



# Enforcement Inspection Guide FY2025

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## **AUTHORITY TO CONDUCT INSPECTIONS**

### **VETERINARY LICENSING ACT TITLE 4, PROFESSIONS RELATED TO ANIMAL HEALTH CHAPTER 801 OCCUPATIONS CODE - VETERINARIANS**

#### **Sec. 801.164. RISK-BASED INSPECTIONS RELATED TO CONTROLLED SUBSTANCES PRACTICES.**

The board may conduct a risk-based inspection of a veterinarian's practice based on information obtained from the veterinarian or another source concerning the veterinarian's use, handling, prescribing, dispensing, or delivery of controlled substances.

#### **Sec. 801.359. CONTROLLED SUBSTANCES RECORDS.**

(a) The board shall require each veterinarian to maintain a recordkeeping system for controlled substances as required by Chapter 481, Health and Safety Code.

(b) The records are subject to review by a law enforcement agency or board representative.

#### **Sec. 801.353. CONFIDENTIALITY; WAIVER.**

(a) A veterinarian may not violate the confidential relationship between the veterinarian and the veterinarian's client.

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(e) This section does not apply to an inspection or investigation conducted by the board or an agent of the board.

#### **Sec. 801.402. GENERAL GROUNDS FOR LICENSE DENIAL OR DISCIPLINARY ACTION.**

A person is subject to denial of a license or to disciplinary action under Section 801.401 if the person:

(14) refuses to admit a board representative to inspect the person's client and patient records and business premises during regular business hours;

### **TEXAS ADMINISTRATIVE CODE TITLE 22, PART 24 CHAPTER 573**

#### **RULE §573.63 Inspection of Facilities and Records**

Licensees shall admit a representative of the Board, during regular business hours, to inspect equipment and business premises; examine and/or copy client and patient records, drug records, including, but not limited to, invoices, receipts, transfer documents, inventory logs, surgery logs; and all other associated records relating to the practice of veterinary medicine or equine dentistry.

#### **RULE §573.75 Duty to Cooperate with Board**

A licensee shall:

(1) cooperate fully with any Board inspection or investigation; and  
(2) respond within twenty-one (21) days of receipt to requests for information regarding complaints and other requests for information from the Board, except where:

(A) the Board in contacting a licensee imposes a different response date; or

(B) the licensee is unable for good cause to meet the response date and requests a different response date.

## ENFORCEMENT DIVISION - STANDARD OPERATING PROCEDURE

It is the policy of the Texas Board Veterinary Medical Examiners to conduct risk-based inspections. The Board will conduct a risk-based inspections of a veterinarian's practice based on information obtained from the veterinarian or another source concerning the veterinarian's use, handling, prescribing, dispensing, or delivery of controlled substances. In addition, the Board will inspect equipment and business premises; examine and/or copy client and patient records, drug records, including, but not limited to, invoices, receipts, transfer documents, inventory logs, surgery logs; and all other associated records relating to the practice of veterinary medicine or equine dentistry.

While inspecting a licensee with identified risks, other licensees operating within the same clinic may be inspected.

As part of its Sunset Review, the Texas Legislature indicated its desire that the Board have an effective, consistent, and timely inspection process. The Sunset Commission recommended all licensees be inspected at least once every eight (8) years.

## REGIONS

Investigators will be assigned to a region(s) and will be responsible for identifying all licensees in their region and will ensure they are inspected at least once every eight (8) years.

Investigators will monitor licensees in their assigned regions and will perform additional inspections when any of the risk criteria is met.

Investigators will not perform inspections outside their assigned region unless directed or approved by a supervisor.

Regions:



## **RISK-BASED CRITERIA**

While making most efficient use of time and resources Investigators will prioritize inspections using the following risks:

1. Licensees not inspected in the past eight (8) years or longer.
2. Licensees with questionable handling, prescribing or dispensing controlled substances.
3. Licensees named in substantive, jurisdictional complaints.
4. Licensees whom the agency has reason to believe dispense or prescribe large amounts of controlled substances.
5. Licensee with the longest period of elapsed time since previous inspection.
6. Licensees with repeated deficiencies.
7. Licensees identified in the PMP for questionable prescribing or dispensing activity.
8. Licensees who have been arrested for criminal offenses.
9. Licensees currently on probated suspensions.

## **PRE-INSPECTION**

Investigators shall research licensees prior to conducting onsite inspections to assess risk.

### **Previous Inspections**

Investigators will search the Enforcement Database for previously conducted inspections.

Investigators will review previous inspection reports for deficiencies identified.

### **Previous Board Orders**

Investigators will search the Common Database for previous Board Orders.

Investigators will review previous Board Orders for deficiencies identified.

### **PMP Database**

Investigators shall run a prescriber activity report for all veterinarians being inspected.

Investigators shall prioritize their review of the prescriber activity report for controlled substances that are a risk of potential abuse and known diversion.

Investigators will review records for: Opioids, Benzodiazepines, Barbiturates, Carisoprodol.

Investigators shall review the report for prescribing large amounts of controlled substances and for potentially harmful prescribing patterns.

### **Licensing Application (Salesforce)**

Investigators will search the Board's licensing application to review licensee's contact information and any notes, Board Orders, etc.

## Websites

Investigators will search for websites for the licensee / clinic employed.

Investigators will review the number of veterinarians and non-veterinarians employed, and type of practice (large, small, mixed animals).

## Pre-Inspection Form

Investigators will document their pre-inspection research and identify the Licensee's associated risks.

Facility	Type	Risk Based	First Name	Last Name	License #	Home Address	Personal Telephone
Personal Email	PMP Reviewed	Yrs Licensed	Previous Inspection	Previous Complaint & Findings (RPC&F)	Board Order	Notes: Pre- Insp./Insp.	

## ONSITE PROCEDURES

### Arrival to Facility

Upon arrival, Investigators will introduce themselves and request to speak to a Licensee.

Investigators will have and present their TBVME identification card during the inspection, whether requested or not.

Investigators will inform the Licensee of the inspection.

Investigators will request an employee list of all licensees working at the clinic.

A Licensee does not have to be present during the inspection.

Once a Licensee has been informed of the inspection, the investigator can be assisted by an office manager, veterinary technician, veterinary assistant, etc.

### Inspection

Investigators will (a) inspect equipment and business premises; (b) examine client and patient records, (c) examine drug records,; and (d) review all other associated records relating to the practice of veterinary medicine or equine dentistry, including, but not limited to, invoices, receipts, transfer documents, inventory logs, surgery logs, and all other associated records relating to the practice of veterinary medicine or equine dentistry.

### Non-Compliance

When identifying violations, investigators will obtain proof(s) of noncompliance by copying records, obtaining records verification forms, taking photographs, taking videos, identifying witnesses and securing witness statements.

Investigators shall notify a supervisor when discovering a violation that may constitute a continuing or imminent threat to the public welfare.

## Out Brief

All Licensees should be briefed on the inspection findings within a reasonable time after the conclusion of the inspection.

Briefs may be done in person or during a follow-up call to the Licensee.

## **REPORTS**

Investigators shall use the TBVME Inspection Forms and Supplemental Inspection Form to document their findings of the inspection.

### Inspection Reports

Investigators will note any deficiencies on the Inspection Report.

All violations observed will be marked as non-compliance on the report.

The inspection report will be reviewed by a supervisor.

Investigators will provide a copy of the inspection report to the licensee after supervisory approval.

### Inspection Supplement Report

Reports that require lengthy narratives will be written in a supplemental inspection report.

### Inspection Report Numbers

All inspections will be assigned a report number.

Upon performing an inspection, the investigator will obtain the next available report number. This should be done the day of the inspection.

The investigator is responsible for completing the log from retrieving the report number through closure.

The investigator is responsible for updating and completing the inspection log.

A supervisor, or designee, will review all inspection files for accuracy and completeness and will be responsible for making the approval entry into the log.

Example:

NUMBER	Date	TYPE	Licensee Number	LAST NAME	First Name	CLINIC NAME
IN25-001	9/3/2024	DVM	16103	Belmar	Marlene	Healthy Smiles Pet Dental
IN25-002	9/4/2024	DVM	12736	De La Prida	Laura	Doc on the Block
IN25-003	9/5/2024	DVM	19231	Gadbois	Rachel	VCA Lake Jackson Animal Hospital
IN25-004	9/4/2024	DVM	3573	Fuston	David	Childress Veterinary Hospital
IN25-005	9/4/2024	DVM	4532	Lindley	Connie	Critter Care Veterinary Clinic

CLINIC ADDRESS	CITY	ZIP	COUNTY	INVESTIGATOR ▼	COMPLAINT	PENDING / CLOSED	APPROVED
17445 Spring Cypress Rd F	Cypress	77429	Harris	Willie Smith	CP25-007	Closed	JE
11935 Ostermeyer Rd	Galveston	77554	Galveston	K'Shel Bell	NO	CLOSED	JE
210 That Way	Lake Jackson	77566	Brazoria	Willie Smith	NO	CLOSED	JE
109 Industrial Circle	Childress	79201	Childress	Terry Luecke	CP25-069	CLOSED	JE
406 19th Street	Childress	79201	Childress	Terry Luecke	NO	CLOSED	JE

## **INSPECTION CLOSURE**

### **No Violations Found**

If no deficiencies are found or are immediately corrected the Inspection shall be closed.

### **Violations Found**

If deficiencies are found during the initial inspection that cannot be immediately corrected a follow-up inspection should be conducted after the initial inspection.

Investigators will follow up with the licensees to ensure deficiencies are corrected. Follow-ups may be performed via phone, email, and/or in person.

Once deficiencies are corrected the Inspection shall be closed.

Should a complaint be opened, the inspection will be closed.

Investigators shall notify a supervisor when discovering a violation that may constitute a continuing or imminent threat to the public welfare.

## **COMPLAINTS**

Investigators may open a complaint for violations of Veterinary Licensing Act Title 4, Professions Related to Animal Health Chapter 801 Occupations Code Veterinarians and Texas Administrative Code Title 22, Part 24.

Complaints may be opened for:

1. Repeat violations in the same categories as a previous inspection.
2. Failure to correct previous deficiencies.
3. Failure to correct current deficiencies.
4. Controlled substance logs violations.
5. Significant discrepancies in controlled substance logs.
6. Controlled substance diversion.
7. Controlled substance harmful prescribing patterns.
8. Controlled substance storage violations.
9. Access Security of Controlled Substances violations.
10. Continued negligence in following Rules or Statutes.

## **COMPLAINT OPENING PROCESS**

When initiating a complaint, Investigators will complete a TBVME complaint form and send to a supervisor.

A supervisor will review the complaint and proof(s) of non-compliance.

If approved, the supervisor will forward the complaint to the Enforcement Specialist who will intake the complaint and assign a case number.

The Enforcement Specialist will assign the complaint for investigation.

## **CONTROLLED DRUGS**

### **Diversion**

Investigators shall evaluate licensees for indications of controlled substances diversion.

Investigators shall evaluate licensees for:

1. Reports of thefts of controlled substances.
2. Reports of losses of controlled substances.
3. Employee pilferage.
4. Forgeries.
5. Illicit prescribing.
6. Illegal sales.
7. Employee substance abuse.
8. Limited access to inventory.
9. Accurate and up to date records.
10. Adequate security.
11. Destruction of controlled substances.

Investigators shall evaluate the licensees' security of controlled substances and inspect internal security protocols.

Investigators shall review:

1. Type of activity conducted,
2. Form of controlled substance,
3. Quantity of controlled substance,
4. Type of safes/vaults, secure enclosures,
5. Key and lock control, alarm systems,
6. Public access,
7. Supervision of employees,
8. Guest/visitor procedures,
9. Adequacy of internal systems for monitoring controlled substances.

## **MINIMUM SECURITY FOR CONTROLLED SUBSTANCES**

Investigators shall confirm that all controlled drugs are secured.

Investigators shall ensure adequate security is present to prevent unauthorized access to controlled substances.

Investigators shall ensure adequate security is present to prevent the diversion of controlled substances.

### **RULE §573.61**

Veterinarians shall adhere to the following to ensure security of controlled substances:

- (1) Establish adequate security to prevent unauthorized access to controlled substances.

- (2) Establish adequate security to prevent the diversion of controlled substances.
- (3) During the course of business activities, do not allow any individual access to controlled substances storage areas except those authorized agents required for efficient operations.
- (4) Controlled substances listed in Schedules I, II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet or security cabinet.
- (5) The term "substantially constructed cabinet" means the following:
  - (A) A structure of wood or metal so constructed as to resist any entry by simple tools of attack such as screw drivers, crow bars, tire tools, pry bars, etc. Hinges should not be mounted with bolts or screws on outside of door and the locking devices should be installed internally as in a dead bolt type or the device should be of a type that has protected mounting screws or bolts to inhibit removal. The cabinet should be permanently constructed or attached to the building structure or fixtures so as to prevent the cabinet from being physically removed from the premises. If the cabinet is a metal file cabinet type, it should be permanently attached to prevent easy removal and have an external locking bar that secures the drawer or drawers.
  - (B) A security cabinet or safe equivalent in construction to a Class 6 Mosler Government Sales Security Filing Cabinet or a Class 5 Mosler Government Safe.
  - (C) A cabinet less substantially constructed may meet security requirements provided the cabinet is located in a room or area entrance to which has been so constructed that hinge mountings inhibit removal and a limited number of employees have keys or combinations to locking device. If combination locks are utilized, the combination can be changed upon termination of employees having knowledge of the combination. A veterinarian must maintain a written list of all persons that have access to the controlled substances storage areas, including the dates on which individuals are added or deleted from the list.

#### **RULE §573.43**

- (a) A licensed veterinarian shall comply with all requirements of the federal Drug Enforcement Administration (DEA) regarding controlled substance registration.
- (b) A licensed veterinarian registered with the DEA must comply with all relevant state and federal statutes and rules, including but not limited to Chapter 481 of the Texas Health and Safety Code, Chapter 13 of Part 1 of Title 37 of the Texas Administrative Code, and Chapter 13 of Title 21 of United States Code.

#### **21 CFR 1301.71(a)**

All registrants, including practitioners, shall provide effective controls and procedures to guard against theft and diversion of controlled substances.

#### **21 CFR 1301.75(b)**

If a practitioner maintains a stock of controlled substances at their DEA registered office, the controlled substances must be stored in a securely locked, substantially constructed cabinet.

### **CONTROLLED SUBSTANCES RECORDS KEEPING FOR DRUGS ON HAND**

Investigators shall confirm the location and amounts of all controlled drugs in the licensee's possession.

Investigators shall have the licensee or licensees' designee perform an inventory of controlled drugs in the Investigator's presence and provide the amount on hand to the investigator.

The investigator will monitor the inventory for accuracy.

Investigators will compare the amount on hand to the controlled drug records to ensure there are no significant variances (Significant Variance means a notable difference, or repeated Minor Variances between the actual measure).

The following factors should be used to determine whether there is a notable difference:

1. The actual quantity of controlled substances missing in relation to the type of business;
2. The specific controlled substances;
3. Whether the difference can be associated with access to those controlled substances by specific individuals, or whether the difference can be attributed to unique activities that may take place involving the controlled substances;
5. Whether the specific controlled substances are likely candidates for diversion;
6. The form of the controlled substance;
7. The ratio of the difference compared to the total amount on-hand and dispensed over the relevant period; and
8. Local trends and other indicators of the diversion potential of the missing controlled substances.

Investigators shall compare a sampling of the controlled substances records reviewed to the patient's records to ensure they match and to validate a legitimate medical purpose documented in the patient's records for the dispensing.

Investigators shall review the controlled substances logs for potentially harmful dispensing patterns:

1. Over dispensing controlled substances,
2. Improperly dispensing controlled substances,
3. Excessively dispensing controlled substances,
4. Dispensing controlled substances without a legitimate medical purpose.

Investigators will ensure the logs contain: (1) date of acquisition; (2) quantity purchased; (3) date administered or dispensed; (4) quantity administered or dispensed; (5) name of client and patient receiving the drug(s); and (6) total balance on hand of the scheduled drug.

Investigators will review 222 forms (Schedules I&II) and invoices (Schedules III-V) if destructions of controlled substances occurred.

Investigators will review DEA Form 41 for controlled drug destructions.

Example Log:

[illegible]

### **Sec. 801.359. CONTROLLED SUBSTANCES RECORDS.**

- (a) The board shall require each veterinarian to maintain a recordkeeping system for controlled substances as required by Chapter 481, Health and Safety Code.
- (b) The records are subject to review by a law enforcement agency or board representative.

### **RULE §573.50**

Texas veterinarians shall maintain at their place of business records of all scheduled drugs listed in the Texas Controlled Substances Act in their possession. These records shall be maintained for a minimum of five years. A record shall be kept for each scheduled drug. The records shall be complete, contemporaneous, and legible. The record shall contain the following information in addition to the name of the drug:

- (1) date of acquisition;
- (2) quantity purchased;
- (3) date administered or dispensed;
- (4) quantity administered or dispensed;
- (5) name of client and patient receiving the drug(s); and
- (6) total balance on hand of the scheduled drug.

### **RULE §573.43**

- (a) A licensed veterinarian shall comply with all requirements of the federal Drug Enforcement Administration (DEA) regarding controlled substance registration.
- (b) A licensed veterinarian registered with the DEA must comply with all relevant state and federal statutes and rules, including but not limited to Chapter 481 of the Texas Health and Safety Code, Chapter 13 of Part 1 of Title 37 of the Texas Administrative Code, and Chapter 13 of Title 21 of United States Code.

### **21 CFR 1304.22(c)**

Practitioners that dispense controlled substances must maintain records of the quantity dispensed, the name and address of the person to whom it was dispensed, the date dispensed, and the written or typewritten name or initials of the individual who dispensed the controlled substance on behalf of the practitioner.

### **21 CFR 1304.21(a)**

Every registrant required to keep records pursuant to § 1304.03 shall maintain, on a current basis, a complete and accurate record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of by him/her, and each inner liner, sealed inner liner, and unused and returned mail-back package, except that no registrant shall be required to maintain a perpetual inventory.

### **21 CFR 1304.03(b)**

A registered individual practitioner is required to keep records, as described in § 1304.04, of controlled substances in Schedules II, III, IV, and V which are **dispensed**, other than by prescribing or administering in the lawful course of professional practice.

## INVENTORY REQUIREMENTS

Investigator will review the licensee's initial inventory (DEA Registrants less than two (2) years).

Investigator will review the licensee's biennial inventory (DEA Registrants more than two (2) years).

Examples:

## Initial Inventory Form

Date: \_\_\_\_\_ Name: \_\_\_\_\_

Complete the following exactly as they appear on the DEA certificate:

Name of DEA registrant: \_\_\_\_\_

Address: \_\_\_\_\_

City, State, Zip: \_\_\_\_\_

DEA registration number: \_\_\_\_\_

Date Registered: \_\_\_\_\_

Make selection in each:

Schedule of Drugs: ☐ Schedule I and II -OR- ☐ Schedule III, IV, V Drug (s)

Time of Inventory Count: ☐ Beginning of Business -OR- ☐ Close of Business

DRUG NAME	FORM	STARTING QUANTITY
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\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

## Biennial Inventory Form

Date: \_\_\_\_\_ Name: \_\_\_\_\_

Complete the following exactly as they appear on the DEA certificate:

Name of DEA registrant: \_\_\_\_\_

Address: \_\_\_\_\_

City, State, Zip: \_\_\_\_\_

DEA registration number: \_\_\_\_\_

Date Registered: \_\_\_\_\_

Make selection in each:

Schedule of Drugs: ☐ Schedule I and II -OR- ☐ Schedule III, IV, V Drug (s)

Time of Inventory Count: ☐ Beginning of Business -OR- ☐ Close of Business

DRUG NAME	FORM	QUANTITY
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## **RULE §573.43**

(a) A licensed veterinarian shall comply with all requirements of the federal Drug Enforcement Administration (DEA) regarding controlled substance registration.

(b) A licensed veterinarian registered with the DEA must comply with all relevant state and federal statutes and rules, including but not limited to Chapter 481 of the Texas Health and Safety Code, Chapter 13 of Part 1 of Title 37 of the Texas Administrative Code, and Chapter 13 of Title 21 of United States Code.

### **21 CFR 1304.11 Inventory Requirements.**

(a) *General requirements.* Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. An inventory taken by use of an oral recording device must be promptly transcribed. Controlled substances shall be deemed to be “on hand” if they are in the possession of or under the control of the registrant, including substances returned by a customer, ordered by a customer but not yet invoiced, stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples. A separate inventory shall be made for each registered location and each independent activity registered, except as provided in [paragraph \(e\)\(4\)](#) of this section. In the event controlled substances in the possession or under the control of the registrant are stored at a location for which he/she is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.

(b) *Initial inventory date.* Every person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the manufacture, distribution, or dispensing of controlled substances, in accordance with [paragraph \(e\)](#) of this section as applicable. In the event a person commences business with no controlled substances on hand, he/she shall record this fact as the initial inventory.

(c) *Biennial inventory date.* After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.

### **THEFT OR SIGNIFICANT LOSS OF CONTROLLED SUBSTANCES**

If an Investigator discovers that a theft or significant loss of a controlled substance has occurred, and a Licensee is aware of the incident, the Investigator will request to review the report made to DEA (DEA 106 Form).

Although not specifically required by the CSA or DEA regulations, a practitioner should also notify local law enforcement and state regulatory agencies.

If there is a question as to whether a theft has occurred or a loss is significant, practitioners should err on the side of caution and report it to DEA and local law enforcement authorities.

When determining whether a loss is significant, under 21 CFR 1301.76(b) some factors to consider are:

1. The actual quantity of controlled substances lost in relation to the type of business;
2. The specific controlled substances;

3. Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;
4. A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known
5. Whether the specific controlled substances are likely candidates for diversion; and
6. Local trends and other indicators of the diversion potential of the missing controlled substances.

The DEA Form 106 should not be used to document or explain minor inventory discrepancies, thereby “balancing the books.”

Minor inventory discrepancies, not attributable to theft, should not be reported to DEA or recorded on a DEA Form 106. If a practitioner is unsure of the significance of a loss after considering the factors described above, they should file a DEA Form 106. Any continuing pattern of loss of seemingly insignificant quantities should always be considered significant.

### **RULE §573.43**

(a) A licensed veterinarian shall comply with all requirements of the federal Drug Enforcement Administration (DEA) regarding controlled substance registration.

(b) A licensed veterinarian registered with the DEA must comply with all relevant state and federal statutes and rules, including but not limited to Chapter 481 of the Texas Health and Safety Code, Chapter 13 of Part 1 of Title 37 of the Texas Administrative Code, and Chapter 13 of Title 21 of United States Code.

### **21 CFR 1301.76(b)**

A practitioner must notify the local DEA Diversion Field Office in writing, within one business day of discovery of a theft or significant loss of a controlled substance.

Practitioners must also complete a DEA Form 106 (Report of Theft or Loss of Controlled Substances) which is used to document the actual circumstances of the theft or significant loss and the quantities of controlled substances involved.

## **DRUG LABELING**

Investigator will review drug labels for drugs dispensed from the clinic.

Investigator will confirm drug labels contain the required information.

Example:

<b>KEEP AWAY FROM CHILDREN FOR VETERINARY USE ONLY !</b>	<b>Alamo Dog &amp; Cat Hospital</b>	
	1619 Pleasanton Road	(210) 922-1231
	Dr. Mark E. LaBrie	Date: 09/24/2024
	Expires: 07/23/2025	Refills: 0
	NEXGARD PLUS GOLD (17.1-33) Single QTY: 1	
Give 1 tablet orally once monthly to prevent and control Heartworms, Fleas, Ticks and Intestinal Parasites		
Oliver	Sp: Canine	PH: 621-4142 (210)
Ponce, Kristy	6150 Elm Valley San Antonio, TX 78242	

**RULE §573.40 Labeling of Medications Dispensed**

(a) A veterinarian shall affix labels to all unlabeled containers containing any medication dispensed and to all factory labeled containers that contain prescription (legend) drugs and/or controlled substances dispensed. The label must be affixed to the immediate container and include:

- (1) the veterinarian's name, address, and telephone number (including area code);
- (2) date of delivery or dispensing;
- (3) patient/client name (and address if drug is a controlled substance);
- (4) species of the animal;
- (5) name, strength, and quantity of the drug dispensed;
- (6) directions for use; and
- (7) cautionary statements as required by law, i.e. not for human consumption, poisonous, withdrawal periods, etc.

(b) If the immediate container is too small to be labeled, the small container shall be enclosed within another container large enough to be labeled.

**RULE §573.44 Compounding Drugs**

(c) Labeling Requirements.

(1) All compounded drugs must bear the labeling information required under §573.40 of this title (relating to Labeling of Medications Dispensed), as well as the following information:

- (A) date on which the drug was compounded;
- (B) name and strength of medically active ingredients;
- (C) identity of treated animals;
- (D) withdrawal/withholding times if needed; and
- (E) condition or disease to be treated.

**Patient Records**

Investigator will review a sampling of patient records for compliance with rules.

Investigator will randomly select patients from the dispensing records and compare to the patient records for compliance in recording controlled drugs administered or dispensed.

Investigator will randomly select patients from the PMP report and compare to the patient records for compliance in recording controlled drugs prescribed.

**RULE §573.52 Veterinarian Patient Record Keeping**

(a) A veterinarian performing a physical examination, diagnosis, treatment or surgery on an animal or group of animals shall prepare a legible written record or computer record concerning the animals containing, at a minimum, the following information:

- (1) name, address, and telephone number of the owner;
- (2) identity of the species, animal, herd, or flock;
- (3) except for herds or flocks, the age, sex, color, and breed;
- (4) dates of examination, treatment and surgery;
- (5) brief history of the condition of each animal, litter, herd, or flock;
- (6) examination findings, if required for diagnosis or treatment and is not difficult to obtain:
  - (A) weight - actual or estimated;
  - (B) temperature;
  - (C) pulse;
  - (D) respiration; and
  - (E) any additional findings needed for diagnosis;

- (7) laboratory and radiographic tests performed and reports;
  - (8) differential diagnosis; referrals/consultations; to/with specialists and the client's response;
  - (9) procedures performed/treatment given and results;
  - (10) drugs (and their dosages) administered, dispensed, or prescribed;
  - (11) surgical procedures shall include a description of the procedure, the name of the surgeon, the type of sedative/anesthetic agent used, the route of administration and the dosage; and
  - (12) anesthesia monitoring performed during surgical procedures.
- (b) Individual records must be maintained on each patient, except that records on livestock or litters of animals may be maintained on a per-client basis. Records pertaining to these animals may be kept in a daily log or billing records, provided that the treatment information is substantial enough to identify these animals and the medical care provided.
- (c) Medical records and radiographs are the physical property of the hospital or the proprietor of the practice that prepared them. Records, including radiographs, must be maintained for a minimum of three years after the last visit.
- (d) Medical records shall be released upon request from a treating veterinarian with a legitimate interest, and shall be returned to the originating practice within a reasonable time if requested. Copies of records must be made available upon request from the owner of an animal at a reasonable cost to the owner and within a reasonable time. A veterinarian may not withhold the release of veterinary medical records for nonpayment of a professional fee.
- (e) All regulated substances shall be recorded as required by federal and/or state regulations.
- (f) Any signed acknowledgement required by §§573.14 and 573.16 - 573.18 (relating to all complementary therapies).

#### **RULE §573.53 Equine Dental Provider Patient Record Keeping**

- (a) Individual records shall be complete, contemporaneous and legible and shall include, but are not limited to:
- (1) name, address, and phone number of the client;
  - (2) identification of patient, including name, breed, age, sex, and description;
  - (3) patient history;
  - (4) dates of visits;
  - (5) other details necessary to substantiate or document the procedure performed; and contemporaneously with the act or observation noted by indicating the time and date of the amendment, supplementation, change or correction, and clearly indicating that there has been an amendment, supplementation, change, or correction.
- (b) Maintenance of Patient Records.
- (1) Patient records shall be current and readily available for a minimum of five years from the date of last treatment by the equine dental provider.
  - (2) Patient records are the responsibility and property of the equine dental provider, provided however, that equine dental providers shall give copies of records to the owner or caretaker authorizing treatment of the patient at the time of treatment, and shall provide copies of records to the supervising veterinarian on request, within 15 business days of the request.
  - (3) An equine dental provider may destroy medical records that relate to any civil, criminal or administrative proceeding only if the equine dental provider knows the proceeding has been finally resolved.

#### **CONTACT INFORMATION**

Investigator will confirm the licensee's contact information is current with Board records.

Investigators will compare the information in the Board's application (Sales Force) to the clinic information and ensure they are one and the same.

## RULE §573.76 Notification of Licensee Addresses

(a) Each licensee shall report to the Board the licensee's:

- (1) name and license number;
- (2) clinic or practice name;
- (3) physical business address;
- (4) mailing address;
- (5) residence address;
- (6) business telephone number; and
- (7) residence and/or cellular telephone number.

(b) A mailing address may be a post office box number. A physical business address shall be a physical location and shall not be a post office box number. If a remote practice location does not have a physical business address, the licensee must provide as the physical business address sufficient directions as to how the practice location may be found.

(c) A relief veterinarian's physical business address shall be the physical business address where the relief veterinarian regularly conducts the largest percentage of his or her relief work at one clinic. If the relief veterinarian does not have one clinic where he or she conducts the largest percentage of his or her work, then the relief veterinarian shall use the physical address of one of the locations where he or she works. If the relief veterinarian is not actively working, then the relief veterinarian may use his or her physical residence address, which shall not be a post office box number.

(d) A licensee shall notify the Board of any change of items required under subsection (a) of this section not later than the 60th day after the change takes place.

### License Displayed

Investigator will inspect the common area open to the public and will ensure the licensee's Board license is displayed.

Example:



**RULE §573.35 Display of License**

Each licensee, including a relief veterinarian, shall post or display at the licensee's practice location, whether mobile or fixed, his or her Board license. This document must be displayed where it is visible to the public. A legible photocopy of the original document is acceptable.

**NOTICE TO CLIENT DISPLAYED**

Investigator will inspect the common area open to the public and will ensure the below notice is displayed:

**NOTICE TO CLIENTS**

To file a commendation or grievance concerning a veterinarian, licensed veterinary technician or equine dental provider please contact:

**Texas State Board of Veterinary Medical Examiners**  
**1801 Congress Ave., Ste. 8.800**  
**Austin, Texas 78701**  
**Phone: (512) 305-7555**  
**Main Fax: (512) 305-7556**  
**Enforcement Fax: (512) 936-0837**

To obtain information about filing a complaint, you may access the Board's voicemail 24 hours a day by calling toll free: 1-800-821-3205.

**RULE §573.29 Complaint Information and Notice to Clients**

(a) A licensed veterinarian or licensed equine dental provider shall provide an effective way to inform clients and other visitors to the premises, clinic or hospital of how to file complaints with the Board. The licensee must provide:

- (1) the following specific address: Texas State Board of Veterinary Medical Examiners, 333 Guadalupe, Suite 3-810, Austin, Texas 78701-3942;
  - (2) the Board's telephone number: (512) 305-7555; fax number: (512) 305-7556; and
  - (3) a toll-free complaint information number: 1-800-821-3205.
- (b) Acceptable forms of providing the information in subsection (a) of this section may include a:
- (1) written notice form, with print size of at least 14 point, prominently displayed in the area of each clinic or hospital that is most frequented by the public;
  - (2) brochure available in the area of each clinic or hospital that is most frequented by the public; or
  - (3) statement on each written bill, invoice or receipt.

## **SANITATION**

Investigator will inspect the clinic to ensure it is in a condition of good order and cleanliness that precludes the probability of disease transmission or patient infection.

Investigator will ensure the licensees are using properly sterilized instruments and clean supplies.

Investigator will ensure facilities are in a clean and sanitary condition without any accumulation of trash, debris, or filth.

Investigator will ensure the facility is free of pest and rodents.

### **RULE §573.79 Maintenance of Sanitary Premises**

Licensees must maintain their offices/clinics/hospitals and the offices/clinics/hospitals in which they work, including mobile facilities, in a clean and sanitary condition without any accumulation of trash, debris, or filth. Such premises shall be maintained in full compliance with all health requirements of the city or county in which located and in conformity with the health laws of the State of Texas; further, they shall use properly sterilized instruments and clean supplies.

### **Sec. 801.402. GENERAL GROUNDS FOR LICENSE DENIAL OR DISCIPLINARY ACTION.**

A person is subject to denial of a license or to disciplinary action under Section 801.401 if the person:

(15) fails to keep the person's equipment and business premises in a sanitary condition;

## **ALTERNATIVE THERAPY FORM**

If licensees are using alternative therapies, Investigators will review patient records to ensure the licensee obtains as a part of the patient's permanent record a signed acknowledgment form when required.

### **RULE §573.14 Alternate Therapies--Chiropractic and Other Forms of Musculoskeletal Manipulation**

(a) Definition. For the purpose of this rule, animal chiropractic and other forms of musculoskeletal manipulation (MSM) are systems of therapeutic application of mechanical forces applied manually through the hands or any mechanical device to treat and/or alleviate impaired or altered function of related components of the musculoskeletal system of nonhuman animals. Animal chiropractic and other forms of MSM in nonhuman animals are considered to be alternate therapies in the practice of veterinary medicine.

(b) Treatment using animal chiropractic and other forms of MSM. Animal chiropractic and other forms of MSM may only be performed by the following.

(1) A licensed veterinarian. Animal chiropractic and MSM may be performed by a licensed veterinarian under the following conditions:

(A) a valid veterinarian/client/patient relationship has been established as defined in the Act;

(B) an examination has been made by the licensee to determine that animal chiropractic/MSM will not likely be harmful to the patient; and

(C) the licensee obtains as a part of the patient's permanent record a signed acknowledgment by the owner or other caretaker of the patient that animal chiropractic or MSM is considered by Texas law to be an alternate therapy.

(2) A non-veterinarian employee or an independent contractor. A non-veterinarian employee or an independent contractor may perform these procedures on an animal under the direct or general supervision of the veterinarian if the conditions in paragraph (1)(A) - (C) of this subsection have been met.

(3) An individual to whom the exceptions of the Act, §801.004, apply.

(c) Responsibility. Whether the animal chiropractic/MSM is performed by a veterinarian or a non-veterinarian employee or an independent contractor working under the supervision of a licensee, the Board will hold the

veterinarian to a level of professional judgment as would be exercised by the average Texas veterinarian who performs or recommends chiropractic/MSM treatments in his/her practice.

#### **RULE §573.16 Alternate Therapies--Acupuncture**

(a) Definition. For the purpose of this rule, acupuncture is:

(1) the insertion of an acupuncture needle and the application of moxibustion to specific areas of a non-human animal's body to relieve the discomfort associated with painful disorders, to induce surgical anesthesia, and for therapeutic purposes; and

(2) the administration of thermal or electrical treatments or the recommendation of dietary guidelines, energy flow exercise, or dietary or herbal supplements in conjunction with the treatment described by paragraph (1) of this subsection. Acupuncture in non-human animals is considered to be an alternate therapy in the practice of veterinary medicine.

(b) Use of Acupuncture in the treatment of animals. Only licensed veterinarians may use acupuncture in the care and medical treatment of animals. No veterinarian may allow a non-veterinarian employee or other agent to perform acupuncture in the treatment of an animal patient.

(c) Client Consent Required. Before acupuncture may be used in the treatment of an animal, the veterinarian must obtain a signed statement from the animal's owner or caretaker acknowledging that acupuncture is an alternate therapy in veterinary medicine and approving its use in the treatment of the animal. Before signing the statement, the veterinarian shall inform the client of the conventional treatments available and their probable ability to cure the problem. The statement shall become a permanent part of the patient's record.

(d) Standard Used in Determining Appropriate Use of Acupuncture. If the Board receives a complaint against a licensee about treatment involving the use of acupuncture, investigation of the complaint may include opinions from other licensees who use acupuncture in their treatment of animals. However, veterinarians who practice acupuncture shall exercise the same degree of humane care, skill, and diligence in treating patients as are ordinarily used in the same or similar circumstances by average members of the veterinary medical profession in good standing in the locality or community, or in similar locations or communities, in which they practice.

(e) Other Board Rules Not Preempted. Nothing in this rule shall remove or limit in any way the applicability of other rules of the Board as they apply to the practice of veterinary medicine.

#### **RULE §573.17 Alternate Therapies--Holistic Medicine**

(a) Definition. For the purpose of this rule, holistic medicine means: the practice of veterinary medicine that believes in a blend of alternative and, if need be, conventional approaches of treatment in an effort to develop a system of complementary medicine to treat the whole patient. In practice, it incorporates less conventional methods such as herbal medicine, acupuncture, chiropractic, homeopathy, and applied kinesiology, with more conventional methods, such as modern drugs, surgery and diagnostics. Use of holistic medicine in non-human animals is considered to be an alternate therapy in the practice of veterinary medicine.

(b) Use of holistic medicine in the treatment of animals. Only licensed veterinarians may use holistic medicine in the medical treatment of animals. No veterinarian may allow a non-veterinarian employee or other agent to perform holistic medicine in the treatment of an animal patient.

(c) Client Consent Required. Before holistic medicine may be used in the treatment of an animal, the veterinarian must obtain a signed statement from the animal's owner or caretaker acknowledging that holistic medicine is an alternate therapy in veterinary medicine and approving its use in the treatment of the animal. Before signing the statement, the veterinarian shall inform the client of the conventional treatments available and their probable ability to cure the problem. The signed statement shall become a permanent part of the patient's record.

(d) Standard Used in Determining Appropriate Use of Holistic Medicine. If the Board receives a complaint against a licensee about treatment involving the use of holistic medicine, investigation of the complaint may include opinions from other licensees who use holistic medicine in their treatment of animals. However, veterinarians who practice holistic medicine shall exercise the same degree of humane care, skill, and diligence in treating patients as are ordinarily used in the same or similar circumstances by average members of the

veterinary medical profession in good standing in the locality or community, or in similar localities or communities, in which they practice.

(e) Other Board Rules Not Preempted. Nothing in this rule shall remove or limit in any way the applicability of other rules of the Board as they apply to the practice of veterinary medicine.

#### **RULE §573.18 Alternate Therapies--Homeopathy**

(a) Definition. For the purpose of this rule, homeopathy is: a system of therapeutics in which diseases are treated by substances which are capable of producing in healthy animals symptoms like those of the disease to be treated, the substance being administered in minute doses. Use of homeopathic remedies in non-human animals is considered to be an alternate therapy in the practice of veterinary medicine.

(b) Use of Homeopathy in the Treatment of Animals. Only licensed veterinarians may use homeopathy in the medical treatment of animals. No veterinarian may allow a non-veterinarian employee or other agent to perform homeopathy in the treatment of an animal patient.

(c) Client Consent Required. Before homeopathy may be used in the treatment of an animal, the veterinarian must obtain a signed statement from the animal's owner or caretaker acknowledging that homeopathy is an alternate therapy in veterinary medicine and approving its use in the treatment of the animal. Before signing the statement, the veterinarian shall inform the client of the conventional treatments available and their probable ability to cure the problem. The signed statement shall become a permanent part of the patient's file.

(d) Standard Used in Determining Appropriate Use of Homeopathy. If the Board receives a complaint against a licensee about treatment involving the use of homeopathy, investigation of the complaint may include opinions from other licensees who use homeopathy in their treatment of animals. However, veterinarians who practice homeopathy shall exercise the same degree of humane care, skill, and diligence in treating patients as are ordinarily used in the same or similar circumstances by average members of the veterinary medical profession in good standing in the locality or community, or in similar localities or communities, in which they practice.

(e) Other Board Rules Not Preempted. Nothing in this rule shall remove or limit in any way the applicability of other rules of the Board as they apply to the practice of veterinary medicine.

### **TEMPORARY CLINICS**

Investigators will search their assigned region for temporary clinics.

Investigators will verify if the required notification was made to the Board prior to operation.

Investigators will inspect temporary clinics for compliance with rules.

#### **RULE §573.71 Operation of Temporary Limited-Service Veterinary Services**

(a) Requirements for operation. Veterinarians operating temporary limited service clinics shall:

- (1) maintain sanitary conditions at the clinic site, including, but not limited to, removal of animal solid waste and sanitizing/disinfecting of urine and solid waste sites;
- (2) provide injections with sterile disposable needles and syringes;
- (3) utilize a non-porous table for examining and/or injecting small animals;
- (4) maintain biologics and injectable medications between temperature ranges of 35 to 45 degrees Fahrenheit;
- (5) perform and complete blood and fecal examinations before dispensing relevant federal legend medications;
- (6) maintain rabies vaccination records and treatment records for five years, indexed alphabetically by the client's last name and by vaccination tag numbers, if issued; and
- (7) provide clients with a printed form that contains the identity of the administering veterinarian and the address of the places where the records are to be maintained.

(b) Required notification to the Board prior to operation. Before any temporary limited-service clinic may be operated, the veterinarian is required to provide notification to the Board office at least 48 hours before the clinic begins operation. Notice may be provided no more than 90 days prior to the clinic operating for a

particular day and any cancellations of operation must be provided to the Board within 48 hours before the clinic was to operate. Notice must include the veterinarian's full name, license number, and daytime phone number; the date the clinic will be held, the specific location of where the clinic will be held, and times of operation; and the permanent address where records for the clinic will be kept. Notice may be by electronic transmission or mail. Mailed notice will be considered to have met the notification requirement if the written notice is postmarked at least five days prior to the operation of the clinic.









### **DIGITAL FILING SYSTEM**

Investigators will be responsible for filing all reports and supporting documents in the digital files.

If there are no documents to file in the folders – investigators will create a sub folder and label as “NA.”

1. Inspection Report – the final approved IN report and IN Supplements will be saved as a PDF and filed in this folder.
2. PMP Report – a proof of Prescriber Activity Report will be filed in this folder.
3. Proofs of Non Compliance – photos, copies, audios, videos, etc. will be filed in this folder.
4. Proofs of Corrections – proofs will be filed in this folder.
5. Additional Documents – this is a “catch all” folder for additional documents.
6. Pre Inspection – pre inspection form will be filed in this folder.
7. Emails – all emails will be filed in this folder.
8. Complaint – if a complaint is opened, a copy will be filed in this folder.

Example Folders:

-  1. Inspection Report
-  2. PMP Report
-  3. Proofs of Non Compliance
-  4. Proofs of Corrections
-  5. Additional Documents
-  6. Pre Inspection Worksheet
-  7. Emails
-  8. Complaint

### **DRESS CODE**

Investigator's appearance contributes to the Board's culture and reputation. Investigators are expected to present themselves in a professional manner that results in a favorable impression by licensees and the public.

Traditional business attire is expected of all investigators. Basic elements for appropriate and professional business attire include clothing that is in neat and clean condition.

Appropriate workplace dress does *not* include clothing that is too tight or revealing; clothing with rips, tears or frays; or any extreme style or fashion in dress, footwear, accessories or fragrances.

Although it is impossible and undesirable to establish an absolute dress and appearance code, Supervisors will apply a reasonable and professional workplace standard to investigators on a case-by-case basis. Supervisors may make exceptions for special occasions or in the case of inclement weather, at which time employees will be notified in advance. An investigator who is unsure of what is appropriate should check with his or her supervisor.

### **Business Professional Attire**

Investigators will wear professional attire when testifying in SOAH hearings, court, and while attending Board meetings.

A business professional dress code is: a suit and tie, pantsuit or professional dress or skirt.

### **Business Casual Attire**

Business casual dress will be permitted when performing inspections.

Business casual dress is defined as follows:

- Casual shirts: All shirts with collars, business casual crewneck or V-neck shirts, blouses, and golf and polo shirts. Examples of inappropriate shirts include T-shirts, shirts with inappropriate slogans or graphics, tank tops, muscle shirts, camouflage and crop tops.
- Pants: Casual slacks and trousers and jeans without holes, frays, etc. Examples of inappropriate pants include shorts, camouflage, and pants worn below the waist or hip line.
- Footwear: Casual slip-on or tie shoes, dress sandals, and clean athletic shoes. Examples of inappropriate footwear include flip-flops and construction or hunting boots.

## **ADDITIONAL INFORMATION (DEA)**

### **SCHEDULES OF CONTROLLED SUBSTANCES**

Drugs and other substances that are considered controlled substances under the CSA are divided into five schedules. A listing of the substances and their schedules is found in the DEA regulations at 21 CFR 1308.11 - 15. A controlled substance is placed in its respective schedule based on whether it has a currently accepted medical use in treatment in the United States and its relative abuse potential and likelihood of causing dependence when abused. 21 U.S.C. 812(b). Some examples of controlled substances in each schedule are listed below.

NOTE: Drugs listed in schedule I have no currently accepted medical use in treatment in the United States and, therefore, may not be prescribed, administered, or dispensed for medical use. 21 U.S.C. 812(b)(1). In contrast, drugs listed in schedules II-V have an accepted medical use and may be prescribed, administered, or dispensed for medical use. 21 U.S.C. 812(b)(2)-(5).

### **Schedule I Controlled Substances**

Substances in this schedule have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. 21 U.S.C. 812(b)(1). Some examples of substances listed in schedule I are heroin, lysergic acid diethylamide (LSD), marijuana (cannabis), peyote, methaqualone, and 3,4-methylenedioxymethamphetamine (MDMA). 21 U.S.C. 812(c), schedule I and 21 CFR 1308.11.

## **Schedule II Controlled Substances**

Substances in this schedule have a high potential for abuse, a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions, and abuse of the drug may lead to severe psychological or physical dependence. 21 U.S.C. 812(b)(2).

Examples of schedule II narcotics include morphine and codeine. Other schedule II narcotic substances and their common name brand products include any combination products containing hydrocodone (Maxidone, Zydane, Vicodin, Lortab, Vicoprofen, Reprexain) and single entity substances such as hydromorphone (Dilaudid), methadone (Dolophine), meperidine (Demerol), oxycodone (OxyContin), and fentanyl (Sublimaze or Duragesic).

Examples of schedule II stimulants include amphetamine (Dexedrine, Adderall), methamphetamine (Desoxyn), methylphenidate (Ritalin), and lisdexamfetamine (Vyvanse). Other schedule II substances include cocaine, amobarbital, and glutethimide. 21 U.S.C. 812(c), schedule II and 21 CFR 1308.12(d).

## **Schedule III Controlled Substances**

Substances in this schedule have a potential for abuse less than substances in schedules I or II, a currently accepted medical use in treatment in the United States, and abuse of the drug may lead to moderate or low physical dependence or high psychological dependence. 21 U.S.C. 812(b)(3).

Examples of schedule III narcotics include morphine combination products containing not more than 50 milligrams (mg) of morphine per 100 milliliters (ml) or per 100 grams, with one or more active, non-narcotic ingredients in recognized therapeutic amounts, and codeine combination products containing not more than 90 mg of codeine per dosage unit with an equal or greater quantity of an isoquinoline alkaloid of opium (e.g., Tylenol with codeine). 21 CFR 1308.14(e)(1)(vi) and (i), respectively. Also included are buprenorphine products used to treat opioid addiction.

Examples of schedule III non-narcotics include benzphetamine (Didrex), phendimetrazine, ketamine, and anabolic steroids such as oxandrolone (Oxandrin). 21 U.S.C. 812(c), schedule III and 21 CFR 1308.13.

## **Schedule IV Controlled Substances**

Substances in this schedule have a low potential for abuse relative to substances in schedule III, a currently accepted medical use in treatment in the United States, and abuse of the drug may lead to limited physical dependence or psychological dependence relative to substances in schedule III. 21 U.S.C. 812(b)(4).

An example of a schedule IV narcotic is tramadol (Ultram).

Examples of other schedule IV substances include alprazolam (Xanax), carisoprodol (Soma), clonazepam (Klonopin), clorazepate (Tranxene), diazepam (Valium), lorazepam (Ativan), midazolam (Versed), temazepam (Restoril), and triazolam (Halcion). 21 U.S.C. 812(c), schedule IV and 21 CFR 1308.14.

## **Schedule V Controlled Substances**

Substances in this schedule have a low potential for abuse relative to substances listed in schedule IV, have a currently accepted medical use in treatment in the United States, and abuse of the drug may lead to limited physical dependence or psychological dependence relative to substances in schedule IV.

Schedule V substances consist primarily of preparations containing limited quantities of certain narcotics. 21 U.S.C. 812(b)(5). These are generally used for antitussive, antidiarrheal, and analgesic purposes. 21 U.S.C. 812(c), schedule V and 21 CFR 1308.15.

Examples include cough preparations containing not more than 200 mg of codeine per 100 ml or per 100 grams (Robitussin AC, Phenergan with Codeine).

\*NOTE: Certain controlled substances may be classified in a different schedule, either higher or lower, in your state. In this event, as is the case with all controlled substance laws and regulations, when state requirements are

more restrictive than federal requirements (or vice versa), registrants must comply with the more restrictive requirements. 21 CFR 1307.02.

## **REGISTRATION REQUIREMENTS**

Unless otherwise exempted as explained in the subsections below, every practitioner who dispenses, which includes by definition administering and prescribing, controlled substances in schedules II through V, must be registered with DEA. 21 U.S.C. 802(10), 21 U.S.C. 822(a)(2), and 21 CFR 1301.11(a). A state license must be obtained. 21 U.S.C. 823(f). “The term practitioner means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.” 21 U.S.C. 802(21).

### **Registration Requirements for Multiple Locations**

As stated above, a separate registration must be obtained for each principal place of business or professional practice where controlled substances are stored, administered, or dispensed. 21 U.S.C. 822(e)(1); 21 CFR 1301.12(a). DEA has provided a limited exception to this requirement: If a practitioner is registered at one location, but practices at others within the same state, an additional registration is not required for any other location in that state at which the practitioner only prescribes controlled substances. 21 CFR 1301.12(b)(3). Another exception is allowed for DEA-registered veterinarian practitioners. The Veterinary Medicine Mobility Act of 2014 amended the CSA to address separate registration requirements for veterinarians. 21 U.S.C. 822(e)(2).

### **Registration Exemption of Agents and Employees**

Individual practitioners who are agents or employees of another practitioner (other than a mid-level practitioner defined under 21 CFR 1300.01), who are registered to dispense controlled substances, may administer or dispense controlled substances under the registration of the employer or principal practitioner in lieu of being registered themselves, and only if authorized or permitted to do so by the jurisdiction where the practice is located. However, this exemption does not extend to prescribing controlled substances. 21 CFR 1301.22 (b).

### **Modification of Registration**

A practitioner may apply to modify a DEA registration at any time. Modifications can include change of business and/or mailing address, name change, or change to handle additional controlled substances. There is no fee for a modification of registration. Modifications are handled in the same manner as applications and must be approved by DEA. 21 CFR 1301.51(a). DEA Registrants may request a modification of registration on the DEA website or contact the local DEA Registration Specialist. If the change in address involves a move to a different state, a practitioner must obtain the proper state-issued license and, if applicable, controlled substances registration from the new state, prior to applying for a modification of registration with DEA. 21 U.S.C. 823(f). DEA will not approve the modification until it receives proof of proper state licensure/registration. If the modification is approved, DEA issues a new Certificate of Registration and, if requested, new schedule I & II order forms (DEA Form 222). A practitioner must maintain the certificate until expiration. See 21 CFR 1301.35(c).

## **PRESCRIPTIONS FOR CONTROLLED SUBSTANCES**

To be valid, a prescription for a controlled substance must be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. The practitioner is responsible for the proper

prescribing and dispensing of controlled substances, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription that is not issued for a legitimate medical purpose in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of [21 U.S.C. 829](#). The person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

[21 U.S.C. 841\(a\)\(1\)](#) and [21 CFR 1306.04\(a\)](#).

### **Issuance of a Prescription**

Under [21 CFR 1306.03](#), a prescription for a controlled substance may only be issued by an individual practitioner who is:

1. Authorized to prescribe controlled substances by the jurisdiction in which they are licensed to practice their profession, and
2. Either registered with DEA or exempted from registration by regulation ([21 CFR 1301.22\(c\)](#) and [21 CFR 1301.23](#)), or
3. An agent or employee of a hospital or other institution acting in the normal course of business or employment under the registration of the hospital or other institution which is registered in lieu of the individual practitioner being registered, provided that additional requirements as set forth in [21 CFR 1301.22\(c\)](#) are met.

### **Prescription Requirements**

A prescription is an order for medication which is dispensed to or for an ultimate user (i.e., patient). A prescription is not an order for medication which is dispensed for immediate administration to the ultimate user (i.e., an order to dispense a drug to an inpatient for immediate administration in a hospital is not a prescription). [21 CFR 1300.01\(b\)](#) (“prescription”).

A prescription for schedule II-controlled substances may be written or electronic, except in certain emergency situations when oral prescriptions may be permissible. [21 CFR 1306.08\(a\), \(b\), 1306.11\(a\), \(d\)](#). A prescription for schedule III-V controlled substances may be written, electronic, or oral. [21 CFR 1306.08\(a\), \(b\), 1306.21\(a\)](#). A prescription for a controlled substance must be dated and signed on the date when issued. The prescription must include the patient’s full name and address, and the practitioner’s full name, address, and DEA registration number. [21 CFR 1306.05\(a\)](#).

Under [21 CFR 1306.05\(a\)](#) the prescription must also include:

- Drug Name
- Strength
- Dosage Form
- Quantity Prescribed
- Directions for Use
- Number of Refills Authorized (if any)

A practitioner or an agent of the practitioner may prepare a written prescription; however, the practitioner is responsible for ensuring that the prescription conforms to all requirements of the law and regulations, both federal and state. [21 CFR 1306.05\(f\)](#). A paper prescription must be written in ink or indelible pencil, typewritten, or printed on a computer, and must be manually signed by the practitioner. [21 CFR 1306.05\(d\)](#). Be aware that there is a corresponding responsibility with the pharmacist who fills the prescription to ensure that the prescription was issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. [21 CFR 1306.04\(a\)](#). An order purporting to be a prescription issued not in the usual course of professional treatment is an invalid prescription within the meaning and intent of the CSA. The person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances. [21 U.S.C. 841\(a\)\(1\)](#), [21 CFR](#)

1306.04(a). In an effort to fulfill their corresponding responsibility, pharmacists may contact the prescribing practitioner.

A practitioner must not issue a prescription to obtain controlled substances for the purpose of general dispensing to patients. 21 CFR 1306.04(b).

### **Prescription Monitoring Program (PMP)**

A PMP (also referred to as a prescription drug monitoring program or PDMP) is a state-administered data collection system used to gather prescription information, primarily for controlled substance prescriptions. PMPs collect, monitor, and analyze electronically transmitted prescribing and dispensing data submitted by pharmacies and, in some states, dispensing practitioners. Access to PMP information is determined by state law. Most states allow practitioners and pharmacists to obtain PMP reports regarding their patients and customers. This is a highly effective tool to aid in proper prescribing and dispensing decisions. The data can be used by practitioners and pharmacists to identify potential "doctor shoppers" and those who attempt to obtain controlled substances by fraud, forgery, or deceit. Many states also provide PMP information to other authorized groups such as law enforcement, licensing and regulatory boards, State Medicaid programs, and state medical examiners.

PMP data is also used to develop medical education programs for practitioners and pharmacists. These programs heighten awareness about diversion, prescription drug abuse, and drug trends. DEA strongly endorses PMPs.

### **RECORDKEEPING REQUIREMENTS**

Practitioners must maintain complete and accurate records on a current basis for each controlled substance purchased, received, sold, stored, distributed, dispensed, or otherwise disposed of. 21 CFR 1304.21(a). These records are required to provide accountability of all controlled substances from the manufacturing process through the dispensing pharmacy and to the ultimate user. The closed system reduces the potential for diversion of controlled substances.

All required records concerning controlled substances must be maintained for at least two years for inspection and copying by duly authorized DEA officials. 21 U.S.C. 827(b) and 21 CFR 1304.04(a). Records and inventories of schedule II controlled substances must be maintained separately from all other records of the registrant. 21 CFR 1304.04(h)(1). All records and inventories of schedules III, IV, and V controlled substances must be maintained either separately from all other records or in such a form that the information required is readily retrievable from the ordinary business records. 21 CFR 1304.04(h)(3).

Pursuant to 21 CFR 1300.01(b), readily retrievable is defined as:

1. Records kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time, and/or
2. Records kept in such a manner that certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records.

Practitioners are not required to keep records of controlled substances that are prescribed in the lawful course of professional practice unless such substances are prescribed for maintenance or detoxification treatment. 21 CFR 1304.03(c). Practitioners are also not required to keep records of controlled substances that are administered unless the practitioner regularly engages in the dispensing or administering of controlled substances and charges patients for such dispensing or administering. 21 CFR 1304.03(d). Practitioners must keep records of controlled substances administered for maintenance or detoxification treatment. 21 CFR 1304.03(d). Practitioners that dispense controlled substances must maintain records of the quantity dispensed, the name and address of the person to whom it was dispensed, the date dispensed, and the written or typewritten name or initials of the individual who dispensed the controlled substance on behalf of the practitioner. 21 CFR 1304.22(c).

## **Disposal of Controlled Substances**

DEA-registered practitioners may dispose of out-of-date, damaged, or otherwise unusable or unwanted controlled substances from office stock by transferring them to a DEA registrant known as a reverse distributor. 21 CFR 1317.05(a)(2). A reverse distributor is authorized to receive controlled substances for destruction or return to the manufacturer. 21 CFR 1300.01. When a practitioner distributes schedule II-controlled substances to a reverse distributor, the reverse distributor must issue an official order form (DEA Form 222) to the practitioner. 21 CFR 1305.03(f). When a practitioner delivers schedule III-V controlled substances to a reverse distributor for purposes of disposal, the practitioner must maintain a record that lists the date and manner of disposal, name, address, and registration number of the person to whom it was distributed and quantity disposed of. 21 CFR 1304.22(a)(1)(ix). The reverse distributor is responsible for completing a DEA Form 41 (Registrants Inventory of Drugs Surrendered) to record the destruction. 21 CFR 1304.21(e). A practitioner must maintain copies of the records documenting the disposal of the controlled substances for a period of two years. 21 U.S.C. 827(b) and 21 CFR 1304.04(a).

Use of a reverse distributor to dispose of unwanted controlled substances is not required. 21 CFR 1317.05(a). If a practitioner desires to dispose of controlled substances in their inventory by means other than delivering the drugs for destruction to a reverse distributor by common or contract carrier pick-up or by reverse distributor pick-up at the registrant's registered location, the registrant must list the controlled substances being disposed of on a DEA Form 41. 21 CFR 1304.21(e). This record must be kept for at least two years. 21 CFR 1304.04(a).

A paper version of the DEA Form 41 may be requested by writing to:

Drug Enforcement Administration

Diversion Control Division

Attn: Registration Section/DRR

P.O. Box 2639

Springfield, VA 22152-2639

Do not send the drugs to DEA unless you have received prior approval from DEA. The disposal of controlled substances must be in compliance with all federal, state, local, and tribal environmental laws and regulations.

As a DEA registrant, you are not eligible to dispose of controlled substances from your office stock using drop boxes designated for disposal of controlled substances by the general public, or during prescription drug take-back events. 21 CFR 1317.05(a).

The following categories of registrants may modify their registration to become collectors, manufacturers, distributors, reverse distributors, narcotic treatment programs, hospital clinics with an on-site pharmacy, and retail pharmacies. 21 CFR 1317.40(a). Individual practitioners, such as medical doctors, dentists, or veterinarians are not included in the aforementioned regulation and are not authorized to be collectors.

Authorized collectors may maintain collection receptacles at their registered locations. They may also operate a mail-back program as long as they have an on-site means of destruction for the mail-back packages. 21 CFR 1317.70. Authorized retail pharmacies and hospital/clinics with an on-site pharmacy may manage collection receptacles at long-term care facilities. 21 CFR 1317.80(b). Practitioners can partner with a collector or law enforcement to make mail-back packages available. 21 CFR 1317.70(c).

## **Pharmaceutical Wastage**

Pharmaceutical wastage, i.e., controlled substances remaining in a vial, tube, transdermal patch, or syringe after administration to a patient, shall not be placed in a collection receptacle as a means of disposal. Rather, practitioners shall continue to record the destruction of pharmaceutical wastage in accordance with 21 CFR 1304.21(e). The disposal regulations contained in 21 CFR Part 1317 do not alter a practitioner's existing obligation to destroy pharmaceutical wastage in accordance with federal, state, tribal, and local laws and regulations (e.g., environmental, hazardous/biohazard, and other safety-related laws and regulations).

Practitioners must also not dispose of any controlled substances in inventory or stock in a collection receptacle. 21 CFR 1317.75(b). The disposal of practitioner inventory (as opposed to pharmaceutical wastage) shall be accomplished in accordance with the disposal requirements of 21 CFR 1317.05(a).

DEA understands that there may be some circumstances where there is no authorized person to dispose of the controlled substances, such as when controlled substances are abandoned at a school or summer camp, and return to the ultimate user is not feasible. In such instances, the affected entities should contact local law enforcement or their local DEA office for guidance on proper disposal procedures.

### **Theft or Significant Loss of Controlled Substances**

A practitioner must notify the local DEA Diversion Field Office in writing, within one business day of discovery of a theft or significant loss of a controlled substance. 21 CFR 1301.76(b). Although not specifically required by the CSA or DEA regulations, a practitioner should also notify local law enforcement and state regulatory agencies. If there is a question as to whether a theft has occurred or a loss is significant, practitioners should err on the side of caution and report it to DEA and local law enforcement authorities.

When determining whether a loss is significant, under 21 CFR 1301.76(b) some factors to consider are:

1. The actual quantity of controlled substances lost in relation to the type of business;
2. The specific controlled substances;
3. Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;
4. A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known
5. Whether the specific controlled substances are likely candidates for diversion; and
6. Local trends and other indicators of the diversion potential of the missing controlled substances.

Practitioners must also complete a DEA Form 106 (Report of Theft or Loss of Controlled Substances) which is used to document the actual circumstances of the theft or significant loss and the quantities of controlled substances involved. 21 CFR 1301.76(b). The online version can be amended by the reporter at any time to reflect complete and accurate information.

A paper version of the form can be obtained by writing to:

Drug Enforcement Administration  
Diversion Control Division  
Attn: Registration Section/DRR  
8701 Morrisette Drive  
Springfield, VA 22152

If completing the paper version, a practitioner must send the original DEA Form 106 to the local DEA Diversion Field Office and keep a copy for their records. Please see the Guidelines for Completing the DEA Form 106 (Appendix C) for additional guidance, or email DEA's regulatory section at [DRG@dea.gov](mailto:DRG@dea.gov). If the theft or loss involves listed chemicals, please see page 53 for information on how to complete a DEA Form 107 (Theft or Loss of Listed Chemicals).

The DEA Form 106 must include the following information:

1. Name and address of the firm (practitioner),
2. DEA registration number,
3. Date of theft or loss (or when discovered if not known),
4. Name and telephone number of local police department (if notified),
5. Type of theft (e.g., night break-in, armed robbery),
6. List of identifying marks, symbols, or price codes (if any) used by the pharmacy on the labels of the containers, and
7. A listing of controlled substances missing, including the strength, dosage form, and size of container (in milliliters if liquid form) or corresponding National Drug Code numbers.

#### **If Investigation Finds No Theft or Loss**

If, after the initial notification to DEA, the investigation of the theft or loss determines no such theft or loss of controlled substances occurred, a DEA Form 106 does not need to be filed. However, for complete and accurate records, it is strongly recommended that the registrant notify DEA in writing of this fact in order to resolve the

initial report and explain why no DEA Form 106 was filed regarding the incident. 21 CFR 1301.76, 1304.21(a), 21 U.S.C. 827(a)(3).

#### Improper Use of DEA Form 106, Theft or Loss of Controlled Substances

The DEA Form 106 should not be used to document or explain minor inventory discrepancies, thereby “balancing the books.” 68 FR 40576 (Jul. 8, 2003). The DEA Form 106 should be used only to document thefts or significant losses of controlled substances. Minor inventory discrepancies, not attributable to theft, should not be reported to DEA or recorded on a DEA Form 106. If a practitioner is unsure of the significance of a loss after considering the factors described above, they should file a DEA Form 106. Any continuing pattern of loss of seemingly insignificant quantities should always be considered significant.

#### Breakage and Spillage of Controlled Substances

While neither the CSA nor DEA’s regulations specifically address the breakage and/or spillage of a controlled substance, DEA offers the following guidance, which was also published in the 2003 Notice of Proposed Rulemaking and guidance document, Reports by Registrants of Theft or Significant Loss of Controlled Substances, 68 FR 40576, 40578 (Jul. 8, 2003). The witnessed breakage or spillage of a controlled substance does not constitute a loss of controlled substances because the registrant can account for the controlled substances. These types of incidents do not require notification to DEA. If there is breakage, spillage, or other damage to controlled substances, but the controlled substances are still recoverable, options one and two for disposing are pursuant to the guidance document. Option three is pursuant to the 2014 Final Rule, Disposal of Controlled Substances, 79 FR 53520, (Sept. 9, 2014).

1. Send those controlled substances to a reverse distributor. 21 CFR 1317.05(a)(2).
2. Contact the local DEA Diversion Field Office to request assistance to dispose of the controlled substances pursuant to 21 CFR 1317.05(a)(4) and 1304.21(e).
3. Promptly destroy that controlled substance in accordance with 21 CFR 1317.90 using an on-site method of destruction. 21 CFR 1317.05.

DEA provided additional guidance on reporting theft/loss in its July 8, 2003 notice of proposed rulemaking. 68 FR 40576, 40578. If the breakage or spillage is clearly observed, but the controlled substances are

not recoverable, then the practitioner should document the circumstances of the breakage in their inventory records. Two individuals who witnessed the breakage should sign the inventory records, indicating what they witnessed. These records should be maintained in the registrant’s files. Under 21 CFR 1304.21(a), a registrant must keep complete and accurate inventory records.

#### In-Transit Loss of Controlled Substances

When all or part of an in-transit shipment of controlled substances fails to reach its intended destination, the supplier is responsible for reporting the in-transit loss of controlled substances to DEA. 21 CFR 1301.74(c). The purchaser is responsible for reporting any loss of controlled substances after they have signed for or taken custody of a shipment. The purchaser must then submit a DEA Form 106. 21 CFR 1301.76(b).

#### Robberies and Burglaries Involving Controlled Substances

The Controlled Substance Registrant Protection Act of 1984 (CSRPA) was enacted to protect DEA registrants against certain crimes. (See 18 U.S.C. 2118 for a complete text of CSRPA). The CSRPA provides for the federal investigation of controlled substance robberies and burglaries (or attempts) if any of the following conditions are met as noted in 18 U.S.C. 2118(a):

- The replacement cost of the controlled substances taken or attempted to be taken is \$500 or more.
- Interstate or foreign commerce was involved in the execution of the crime.
- A person was killed or suffered significant bodily injury as a result of the crime.

The perpetrator(s) convicted of violating CSRPA’s provisions may be subject to fines and/or imprisonment. 18 U.S.C. 2118 (c).

#### Recommended Safeguards for Prescribers

Additional measures to ensure security include:

- Keeping all unused prescription pads in a safe place where they cannot be stolen.
- Minimizing the number of prescription pads in use.

- Writing out the quantity prescribed in addition to writing the number prescribed to discourage alterations to the prescription, e.g., forty (40).
- Not preprinting your DEA registration number on your prescription pads.
- Cooperating with any pharmacist who contacts you to verify information about a prescription order; a corresponding responsibility rests with the pharmacist who dispenses the prescription. 21 CFR 1306.04(a).
- Using tamper-resistant prescription pads.
- Using Prescription Monitoring Program reports if available.

## **APPENDIX A – Definitions Based on the Controlled Substances Act and DEA’s Regulations**

The following definitions may be found in 21 CFR Part 1300 and/or 21 U.S.C. 802 and 823 except as otherwise noted.

### **Administer**

The direct application of a controlled substance to the body of a patient or research subject by 1) a practitioner (or in their presence by their authorized agent), or 2) the patient or research subject at the direction and in the presence of the practitioner, whether such application is by injection, inhalation, ingestion, or any other means. 21 U.S.C. 802(2).

### **Controlled Substance**

A drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V. 21 U.S.C. 802(6); 21 CFR 1300.01(b).

### **Detoxification Treatment**

The dispensing for a certain defined time period (i.e., short-term and long-term detoxification treatment) of a narcotic drug(s) in decreasing doses to an individual to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such time period. 21 CFR 1300.01(b). This regulation contains additional information related to the time periods for short-term and long-term detoxification treatment.

### **Dispense**

To deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling, or compounding necessary to prepare the substance for such delivery. 21 U.S.C. 802(10).

### **Distribute**

To deliver (other than by administering or dispensing) a controlled substance or a listed chemical. The term “distributor” means a person who so delivers a controlled substance or a listed chemical. 21 U.S.C. 802(11).

### **Electronic Prescription**

A prescription that is generated on an electronic application that meets the requirements of 21 CFR 1311.120(b) and transmitted through the application for practitioner’s review and approval with all of the data as noted under 21 CFR 1311.120(b)(9).

### **Individual Practitioner**

A physician, dentist, veterinarian, or other individual licensed, registered or otherwise permitted, by the United States or the jurisdiction in which they practice, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner. 21 CFR 1300.01(b).

### **Institutional Practitioner**

A hospital or other person (other than an individual) licensed, registered or otherwise permitted, by the United States or the jurisdiction in which it practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacy. 21 CFR 1300.01(b).

### **Inventory**

All factory and branch stocks in finished form of a basic class of controlled substance manufactured or otherwise acquired by a registrant, whether in bulk, commercial containers, or contained in pharmaceutical preparations in the possession of the registrant (including stocks held by the registrant under separate registration as a manufacturer, importer, exporter, or distributor). 21 CFR 1300.01(b).

### **(Jurisdiction of the) United States**

When used in a geographic sense, means all places and waters, continental or insular, subject to the jurisdiction of the United States, which, in addition to the customs territory of the United States, include but are not limited to the U.S. Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands. 21 CFR 1300.01(b).

### **Long Term Care Facility (LTCF)**

A nursing home, retirement care, mental care, or other facility or institution which provides extended health care to resident patients. 21 CFR 1300.01(b).

### **Maintenance Treatment**

The dispensing for a period in excess of twenty-one days, of a narcotic drug or narcotic drugs in the treatment of an individual for dependence upon heroin or other morphine-like drug. 21 CFR 1300.01(b).

### **Mid-level Practitioner (MLP)**

An individual practitioner, other than a physician, dentist, veterinarian, or podiatrist, who is licensed, registered, or otherwise permitted by the United States or the jurisdiction in which they practice, to dispense a controlled substance in the course of professional practice. 21 CFR 1300.01(b). This regulatory definition also lists some examples of MLPs.

### **Paper Prescription**

A prescription created on paper or computer generated to be printed or transmitted via facsimile and includes a manual signature. 21 CFR 1300.03.

### **Person**

Includes any individual, corporation, government or governmental subdivision or agency, business trust, partnership, association, or other legal entity. 21 CFR 1300.01(b).

## **Prescription**

An order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user (e.g., an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription). 21 CFR 1300.01(b).

## **Qualified Practitioner**

A practitioner who (i) is licensed under state law to prescribe controlled substances; and (ii) is not solely a veterinarian. 21 U.S.C. 823(l)(4)(B).

## **Readily Retrievable**

Certain records are kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time, and/or records that are kept on which certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records. 21 CFR 1300.01(b).

## **Reverse Distributor**

A person registered with DEA as a reverse distributor who acquires controlled substances from another DEA registrant or law enforcement for the purpose of:

- Returning unwanted, unusable, or outdated controlled substances to the manufacturer or another registrant authorized by the manufacturer to accept returns on the manufacturer's behalf; or
- Destruction.

21 CFR 1300.01(b).

## **Scheduled Listed Chemical Product**

Scheduled listed chemical product is a product that contains ephedrine, pseudoephedrine, or phenylpropanolamine and may be marketed or distributed lawfully in the United States under the federal Food, Drug, and Cosmetic Act as a nonprescription drug. Ephedrine, pseudoephedrine, and phenylpropanolamine include their salts, optical isomers, and salts of optical isomers. Scheduled listed chemical products do not include any products that are controlled substances under 21 CFR Part 1308. 21 U.S.C. 802(45)(A).

## **Ultimate User**

A person who has lawfully obtained, and who possesses, a controlled substance for their own use or for the use of a member of their household or for an animal owned by them or by a member of their household. 21 U.S.C. 802(27); 21 CFR 1300.01(b).

## **Valid Prescription**

A prescription that is issued for a legitimate medical purpose in the usual course of professional practice by (1) A practitioner who has conducted at least one in-person medical evaluation of the patient or (2) a "covering practitioner." 21 U.S.C. 829(e)(2)(A), 21 CFR 1306.04(a).