannot be held more than once every two weeks and no more than four hours in any one day at any single location.



1 of 6

State of Florida
Department of Business and Professional Regulation
Board of Veterinary Medicine
Application for a Limited-Service Veterinary Medical Practice Permit
Form # DBPR VM 3

APPLICATION CHECKLIST – IMPORTANT – Submit all items on the checklist below with your application to ensure faster processing.

APPLICATION REQUIREMENTS

ALL License Applicants must submit:

❑ Complete this application.
❑ Fees:
- $250 for Limited-Service Medical Practice Permit
- Make check payable to the Florida Department of Business and Professional Regulation.

❑ Read Rule 61G18-15.007, Florida Administrative Code, which outlines the minimum standards for a limited service practice.
❑ Each limited service clinic must be registered with the Florida Department of Business and Professional Regulation by name, address, date of clinic, time and duration **at least 28 days prior** to offering the clinic. To register clinics for limited service veterinary medical practice you must submit Form # DBPR VM 4- Limited-Service Veterinary Medical Practice Clinic Registration which can be found at www.myfloridalicense.com.
❑ If the owner of the establishment is not a Florida-licensed veterinarian, the owner will have their name submitted by the department for a statewide criminal records correspondence check through the Florida Department of Law Enforcement.
❑ Supporting legal documentation, if necessary. See Section IV of Instructions.

Please mail your completed application, documentation and required fee(s) to:
Department of Business and Professional Regulation
2601 Blair Stone Road
Tallahassee, FL 32399-0783

Limited-Service Veterinary Medical Practice
A limited-service veterinary medical practice clinic is where a veterinarian performs vaccinations and/or immunizations against disease on multiple animals and where the veterinarian may also perform preventative procedures for parasitic control.

MINIMUM STANDARDS FOR LIMITED-SERVICE VETERINARY MEDICAL PRACTICES
See Rule 61G18-15.007, 61G18-15.0071 and 61G18-15.0072 Florida Administrative Code for more information.

All locations where limited-service veterinary medicine is practiced must comply with the following:
1. Legible sign to identify permit holder and legible sign to identify veterinarian on site by name and license number.
2. Clean safe location conducive to handling animals and consultations with the public.
3. Meet local sanitation requirements.
4. Display a copy of the limited-service clinic premise permit.
5. Provide a list of the name, address and hours of operation of all facilities that provide or advertise emergency services that are located within a 30-minute or 30-mile radius.
6. Lined waste receptacle.
7. A sink with fresh, clean running water for cleaning and first aid, disposable towels and soap within ten feet of the examination area. Sinks located in restrooms may not be used to satisfy this requirement
8. Safe, clean examination work area constructed of a smooth impervious material.
9. Storage of supplies and equipment to preclude public access.
10. Separate area for clerical work.

DBPR VM 3 Eff. Date: November 2020 Incorporated by Rule: 61-35.025

LIMITED-SERVICE PERMIT:

- All locations must be registered with the board at least 28 days prior to the offering of the limited-service clinic. A copy of the limited-service permit must be clearly visible at each limited-service clinic.
- A veterinarian must remain on site throughout the duration of a limited-service clinic and must be in charge of all medical decisions made.

(SEMI)RECENT RULE CHANGES (2019)

- 61G18-15.007 Minimum Standards for Limited-Service Veterinary Medical Practices.
- Limited time means no more than once every two (2) weeks and no more than four (4) hours in any one day for any single location. Can go up to eight (8) hours per day up to two (2) days per week if the limited-service clinic is held inside a climate-controlled building which meets al local building and safety codes and the limited-service clinic provider has been operating for no less than five (5) years and has professional liability coverage. If operating for the eight (8) hours, there are additional requirements under 61G18-15.0071 for patient records and 61G18-15.0072 for the written statement that must be provided.

PREMISES PERMIT

- Any establishment, permanent or mobile, where a licensed veterinarian practices must have a premises permit issued by the department. Upon application and payment of a fee not to exceed $250, as set by rule of the board, the department shall cause such establishment to be inspected. A premises permit shall be issued if the establishment meets minimum standards, to be adopted by rule of the board, as to sanitary conditions, recordkeeping, equipment, radiation monitoring, services required, and physical plant.

APPLYING FOR A PERMIT

- All establishments where veterinary medicine is practiced are required to have a permit issued by the Department of Business and Professional Regulation.
- An application for a permit must be filed with the Department at least 14 days before the establishment opens. Before a permit is issued, the establishment must be inspected to ensure it complies with the minimum standards for sanitary conditions and physical plant, as set forth by Board rule.

REINSPECTION:

- If the inspection reveals deficiencies, the establishment may be reinspected prior to issuance of the permit. The decision to reinspect is made by the Department on a case by case basis, but is based on the number and severity of deficiencies documented on the initial inspection report.

RESPONSIBLE VETERINARIAN:

- The applicant must designate a responsible veterinarian in whose name the permit is jointly issued. If a change in the responsible veterinarian occurs, the permittee (not necessarily the responsible veterinarian), has 10 days to notify the Board office in writing of the change and must include the name of the new responsible veterinarian. Not doing so requires the permittee to fill out an entirely new application.
- It shall be the duty of the licensed veterinarian named on the permit to return the permit to the department when the named veterinarian ceases to be responsible for the management of the establishment or notify the Board that the veterinarian is no longer the responsible veterinarian at that location.

61G18-15.002, F.A.C. MINIMUM STANDARDS FOR PREMISES WHERE VETERINARY MEDICINE IS PRACTICED:

- Exterior:
  - 1. Legible sign to identify location.
  - 2. Facility clean and in good repair.
  - 3. Telephone number for emergency veterinary care shall
  - be visible and legible from the exterior.
- If premises where veterinary medicine is practiced have grounds, they must be clean and orderly.

61G18-15.002, F.A.C. MINIMUM STANDARDS FOR PREMISES WHERE VETERINARY MEDICINE IS PRACTICED:

- Interior:
  1. Restroom – clean and orderly.
  2. Office: (a.) Clean and orderly; (b.) License renewal and premise permit displayed.
  3. A telephone must be answered 24 hours a day which one may call for emergency service.
  4. Examination areas: (a.) Clean and orderly; (b.) Lined waste receptacle; (c.) Sink and disposable towels. Sinks located in restrooms may not be used to satisfy this standard; (d.) Examination table constructed of smooth impervious material.

61G18-15.002, F.A.C. MINIMUM STANDARDS FOR PREMISES WHERE VETERINARY MEDICINE IS PRACTICED:

- 5. Pharmacy.
  - Clean and orderly.
  - Blood storage or blood donor available.
  - Existence of accurate controlled substance log and individual patient records.
  - If controlled substances are on premises, a locking, secure cabinet for storage.
  - DEA certificate on premises.
  - Segregated area for the storage of expired drugs.
  - Disposable needles and syringes.
  - All drugs stored in the pharmacy must be properly labeled with drug name, strength, and expiration date.

61G18-15.002, F.A.C. MINIMUM STANDARDS FOR PREMISES WHERE VETERINARY MEDICINE IS PRACTICED:

5. Pharmacy (Continued):
   - If drugs are dispensed to the public the drugs are to be distributed in child-resistant containers unless a specific written request for non-child-resistant containers is made by the animal owner. All containers distributed must be labeled with the name of the drug contained within, the strength and quantity of the drug, the expiration date of the drug, instructions as to the use of the drug, the name and species of the animal for which the drug is intended to be administered, the last name of the animal's owner, and the name, address and telephone number of the veterinarian prescribing the drug.

61G18-15.002, F.A.C. MINIMUM STANDARDS FOR PREMISES WHERE VETERINARY MEDICINE IS PRACTICED:

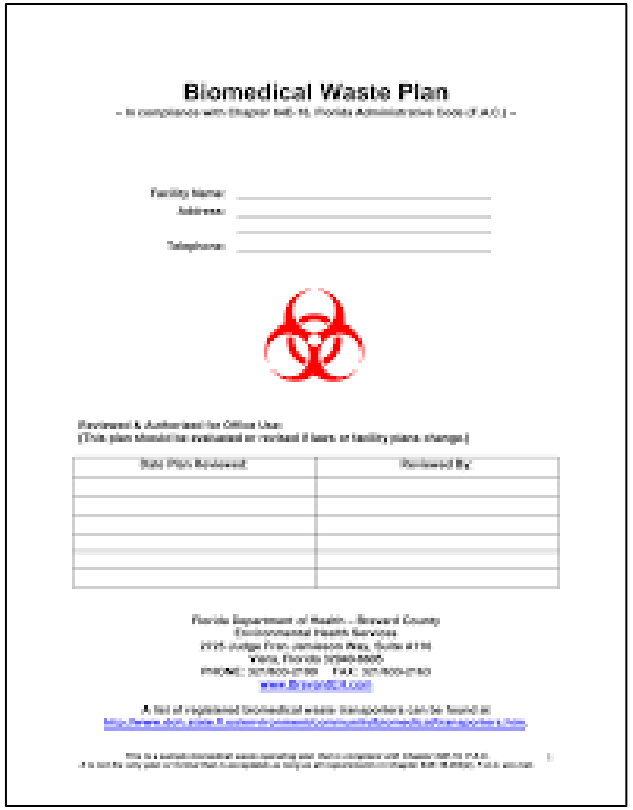
- Medical records as required by Rule 61G18-18.002, F.A.C.
- Laboratory.
  - Microscope.
  - Centrifuge.
  - Urinalysis equipment or outside laboratory services available.
  - Hematology facilities or outside laboratory service available.
  - Blood chemistry facilities or outside laboratory service available.
  - Microbiological capability or outside laboratory service available.

61G18-15.002, F.A.C. MINIMUM STANDARDS FOR PREMISES WHERE VETERINARY MEDICINE IS PRACTICED:

- Facilities and equipment to render immediate resuscitative care.
  - Clean and orderly.
  - Sterile instruments, drapes, caps and masks.
  - Operating table appropriate to the proposed use constructed of smooth impervious material.
  - Oxygen and equipment for its administration.
  - Anesthesia equipment.
- Holding areas shall be capable of sanitation and shall be maintained by including proper ventilation, sufficient lighting and be of a size consistent with the welfare of the animal.

61G18-15.002, F.A.C. MINIMUM STANDARDS FOR PREMISES WHERE VETERINARY MEDICINE IS PRACTICED:

- Garbage and trash disposal.
  - Sanitary cans lined with disposable bags.
  - Effective insect and rodent control.
- Carcass disposal – any adequate method used in area, provided the sanitary code is not violated.
- Emergency lighting which must include at least a functioning rechargeable battery-operated light.
- Fire extinguisher, with current annual inspection.
- Refrigeration of stored drugs, biologicals, lab samples, reagents and other perishable items.
- Comply with the requirements of Rule 64E-16, F.A.C., concerning the handling and disposal of biohazardous waste.



Biomedical Waste Plan

– In compliance with Chapter 64E-16, Florida Administrative Code (F.A.C.) –

Facility Name: _____

Address: _____

Telephone: _____

Reviewed & Authorized for Office Use:
(This plan should be evaluated or revised if laws or facility plans change.)

Date Plan Reviewed	Reviewed By:

Florida Department of Health – Broward County
Environmental Health Services
2727 Judge Fran Jamieson Way, Suite #119
Viera, Florida 32940-6605
PHONE: 321/633-2100 FAX: 321/633-2143
www.BrowardDOH.com

A list of registered biomedical waste transporters can be found at:
http://www.dep.state.fl.us/waste/categories/medical/default.htm

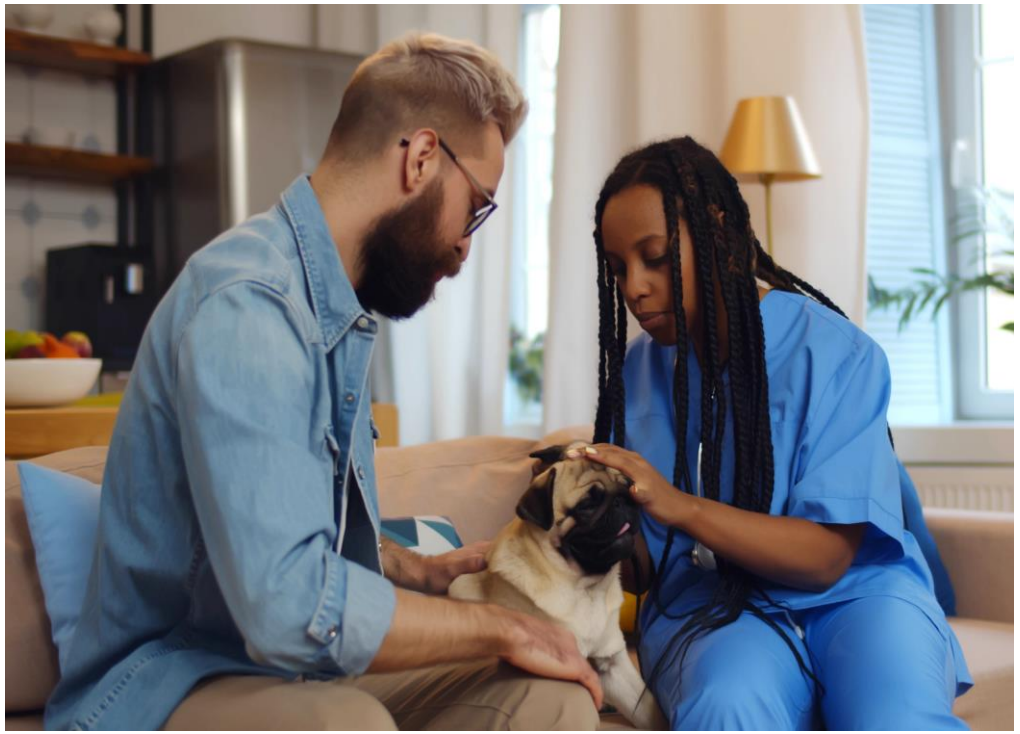
61G18-15.002, F.A.C. MINIMUM STANDARDS FOR PREMISES WHERE VETERINARY MEDICINE IS PRACTICED:

- All premises must have facilities for radiology, surgery and long-term hospitalization, or in lieu thereof, written evidence that arrangements have been made with a local clinic or hospital must be available for inspection. Local is defined as within 30 minutes or 30 miles whichever is greater to provide the service outside the premise.

61G18-15.0035, F.A.C. MINIMUM STANDARDS FOR MOBILE PREMISES PERMITS

- Minimum standards for equipment for mobile premises permits are the same as for other premises where veterinary medicine is practiced, except for the requirements in subsections 61G18-15.002(1) and (2)(a)1., F.A.C.
- Veterinarians must have a written agreement with a local clinic or hospital for the provisions of long-term hospitalization, surgery, or radiology, if these services are not available at the mobile clinic itself.
- Veterinarians must have a written agreement with a local clinic for the provision of emergency services and display a notice to that effect within the mobile unit to so inform clients.
- Veterinarians must furnish a permanent address at which they can be reached to their clients in order that their clients may obtain their veterinary medical records.

61G18-15.006, F.A.C. MINIMUM STANDARDS FOR HOUSE-CALL PRACTICES



- Veterinarians practicing on a house-call basis and who practice where the animal is kept must meet the requirements of Rule 61G18-15.002 or 61G18-15.0035, F.A.C., except that no premises permit is required.

AGRICULTURAL VETERINARY MEDICINE

- Any practitioner who provides veterinary services solely to agricultural animals shall not be required to obtain a premises permit, but must provide for appropriate equipment and facilities, as established by rule. (§474.215(6), F.S.).
- Agricultural veterinary medicine is practiced upon livestock as defined by Section 828.23(3), F.S. “Livestock” means cattle, calves, sheep, swine, horses, mules, goats, ostriches, rheas, emus, and any other domestic animal that can or may be used in the preparation of animal products.

61G18-15.005 PERIODIC INSPECTIONS

- 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.
- 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.

BE READY FOR A FACILITY INSPECTION

- Train your staff on how to handle inspections when you are absent by developing a plan.
- Overwhelm the inspector with kindness!
- Staff should know the location of any important documents, permits, etc. You should have a binder with copies of all licenses, permits, or documents that may be required. If you don't have radiology, surgery, or long-term hospitalization in-house and instead rely on a written arrangement with a local clinic, make sure a copy of that document is in the binder. Make sure that a copy of your biomedical waste handling plan is on the binder.
- Have the senior staff member show the inspector around the premises. If the inspector asks a question that is vague or open to interpretation, it is always acceptable to tell the inspector that staff will write the question down and the veterinarian will respond later.

61G18-17.006 DISEASES WHICH ONLY A VETERINARIAN MAY IMMUNIZE OR TREAT

- For the purpose of implementing the exemption provisions of subsection 474.203(5)(a), F.S., the Board recognizes that the following diseases are communicable to humans and are of public health significance, and that only a veterinarian may immunize or treat an animal for these diseases:
  - (1) Brucellosis.
  - (2) Tuberculosis.
  - (3) Rabies.
  - (4) Equine Encephalomyelitis.

HB 849 (2024) - PROVIDING EQUITY IN TELEHEALTH SERVICES (PETS) ACT,

- The bill defines "Veterinary Telehealth" as the use of synchronous or asynchronous telecommunications technology to provide health care services.
- Authorizes a veterinarian practicing veterinary telehealth to perform an initial patient evaluation to establish a V/C/P/R if the evaluation is conducted using synchronous audiovisual communication (and not audio only, text messaging, questionnaires, chatbots or other similar means).
- The Veterinarian must employ sound professional judgment to determine whether using veterinary telehealth is an appropriate methods for delivering medical advice or treatment to the patient.
- If the evaluation is sufficient to diagnose and treat, the veterinarian is not required to research medical history or conduct a physical examination before using veterinary telehealth to provide veterinary care to the patient.

HB 849 (2024) - PROVIDING EQUITY IN TELEHEALTH SERVICES (PETS) ACT,

- If the initial patient evaluation is performed using veterinary telehealth, must provide the client with a statement containing the veterinarian's name, license number, contact information, and the contact information for at least one physical veterinary clinic in the vicinity and instructions for how to receive follow-up care or assistance in case of technological or equipment failure or an adverse reaction. The veterinarian shall obtain a signed and dated statement indicating the client has received the required information before practicing veterinary telehealth.
- A veterinarian practicing veterinary telehealth may only order, prescribe, or make available veterinary drugs (i.e. not human labeled drugs used off-label). One month for flea and tick control and 14 days of treatment for other animal drugs. Prescriptions may not be renewed without a subsequent in-person examination.
- A veterinarian practicing veterinary telehealth may not order, prescribe or make available human-labeled drugs or compounded antibacterial, antifungal, antiviral, or antiparasitic medication unless the veterinarian has conducted an in-person physical examination of the animal or has made medically appropriate and timely visits to the premises where the animal is kept.
- Must be familiar with available veterinary resources, including emergency clinics near the patient's location and be able to provide the client with a list upon request.
- Cannot use veterinary telehealth to issue travel certificates or veterinary inspection certificates.

CS/HB 303 (2024) RABIES VACCINATIONS

Allows persons acting under the indirect supervision of a veterinarian who are employees, agents, or contractors of a county or municipal animal control authority or Sheriff to administer rabies vaccinations to dogs, cats and ferrets in the custody of the animal control authority or Sheriff that are to be transferred, rescued, fostered, adopted or reclaimed by the owner. **Indirect supervision** means that the supervising veterinarian is required to be available for consultation through telecommunication but not required to be physically present. The veterinarian that supervises the administration of the rabies vaccination can issue the rabies vaccination certificate.

(SEMI)RECENT RULE CHANGES (2020)

- 61G18-16.002 Continuing Education Requirements for Active Status License Renewal.
- (2) Licensed veterinarians shall complete a minimum of thirty (30) hours of continuing professional education in veterinary medicine every biennium…
- (a) No change.
- (b) Not more than fifteen (15) hours shall be non-interactive, correspondence courses. Interactive Distance Education Courses Computer on-line programs that involve on-line, real time, live or delayed participatory questioning or responses are not correspondence courses.
- (c) "Interactive Distance Education Course" means a competency based learning course presented through live, synchronous technology or through prerecorded video coupled with a means for course attendees to ask questions of the instructor(s) and receive responses in a timely manner. Such courses may be presented through video conferencing technologies or interactive computer based applications.

(SEMI)RECENT RULE CHANGES (2020)

- 61G18-16.002 Continuing Education Requirements for Active Status License Renewal.
- (e) A licensed veterinarian shall receive credit for no more than five (5) hours of continuing professional education in business or practice management courses during any biennium period.
- (f) A licensed veterinarian shall receive credit for no more than five (5) hours of continuing professional education in wellness and wellbeing seminars during any biennium period.

(SEMI)RECENT RULE CHANGES (2021)

- 61G18-30.005 Terms of Probation.(1) through (3) No change.
- (3) The licensee's probation may be subject to the following terms and conditions:
- (a) through (h) No change.
- (i) Medical Records Probation: When the violation is related to the failure to keep adequate medical records the Board may impose probation as specified below to monitor and improve the respondent's medical record keeping.
- 1. The probationer shall complete an approved continuing education course on Medical Record Keeping of at least 4 hours within 30 days of the final order. Respondent must submit information on the course to be taken to the Board Office and it must be approved by the Board Chairman or his designee before the respondent takes the course.

(SEMI)RECENT RULE CHANGES (2020)

- 2. As a condition of probation, Respondent shall submit themselves to two (2) unannounced collections of medical records by a Department investigator per year during Respondent's probationary period. During each collection, the Department investigator shall be permitted to select and copy, at the Respondent's expense, the medical records of five (5) patients of the investigator's choosing; said records shall be submitted to the Board office for review and approval by a board member assigned by the Board Chairman. Respondent shall facilitate said inspections in whatever manner required by the Department. Records must include records that were created on or after the date of the final order.
- 3. If the reviewer finds records to be not in compliance with rule 61G18-18.002, F.A.C. a copy of the reviewers report will be provided to the Respondent and the Board and the respondent will be required to appear for an additional probation appearance at the next regularly schedule meeting of the Board. Violations of rule 61G18-18.002, F.A.C. may result in disciplinary action.

RECENT RULE CHANGES (2023)

61G18-12.014 Premises Permit or Mobile Clinic Permit Fee.

Each application for a premises permit or a mobile clinic permit must be accompanied by payment of a fee of $250.00. The fee shall be waived if the premise is owned by a business with a current 501(3)(c) designation form from the Internal Revenue Service.

61G18-12.008 Reactivation Fee.

The fee for reactivation of an inactive status license shall be fifty dollars ($50.00) and the active renewal fee less the inactive renewal fee if paid previously in the renewal cycle.

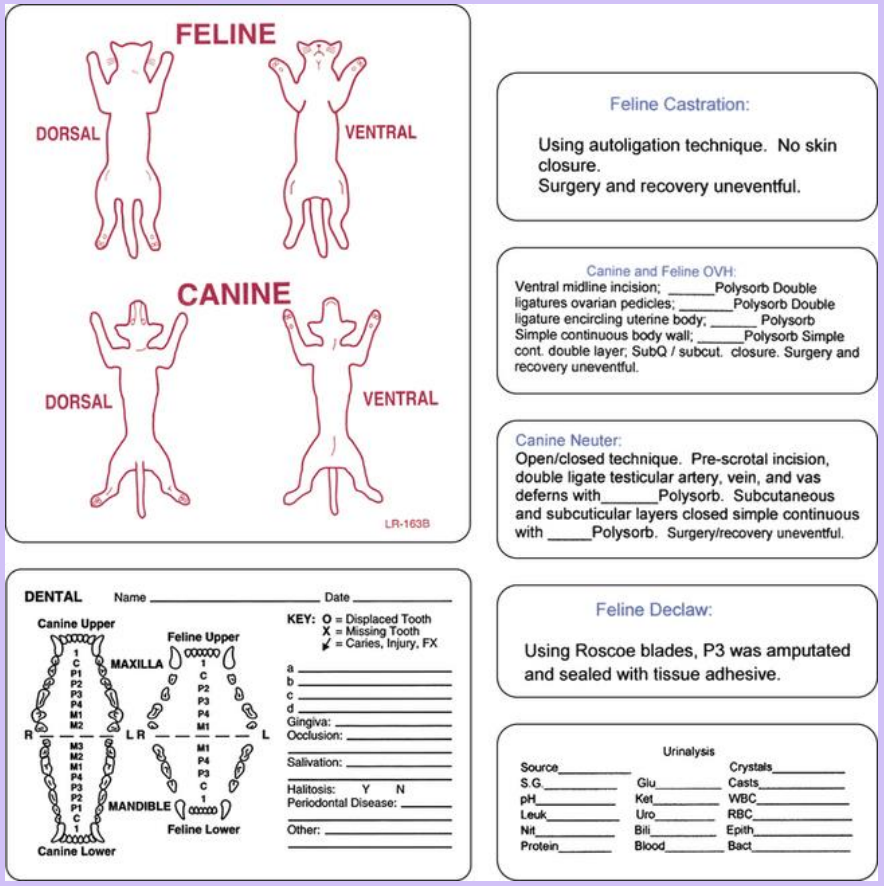
RECORDS

Section 6

RECORD KEEPING

- Inadequate record keeping is the most common cause of disciplinary action against veterinarians. Cases are often seen where veterinarians fail to adequately keep records of patient visits, diagnosis, treatment and other relevant information. You are required by statute to keep these records, and they can be your best defense against complaints made against you.

RECORD KEEPING



- Chapter 61G18-18, Florida Administrative Code, details the proper handling of medical records.

61G18-18.002 MAINTENANCE OF MEDICAL RECORDS:

- There must be an individual medical record maintained on every patient examined or administered to by the veterinarian, except when a veterinarian is providing services to a client owning or leasing 10 or more animals of the same species at a location where the client keeps the animals.
- In that case, only one medical record may be kept for the group of animals. This record must include the species and breed of the animals, and the approximate number of the animals in the group.
- However, when one specific animal is treated, the record must include the identification, diagnosis, and treatment regime of the individual animals examined and treated at each visit to the location, as well as all other information required by this rule.

61G18-18.002 MAINTENANCE OF MEDICAL RECORDS:

- Each record must be maintained for a period of not less than three years after date of last entry. The medical record must contain all clinical information pertaining to the patient with sufficient information to justify the diagnosis or determination of health status and warrant any treatment recommended or administered.

61G18-18.002 MAINTENANCE OF MEDICAL RECORDS:

- Must be created as treatment is provided or within 24 hours from the time of treatment and include:
- Date each service is performed.
- Name of owner or agent
- Patient identification
- Record of any vaccinations administered
- Complaint or reason for provision of services
- History
- Physical examination to include (but not limited to) weight, temperature, pulse and respiration (or note why it was not collected)
- Any present illness or injury noted
- Provisional diagnosis or health status determination

61G18-18.002 MAINTENANCE OF MEDICAL RECORDS:

- In addition, medical records shall contain the following information if these services are provided or occur during the examination or treatment of an animal or animals:
  - Clinical laboratory reports
  - Radiographs and their interpretation
  - Consultation
  - Treatment – medical, surgical
  - Hospitalization
  - Drugs prescribed, administered, or dispensed along with the route, strength, and dosage of the drug and time said drug was administered if not otherwise discernible from the record.
  - Tissue examination report
  - Necropsy findings

CONFIDENTIALITY:

- A veterinarian shall maintain confidentiality of all patient records in his/her possession or under his/her control. All patient records shall not be disclosed without the consent of the client. Appropriate disclosure may be made without such consent:
  - (a) in any civil or criminal action, unless otherwise prohibited by law, upon the issuance of a subpoena from a court of competent jurisdiction and proper notice by the party seeking such records to the client or his/her legal representative;
  - (b) when required by the Board's rules.

STATUTE CHANGE REGARDING CONFIDENTIALITY (2019)

- 474.2165 Ownership and control of veterinary medical patient records; report or copies of records to be furnished.—
- (4) Except as otherwise provided in this section, such records may not be furnished to, and the medical condition of a patient may not be discussed with, any person other than the client or the client's legal representative or other veterinarians involved in the care or treatment of the patient, except upon written authorization of the client. However, such records may be furnished without written authorization under the following circumstances:
- (d) In any criminal action or situation where a veterinarian suspects a criminal violation. If a criminal violation is suspected, a veterinarian may, without notice to or authorization from the client, report the violation to a law enforcement officer, an animal control officer who is certified pursuant to s. 828.27(4)(a), or an agent appointed under s. 828.03. However, if a suspected violation occurs at a commercial food-producing animal operation on land classified as agricultural under s. 193.461, the veterinarian must provide notice to the client or the client's legal representative before reporting the suspected violation to an officer or agent under this paragraph. The report may not include written medical records except upon the issuance of an order from a court of competent jurisdiction.

WHO IS THE CLIENT?

- 474.202(3), F.S. "Client" means the owner or caretaker of an animal who arranges for its veterinary care.
- If there is a question about ultimate ownership, the person that has custody of the animal and arranges (pays) for its veterinary care becomes the "client" and thus entitled to the confidentiality provided by §474.2165, F.S.
- What happens when a person brings an animal with a microchip that is registered to somebody else?

A STICKY WICKET

- A person can bring an animal with a microchip registered to somebody else for several reasons: The person purchased the animal; received it as a gift; found the animal; or stole the animal.
- Discuss with the person that the microchip is registered to somebody else, and that the reason owners microchip animals is to assist in finding them if they are lost. If the person indicates that is the case, then the owner should be contacted.
- If the person tells you they purchased or received the animal as a gift, and you have no reason to believe otherwise, you have no further duty to inquire or contact the person registered to the microchip. You can then establish a VCPR and the person becomes your client.
- If you have seen fliers showing the animal as lost or stolen, then you may have reason to believe otherwise. Do not establish a VCPR (i.e. do not accept any $$ or treat the animal).
- If it so happens that you have a VCPR with the animal and the actual owner, then you should retain the animal and contact the owner.

PET REUNIFICATION STATUTE – 823.151, F.S. (2018)

- 823.151 Lost or stray dogs and cats.—(1) The Legislature finds that natural disasters, such as hurricanes, may result in an increase in owned dogs and cats becoming lost or stray. The Legislature further finds that dog and cat owners statewide should be afforded the opportunity to quickly and reliably claim their lost pets. It is therefore declared to be the public policy of the state that animal control agencies and humane organizations shall adopt policies and procedures to help return lost cats or dogs to identified owners.
- (2)(a) A public or private animal shelter, humane organization, or animal control agency operated by a humane organization or by a county, municipality, or other incorporated political subdivision that takes receivership of any lost or stray dogs or cats shall adopt written policies and procedures to ensure that every reasonable effort is made to quickly and reliably return owned animals to their owners. Such policies and procedures shall include…..

PROVIDING PATIENT RECORDS:

- A veterinarian shall, upon a written request, furnish, in a timely manner without delays for legal reviews, a true and correct copy of all of the patient records to the client, or to anyone designated by the client. Such records release shall not be conditioned upon payment of a fee for services rendered, except for the reasonable cost of duplication.
- What constitutes a reasonable cost of duplication? Not more than $1.00 per page for the first 25 pages, and not more than 25 cents per page for each page in excess of 25 pages.
- What about reproducing x-rays? Actual costs. In other words, the cost of the material and supplies used to duplicate the record, as well as the labor costs and overhead costs associated with such duplication.

PROVIDING PATIENT RECORDS:

- It's important to let staff know that just because a client has not paid their bill, this does not mean that records can be withheld.

RECENT RULE CHANGES (2023)

61G18-18.001 Medical Records of Deceased Veterinarian, Retention, Time Limitations.
(1) No Change.
(2) Within one (1) month from the date of death of the veterinarian, the executor, administrator, personal representative or survivor of the deceased veterinarian shall do one of the following:
(a) Cause to be published in the newspaper of greatest general circulation in the county where the veterinarian resided or practiced, a notice indicating to the owners of the patients of the deceased veterinarian, that the veterinarian's medical records are available to the owners of the patients or their duly constituted representative from a specific person at a certain location. At the conclusion of a twenty-two (22) month period of time from the date of the veterinarian's death, or thereafter, the executor, administrator, personal representative, or survivor shall cause to be published once during each week for four (4) consecutive weeks, in the newspaper of greatest general circulation in the county where the veterinarian resided, a notice indicating to the owners of the patients of the deceased veterinarian that the veterinarian's medical records will be disposed of or destroyed one (1) month or later from the last day of the fourth week of publication of notice.
(b) Send electronic notifications, either mail or text, to all clients that have been seen within the last 3 years a notice indicating to the owners of the patients of the deceased veterinarian, that the veterinarian's medical records are available to the owners of the patients or their duly constituted representative from a specific person at a certain location and that the veterinarian's medical records will be disposed of or destroyed in 2 years.
(c) Maintain the existing practice website for a period of 2 years posting a notice indicating to the owners of the patients of the deceased veterinarian, that the veterinarian's medical records are available to the owners of the patients or their duly constituted representative from a specific person at a certain location and that the veterinarian's medical records will be disposed of or destroyed in 2 years.
~~(3) At the conclusion of a twenty-two (22) month period of time from the date of the veterinarian's death, or thereafter, the executor, administrator, personal representative, or survivor shall cause to be published once during each week for four (4) consecutive weeks, in the newspaper of greatest general circulation in the county where the veterinarian resided, a notice indicating to the owners of the patients of the deceased veterinarian that the veterinarian's medical records will be disposed of or destroyed one (1) month or later from the last day of the fourth week of publication of notice.~~

RECENT RULE CHANGES (2023)

61G18-18.0015 Medical Records; Relocating or Terminating Practice; Retention and Disposition.
(1) No Change.
(2) No later than one month after the veterinarian or entity terminates practice or relocates practice and is no longer available to patients or clients, the veterinarian or entity shall do one of the following;
(a) Cause to be published in the newspaper of greatest general circulation in the county where the veterinarian or entity resided or practiced, a notice indicating to the owners of the patients of said veterinarian or entity that the medical records are available to the owners of the patients or their duly constituted representative from a specific person at a specific location. At the conclusion of a 3 year period of time from the date that the veterinarian or entity terminated practice or relocated practice and was no longer available to patients or clients, the veterinarian or entity shall cause to be published once during each week for 2 consecutive weeks, in the newspaper of greatest general circulation in the county where the veterinarian resided or practiced, a notice indicating to the owners of the patients of the veterinarian or entity that the medical records may be disposed of or destroyed one month or later from the last day of the 4th week of publication of notice. However, nothing herein shall be construed to require that a veterinarian or entity ever destroy the medical records; it permits destruction of records after 3 years and requires notification to clients that the records can be destroyed.
(b) Send electronic notifications, either email or text, to all clients that have been seen within the last 3 years a notice indicating to the owners of the patients of the veterinarian or terminated or relocated practice, that the veterinarian's medical records are available to the owners of the patients or their duly constituted representative from a specific person at a certain location and that the veterinarian's medical records will be disposed of or destroyed in 2 years.
~~(3) At the conclusion of a 3 year period of time from the date that the veterinarian or entity terminated practice or relocated practice and was no longer available to patients or clients, the veterinarian or entity shall cause to be published once during each week for 4 consecutive weeks, in the newspaper of greatest general circulation in the county where the veterinarian resided or practiced, a notice indicating to the owners of the patients of the veterinarian or entity that the medical records may be disposed of or destroyed one month or later from the last day of the 4th week of publication of notice. However, nothing herein shall be construed to require that a veterinarian or entity ever destroy the medical records; it permits destruction of records after 3 years and requires notification to clients that the records can be destroyed.~~

DRUG LOGS

- The board also hears many cases where drugs are not handled properly; i.e., logs are incomplete, expired drugs are not segregated, controlled substances are not secured and drugs are not properly labeled.
- Rule 61G18-15.002(2) provides some of the requirements for the storage and dispensing of drugs.

VETERINARY PRESCRIPTION DRUGS

Section 7

PRESCRIPTION DRUGS ARE REGULATED AT 3 STAGES:

- Laws and Regulations controlling how a practitioner brings drugs into the practice. Drugs must be acquired from duly permitted manufacturers or wholesalers.
- Laws and Regulations controlling how a practitioner keeps drugs in the practice. Security, inventories, removal of expired medications, etc.
- Laws and Regulations controlling how prescription drugs leave the practice. Dispensed only pursuant to a valid VCP, properly labeled, etc.

DISPENSING DRUGS IS PART OF THE PRACTICE OF VETERINARY MEDICINE

"Practice of veterinary medicine" means diagnosing the medical condition of animals and prescribing, dispensing, or administering drugs, medicine, appliances, applications, or treatment of whatever nature for the prevention, cure, or relief of a wound, fracture, bodily injury, or disease thereof; performing any manual procedure for the diagnosis of or treatment for pregnancy or fertility or infertility of animals; or representing oneself by the use of titles or words, or undertaking, offering, or holding oneself out, as performing any of these functions. The term includes the determination of the health, fitness, or soundness of an animal. §474.202(9), F.S.

A VETERINARIAN IS NOT A PHARMACIST

- Although the definition of the practice of Veterinary Medicine includes dispensing drugs, veterinary prescription drugs can only be used, prescribed or dispensed within the context of a valid veterinarian/client/patient relationship (VCPR).
- A veterinarian *cannot* fill another veterinarian's prescription.
- A veterinarian can be disciplined for "using the privilege of ordering, prescribing, or making available drugs outside of a VCPR. §474.214(1)(y), F.S.
- Any drug leaving your practice should be in "patient specific form."

A VETERINARIAN IS NOT A PHARMACIST

- NPI numbers are used to indicate those that are eligible to prescribe for Medicare/Medicaid patients but since animal patients aren't eligible for Medicare/Medicaid and veterinarians are only legally allowed to prescribe for animal patients, ***veterinarians don't have NPI numbers***.
- In human medicine – QD = Once Daily
- In veterinary medicine – SID = Once Daily
- Dosing between species varies greatly and there isn't a good way for pharmacists to predict what does and doesn't extrapolate from humans or other species, so looking up veterinary doses becomes essential for dose checking.

A VETERINARIAN IS NOT A PHARMACIST

- Veterinary health information systems don't have integrations with a DEA-compliant electronic prescribing system at this point.
- This can lead to confusion when a pharmacist refers to something related to electronic prescriptions and the veterinarian assumes they are referring to typed prescriptions from their own computer system.
- Frequent issue: Pharmacies refusing to fill a prescription without a veterinarian's DEA registration no. Some veterinarians do not have a DEA registration no.

VETERINARY PRESCRIPTION DRUGS

- Veterinary prescription drugs must be properly labeled before being dispensed.
- Appropriate dispensing and treatment records must be maintained, and veterinary prescription drugs should be dispensed only in quantities required for the treatment of the animal(s) for which the drugs are dispensed.

LABELING REQUIREMENTS: RULE 61G18-15.002(2)(a)(5)(i), F.A.C.

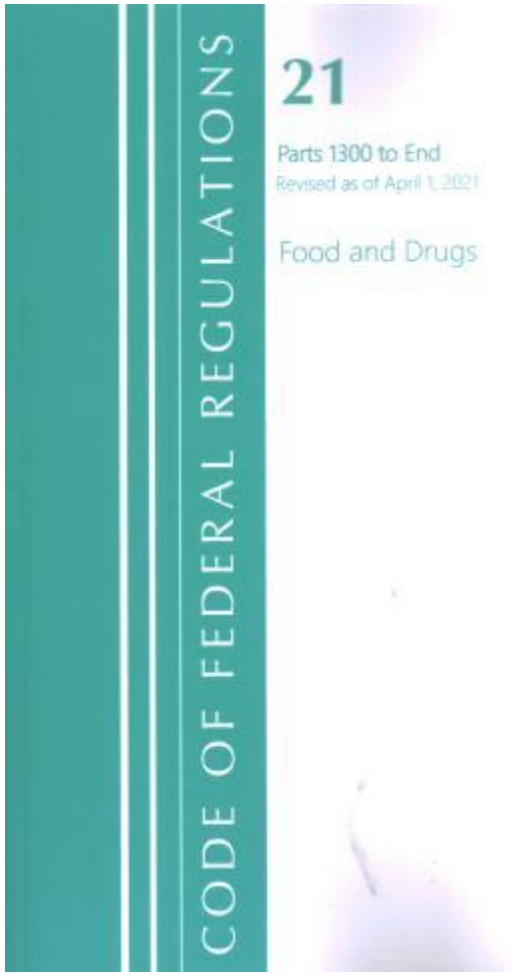
- If drugs are dispensed to the public the drugs are to be distributed in child-resistant containers unless a specific written request for non child-resistant containers is made by the animal owner.
- All containers distributed must be labeled with the **name** of the drug contained within, the **strength and quantity** of the drug, the **expiration date** of the drug, **instructions** as to the use of the drug, the **name and species of the animal** for which the drug is intended to be administered, the **last name of the animal's owner**, and the **name, address and telephone number of the veterinarian** prescribing the drug.

VETERINARIAN/CLIENT/PATIENT RELATIONSHIP

- "Veterinarian/client/patient relationship" means a relationship where the veterinarian has assumed the responsibility for making medical judgments regarding the health of the animal and its need for medical treatment.
- A VCPR exists when all of the following conditions have been meet:
  - The veterinarian has sufficient knowledge of the animal(s) to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s), which means that the veterinarian is personally acquainted with the keeping and caring of the animal and has seen the animal(s) or has made medically appropriate and timely visits to the premises where the animal(s) are kept.
  - The veterinarian is available or provides for follow up care and treatment in case of an adverse reaction or failure of the regimen of therapy.
  - Maintains records which document patient visits, diagnosis, treatment, and other relevant information.
- The documented patient/client/veterinarian relationship cited in Section 474.214, F.S., is defined as a veterinarian's record of a client's animal which documents that the veterinarian has seen the animal in a professional capacity within a period of 12 months or less.

FEDERAL REGULATIONS FOR PRESCRIPTIONS

- 21 CFR Part 1306.03 – Persons Entitled to Issue Prescriptions
  - A prescription for a controlled substance may be issued only by an individual practitioner who is authorized to prescribe controlled substances by the jurisdiction (state) in which he/she is licensed to practice his/her profession.
- A practitioner may not write a prescription to obtain supplies for the veterinary practice or for the purpose of general dispensing to patients.
- A prescription issued by an individual practitioner may be communicated to a pharmacist by an employee or agent of the individual practitioner.



MANNER OF ISSUANCE OF PRESCRIPTIONS

- 21 CFR Part 1306.05 – Manner of Issuance of Prescriptions
- All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the name, address and registration number of the practitioner.
- ***Florida***:
  - If the prescription is for an animal, the full name and address of the owner and the species of the animal.
  - Include numerical and written notation of quantity
  - A notation of the date in numerical month/day/year format or with the abbreviated (or complete) month written.

MANNER OF ISSUANCE OF PRESCRIPTIONS

- Controlled Substances Listed in Schedule II
  - Can NOT be re-filled
  - 21 CFR Part 1306.12: An individual practitioner may issue multiple prescriptions authorizing the patient to receive a total of **up to a 90-day** supply of a Schedule II controlled substance provided the following conditions are met:
    - The prescription is for a clear and legitimate purpose;
    - Written instructions on when to fill dates are included;
    - No perceived risk of diversion/abuse;
    - Permitted by state law (it is permitted in Florida).

ELECTRONIC PRESCRIPTIONS FOR CONTROLLED SUBSTANCES

- Voluntary option.
- Both the practitioner and the pharmacy must be enrolled and approved by the DEA.
- Florida allows this option.
- DEA's CSOS program allows for secure electronic controlled substances orders without the supporting paper DEA Form 222. Using a technology called PKI, CSOS requires that each individual purchaser enroll with DEA to acquire a CSOS digital certificate.
- Apply online at www.deadiversion.usdoj.gov

FEDERAL DRUG LAWS

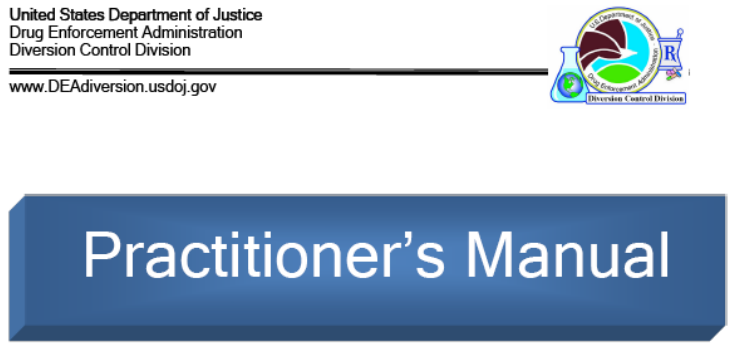
Section 8

FEDERAL LEVEL – WHO REGULATES WHAT?

- EPA regulates Pesticides:
  - ✓Insecticides, Fungicides, Rodenticides
- USDA regulates Biologics:
  - ✓Vaccines, Antisera, Diagnostic Kits, GM Organisms
- FDA regulates Animal Drugs and Devices:
  - ✓Therapeutic and production drugs, DEA-Controlled Drugs, Medical Devices, Genetically-Engineered Animals

DEA REGULATION ROADMAP

- Licensure and renewals
- Ordering
- Storage and security
- Use and dispensing
- Transfer, loss, and theft
- Inventory
- Disposal
- GET A COPY OF THE DEA PRACTITIONER'S MANUAL!
- (Google "DEA Practitioners Manual")


United States Department of Justice
Drug Enforcement Administration
Diversion Control Division
www.DEAdiversion.usdoj.gov

Practitioner's Manual

AN INFORMATIONAL OUTLINE OF THE CONTROLLED SUBSTANCES ACT

Revised 2023[1]

1 This manual replaces all previous editions of the Practitioner's Manual issued by the Drug Enforcement Administration, both hard copy and electronic.

WHAT DO DEA REGULATIONS & ADVANCED CALCULUS HAVE IN COMMON?

Very few people understand either concepts.

Most rules are written for physicians and pharmacies dealing with human patients- not for veterinarians.

DEA REGISTRATION

- In order for Florida licensed veterinarians to be able to prescribe, administer or dispense controlled substances, they must be registered with the U.S. Drug Enforcement Agency (DEA).
- **Registration costs $888 for 3 years.**
- DEA Form-224
- As of May 2022, the DEA now requires all applications for DEA registrations, and renewal of those registrations, to be submitted online.
- *Email Addresses are now required* – Registrants must have a current and active email address listed on their registration in order to receive important information from the DEA, such as registration renewal notices.

DEA REGISTRATION

- The DEA Certificate of Registration (DEA Form 223) must be maintained at the registered location in a readily retrievable manner and kept available for official inspection.
- "A separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, imported, exported or dispensed by a person." C.F.R. 1301.12.
- A veterinarian practicing at more than one location must register each such location.
- The only exception is the practitioner who uses or dispenses controlled substances as an agency of a veterinarian who is registered at each location.

DEA REGISTRATION: RELIEF VETERINARIANS

- You must furnish your DEA registration number to obtain Schedule III, IV, and V controlled substances from suppliers. Veterinarians must use DEA Order Form-222 to obtain Schedule II substances.
- A DEA registration is connected to one principal place of business. Relief veterinarians often work in more than one location and, in many cases, more than one state simultaneously.
- The Veterinary Mobility Act of 2014 (Mobility Act) only focused on veterinary DEA registrants crossing state lines with their own controlled substance inventory to treat their own patients. Therefore, the Mobility Act does not cover standard relief veterinarians who travel to facilities to use that facility's controlled substances to treat their patients.

DEA REGISTRATION: MOBILE CLINICS

- Veterinarians who operate mobile clinics should be registered at the location where the controlled substances are stored.
- Records should be maintained as if the mobile unit were part of the registrant's permanent location.

MOBILE CLINICS

- DEA previously took the position that transporting controlled substances off clinic premises was a violation of the Controlled Substances Act.
- As a result, the Veterinary Medicine Mobility Act of 2014 (amending 21 U.S.C.A. § 822), was enacted. The VMMA revised the Controlled Substance Act.
- Now, a registrant veterinarian shall not be required to have a separate registration in order to transport and dispense controlled substances in the usual course of veterinary practice at a site other than the registrant's registered principal place of business or professional practice, so long as the site of transporting and dispensing is located in a State where the veterinarian is licensed to practice veterinary medicine and is not a principal place of business or professional practice.
- Includes drugs for pain management, anesthesia, and euthanasia.

DEA REGISTRATION MODIFICATION

- Registrations must be renewed every three (3) years.
- Starting June 2020, DEA will no longer send renewal notifications by US Postal Service. Instead, an electronic reminder to renew will be sent at 60, 45, 30, 15, and 5 days prior to the expiration date of the registration to the associated email address. All registrants should ensure that the email address listed on their registration is correct and active.
- Practitioners who wish to modify their Drug Enforcement Administration Registration for a name change or change of address should let their local DEA office know ahead of time, so appropriate registration changes can be made.

DEA REGISTRATION MODIFICATION

- If you are relocating to a new state, the DEA will need a copy of your new state license and a copy of the state-controlled substance registration, if applicable.
- Information concerning the DEA registration process can also be obtained by contacting the Registration Call Center at (800) 882-9539.

DEA IDENTIFICATION OF CONTROLLED SUBSTANCES

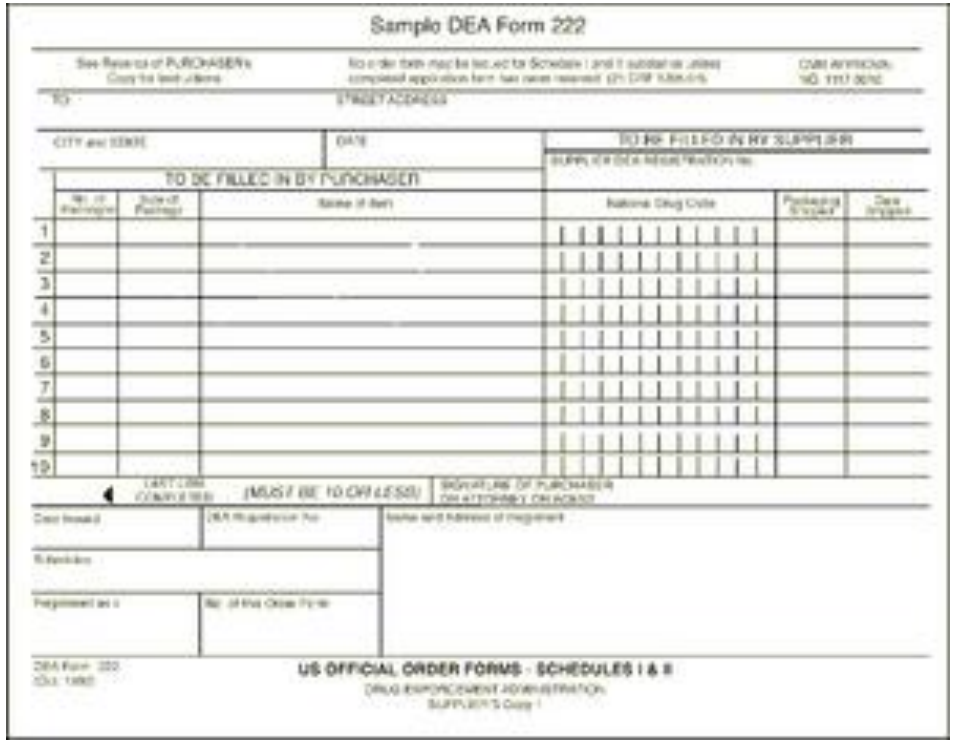
- Controlled substances are labeled with a large "C" and contain a roman numeral in the center to identify the schedule of the substance.
- The drugs and drug products that come under the jurisdiction of the Controlled Substance Act are divided into 5 schedules.

ORDERING CONTROLLED SUBSTANCES

- Due to their potential for addiction, Schedule II drugs get more attention during their manufacturing, distribution, and dispensing.
- To order Schedule II substances, a federal single-sheet order form must be used. These forms replace the old triplicate forms, and can be obtained by requesting them on the initial application form (DEA-224) by checking block "3."
- There will be a two-year transition period (from October 30, 2019) which will allow the existing triplicate version of the form to continue to be used.
- They may also be obtained from the DEA Registration Unit in Washington, D.C. or online at https://www.deadiversion.usdoj.gov.

ORDERING CONTROLLED SUBSTANCES

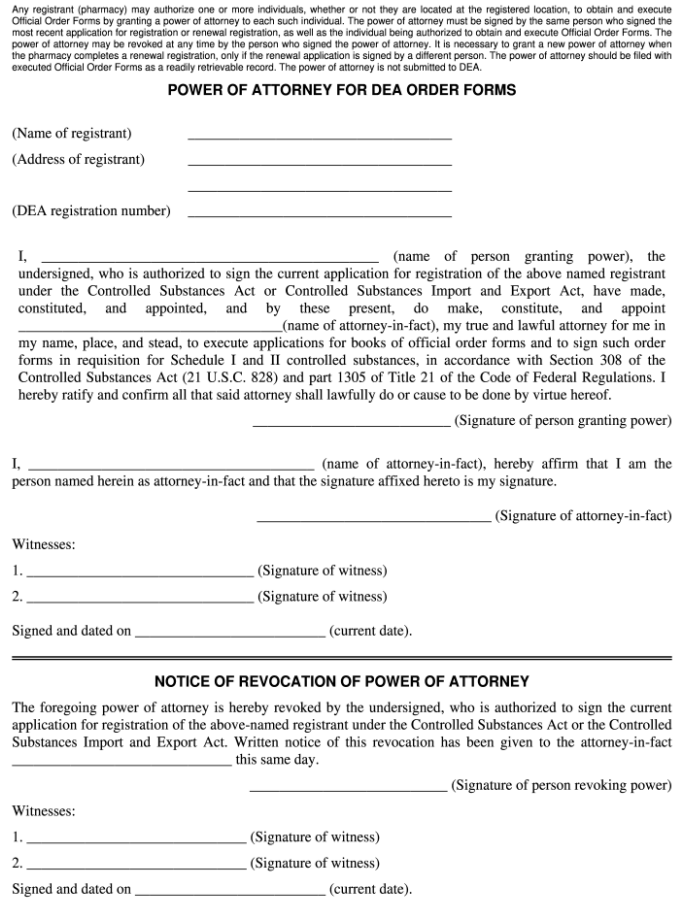
- If using the new DEA single-sheet order Form-222 to obtain CIIs, be sure to:
  - Fill out the correctly or it will be sent back to the supplier.
  - The Purchaser must make a copy of the single sheet DEA Form 222 before submitting the form to their supplier.
- The supplier will receive the order and process as normal.
- Upon receipt of the CII controlled substance, the Purchaser must indicate the date and amount of CII controlled substances received on the copy of the DEA Form 222 and keep the completed copy as a record.
- The supplier will keep the original DEA Form 222 for its own record.


Sample DEA Form 222

US OFFICIAL ORDER FORMS - SCHEDULES I & II

ORDERING CONTROLLED SUBSTANCES

- A Power of Attorney for DEA 222 forms may be granted for ordering and stocking inventory.
- A POA for executing the new DEA-222s may be issued: (1) by the registrant if an individual, (2) by a partner if the registrant is a partnership, or (3) by an officer if the registrant is a corporation, corporate division, association, trust, or other entity, any corporate officer may sign the POA.



Any registrant (pharmacy) may authorize one or more individuals, whether or not they are located at the registered location, to obtain and execute Official Order Forms by granting a power of attorney to each such individual. The power of attorney must be signed by the same person who signed the most recent application for registration or renewal registration, as well as the individual being authorized to obtain and execute Official Order Forms. The power of attorney may be revoked at any time by the person who signed the power of attorney. It is necessary to grant a new power of attorney when the pharmacy completes a renewal registration, only if the renewal application is signed by a different person. The power of attorney should be filed with executed Official Order Forms as a readily retrievable record. The power of attorney is not submitted to DEA.

POWER OF ATTORNEY FOR DEA ORDER FORMS

(Name of registrant) _____

(Address of registrant) _____

_____

(DEA registration number) _____

I, _____ (name of person granting power), the undersigned, who is authorized to sign the current application for registration of the above named registrant under the Controlled Substances Act or Controlled Substances Import and Export Act, have made, constituted, and appointed, and by these present, do make, constitute, and appoint _____(name of attorney-in-fact), my true and lawful attorney for me in my name, place, and stead, to execute applications for books of official order forms and to sign such order forms in requisition for Schedule I and II controlled substances, in accordance with Section 308 of the Controlled Substances Act (21 U.S.C. 828) and part 1305 of Title 21 of the Code of Federal Regulations. I hereby ratify and confirm all that said attorney shall lawfully do or cause to be done by virtue hereof.

_____ (Signature of person granting power)

I, _____ (name of attorney-in-fact), hereby affirm that I am the person named herein as attorney-in-fact and that the signature affixed hereto is my signature.

_____ (Signature of attorney-in-fact)

Witnesses:

1. _____ (Signature of witness)
2. _____ (Signature of witness)

Signed and dated on _____ (current date).

NOTICE OF REVOCATION OF POWER OF ATTORNEY

The foregoing power of attorney is hereby revoked by the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act or the Controlled Substances Import and Export Act. Written notice of this revocation has been given to the attorney-in-fact _____ this same day.

_____ (Signature of person revoking power)

Witnesses:

1. _____ (Signature of witness)
2. _____ (Signature of witness)

Signed and dated on _____ (current date).

ORDERING CONTROLLED SUBSTANCES

- All other controlled substances are ordered in the same manner as any other medication. The supplier will ask for a copy of your current DEA registration form.
- There are no special requirements for Schedule III, IV, and V purchases.
- Obtaining controlled substances from a local pharmacy for "in-house" or "re-sale" use is prohibited, unless the pharmacy also has a Ch. 499 permit.
- Prescriptions for controlled substances to be filled by a local pharmacy should be written only for specific patients.
- For non-controlled drugs, a state license number is the only number legally required. This can create issues with pharmacy computer systems and discount cards that are designed to work best with NPI/DEA numbers.

ORDERING NON-CONTROLLED SUBSTANCES

- **Question**: Should you provide your DEA registration number to a pharmacy or distributor when purchasing or prescribing substances that are not DEA controlled substances?
- **Answer**: NO. While there is no legal basis for the DEA to prevent you from doing so, the DEA strongly opposes the use of your DEA number for anything other than its intended purpose, which is to provide certification of DEA registration in transactions involving controlled substances.

DEA RECORDS AND PRESCRIPTIONS

- Veterinarians must keep records for all controlled substances used or dispensed.
- These must be kept for 3 years by Florida law.
- Records for Schedule III, IV, and V controlled substances can be maintained as part of patient records, by must be readily retrievable.
  - DEA defines Readily Retrievable to mean "the record is kept or maintained in such a manner that it can be separated out from all other records in a reasonable time or that it is identified by an asterisk, redline, or some other identifiable manner such that it is easily distinguishable from all other records."

DEA RECORDS AND PRESCRIPTIONS

- Schedule II records must be kept separately.
- You must maintain records or invoices of controlled substances received for a 2-year period after the last quantity of each controlled substance on the invoice has been depleted.
- According to the DEA: A registered practitioner is required to keep records of controlled substances that are dispensed to the patient, other than by prescribing or administering, in the lawful course of professional practice. A registered practitioner is not required to keep records of controlled substances that are prescribed in the lawful course of professional practice, unless such substances are prescribed in the course of maintenance or detoxification treatment. A registered practitioner is not required to keep records of controlled substances that are administered in the lawful course of professional practice unless the practitioner regularly engages in the dispensing or administering of controlled substances and charges patients, either separately or together with charges for other professional services, for substances so dispensed or administered.

DEA RECORDS AND PRESCRIPTIONS

- Although the DEA does not require registrants to keep records of prescriptions issued, approximately 40% of states require multiple copies of controlled substance prescriptions.
- Prescriptions for Schedule II drugs must be in writing and cannot be refilled. Prescriptions for Schedule III or IV may be issued orally or in writing and can be refilled only up to five times in 6 months.

PURCHASING RECORDS FOR DISPENSERS & RESEARCHERS

- Pursuant to Sec. 21 CFR 1304.22(c), each person registered or authorized to dispense or conduct research with controlled substances must keep "Purchasing" records documenting:
  - Name of controlled substance
  - Size and strength
  - Amount purchased
  - Name, address, registration number of company from which substance was purchased
  - Invoice or shipping document must be annotated with the handwritten date of receipt
  - Initials are encouraged – but not required or mandatory

21 CFR PART 1304.11: INITIAL INVENTORY

- On the date of receipt and stocking of any controlled substance, you must perform an initial inventory of the controlled substances on hand.
- The following information must be documented:
  - Date
  - Documentation of whether the inventory was taken at Opening or Close of business, or if the practice location is open 24 hours a day, the time of the inventory.
  - Drug name
  - Drug strength
  - Dosage form (e.g. 15mg tablet)
  - Number of dosage units in the commercial container (e.g. 50 tablet bottle)
  - Number of commercial containers of each finished form (e.g. ten 50 tablet bottles)
  - Physical measure or count of each controlled substance
    - Exact count or measure for CIIs
    - Estimate for others unless greater than 1,000

21 CFR PART 1304.11: INITIAL INVENTORY

- The initial inventory of Schedule II drugs must be maintained on a separate form and document then the initial inventory of Schedule III—V drugs.
- Do not perform an inventory that combines Schedule II drug counts with drugs in Schedule III—V, and do not include any non-controlled drugs on inventory documents.
- If you begin business with no controlled substances on hand, you must record this as the initial inventory (make a record showing ZERO inventory).

21 CFR PART 1304.11: BIENNIAL INVENTORY

- In addition to an initial inventory, you must make a biennial inventory of all controlled substances on hand.
- The inventory must be made every 2 years from initial registration and opening inventory.
- A separate inventory must be made for each registered location and registration.
- Biennial inventories must always be separate documents that stand-alone and are maintained separately.
- Must include same types of information as the initial inventory.
- No requirement to submit a copy of the biennial inventory to the DEA.

21 CFR PART 1304.11: BIENNIAL INVENTORY

- The following information should be included:
  - Name, address, and registration number of each registrant.
  - Name, unit size, and total quantity of each controlled substance.
  - Date and time of inventory.
  - Signature of person(s) making the inventory
  - Separate records for Schedule II drugs.
  - And new controlled drugs introduced must be put on inventory list with quantity and date.

RECAP OF DEA RECORDKEEPING REQUIREMENTS

- All records listed below must be considered part of your controlled drug records:
  - Blank and Executed 222 Forms
  - CII Invoices (kept separately)
  - CIII-V Invoices
  - Dispensing Records
  - Biennial Inventory
  - Disposal Records
  - Loss or Theft Records

TRANSFER & DISPOSAL OF CONTROLLED SUBSTANCES

DEA: TRANSFERS OF CONTROLLED SUBSTANCES

- You may transfer or receive a limited number of controlled substances to or from another practitioner if you are both DEA registrants. Both registrants must maintain records of the transaction.
- Records of Schedule II controlled substance transfers must be kept on DEA Order Form-222.
- Records of Schedule III, IV, and V controlled substances may be in the form of invoices.
- The total amount transferred by a registrant must not be more that 5% of the total number of dosage units used, dispensed, or prescribed during the same calendar year.

WARNING!!

- Just because you can transfer Controlled Substances by Federal Law does not mean you can do so under State Law. “Wholesale distribution” means distribution of prescription drugs to persons other than a consumer or patient, but does not include:
- The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug for emergency medical reasons. For purposes of this subparagraph, the term “emergency medical reasons” includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage. A drug shortage not caused by a public health emergency does not constitute an emergency medical reason.

FLORIDA: ONE-TIME TRANSFER EXEMPTION

- Exemption from the definition of "Wholesale Distribution" in sec. 499.003(53)(f).
- Provides for one-time transfer of drugs from one pharmacy to the other in case of sale.
- No specific exemption applicable to veterinarians, but the principle is the same.
- Requirements: Detailed inventory and invoice showing drugs being transferred, signed by selling vet and buying vet.

BROKEN OR DAMAGED CONTROLLED SUBSTANCES

- If controlled substance containers are broken or damaged, or controlled substances spilled, the substances are not considered "LOST" because they can be accounted for. When breakage, spillage or damage of controlled substances occur, the affected controlled substances must be disposed of and account for according to DEA requirements.
- If Recoverable: Complete the requirements in 21CFR Part 1304.21, Destruction and Disposal of Controlled Substances (DEA Form 41).
- If Unrecoverable: Document circumstances in inventory records. Two individuals who witnessed must sign the inventory records indicating what they witnessed

EXPIRED CONTROLLED SUBSTANCES

- A practitioner may dispose of out-of-date, damaged, or otherwise unusable or unwanted controlled substances by transferring them to a “reverse distributor” which is an entity registered with DEA and authorized to receive such materials. You use a DEA 222 to transfer Schedule IIs and an invoice for all other Schedules. The practitioner must maintain copies of records documenting the transfer and disposal for 2 years.

SAFETY & LOSS/THEFT REPORTING

SOME PERCENTAGES

- A DEA study found that 37% of inspected veterinary clinics had discrepancies in their controlled substance inventories, highlighting the need for accurate record-keeping and management.
- In a survey of veterinarians, over %60 admitted to having witnessed or heard of drug diversion within their practices.

DEA: SAFETY REQUIREMENTS

- 21 CFR Part 1301.75
- You must keep controlled substances in a securely locked, substantially constructed cabinet or safe.
- If a moveable lock-box is used, it must be securely affixed to a wall, floor, or cabinet.
- Similarly, lightweight filling cabinets or fire safes are inappropriate since they can be easily picked up and removed.
- Excess supplies should remain in a fixed secure location.
- Thiafentanil, carfentanil, etorphine, hydrochloride, and diprenorphine shall be stored in a Class V security container (over 750 pounds).

DEA: SAFETY REQUIREMENTS

- There are no additional security requirements for vehicles other than a substantial container must be used if the vehicle is unsupervised (i.e. in a parking lot or store).
- Mobile units should be stocked with only enough of each controlled drug necessary for basic operation.
- Keeping drugs in a bag is not adequate. If the vehicle is not equipped with locking bins or compartments, then a small lockable box should be affixed to the vehicle.
- It is not necessary to remove the drugs from the vehicle for storage if a strong, non-moveable safe box is available.

DEA: SAFETY REQUIREMENTS

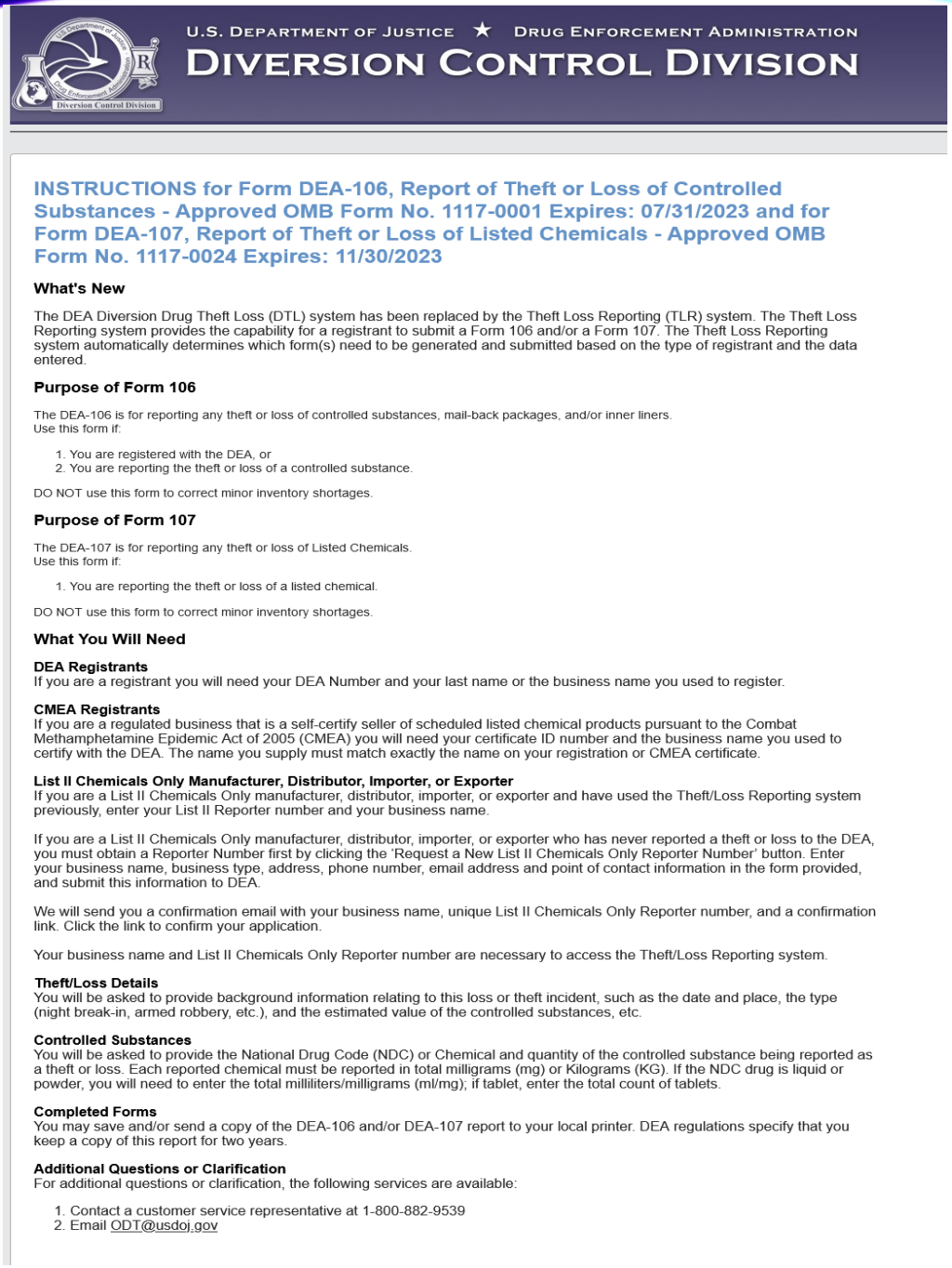
- A good rule of thumb is that a practitioner should only have as many controlled substances in stock as is necessary to practice veterinary medicine (practical minimum).
- If your practice requires a substantial quantity of controlled substances on hand, the DEA recommends more substantial security, such as a larger safe, an alarm system, video surveillance, etc.
- Limit the amount of employees that have access to controlled substances.

DEA: ACCOUNTABILITY OF CONTROLLED SUBSTANCES

- Whenever a practice administers a controlled substance to a patient, it must be recorded both on the patient's medical record AND a "readily retrievable" log or controlled substance record. See §893.07, F.S.- Records
- Entries into the controlled substance records should be completed in a timely manner. See Rule 61G18-18.002, F.A.C.
- You must report thefts or other significant loss of controlled substances or records promptly to the DEA.
- Completing DEA Form-106 is required in such cases. The DEA has created an online system to complete this form at:
  - https://www.deadiversion.usdoj.gov/webforms/dtlLogin.jsp

DEA Form 106

Online Screen Shot



U.S. Department of Justice ★ Drug Enforcement Administration

DIVERSION CONTROL DIVISION

INSTRUCTIONS for Form DEA-106, Report of Theft or Loss of Controlled Substances - Approved OMB Form No. 1117-0001 Expires: 07/31/2023 and for Form DEA-107, Report of Theft or Loss of Listed Chemicals - Approved OMB Form No. 1117-0024 Expires: 11/30/2023

What's New

The DEA Diversion Drug Theft Loss (DTL) system has been replaced by the Theft Loss Reporting (TLR) system. The Theft Loss Reporting system provides the capability for a registrant to submit a Form 106 and/or a Form 107. The Theft Loss Reporting system automatically determines which form(s) need to be generated and submitted based on the type of registrant and the data entered.

Purpose of Form 106

The DEA-106 is for reporting any theft or loss of controlled substances, mail-back packages, and/or inner liners.
Use this form if:

1. You are registered with the DEA, or
2. You are reporting the theft or loss of a controlled substance.

DO NOT use this form to correct minor inventory shortages.

Purpose of Form 107

The DEA-107 is for reporting any theft or loss of Listed Chemicals.
Use this form if:

1. You are reporting the theft or loss of a listed chemical.

DO NOT use this form to correct minor inventory shortages.

What You Will Need

DEA Registrants
If you are a registrant you will need your DEA Number and your last name or the business name you used to register.

CMEA Registrants
If you are a regulated business that is a self-certify seller of scheduled listed chemical products pursuant to the Combat Methamphetamine Epidemic Act of 2005 (CMEA) you will need your certificate ID number and the business name you used to certify with the DEA. The name you supply must match exactly the name on your registration or CMEA certificate.

List II Chemicals Only Manufacturer, Distributor, Importer, or Exporter
If you are a List II Chemicals Only manufacturer, distributor, importer, or exporter and have used the Theft/Loss Reporting system previously, enter your List II Reporter number and your business name.

If you are a List II Chemicals Only manufacturer, distributor, importer, or exporter who has never reported a theft or loss to the DEA, you must obtain a Reporter Number first by clicking the 'Request a New List II Chemicals Only Reporter Number' button. Enter your business name, business type, address, phone number, email address and point of contact information in the form provided, and submit this information to DEA.

We will send you a confirmation email with your business name, unique List II Chemicals Only Reporter number, and a confirmation link. Click the link to confirm your application.

Your business name and List II Chemicals Only Reporter number are necessary to access the Theft/Loss Reporting system.

Theft/Loss Details
You will be asked to provide background information relating to this loss or theft incident, such as the date and place, the type (night break-in, armed robbery, etc.), and the estimated value of the controlled substances, etc.

Controlled Substances
You will be asked to provide the National Drug Code (NDC) or Chemical and quantity of the controlled substance being reported as a theft or loss. Each reported chemical must be reported in total milligrams (mg) or Kilograms (KG). If the NDC drug is liquid or powder, you will need to enter the total milliliters/milligrams (ml/mg); if tablet, enter the total count of tablets.

Completed Forms
You may save and/or send a copy of the DEA-106 and/or DEA-107 report to your local printer. DEA regulations specify that you keep a copy of this report for two years.

Additional Questions or Clarification
For additional questions or clarification, the following services are available:

1. Contact a customer service representative at 1-800-882-9539
2. Email ODT@usdoj.gov

DEA Form 106

- Fillable PDF version available online.

- Submit to your Local Diversion Field Office: https://deadiversion.usdoj.gov/contactDea

DEA FORM **106**

Report of Theft or Loss of Controlled Substances

OMB No. 1117-0001 (Exp. Date 7/31/2023)

U.S. Department of Justice
Drug Enforcement Administration
Diversion Control Division

Type of Report: *(check one box only)* ☐ New Report ☐ Amendment Key *(prior report dated)*: _____

1. DEA Registration Number: _____

Name of Business: _____

Address: _____

City: _____ State: _____ ZIP Code: _____

Point of Contact: _____

Email Address: _____ Phone No.: _____

Date of the Theft or Loss (*or first discovery of theft or loss*): _____ Number of Thefts and Losses in the past 24 months: _____

Principal Business of Registrant: ☐Pharmacy ☐Practitioner ☐Manufacturer ☐Hospital/Clinic ☐Distributor ☐NTP ☐Other (Specify) _____

2. Type of Theft or Loss: -

3. Loss in Transit. *(*Fill out this section only if there was a loss in transit, or hijacking of transport vehicle.)*

Name of Common Carrier: _____

Telephone Number of Common Carrier: _____ Package Tracking Number: _____

Have there been losses in transit from this same carrier in the past? ☐ No ☐ Yes *(If yes, how many, excluding this theft or loss?)*: _____

Was the package received and accepted by the consignee? ☐ No ☐ Yes *(If yes, the consignee is responsible for reporting the theft or loss.)*

If the package was accepted by the consignee, did it appear to be tampered with? ☐ No ☐ Yes

Name of Consignee / Supplier: _____

Enter the Name of Consignee (if reported by the supplier), or the Name of Supplier (if the package was accepted by the consignee).
If the consignee does not have a DEA Registration Number, e.g. if this was a shipment to a patient, or a nursing home emergency kit, enter "Patient" or "Nursing Home Kit."

DEA Registration Number of Consignee / Supplier: _____

Enter the DEA Registration Number of Consignee (if reported by the supplier), or DEA Registration Number of Supplier, (if the package was accepted by the consignee). If the controlled substances were shipped to a non-registrant, leave blank, unless a registered pharmacy shipped to an emergency kit held on site at a nursing home. In this case, the supplying pharmacy is required to report the theft or loss.

4. If this was a robbery, were any people injured? ☐ No ☐ Yes *(If yes, how many?)*: _____ Were any people killed? ☐ No ☐ Yes *(If yes, how many?)*: _____

5. What is the total value of the **controlled substances** stolen or lost?: $ _____
(This is the amount you paid for the controlled substances, not the retail value.)

6. Was theft reported to Police? ☐ No ☐ Yes *(If yes, fill out the following information)*:

Name of Police Department: _____ Police Report number: _____

Name of Responding Officer: _____ Phone No.: _____

7. Which corrective measure(s) have you taken to prevent a future theft or loss?

- ☐ Installed monitoring equipment (e.g. video camera).
- ☐ Increased employee monitoring (e.g. random drug tests).
- ☐ Installed metal bars or other security on doors or windows.
- ☐ Secured Controlled Substances within safe.
- ☐ Other (Please describe on last page).
- ☐ Provided security training to staff.
- ☐ Requested increased security patrols by Police.
- ☐ Hired security guards for premises.
- ☐ Terminated employee.

8. Were any pharmaceuticals or merchandise taken? ☐ No ☐ Yes *(Estimated Value)*:

Form DEA-106 Pg. 1

ACCOUNTABILITY OF CONTROLLED SUBSTANCES

- Regarding "significant loss," there is no single objective standard that can be established and applied to all registrants to determine whether a loss is "significant."
- Any unexplained loss or discrepancy should be reviewed within the context of a registrant's business activity and environment.

ACCOUNTABILITY OF CONTROLLED SUBSTANCES

- When determining whether a loss is significant, the registrant should consider the following factors:
  - Determine the actual quantity lost in relation to the type of business.
  - Determine the pattern of such losses, and the results of efforts taken to resolve them, if known.
  - Are specific controlled substances being lost, and do the losses appear to be random?
  - Are the specific controlled substances likely candidates for diversion?
  - Can losses of controlled substances be associated with access to that controlled substance by specific individuals?

WHAT TO EXPECT IF YOU REPORT A THEFT OR LOSS OF CONTROLLED SUBSTANCES

- You should be ready for a visit by DEA agents.
- The DEA will audit every possible aspect of your handling of controlled substances. Invoices; biennial inventories, safety requirements, etc.
- You may end up having to enter into an MOA (Memorandum of Agreement) with DEA that may suspend your ability to handle Schedule II controlled substances; require that you prepare a corrective action plan; require the submission of reports; etc.

DEA: OVERSIGHT OF CONTROLLED SUBSTANCES

- 21 CFR Part 1301.76 - As a DEA Registrant, you shall not employ as an agent or employee (including volunteers) who has access to controlled substances any person who:
  - Has a drug conviction (unless the DEA grants a rule waiver for that person);
  - Has been denied a DEA license;
  - Has had their DEA license revoked;
  - Has been forced to surrender their DEA license.

DEA: OVERSIGHT OF CONTROLLED SUBSTANCES

- Screening procedures: According to the Code of Federal Regulations, it is assumed that the following questions will become a part of an employer's comprehensive employee screening program:
  - Within the past five years, have you been convicted of a felony, or within the past two years, of any misdemeanor or are you presently formally charged with committing a criminal offense?
  - In the past three years, have you ever knowingly used any narcotics, amphetamines or barbiturates, other than those prescribed to you by a physician?
- The DEA recommends that inquiries concerning employees' criminal records be made at the local level (local court and law enforcement agencies) and to the DEA itself.

ADDITIONAL DUE DILIGENCE

- Veterinarians that dispense controlled substances have a duty to prevent diversion of controlled substances. In pharmacy practice the term “red flags” is used to describe suspicious circumstances that may cause a pharmacist to question the legitimacy of a prescription.
- Any circumstance that appears to indicate that the client is getting controlled substances from more than one veterinarian (“doctor-shopping”) is a red flag. Clients that “lose” controlled substances and request a replacement is a red flag.
- Clients should be informed that as part of this due diligence the client may only obtain controlled substances from one veterinarian.
- Clients should also be informed that part of the due diligence may require examining the animal on a more frequent basis. You do not want to authorize continuing refills on an animal that may have died.
- Clients who “lose” controlled substances and request replacement of same should be warned the first time that any additional loses will result in discharge from the practice.

ADDITIONAL DUE DILIGENCE

- Implement a controlled substances management plan.
- Train your staff.
- Conduct regular audits.
- Invest in inventory management technology.

REVIEW: THE DEA AND YOU

- To remain in the DEA's good graces, make sure you are up to date on the laws and rules relating to:
  - Initial licensure
  - Updating/Renewing a license
  - Ordering the various Schedules of Controlled Substances
  - Keeping Inventories of Controlled Substances
  - Controlled Substance Recordkeeping
  - Prescribing
  - Loss or Transfer of Controlled Substances
  - Disposal

ELDU, AMDUCA, & COMPOUNDING

EXTRA-LABEL DRUG USE (ELDU)

- "Extra-label use" is defined as:

Actual use or intended use of a drug in an animal in a manner that is not in accordance with the approved labeling. This includes, but is not limited to, use in species not listed in the labeling, use for indications (disease and other conditions) not listed in the labeling, use at dosage levels, frequencies, or routes of administration other than those stated in the labeling, and deviation from labeled withdrawal time based on these different uses.

EXTRA-LABEL DRUG USE

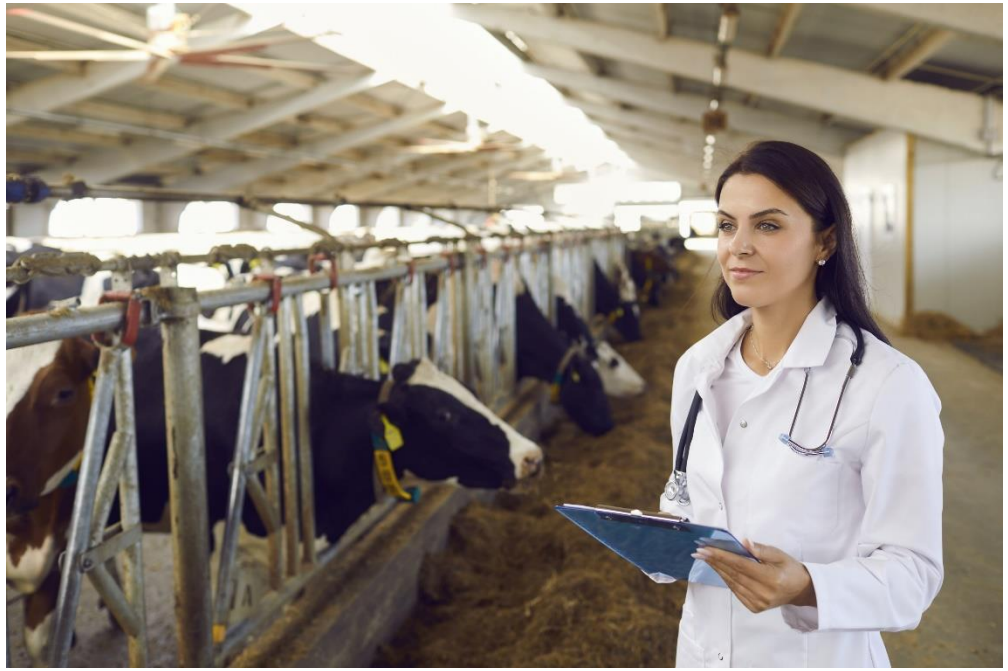
- Under the provisions of the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA), the FDA recognizes the professional judgment of veterinarians, and allows the extra-label use of drugs by veterinarians under certain conditions (21 CFR 530).
- Any drug used in an extra-label manner is by definition a prescription drug since the involvement of a veterinarian is required.
- Extra-label use of drugs may only take place within the scope of a valid veterinarian-client-patient relationship (VCPR)

HUMAN-LABEL DRUG PRODUCTS

- Veterinarians, as licensed health professionals have the right to purchase or prescribe human labeled prescription drugs and to use them according to their best medical judgment in compliance with relevant laws and regulations.
- The FDA has confirmed that manufacturers may legally sell human-labeled prescriptions drugs to veterinarians upon their order.
- Veterinarians have full responsibility when using human-labeled prescription products in the treatment of animals and must recognize that manufacturers cannot promote the sale of those products to veterinarians.
- When human medications are needed for animals, it is important for the veterinarian to know what potential inactive ingredients might be toxic to their patients. If those toxic ingredients are present, they then must determine if the concentrations are high enough for concern.

EXTRA-LABEL DRUG USE

- In the absence of a valid VCPR, if an approved new animal drug is used for a use for which it is not labeled, such use has caused the drug to be deemed unsafe and therefore adulterated under the Act (21 U.S.C. 351(a)(5)).
- The FDA has taken legal action against veterinarians who were responsible for creating violative drug tissue residues in the human food supply, especially when these were the result of drugs used contrary to label instructions.
- Nevertheless, extra-label drugs used in treating food-producing animals may be considered by a veterinarian when the health of animals is immediately threatened and suffering or death would result from failure to treat the affected animals.



WHAT DRUGS ARE CURRENTLY RESTRICTED FROM ELDU?

- FDA may prohibit the extralabel use of an approved new animal or human drug or class of drugs in animals if FDA determines that:
- An acceptable analytical method for residue detection needs to be established and such method has not been established or cannot be established, or
- The extralabel use of the drug or class of drugs presents a risk to public health.
- A prohibition may be a general ban on the extralabel use of the drug or class of drugs or may be limited to a specific species, indication, dosage form, route of administration, or combination of factors.
- The list can be found at 21 C.F.R., Part 530.41.

DRUGS RESTRICTED FROM ELDU IN FOOD PRODUCING ANIMALS

- To date, the following drugs, families of drugs, and substances are prohibited for extralabel animal and human drug uses in food-producing animals (regardless of whether or not the criteria for ELDU are met):
  1. Chloramphenicol;
  2. Clenbuterol;
  3. Diethylstilbestrol (DES);
  4. Dimetridazole;
  5. Ipronidazole;
  6. Other nitroimidazoles;
  7. Furazolidone;
  8. Nitrofurazone;
  9. Sulfonamide drugs in lactating dairy cattle (except approved use of sulfadimethoxine, sulfabromomethazine, and sulfaethoxypyridazine);
  10. Fluoroquinolones;

DRUGS RESTRICTED FROM ELDU IN FOOD PRODUCING ANIMALS

11. Glycopeptides;

12. Phenylbutazone in female dairy cattle 20 months of age or older.

13. Cephalosporin (not including cephapirin) use in cattle, swine, chickens and turkeys:
    (i)For disease prevention purposes;
    (ii) At unapproved dose levels, frequencies, durations or routes of administration; or
    (iii) If the drug is not approved for that species and production class.

The following drugs, or classes of drugs, approved for treating or preventing influenza A in humans, are prohibited from ELDU in chickens, turkeys, and ducks regardless of whether or not ELDU criteria are met:

- Adamantanes;
- Neuraminidase inhibitors.

Extralabel use of drugs in treating food-producing animals for improving rate of weight gain, feed efficiency, or other production purposes is prohibited under AMDUCA.

ELDU FOR COMPANION ANIMALS

- Currently, no approved drugs are prohibited from extra-label use in companion animals.
- You should discuss with the client the use of non-veterinary drugs in the treatment of their animal(s), and your records should so reflect.

LABELING OF DRUGS PRESCRIBED FOR EXTRA-LABEL USE

- The label on a drug dispensed for ELU, whether by a veterinarian or dispensed by a pharmacist on the order of a veterinarian, must have the following information:
  - Name and address of the prescribing veterinarian (and the pharmacy if dispensed this way).
  - Animal identification (individual for companion animals, or group or pen if food animal).
  - Indication (what condition is the drug being used to treat).
  - Number of animals treated (in the case of food animals).
  - Dosage, route, and duration of treatment.
  - Withdrawal intervals.
  - Any cautionary statements (for example: not for use in horses intended for food).

COMPOUNDING UNDER AMDUCA

- The extra-label drug use regulation also provides for the legal compounding of animal drugs from approved animal drugs and approved human drugs. The compounding must be in compliance with the provisions of this regulation. The regulation provides additional requirements for extra-label compounding
- The original extra-label drug use regulation does not allow for legal animal drug compounding from active pharmaceutical ingredients (bulk drugs).

COMPOUNDING

- The Federal Food, Drug, and Cosmetic Act (the Act) does not distinguish compounding from manufacturing or other processing of drugs for use in animals.
- FDA acknowledges the use of compounding within certain areas of veterinary practice.
- The current state of veterinary medicine requires products to treat many conditions in a number of different species, some of which are known to have unique physiological characteristics.
- Furthermore, FDA regulations specifically permit the compounding of products from approved animal or human drugs under the conditions set forth in 21 CFR 530.13.

COMPOUNDING

- The FDA chooses to enforce its "regulatory discretion" and "ordinarily" will not take regulatory action when:
  - A legitimate need is identified.
  - There is a need for an appropriate dosage regimen for the particular species, size, age, or medical condition, and
  - There is no marketed approved animal drug which, when used in conformity with the regulations as set forth in AMDUCA, may treat the condition diagnosed in the available dosage form, or there is some other rare extenuating circumstance.
- The FDA places its highest priority on compounding products for use in food animals.

CAUTION: FLORIDA LAW ALLOWS VETERINARIANS TO DISPENSE COMPOUNDED DRUGS OBTAINED FROM A PHARMACY, BUT…

- The 2015 Florida Legislature passed a bill (HB 1049) that allows veterinarians to dispense compounded drugs.
- HOWEVER…
- The FDA Draft Guidance Document from May 2015 regarding compounding animal drugs from bulk drug substances only allows a veterinarian to sell a compounded drug the veterinarian compounded him/herself.

FDA DRAFT GUIDANCE

- The U.S. Food and Drug Administration withdrew draft Guidance for Industry (GFI) #230, "Compounding Animal Drugs from Bulk Drug Substances."
- In November 2019, the FDA issued the draft GFI #256, "Compounding Animal Drugs from Bulk Drug Substances."
- The draft guidance issued in November 2019 proposed conditions under which the FDA generally would not intend to take action against the compounding of animal drugs from bulk drug substances, with the goal of making such animal drugs available for patient care without jeopardizing the safety of animals and humans or compromising the animal drug approval process.

FDA DRAFT GUIDANCE

- Current law does not permit compounding of animal drugs from bulk drug substances, but the FDA recognizes that there are circumstances where there is no approved drug that can be used or modified through compounding to treat a particular animal with a particular condition. In those limited situations, an animal drug compounded from bulk drug substances may be an appropriate treatment option.

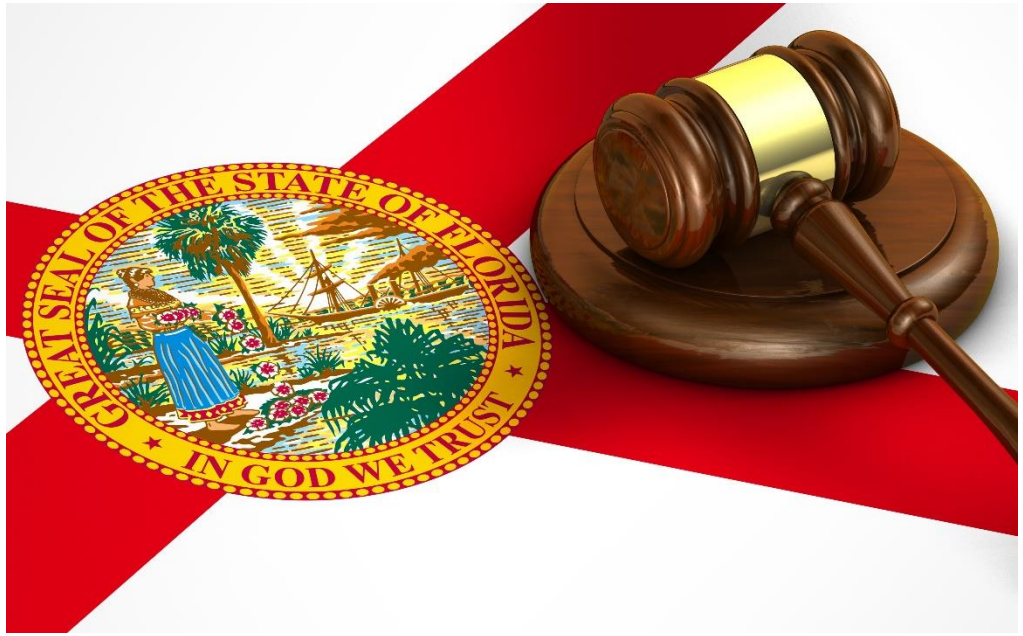
FDA DRAFT GUIDANCE

- FDA does not intend to take enforcement action against the compounding of animal drugs from bulk drug substances for any nonfood-producing animal for certain violations of the FD&C Act.
- FDA does not intend to take enforcement action against the compounding of animal drugs from bulk drug substances as office stock for non-food producing animals for certain violations of the FD&C Act.
- FDA does not intend to take enforcement action against the compounding of drugs from bulk drug substances intended for use as antidotes for treating toxicoses in food-producing animals for certain violations of the FD&C Act.

FLORIDA DRUG LAWS

Section 9

§465.0255, F.S.- EXPIRATION DATE OF MEDICINAL DRUGS; DISPLAY; RELATED USE AND STORAGE INSTRUCTIONS:



- The manufacturer, repackager, or other distributor of any medicinal drug shall display the expiration date of each drug in a readable fashion on the container and on its packaging. The term "readable" means conspicuous and bold.

§465.0255, F.S.- EXPIRATION DATE OF MEDICINAL DRUGS; DISPLAY; RELATED USE AND STORAGE INSTRUCTIONS:

- Each pharmacist for a community pharmacy dispensing medicinal drugs and each practitioner dispensing medicinal drugs on an outpatient basis shall display on the outside of the container of each medicinal drug dispensed, or in other written form delivered to the purchaser:
  - The expiration date when provided by the manufacturer, repackager, or other distributor of the drug; or
  - An earlier beyond-use date for expiration, which may be up to 1 year after the date of dispensing.

FLORIDA RECORDKEEPING: §893.07

- The record of all controlled substances sold, administered, dispensed, or otherwise disposed of shall show:
  - The date of selling, administering, or dispensing.
  - The correct name and address of the person to whom or for whose use, or the owner and species of animal for which, sold, administered, or dispensed.
  - The kind and quantity of controlled substances sold, administered, or dispensed.

FLORIDA RECORDKEEPING: §893.07

- In either case, records shall be kept and made available for a period of at least 2 years for inspection and copying by law enforcement officers whose duty it is to enforce the laws of this state relating to controlled substances.
- Each person shall maintain a record which shall contain a detailed list of controlled substances lost, destroyed, or stolen, if any; the kind and quantity of such controlled substances; and the date of the discovering of such loss, destruction, or theft.

FLORIDA: ACCOUNTABILITY OF CONTROLLED SUBSTANCES

- Section 893.07(5)(b), F.S.
- You must report thefts or other significant loss of controlled substances to the sheriff of that county within 24 hours after discovery.
- A person who fails to report a theft or significant loss of a controlled substance listed in Section 893.07(3), (4), or (5) within 24 hours after discovery commits a misdemeanor of the second degree.
- A person who fails to report a theft or significant loss of a controlled substance listed in Section 893.07(2) within 24 hours after discovery commits a misdemeanor of the first degree.

OTHER CHAPTER 893 PROVISIONS

- §893.04: Pharmacist and practitioner.
- §893.05: Practitioners and persons administering controlled substances in their absence.
- §893.055: Prescription drug monitoring program.
- §893.06: Distribution of controlled substances; order forms; labeling and packaging requirements.
- §893.065: Counterfeit-resistant prescription blanks for controlled substances listed in Schedule II, Schedule III, or Schedule IV. (Not applicable to veterinarians, but highly recommended)

CHAPTER 499, F.S.: DRUGS, DEVICES, COSMETICS, AND HOUSEHOLD PRODUCTS.

- §499.005 Prohibited acts.--It is unlawful for a person to perform or cause the performance of any of the following acts in this state:

  (14) The purchase or receipt of a prescription drug from a person that is not authorized under this chapter to distribute prescription drugs to that purchaser or recipient.

  (15) The sale or transfer of a prescription drug to a person that is not authorized under the law of the jurisdiction in which the person receives the drug to purchase or possess prescription drugs from the person selling or transferring the prescription drug.
- § 499.006 Adulterated drug or device.--A drug or device is adulterated:

  (9) If it is a drug or device for which the expiration date has passed

CHAPTER 499, F.S.: DRUGS, DEVICES, COSMETICS, AND HOUSEHOLD PRODUCTS.

- 499.01 Permits.--

  (1) Prior to operating, a permit is required for each person and establishment that intends to operate as:

  - (a) A prescription drug manufacturer
  - (d) A prescription drug wholesale distributor
  - (f) A retail pharmacy drug wholesale distributor
  - (j) A veterinary prescription drug retail establishment;
  - (k) A veterinary prescription drug wholesale distributor;
  - (l) A limited prescription drug veterinary wholesale distributor;
  - (q) Health care clinic establishment.

HEALTH CARE CLINIC ESTABLISHMENT PERMIT: DO YOU NEED IT?

- Health care clinic establishment permit.—Effective January 1, 2009, a health care clinic establishment permit is required for the purchase of a prescription drug by a place of business at one general physical location that provides health care or veterinary services, which is owned and operated by a business entity that has been issued a federal employer tax identification number. For the purpose of this paragraph, the term "qualifying practitioner" means a licensed health care practitioner defined in s. 456.001, or a veterinarian licensed under chapter 474, who is authorized under the appropriate practice act to prescribe and administer a prescription drug.
- This paragraph does not apply to the purchase of a prescription drug by a licensed practitioner under his or her license.
- Therefore, if a veterinarian purchases prescription drugs under their license, they do not need a HCCE permit. However, if a veterinarian is purchasing prescription drugs under their practice's name, they will need an HCCE permit.

WHAT IS THE LEGAL STATUS OF CBD?

- There are numerous myths about the legality of CBD products and their availability. A section of the 2018 Farm Bill removes hemp-derived products from their current Schedule I status under the Controlled Substances Act, but the legislation does not legalize CBD generally.

LATEST FLORIDA RULES ON CBD

- New hemp rules were recently promulgated by the Florida Department of Agriculture and Consumer Services ("FDACS"). These rules went into effect on January 2, 2020.
- The most important rule is Rule 5E-3, F.A.C., which addresses Hemp extract in pet food, pet treats, specialty pet food, and specialty pet treats.

LATEST FLORIDA RULES ON CBD

- Biggest takeaways from the new CBD rules:
  - Pet food, pet treats, specialty pet food, and specialty pet treats may contain Hemp extract.
  - Veterinarians may sell the above products without obtaining any additional licenses or permits.
  - If veterinarians sell the above products, they must make sure that the labels on the container comply with Section 581.217, Fla. Stat., as well as Rule 5E-3, F.A.C.
  - Veterinarians may sell the above products, as long as the products are not "drugs" as defined in Section 580.031(9), Fla. Stat.

LATEST FLORIDA RULES ON CBD

- Additional label requirements found in 5E-3:
  - If specific cannabinoids are claimed, the number of milligrams of each cannabinoid per serving must be declared on the label. The serving size shall be displayed on the label of the product.
  - Pet food, pet treats, specialty pet food and specialty pet treats consisting of or containing Hemp extract shall be labeled “Not for human consumption.”

FINAL THOUGHTS ON CBD

- Veterinarians that promote the use of CBD/Hemp Products in their practices must be careful to ensure that the labels of the products used do not make medicinal-type claims.
- Just as in the case of "Prescription Diets" the veterinarian can explain that the products "help" in certain conditions and may provide "relief" or "alleviate" certain symptoms, but that they are not medicines and not intended to cure or treat a specific condition.
- Just like aspirin can alleviate arthritic pain but can't cure it.

XYLAZINE

- Xylazine is a sedative and analgesic as well as a muscle relaxant.
- Xylazine HCl Injection is used in horses to produce a state of sedation accompanied by a shorter period of analgesia. A sleeplike state is usually maintained for 1-2 hours, while analgesia lasts from 15-30 minutes.
- At the federal level, xylazine is not on the list of controlled substances. A **2018 Florida law, however, treats xylazine as a Schedule I controlled substance**, since it has no medically approved uses in humans.
- However, the U.S. Food and Drug Administration announced in February 2023 that it was taking action to restrict unlawful importing of the veterinary drug xylazine, which has been "increasingly found" in the nation's illicit drug supply.

FREQUENTLY ASKED QUESTIONS:

- **Do all practitioners in a group practice need to be DEA registered?**
  - No. A veterinarian who is an agent or employee of another DEA registered veterinarian may in the normal course of business or employment, administer or dispense a controlled substance. Keep in mind that the non-registered veterinarian cannot write a prescription, so he/she can only dispense based upon the prescription of the DEA-registered veterinarian.
- **Do we need to see a pet within 12 months to dispense Rx food?**
  - There is no such thing as "Prescription Food." It is a nice marketing tool and helpful to address certain conditions, but none of the prescription diets carry the Federal warning.
- **I am a veterinarian in a multi-vet practice. The prescribing veterinarian is out on vacation. The client has stopped by to request a refill. Can I authorize the refill without having examined the animal?**
  - If you have access to the patient records and can confirm that the animal is on that medication for a legitimately diagnosed condition, you may authorize/prescribe.

FREQUENTLY ASKED QUESTIONS:

- **Another veterinarian has called to let me know that he/she will now be taking care of a patient. They have asked for copies of the patient records. Do I need the client's authorization to send copies of the records?**
  - No. Veterinary records may be furnished to another veterinarian who is involved in the care or treatment of a patient without written authorization of the client.
- **Am I legally obligated to treat a patient even if the client is irate or has verbally threatened the staff? Must an Emergency Clinic see anyone and everyone because they are an emergency clinic?**
  - There are no laws or rules on this issue. Even if you are the only veterinary clinic within a 1-hour radius, if a client becomes belligerent and threatens staff you have the absolute right to fire or discharge a client. You have to do it in a way that does not create an immediate problem with the health/safety of the patient. So, you cannot fire the client when they show up at 3:00AM in an emergency. That would constitute patient abandonment. Instead, you must send the client a certified letter that states that the clinic will be unable to provide any future services (you do not have to give a reason). Offer to provide patient records and give the info regarding the closest emergency clinic.

FREQUENTLY ASKED QUESTIONS:

- **Is there a new Federal Animal Cruelty Law?**
  - Sort of. The Animal Crush Video Prohibition Act was signed into law on December 9, 2010. That law made it a crime to create or distribute videos that depict "nonhuman mammals, birds, reptiles, or amphibians" being "intentionally crushed, burned, drowned, suffocated, impaled, or otherwise subjected to serious bodily injury," provided that such video is "obscene," and provided the creation or distribution is done in or affecting interstate or foreign commerce.
  - However, the 2010 law did not make the underlying crushing, burning, drowning, suffocating, impaling or other animal cruelty a federal crime.
  - On November 25, 2019, the Preventing Animal Torture and Cruelty (PACT) law was enacted. That law now makes the underlying torture in producing the videos a federal crime. The law specifically exempts normal and customary veterinary, agricultural husbandry or other animal management practice, as well as hunting, slaughter of animals for food, pest control, actions necessary to protect the life or property of a person, medical or scientific research, or euthanasia of an animal.

FREQUENTLY ASKED QUESTIONS:

- **Can a pharmacist take a prescription over the phone?**
- **Yes.** "Prescription" includes any order for drugs or medicinal supplies written or transmitted by any means of communication by a duly licensed practitioner authorized by the laws of the state to prescribe such drugs or medicinal supplies and intended to be dispensed by a pharmacist. The term also includes an orally transmitted order by the lawfully designated agent of such practitioner.

COMMON CAUSES FOR DISCIPLINARY ACTION

Section 10

COMMON CAUSES FOR DISCIPLINARY ACTION

- Found in §474.213, F.S. and Rule 61G18-30.001, F.A.C.
- They Include:
  - Inadequate Record Keeping
  - Knowingly employing unlicensed persons in the practice of veterinary medicine.
  - Knowingly operating a veterinary establishment or premises without a valid premise permit.

COMMON CAUSES FOR DISCIPLINARY ACTION

- Having a license or the authority to practice veterinary medicine revoked, suspended, or otherwise acted against, including the denial of licensure, by the licensing authority of any jurisdiction, including any agency or subdivision thereof.
- If you have licenses in another state(s), you must keep in mind that any disciplinary action in the other state(s) may result in disciplinary action against your Florida license, and vice-versa. If you voluntarily relinquish the license in the other state after an investigation was started, that will be deemed to constitute disciplinary action. Also keep in mind that discipline against "the authority to practice" by the licensing authority of any jurisdiction "including any agency or subdivision thereof" will subject your license to discipline. Action by the USDA against your authority to issue health certificates, or action by the pari-mutuel or racing commission against a license or permit at the racetrack may result in discipline.

CRIMINAL OFFENSES

- Being convicted or found guilty, regardless of adjudication, of a crime in any jurisdiction which directly relates to the practice of veterinary medicine or the ability to practice veterinary medicine. Any crime which demonstrates a lack of regard for animal life relates to the ability to practice veterinary medicine. In addition, crimes relating to the ability to practice veterinary medicine shall include, but not be limited to, crimes involving any violation of state or federal drug laws.
- If you are ever accused of a crime, you need to keep in mind the possible adverse consequences to your license. Even if you plead "no contest" and the Judge withholds adjudication of guilt (which means that you will not have a criminal record) the Board can still discipline you "regardless of adjudication." There are other dispositions, such as Pre-Trial Intervention or Drug Court that may allow you to enter a not guilty plea and have the case eventually dismissed if you comply with court ordered conditions, in which case you will not have been convicted or found guilty. Also, and as part of a plea bargain, you may have the chance to enter a plea to a crime that may not be as directly related to the practice as the original crime you were accused of. Your criminal defense attorney should consult with an administrative law attorney to best coordinate your defense.

ADDITIONAL CAUSES FOR DISCIPLINARY ACTION

- Being unable to practice veterinary medicine with reasonable skill and safety to patients by reason of illness, drunkenness, use of drugs, narcotics, chemicals, or any other material or substance or as a result of any mental or physical condition.
- Knowingly maintaining a professional connection or association with any person who is in violation of the provisions of Chapter 474, F.S., or the rules of the Board.
- Paying or receiving kickbacks, rebates, bonuses, or other remuneration for receiving a patient or client or for referring a patient or client to another provider of veterinary services or goods. In construing this section, the Board shall deem that a referral to an entity with which the veterinarian has a contractual relationship, for the sale of non-veterinary, non-medical pet food or pet supplies, does not constitute a kickback, so long as the client is aware of the relationship.
- Performing or prescribing unnecessary or unauthorized treatment.

EVEN MORE CAUSES FOR DISCIPLINARY ACTION

- Engaging in fraud in the collection of fees from consumers or any person, agency, or organization paying fees to practitioners.
- Fraud, deceit, negligence, incompetency, or misconduct in the practice of veterinary medicine.
- Being convicted of a charge of cruelty to animals.
- Being guilty of incompetence or negligence by failing to practice veterinary medicine with that level of care, skill, and treatment which is recognized by a reasonably prudent veterinarian as being acceptable under similar conditions and circumstances.
- Failing to keep the equipment and premises of the business establishment in a clean and sanitary condition or having a premise permit suspended or revoked pursuant to Section 474.215, F.S.

DO NOT REFUSE AN INSPECTION

- Refusing to permit the Department to inspect the business premises of the licensee during regular business hours.
  - This includes the inspection and review of controlled drug logs.
  - Florida DBPR inspectors have the authority to review those logs.
  - Failure to provide controlled drug logs to DBPR inspectors for review constitutes a violation of the veterinary medicine practice act.

ADDITIONAL CAUSES FOR DISCIPLINARY ACTION

- Using the privilege of ordering, prescribing, or making available medicinal drugs or drugs defined in Chapter 465, F.S., or controlled substances as defined in Chapter 893, F.S., for use other than for the specific treatment of animal patients for which there is a documented veterinarian/client/patient relationship.
- Violating any of the requirements of Chapter 499, F.S., the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 seq., the Comprehensive Drug Abuse Prevention and Control Act of 1970, more commonly known as the Federal Drug Abuse Act; or Chapter 893, F.S.

WHAT CAN A VETERINARY TECHNICIAN DO?

- Starting point is the exemption at §474.203(7), F.S.:
- (7) Any veterinary aide, nurse, laboratory technician, preceptor, or other employee of a licensed veterinarian who administers medication or who renders auxiliary or supporting assistance under the responsible supervision of a licensed veterinarian, including those tasks identified by rule of the board requiring immediate supervision. However, the licensed veterinarian is responsible for all such acts performed under this subsection by persons under her or his supervision.
- This exemption is necessary because many of the things veterinary technicians do can be defined as the practice of veterinary medicine.

WHAT CAN A VETERINARY TECHNICIAN DO?

- 61G18-17.005 Tasks Requiring Immediate Supervision.
- All tasks which may be delegated to a veterinary aide, nurse, laboratory technician, intern, or other employee of a licensed veterinarian shall be performed only under the "immediate supervision" of a licensed veterinarian as that phrase is defined in subsection 474.202(5), F.S., with the exception of the following tasks which may be performed without the licensed veterinarian on the premises:
- (a) The administration of medication and treatment, excluding vaccinations, as directed by the licensed veterinarian; and
- (b) The obtaining of samples and the performance of those diagnostic tests, including radiographs, directed by the licensed veterinarian.
- (2) The administration of anesthesia and tranquilization by a veterinary aide, nurse, laboratory technician, intern, or other employee of a licensed veterinarian requires "immediate supervision" as that phrase is defined in subsection 474.202(5), F.S.
- (3) The administration of any vaccination by a veterinary aide, nurse, technician, intern or other employee of a licensed veterinarian which is not specifically prohibited by Rule 61G18-17.006, F.A.C., requires "immediate supervision" as that phrase is defined in subsection 474.202(5), F.S.

WHAT CAN A VETERINARY TECHNICIAN DO?

- 61G18-17.006 Diseases which Only a Veterinarian May Immunize or Treat.
- For the purpose of implementing the exemption provisions of Section 474.203(5)(a), F.S., the Board recognizes that the following diseases are communicable to humans and are of public health significance, and that only a veterinarian may immunize or treat an animal for these diseases:
  - Brucellosis.
  - Tuberculosis.
  - Rabies.
  - Equine Encephalomyelitis.

- Where is the limit? A veterinarian is subject to discipline for:
  - (hh) Delegating professional responsibilities to a person when the licensee delegating such responsibilities knows or has reason to know that such person is not qualified by training, experience, or licensure to perform them.

CAN A VETERINARY TECHNICIAN PERFORM EUTHANASIA?

61G18-16.005 Euthanasia of Dogs and Cats; Technician Certification Course.

(1) Euthanasia shall be performed only by:

(a) A licensed veterinarian; or

(b) An employee or agent of a public or private agency, animal shelter or other facility that is operated for the collection and care of stray, neglected, abandoned or unwanted animals, as provided herein.

(2) Any employee or agent of a public or private agency, animal shelter or other facility that is operated for the collection and care of stray, neglected, abandoned or unwanted animals who performs euthanasia shall successfully complete a 16-hour euthanasia technician certification course. Any employee or agent who before October 1, 1993, has performed euthanasia shall obtain certification by October 1, 1994. Any employee or agent who after October 1, 1993, begins performing euthanasia must have successfully completed the euthanasia technician certification course before performing any euthanasia.

CRIMINAL SELF-REPORTING

- §455.213 General licensing provisions.--
  - During the 2009 Legislative Session, the Florida Legislature passed House Bill 425, which became law on October 1, 2009. Beginning October 1, 2009, House Bill 425 requires all professional licensees to report to the department within 30 days of being convicted or found guilty of, or having plead nolo contendere or guilty to a crime in any jurisdiction. A licensee who fails to report that information may be subject to disciplinary action, including fines, suspension or license revocation.
  - DBPR has an online criminal self report document that can be found on the Board's website

WHAT CAN THE BOARD DO TO YOU FOR A VIOLATION?

- Range of Penalties:
  - Denial of an application for licensure.
  - Revocation or suspension of a license.
  - Imposition of an administrative fine not to exceed $5,000 for each count or separate offense.
  - Issuance of a reprimand.
  - Placement of the licensee on probation for a period of time and subject to such conditions as the board may specify.
  - Restriction of the authorized scope of practice by the licensee.
- Also: Aggravating and Mitigating Circumstances

PROSECUTORS CAN BE CREATIVE

- The Department's Prosecutor can charge you with a Chapter 474 violation only applicable to Veterinarians, a Chapter 455 violation applicable to any DBPR licensee, or both.
- The same action can be charged as more than one violation (e.g. making deceptive or fraudulent representations in the practice under §455.227(1)(m); Fraud related to the practice under §474.214(1)(o); exercising influence on the client for financial gain under §455.227(1)(n)….

EMERGENCY SUSPENSION, RESTRICTION, OR LIMITATION OF A LICENSE:

- If the agency finds that immediate serious danger to the public health, safety, or welfare requires emergency suspension, restriction, or limitation of a license, the agency may take such action by any procedure that is fair under the circumstances
- Example of such a situation: Being arrested for a crime pertaining to substance abuse of diversion.

DISCIPLINARY PROCESS

- §455.225, F.S., Disciplinary proceedings:
  - A complaint is legally sufficient if it contains ultimate facts that show that a violation of this chapter, of any of the practice acts relating to the professions regulated by the department, or of any rule adopted by the department or a regulatory board in the department has occurred.
  - The department may investigate an anonymous complaint if the complaint is in writing and is legally sufficient, if the alleged violation of law or rules is substantial, and if the department has reason to believe, after preliminary inquiry, that the violations alleged in the complaint are true.
  - Division of Regulation: enforcement authority for the professional boards and programs.

DUE PROCESS RIGHTS

- Your License is considered a substantial property interest.
- Therefore, it is protected by Due Process rights found in the Constitution.

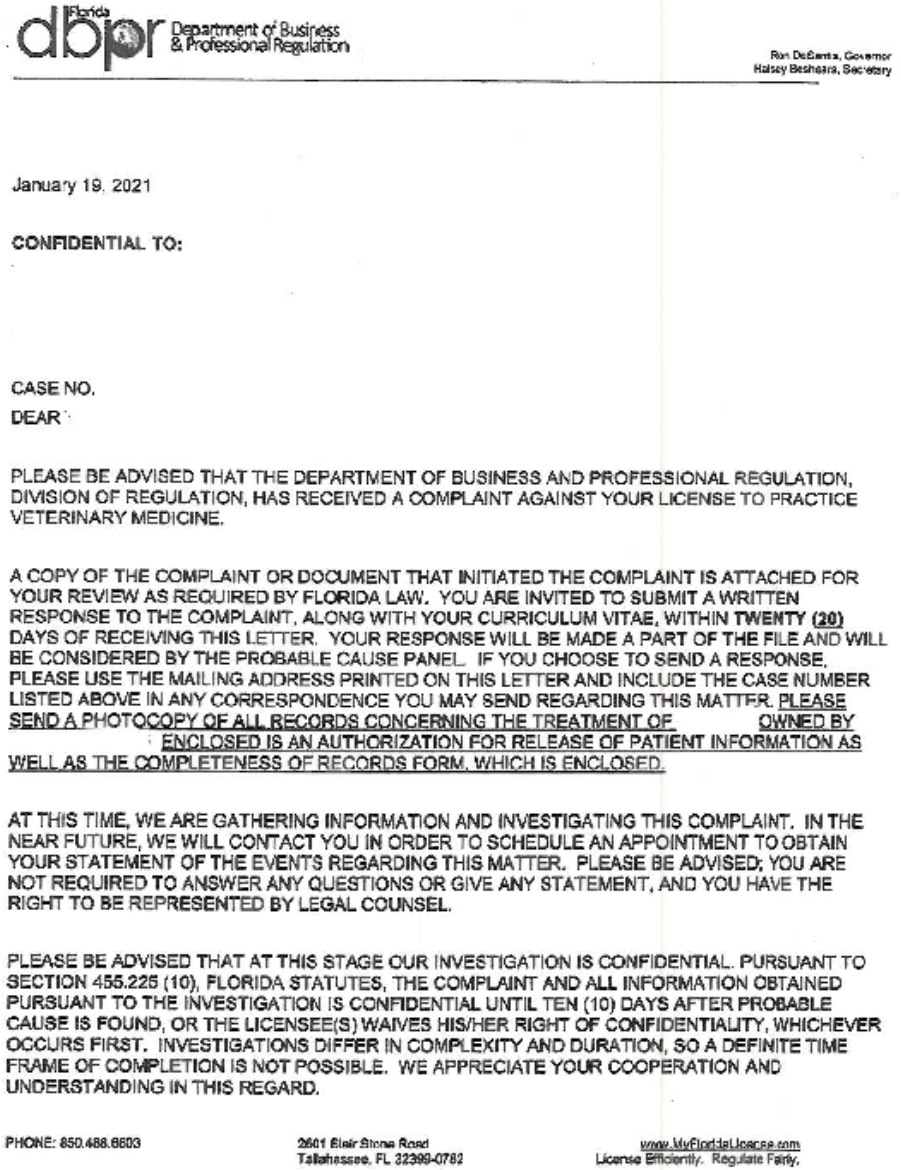
THREE DIFFERENT LEGAL SYSTEMS

- Civil. Burden of proof is a "preponderance of the evidence." This means more likely than not, which can be roughly anything over 51%.
- Criminal. Burden of proof is "beyond a reasonable doubt." Roughly 90%.
- Administrative Disciplinary Proceeding. The law considers these proceedings as "penal" in nature. The burden of proof is "clear and convincing" evidence. Roughly 75%.

ADMINISTRATIVE DISCIPLINARY PROCEEDINGS

- Because it is a "penal" proceeding, the law recognizes that a licensee has many (but not all) of the rights of a criminal defendant, such as the right to remain silent, the right to confront witnesses, and the right to review any evidence against you.

NOTICE OF INVESTIGATION



Florida dbpr Department of Business & Professional Regulation

Ron DeSantis, Governor
Halsey Beshears, Secretary

January 19, 2021

CONFIDENTIAL TO:

CASE NO.

DEAR

PLEASE BE ADVISED THAT THE DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION, DIVISION OF REGULATION, HAS RECEIVED A COMPLAINT AGAINST YOUR LICENSE TO PRACTICE VETERINARY MEDICINE.

A COPY OF THE COMPLAINT OR DOCUMENT THAT INITIATED THE COMPLAINT IS ATTACHED FOR YOUR REVIEW AS REQUIRED BY FLORIDA LAW. YOU ARE INVITED TO SUBMIT A WRITTEN RESPONSE TO THE COMPLAINT, ALONG WITH YOUR CURRICULUM VITAE, WITHIN **TWENTY (20)** DAYS OF RECEIVING THIS LETTER. YOUR RESPONSE WILL BE MADE A PART OF THE FILE AND WILL BE CONSIDERED BY THE PROBABLE CAUSE PANEL. IF YOU CHOOSE TO SEND A RESPONSE, PLEASE USE THE MAILING ADDRESS PRINTED ON THIS LETTER AND INCLUDE THE CASE NUMBER LISTED ABOVE IN ANY CORRESPONDENCE YOU MAY SEND REGARDING THIS MATTER. PLEASE SEND A PHOTOCOPY OF ALL RECORDS CONCERNING THE TREATMENT OF OWNED BY ENCLOSED IS AN AUTHORIZATION FOR RELEASE OF PATIENT INFORMATION AS WELL AS THE COMPLETENESS OF RECORDS FORM, WHICH IS ENCLOSED.

AT THIS TIME, WE ARE GATHERING INFORMATION AND INVESTIGATING THIS COMPLAINT. IN THE NEAR FUTURE, WE WILL CONTACT YOU IN ORDER TO SCHEDULE AN APPOINTMENT TO OBTAIN YOUR STATEMENT OF THE EVENTS REGARDING THIS MATTER. PLEASE BE ADVISED; YOU ARE NOT REQUIRED TO ANSWER ANY QUESTIONS OR GIVE ANY STATEMENT, AND YOU HAVE THE RIGHT TO BE REPRESENTED BY LEGAL COUNSEL.

PLEASE BE ADVISED THAT AT THIS STAGE OUR INVESTIGATION IS CONFIDENTIAL. PURSUANT TO SECTION 455.225 (10), FLORIDA STATUTES, THE COMPLAINT AND ALL INFORMATION OBTAINED PURSUANT TO THE INVESTIGATION IS CONFIDENTIAL UNTIL TEN (10) DAYS AFTER PROBABLE CAUSE IS FOUND, OR THE LICENSEE(S) WAIVES HIS/HER RIGHT OF CONFIDENTIALITY, WHICHEVER OCCURS FIRST. INVESTIGATIONS DIFFER IN COMPLEXITY AND DURATION, SO A DEFINITE TIME FRAME OF COMPLETION IS NOT POSSIBLE. WE APPRECIATE YOUR COOPERATION AND UNDERSTANDING IN THIS REGARD.

PHONE: 850.488.6603

2601 Blair Stone Road
Tallahassee, FL 32399-0782

www.MyFloridaLicense.com
License Efficiently. Regulate Fairly.

IF YOU ONLY REMEMBER ONE THING FROM THIS PRESENTATION:

- When an investigation of any subject is undertaken, the department shall promptly furnish to the subject or the subject's attorney a copy of the complaint or document that resulted in the initiation of the investigation.
- The subject may submit a written response to the information contained in such complaint or document within 20 days after service to the subject of the complaint or document. The subject's written response shall be considered by the probable cause panel.

IMPORTANT:

- Biggest Mistakes Veterinarians Make When Receiving a Notice of Disciplinary Action:
  - Not responding at all (i.e. hoping it will go away).
  - Submitting a response without understanding the consequences.
  - Failing to request a copy of the Department's Investigative File.
  - Submitting to an interview with a DBPR investigator.

IMPORTANT:

- Upon completion of the investigation and pursuant to a written request by the subject, the department shall provide the subject an opportunity to inspect the investigative file or, at the subject's expense, forward to the subject a copy of the investigative file. The subject may file a written response to the information contained in the investigative file.
- Such response must be filed within 20 days, unless an extension of time has been granted by the department.

IMPORTANT:

- When its investigation is complete and legally sufficient, the department shall prepare and submit to the probable cause panel of the appropriate regulatory board the investigative report of the department. The report shall contain the investigative findings and the recommendations of the department concerning the existence of probable cause.
- The determination as to whether probable cause exists shall be made by majority vote of a probable cause panel of the board, or by the department, as appropriate.
- All proceedings of the panel and all documents and information obtained during an investigation are confidential only until an investigation ceases to be active. An investigation ceases to be active when the case is dismissed without a finding of probable cause or 10 days after probable cause is found.

IMPORTANT:

- In lieu of a finding of probable cause, the probable cause panel, or the department when there is no board, may issue a letter of guidance to the subject.
- If the probable cause panel finds that probable cause exists, it shall direct the department to file a formal complaint against the licensee.

OTHER PROBABLE CAUSE PANEL OPTIONS:

- Send the case for further expert review.
- Outright dismissal.
- Reconsideration?
  - On very rare instances, it may be possible to bring a case back to the probable cause panel for reconsideration.

WHAT ARE YOUR OPTIONS?

- Formal Hearing before an Administrative Law Judge. Facts in dispute
- Informal Hearing before the Board. You admit the facts and argue the law, or offer mitigating circumstances
- Settlement Stipulation
- Do nothing (Default)

HEARING BEFORE AN ALJ

- § 455.225(5), F.S.: A formal hearing before an administrative law judge from the Division of Administrative Hearings shall be held pursuant to Chapter120, F.S., if there are any disputed issues of material fact the administrative law judge shall issue a recommended order pursuant to Chapter 120. If any party raises an issue of disputed fact during an informal hearing, the hearing shall be terminated and a formal hearing pursuant to Chapter 120 shall be held.

FINAL AGENCY ACTION

- § 455.225(6), F.S.: The appropriate board, with those members of the panel, if any, who reviewed the investigation pursuant to subsection (4) being excused, or the department when there is no board, shall determine and issue the final order in each disciplinary case. Such order shall constitute final agency action. Any consent order or agreed settlement shall be subject to the approval of the department.

RECOMMENDED ORDER

- After a formal hearing, a Recommended Order is prepared by the ALJ and submitted to the Board for Final Action.
- The Recommended Order contains findings of fact, conclusions of law, and a recommended penalty.
- Exceptions to a Recommended Order:
  - The parties can file exceptions to findings of fact or conclusions of law.
  - The Board may reject a finding of fact only after a review of the record and a determination that the finding of fact was not supported by competent and substantial evidence.
  - The Board has more leeway to reject a conclusion of law.

APPEAL

- Any Final Order of the Board may be appealed to the First District Court of Appeal in Tallahassee, or to a Court of Appeal in the District where the respondent resides.

RISK MANAGEMENT TIPS

Definition of Risk Management

- The forecasting and evaluation of civil, administrative, and criminal risks, combined with the identification of procedures to avoid or minimize their impact.

3 TYPES OF RISK:

- Civil: Lawsuits for Negligence, Breach of Contract, etc.
- Criminal: Prosecution for Criminal Offenses, D.U.I., etc.
- Administrative: Prosecution by the DBPR/Board of Veterinary Medicine for violation of a statute or rule.

BIGGEST CIVIL RISKS

- Negligence: Pursuant to §474.214(1)(r), F.S. a veterinarian can be disciplined for "Being guilty of incompetence or negligence by failing to practice medicine with that level of care, skill, and treatment which is recognized by a reasonably prudent veterinarian as being acceptable under similar conditions and circumstances."
- Premises Liability: You have a duty to maintain your premises in a way that would prevent injuries from occurring to patients and clients entering your premises: Floors must be dry, kennels must be secure, hazardous substances must be safely kept, etc.
- Non-Compete Clauses: The time to discuss is before you sign one.

BIGGEST CRIMINAL RISKS

- Controlled Substances: Use or diversion of controlled substances is a known risk for any practitioner that has the legal authority to purchase or store such substances.

- Do not prescribe controlled substances to your own pets!

BIGGEST ADMINISTRATIVE RISKS

- Bad Recordkeeping. Even if you were not negligent, you can be disciplined for bad records. If an offer to perform a medically justified treatment is turned down by the client, note it in the patient records!
- Avoidable complaints. Caused by breakdowns in communication or failure to manage expectations. These can be minimized by using adequate disclosure and informed consent forms, outlining:
  - Services recommended and risks associated.
  - The costs of said services.
  - Locations on the form for the client to sign or initial if a recommended service is refused.
  - Request for consent to use extra-label human drugs.
- Listen to what your clients say!!
- Do not Ignore a Notice from the Government!!

BEST RISK MANAGEMENT TIP

When in doubt talk to your Lawyer!!

END OF PRESENTATION

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