This Chapter Contains:

- State and Federal Laws Relating to Controlled Substances and Other Medications
- Drugs Used in Animal Shelters
- Acquiring Controlled Substances
- Record Keeping of Controlled Substances
- Storage and Security of Controlled Substances

# State and Federal Laws Relating to Controlled Substances and Other Medications

There are specific <u>laws</u> and <u>regulations</u> governing who has the right to possess and dispense various drugs. These regulations apply to medications indicated for both human and animal use. Drugs are included in Scheduled and Penalty Groups based on their effects, potential for abuse, history and current patterns of abuse, risk to public health, or potential to produce psychological or physical dependence.

The United States Drug Enforcement Administration (DEA) enforces the federal laws and the Texas Department of Public Safety (DPS) enforces state laws relating to dangerous and <u>controlled drugs</u>.

There are three main chapters of laws associated with dangerous drugs and controlled substances:

#### 1. Texas Health and Safety Code, Chapter 483, Texas Dangerous Drug Act

The Texas Dangerous Drug <u>Act</u> (Texas Health and Safety Code, Chapter 483, Section 483.001) defines a "dangerous drug" as:

"a device or a drug that is unsafe for self-medication and that is not included in Schedules I through V or Penalty Groups 1 through 4 of Chapter 481 (Texas Controlled Substances Act). The term includes a device or a drug that bears or is required to bear the legend:

(A) 'Caution: federal law prohibits dispensing without prescription' or 'Rx only' or another legend that complies with federal law; or

(B) 'Caution: federal law restricts this drug to use by or on the order of a licensed veterinarian."

This Act contains information on who can possess, obtain, and prescribe dangerous drugs, plus information on prescriptions, inventory, and seizure of drugs:

• Section 483.041 - an officer or employee of the federal, state, or local government is allowed to possess dangerous drugs in the usual course of business or practice or in the performance of official duties.

#### 2. Texas Health and Safety Code, Chapter 481, Texas Controlled Substances Act

This act provides information associated with drugs included in the Scheduled and Penalty Groups. Some pertinent sections under this code for animal control include:

• Section 481.067 (a) - a person who is registered to manufacture, distribute, analyze, or dispense a controlled substance shall keep records and maintain inventories in compliance with recordkeeping and inventory requirements of federal law and with additional rules the director\* adopts.

• Section 481.111 (b) - the language in the statute is as follows:

"(b) The provisions of this chapter relating to the possession of denatured sodium pentobarbital do not apply to possession by personnel of a humane society or an animal control agency for the purpose of destroying injured, sick, homeless, or unwanted animals if the humane society or animal control agency is registered with the Federal Drug Enforcement Administration. The provisions of this chapter relating to the distribution of denatured sodium pentobarbital do not apply to a person registered as required by Subchapter C, who is distributing the substance for that purpose to a humane society or an animal control agency registered with the Federal Drug Enforcement Administration."

• Section 481.181 - the director\* may enter controlled premises at any reasonable time and conduct an inspection of the premises pertaining to items covered under this Act, plus be able to inspect, copy, and verify the correctness of a record, report, or other document required to be made or kept under this chapter and to perform other functions under this chapter.

\*(In Chapter 481, "director" refers to the director of the Department of Public Safety or his/her designee.)

### 3. Title 21 – Food and Drugs, Chapter II, Drug Enforcement Administration

This is a United States (federal) code governing all dangerous and controlled drugs and addresses the issue of registration, storage, and documentation:

• Section 1301 – Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances: http://www.deadiversion.usdoj.gov/21cfr/cfr/2101cfrt.htm.

• Section 1304 – Records and Reports of Registrants:

http://www.deadiversion.usdoj.gov/21cfr/cfr/2104cfrt.htm.

# **Drugs Used in Animal Shelters**

#### **Dangerous Drugs**

These include a device or drug that is unsafe for self-medication and is not one of the controlled drugs (drugs in Scheduled or Penalty Groups), such as:

- Xylazine used for tranquilization or sedation prior to euthanasia
- Isoflurane (or other inhalants) used for anesthesia during surgery
- Acepromazine used for tranquilization or sedation prior to euthanasia

#### **Controlled Drugs**

The most common controlled drugs used in shelters belong in Schedules II through IV.

**Schedule II** - The substances in this schedule have a high potential for abuse with severe psychological or physical dependence liability. Schedule II controlled substances consist of certain narcotic, stimulant, and depressant drugs.

An example of a Schedule II drug used in animal control is:

• Sodium Pentobarbital – used for euthanasia of animals

**Schedule III** – The substances in this schedule have an abuse potential less than those in Schedules I and II and include compounds containing limited quantities of certain <u>narcotic</u> and non-narcotic drugs.

Examples of Schedule III drugs used in animal control are:

- Sodium Pentobarbital Combination used for euthanasia of animals
- Ketamine used for tranquilization of animal for capture or sedation prior to euthanasia
- Tiletamine/Zolazepam used for tranquilization or sedation prior to euthanasia

**Schedule IV** – The substances in this schedule have a lower potential for abuse than substances in Schedules I – III and may lead to a more limited physical or psychological dependence.

An example of a Schedule IV drug used in animal control is:

• Diazepam – used for sedation of animals prior to euthanasia

# **Acquiring Controlled Substances**

All medications can be obtained using a veterinarian's DEA registration. If the shelter does not employ a veterinarian, a veterinarian with a current registration may be able to work with a shelter to serve in this capacity if a veterinary-client-patient relationship is created with each animal.

#### **Denatured Sodium Pentobarbital:**

According to Section 481.111 of the Health and Safety Code, denatured sodium pentobarbital is the controlled substance that animal control facilities can order directly. Your facility must have a number issued from the Texas Department of State Health Services Zoonosis Control (ZC) in order to register with the DEA. If you are unsure how to do this, contact your Regional ZC office. Once you have been registered with the

DEA, your agency will get a registration certificate that allows you to buy denatured sodium pentobarbital for euthanasia. This certificate is not transferable. You must supply a copy of your DEA registration certificate to drug and veterinary supply companies before they will sell denatured sodium pentobarbital to you.

# **Record Keeping of Controlled Substances**

#### **Initial Inventory**

A registrant must take an inventory of all controlled substances in stock on the date he/she first engages in such activities. In the event there are no controlled substances at the facility at the initial inventory, a zero inventory should be recorded.

The inventory record must:

- 1. List the name, address, and DEA registration number of the registrant.
- 2. Indicate the date and time the inventory is taken.
- 3. Be signed by the person or persons responsible for taking the inventory.
- Be maintained at the location appearing on the registration certificate for at least two years.
- Keep records of Schedule II drugs separate from all other controlled substance records.
- Include the drug name, strength, form (for example, tablets, injectables, etc.), number of units, unit volume, and total quantity in stock.

#### **Biennial Inventory**

Every two years following the date of the initial inventory, a new inventory is required. The information required on the biennial inventory is the same as that for the initial inventory. The biennial inventory date can be changed to a more convenient date provided it is within six months of the required date and written notification is given to

the nearest DEA field office in advance of the date on which the registrant desires to take the inventory. A registrant must keep the biennial inventory record for two years and is not required to submit a copy to the DEA. Many registrants complete this inventory more often than every two years to enhance security and record keeping.

All inventories and records of controlled substances in Schedule II must be maintained separately from all other records of the registrant. All inventories and records of controlled substances in Schedules III, IV, and V must be maintained separately or must be in such form that they are readily retrievable from the ordinary records of the registrant. This means that animal surgery, euthanasia, or research records are not sufficient for the inventory.

All records pertaining to controlled substances shall be made available for inspection and copying by duly authorized officials of the DEA.

#### **Record Keeping Required for Daily Use in the Shelter**

A detailed log recording the exact use of controlled substances is required to be maintained at all times. These records should be kept in a bound log book with numbered pages rather that in anything with detachable pages, such as a loose-leaf binder. The following information is recommended to be included in the euthanasia log:

- the in-house assigned bottle number;
- date drug was dispensed/administered;
- the name of the person using the drug;
- species and breed of animal involved;
- animal identification number and weight;
- route administered;
- dosage amount of the drug used;

- total amount of the drug on hand after each use; and
- supervisor reconciliation of amount of drug used with drug remaining in stock.

#### **Order Forms**

**Schedule II drugs**: A registrant who has need for controlled substances in Schedule II must obtain these drugs by the use of a triplicate order form (DEA-222). Order forms can be obtained by requesting them on the initial application by checking block "3" of the Form DEA-224 or 225. Once a registrant has obtained DEA order forms, a separate requisition form, DEA-222A, will be mailed to the registrant in order to request additional books. No charge is made for order forms; they can also be ordered online at https://www.deadiversion.usdoj.gov/webforms/orderFormsRequest.jsp.

The Code of Federal Regulations requires that the official order form must be complete, legible, and properly prepared, with no signs of alteration, erasure or change of any description. Suppliers may refuse to accept forms that are not correctly and completely filled out and signed.

A common omission on DEA order forms is failure to complete the "number of packages" and "date received" section. It is important that persons responsible for executing Schedule II order forms verify the quantities received by dating and completing the right hand side of the order form.

**Schedule III through V drugs**: A registrant receiving controlled substances in these schedules must maintain records of transactions by filing supplier's invoices or maintaining a log book. The date of controlled substance receipt and any differences from the quantities ordered should be noted on the invoice. These records generally contain similar information as order forms and are to be retained for a two-year period.

# **Storage and Security of Controlled Substances**

Store the central supply (unopened, sealed bottles) of controlled substances in a securely locked, substantially-constructed safe or steel cabinet that is bolted or cemented to the floor or wall in such a way that it cannot be readily removed.

Access to the drug supply should be limited to supervisors, veterinarians, and properly trained euthanasia technicians. Any employee who has access to controlled substances may not have been convicted of a felony relating to controlled substances.

For high-volume shelters with a large supply of controlled substances kept on hand, a security alarm or surveillance system may be installed and may be required if there are any thefts and/or losses. Any drug disappearance of this nature must be reported to the DEA using the DEA Form 106. If outdated drugs need to be destroyed, contact the DEA for specific instructions.

For additional information, contact the DEA at:

10160 Technology Blvd. East Dallas, Texas 75220 214-366-6900

660 South Mesa Hills Drive, Suite 2000 El Paso, Texas 79912 915-832-6000 1433 West Loop South, Suite 600 Houston, Texas 77027 713-693-3000

> 10127 Morocco, Suite 200 San Antonio, Texas 78216 210-442-5600

https://www.dea.gov/