



# Guide to Controlled Drug Management in the High-Quality, High-Volume Spay/Neuter Setting



The ASPCA Spay/Neuter Alliance has created these guidelines to aid licensed veterinarians & clinics in determining proper ordering, storage & handling of controlled drugs.

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## **Overview**

Your spay/neuter program will use some combination of controlled drugs, which are regulated by the Drug Enforcement Agency (DEA).

Your organization must follow DEA and state regulations in the way that it orders, stores and tracks the usage of these drugs.



#### Highlights

- A licensed veterinarian must have a controlled drug license to order, prescribe, administer and dispense controlled drugs.
- Controlled drugs must be stored behind two locks. This means they need to be in a locked box which is also contained within a locked unit. The outer locked area must be permanently and securely fixed in place.
- Access to your controlled substances should be limited to as few people as possible.
- Controlled drugs must be received, inventoried and logged in very specific ways. The DEA regulates how those records are to be kept.



The information contained in this summary resource is not designed to provide legal advice, but rather to provide an overview of this important topic. Each organization is responsible for understanding and following all Federal and State regulations regarding controlled substances.

### **Important!**

Always learn state-controlled drug regulations in addition to federal requirements and be sure to comply with both.



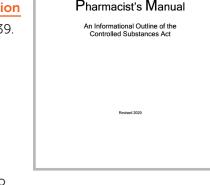


#### **DEA Registration Application**

Before anything else, the lead practitioner must apply for DEA registration for the facility (DEA Form 224) for schedules II, III, IV. The applicant can either fill out a hard copy application or complete the form online. Applications can be found/requested either on the **DEA Diversion** website or by calling the DEA registration call center at (800) 882-9539.

Registrations must be renewed every three years.

**NOTE:** If a practitioner is a contracted veterinarian who is an agent or employee of another practitioner registered to dispense controlled substances within the facility may, when acting in the normal course of business or employment, administer or dispense (other than by issuance of prescription) controlled drugs if authorized or permitted to



do so by the jurisdiction in which he or she practices, under the registration of the employer or principal practitioner in lieu of being registered him/herself.

#### Ordering

Schedule II controlled substances are used in the high-quality, high-volume spay/neuter clinic setting and may be ordered by filling out a separate DEA Form 222 for each or by electronically completing the <u>DEA Controlled Substance Ordering System</u>. Hard copy triplicate forms\* are supplied by the DEA; replacements can be requested on the DEA's website or by calling (800) 882-9539. The order forms are pre-numbered and should be used sequentially. The original and second copy of the form is sent to the vendor while the third copy is retained by the practice.

Ordering controlled drugs in Schedules III through V is done in much the same way as any other product in inventory. The supplier will normally ask for a copy of the current DEA registration to keep on file. There are no special paperwork requirements for Schedule III through V drug purchases and copies of inventory can be kept together but separate from Schedule II.

It is important to decide upon order point for each product. This is the minimum number in stock so when you are down to so many bottles they will be reordered in sufficient time.

\* The triplicate form used to order Schedule II drugs is being phased out, and Schedule II drugs will soon be ordered exclusively through a single-sheet order form which can then be electronically stored. The requirement to store Forms 222 separately from all other records may be met for electronic copies by storing them in such a way that they can be readily retrieved separately from all other records. Purchasers must be able, during an inspection or upon other DEA requests, to readily retrieve their electronic copies of Forms 222, with any related statements or other documents, and without any other records. Section 1305.17(e) Electronic copies of Forms 222 do not need to be stored on a different server or electronic system from a registrant's other records to meet these requirements.



#### Inventory

When the order is received, the practice's retained copy of the DEA Form 222 must be "closed out" with the quantity and date that the drug is received. Completed forms and all three copies of voided or unusable forms must be retained for at least two years. Completed forms must be maintained separate from all other documents; this usually means in a specific folder of their own and not interspersed in the accounting or non-controlled drugs inventory records. (see note above for eventual electronic storage of 222 forms).

Each registrant who maintains an inventory of controlled drugs must maintain a complete and accurate record of the controlled drugs on hand and the date that the inventory was conducted. This record must be in written, typewritten, or printed form. After an initial inventory is taken, the registrant shall take a new inventory of all controlled drugs on hand at least every two years. Each inventory must contain the following information:

- The date the shipment was received
- For each type of controlled drug received the following is recorded:
  - Number of bottles
  - Lot number
  - Expiration date
  - Number assigned to the bottles
- Two sets of initials for receiving (highly recommended)



#### Storage & Use

- Controlled drugs must be stored in a locked cabinet with limited access. A substantial container and a significant primary lock are the basic requirements.
- A continual inventory must be maintained.
- Inventory forms must conform to DEA and State regulations. Drug Services can provide sample forms that have been approved by the Board of Pharmacy.
- All controlled drug records must be maintained for a minimum of two years, however, some states require your records be kept for a longer period, so check local requirements.
- Any unexplained/unaccounted drug losses or discrepancies discovered require notification to the DEA.





#### **Wasted/Expired Drugs**

The DEA has specific rules that must be followed for disposing of expired or no-longer-needed controlled drugs. The correct procedure depends on whether the drug is an unused dose or unused stock. And of course, if there is a state-level requirement governing disposal of drugs, the more stringent procedures would apply.

An unused dose is the amount of controlled drug that was removed from the supply for a particular patient and was not actually administered or dispensed. Because the product may be contaminated in some way, it is not possible to return the unused portion to the supply system. Unused doses are normally squirted into absorbent material for disposal in the regular trash. If the unused dose was already logged out of the hospital's system using the "drawn/given" method, there are no special record keeping rules except to note the wasted amount on the drug log.

Unused stocks are quantities of controlled drugs that have never been "allocated" to a particular patient and are still "on the books" of the practice.

Very small amounts of schedule III through V substances (such as minute amounts of tiletaminezolazepam that has been reconstituted and has now expired or thiopental sodium that has precipitated) may be disposed of by squirting it in absorbent material for disposal in the regular trash. When this happens, an entry on the log stating date, time, drug, quantity, and method of disposal is sufficient. This method is only for the infrequent disposal of reconstituted drugs, not for the disposal of unreconstituted but expired drugs. Although not required, it would be prudent to have two persons initial or sign the log as witnessing the disposal.

For the remainder of unused stocks, the first step in disposal should be to contact the original supplier of the drug and inquire about returning it for credit or disposal. Often, drug manufacturers and distributors will replace outdated drugs with fresh supplies as long as the expiration date was in the recent past.

If returning the drugs are not an option, disposal of unused stocks of controlled drugs is usually accomplished using "Reverse Distributors." The DEA will no longer accept drugs for disposal but has licensed private companies to receive controlled drugs that are expired or no longer wanted. These companies typically charge a fee for the service, but the administrative aspect of the process is greatly streamlined for the veterinary practice. A current list of reverse distributors is available from any DEA office and a short, compiled list of reverse distributors is available on the Safetyvet website.

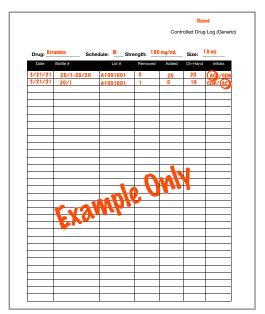
Of course, security and accountability for the drugs should be maintained until they are shipped, and confirmation is received from the reverse distributor.



### **Further Resources**

### **Closed Bottle Log & Numbering**

- **1.** Controlled drug orders must be processed the day they are received, and bottles must be individually numbered.
- 2. Orders arrive with an invoice, on which you will record:
- The date the shipment was received;
- For each type of controlled drug you received you will record the: Number of bottles, Lot number, Expiration date,
- Number assigned to the bottles;
- Require two sets of initials for receiving.
- Each controlled drug will have its own closed bottle log sheet; use tabs in a binder for ease of use.
- Each log page will include: Drug name; Schedule; Strength; Size; Date; Bottle #; Lot #; Removed; Added; On-hand; Initials.





#### **Open Bottle Log**

- **1.** Each controlled drug will have its own open bottle log sheet; use tabs in the binder for ease of use.
- 2. Make sure to remove the bottle from the closed bottle log first, then enter into the open bottle log for usage.
- Each log page will include: Drug name; Schedule; Strength; Size; Date; Bottle #; Lot #; Removed; Added; On-hand; Initials.





### Daily Use Drug Log (Feline)

- **1.** Use white color for feline drug log to distinguish from separate yellow canine drug log
- 2. Sequential patient list with a unique ID# (that is linked to the client's address) is clearly added/labeled
- **3.** Check beginning and end controlled drug volumes with two sets of initials for accuracy
- 4. Veterinarians double-check schedule II end-of-day totals and initials
- 5. Registered veterinary technician adds end of day totals to next day daily log the night before

ASPCA Spay/Neuter Alliance					Feline Dru	ug L	og								
	Team	Docto	or: 🔺	Сте	am Leader: CE	w	Date:	3/21/21	Start: 5 mL			Page # 1			
Cat Name	Vax.	Sex	Age	Kgs	ID #	ET	Dr.	Sx. Info.	Drug Info	TTDex*	MEL*	GABA	Other		
<sup>1)</sup> Puddles M Patient Info:	?			1.9	20-4394				Bottle # Amt. Used Waste	0.07	0.04	0.5	Midazolam 0.16 mLs IM		
<sup>2)</sup> Joy HSL	:								Bottle #				Buprenorphine		
Patient Info:				4.5	20-5126			P3	Amt. Used Waste	0.16	0.09	0.5	0.15 mLs TM (PM) + 0.15 mLs TM (AM)		
3) Patient Info:	_								Bottle # Amt. Used Waste						
4)									Bottle # Amt. Used						
Patient Info: 5)									Waste						
9) Patient Info:									Bottle # Amt. Used						
6)	-								Waste						
Patient Info:	_								Bottle # Amt. Used Waste						
7)									Bottin#						
Patient Info: 8)						1			te						
Patient Info:	-						K		Bottle # Amt. Used Waste						
9)	6		Y			5			Bottle # Amt. Used						
Patient Info:	V								Amt. Used Waste						
10) Patient Info:									Bottle # Amt. Used						
									Waste						
Start Time:	Stop Time:			]			Remaining Total 4.			* All drug	doses in r	mL			
					Updated: 1	1/1/1	8								





### Daily Use Drug Logs (Canine)



- **1.** Use yellow paper for canine drug log to distinguish from separate white feline drug log
- 2. Sequential patient list with a unique ID# (that is linked to the client's address) is clearly added/labeled
- **3.** Check beginning and end controlled drug volumes with two sets of initials for accuracy
- 4. Veterinarians double-check schedule II end-of-day totals and initials
- 5. Registered veterinary technician adds end of day totals to next day daily log the night before

ASPCA Spay/Neuter Alliance Canine Drug Log																
	Team D	octor:	AC		Feam Leader:	CEW	Date: 3/21	/21	Start:	50mL	20mL	10mL	P	Page #	1	
Dog Name	Vax.	Sex	Age	Kgs	ID #	Dr.	Sx. Info.	Drug Info		MOR/HYD*	KET*	DIAZ/ MIDAZ*	MEL*	PO MEL	Other	
1) Maynard MPR Patient Info:	0	м	A	20	20-4294			START Bottle 20/1 (H 20/1 (K Waste 20/1 (M				1.60			Torb 0.4 mLs IV	
2) Poddington Patient Info:	_				20-4132			START Bottle # Waste				1.0. 1.0. +2.0 4.0				
3) Tiny Dancer Patient Info:					20-4255			START Bottle Waste			Π	2.5				
4) Giggles Patient Info:					20-4390		No Sx ABS	START Bottle # Waste							CEW	
5) Oogum Boogum Patient Info:	-				20-4394			START Bottle Waste			T	0.16				
8) Granola Jones Patient Info:	0	м	A	5	20-4629			START Bottle # Waste				0.35				Praw
7) Zed Patient Info:	-				20-4101			START Bottle 20/2 (M) Waste				2.0 1.0 3.0				first
8) Boomer Patient Info: NT Caution	R	F JM	A	3.5	20-4666			START Bottle # Waste	_	+0.02 0.02 IM	20/1 *0.11 0.1 IM	20/1 0.25 IV	0.14	0.20	Puppy magic 0.10 PexMed IM	
9) Patient Info:							10	START Bottle Waste								
10) Patient Info:					M		pre	TART Bottle # Waste	J							
Start Time:	Sto	2		<u>, (</u>			Remaini	ng Total				9⁄0	CEAA			
					Upda	ated: 11/1	//18			7	J	J		' All dru	g doses in mL 3/21/21	CEN