Regulations for the Veterinary Hospital Pharmacy
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Veterinarians and the State Board of Pharmacy

The Board of Veterinary Medicine regulates and licenses people practicing veterinary medicine in the State. Although there are professional standards defining “veterinary/client/patient relationship” and proper prescribing of medications, it falls to the Board of Pharmacy in the state to regulate how prescription medications are dispensed to the general public. To simplify, the Board of Veterinary Medicine controls the professional PRESCRIBING of prescription medications and the Board of Pharmacy regulates the DISPENSING process for prescription medications. Veterinary practices must follow the regulations of both agencies.

Since veterinary practices are not licensed as retail pharmacies, it is normally against state pharmacy regulations to fill a prescription for a legend (prescription) drug that was written (or phoned in from) outside the practice. In-house veterinary pharmacies are allowed to dispense prescription medication only to current patients of that practice when ordered by a veterinarian in that practice.

Over-the-Counter Sales

Veterinarians are routinely faced with clients requesting medications or drugs without presenting the patient for a diagnosis. Under the requirements of the Food, Drug and Cosmetic Act, only products specifically labeled and packaged for over-the-counter sale may be dispensed in this manner. The same drug substances can be marketed in a number of different dosage forms, intended for use by different routes of administration, and in different species of animals. Thus, these drug products may be prescription drugs in some cases and OTC in others.

Any medication or drug labeled with "Caution: to be dispensed by or on the order of a licensed veterinarian" is considered a prescription (or legend) medication and must be dispensed under those rules. There are no exceptions. Veterinarians who sell prescription medications without a veterinarian-client-patient relationship could face loss of licensure as well as a fine, but retail store owners risk only the fine and discontinuance of the product.

There are no special record keeping requirements for over-the-counter sales, but as a professional matter, it is highly recommended that every drug or product dispensed to a client be entered on the patient's medical record or on the practice computer.
Dispensing Prescription Medications

Veterinarians may only dispense or administer a prescription drug (one that is labeled for use by or on the order of a veterinarian or physician) when he or she has a working knowledge of the conditions and treatment regimes of a particular patient and client. This is known as the veterinarian-client-patient relationship. This relationship is built on a simple foundation: the physical examination. Without the examination, the veterinarian-patient-client relationship does not exist.

In the food animal industry, it is customary to treat patients as groups in certain instances. The same relationship must still exist, but the examination can be of a herd or flock instead of a particular animal. Food animal veterinarians should be especially cautious of dispensing medications to clients who may not have a thorough understanding of the problem and the treatment protocol.

Clear directions including the drug name and quantity dispensed, dosage, route, and frequency of administration must be written in the medical record or treatment sheet for all prescription drugs dispensed. The client should be especially cautioned (and it should appear on the prescription label) about the necessity for withholding milk or meat from treated animals in cases where residues of the drug may contaminate the product.

Packaging and Labeling

Prescription medications MUST be dispensed only in child-proof containers, even small quantity prescriptions such as a single tapeworm tablet, unless the client requests otherwise. Envelopes, baggies, or other similar containers can only be used to comply with the client's expressed verbal or written wishes for non-child-proof containers. The client may be asked if he or she would prefer an envelope or non-child-proof container BEFORE it is dispensed. When the client requests or approves of other dispensing containers, a note to that effect should be made on the medical record or treatment sheet. Although this is not mandated, medications that are pre-packaged for dispensing to clients, such as ophthalmic drops and ointments, fit nicely into a plastic pill vial. This practice gives the proper impression to the client (prescription medicine rather than an over-the-counter product) and provides an ideal place to adhere the prescription label.

Every container of prescription medication dispensed from a veterinary practice must comply with the labeling requirements of the Food and Drug Administration (FDA). At a minimum, the following information must be clearly printed or typed on a label affixed to the dispensing container:

- Identification of the hospital - including street address, city, state, and phone number,
- Name of the prescribing veterinarian,
- The current date,
- The name of the patient - for veterinary prescriptions, the name of the animal, and the last name of the owner are acceptable,
- The name, strength, and quantity of the drug,
- Clear directions for use,
- Expiration date if the supply being dispensed will not be used up during the current treatment period (e.g., more than a month's supply),
• The number of authorized refills (optional, but printing NO REFILLS on the label is a good method to keep clients from calling back several months later and wanting "more of the stuff we had before"),
• Any special precautions (e.g., keep refrigerated, or shake well before use),
• The phrase "For veterinary use only" is recommended when the drug is one approved for use on animals only (Note: this phrase is routinely printed on all prescription labels from veterinary hospitals because it's easier than trying to decide which ones to label and which ones to omit).
• The phrase "Keep out of the reach of children" is also recommended and routinely used on all veterinary prescriptions.

Most labels are placed directly on the vial and clear tape is placed over the writing to prevent alterations or smudging. For the times when the directions are going to be lengthy (as in the initial steroid therapy) the label can contain all the regular information with a statement saying "See enclosed directions." The specific, detailed directions can then be rolled up and placed on the inside of the vial with the tablets. Directions such as "Give as directed" are very vague and should be avoided.

**Compounding Medications**

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

However, FDA is greatly concerned about veterinarians and pharmacies that are engaged in manufacturing and distributing unapproved new animal drugs in a manner that is clearly outside the bounds of traditional pharmacy practice and that violates the Act (e.g., compounding that is intended to circumvent the drug approval process and provide for the mass marketing of products that have been produced with little or no quality control or manufacturing standards to ensure the purity, potency, and stability of the product). These activities are the focus of this guidance. Pharmacies and veterinarians who engage in activities analogous to manufacturing and distributing drugs for use in animals may be held to the same provisions of the Act as manufacturers.

With regard to compounding from bulk drug substances, two Federal Appeals Court decisions, United States v. Algon Chemical Inc., 879 F.2d 1154 (3d Cir. 1989) and United States v. 9/1 Kg. Containers, 854 F.2d 173 (7th Cir. 1988), affirmed the FDA position that the Act does not permit veterinarians to compound unapproved finished drug products from bulk drug substances, unless the finished drug is not a new animal drug. The principle established by the court applies equally to compounding by pharmacists.

Neither the Act nor its implementing regulations exempt veterinarians or pharmacists from the approval requirements in the new animal drug provisions of the Food, Drug, and Cosmetic Act.
“Compounding” does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.

Generally, FDA will defer to state authorities regarding the day-to-day regulation of compounding by veterinarians and pharmacists of animal and human drugs that are intended for use in animals. FDA anticipates that, in such cases, cooperative efforts between the states and the Agency will result in coordinated investigations, referrals, and follow-up actions by the states.

However, when the scope and nature of activities of veterinarians and pharmacists raise the kinds of concerns normally associated with a drug manufacturer and result in significant violations of the new animal drug, adulteration, or misbranding provisions of the Act, FDA has determined that it will seriously consider enforcement action. In determining whether to initiate such an action, the Agency will consider whether the veterinarian or pharmacist engages in any of the following acts:

1. Compounding of drugs for use in situations (a) where the health of the animal is not threatened, and (b) where suffering or death of the animal is not likely to result from failure to treat.
2. Compounding of drugs in anticipation of receiving prescriptions, except in very limited quantities in relation to the amounts of drugs compounded after receiving prescriptions issued within the confines of a valid VCPR.
3. Compounding of drugs that are prohibited for extra-label use in food-producing or nonfood-producing animals, under 21 CFR 530.41(a) and (b) respectively, because the drugs present a risk to the public health.
4. Compounding finished drugs from human or animal drugs that are not the subject of an approved application, or from bulk drug substances, other than those specifically addressed for regulatory discretion by the FDA, Center for Veterinary Medicine, e.g., antidotes. Inquiries about compounding from unapproved drugs or bulk drug substances should be directed to CVM, Division of Compliance, 301-827-1168.
5. Compounding from approved human drugs for which FDA has implemented a restricted distribution system.
7. Compounding drugs for third parties who resell to individual patients, or offering compounded drug products at wholesale to other state licensed persons or commercial entities for resale.
8. Failing to operate in conformance with applicable state law regulating the practice of pharmacy.
9. Compounding of drugs for use in animals where an approved new animal drug or approved new human drug used as labeled or in conformity with 21 CFR Part 530 will, in the available dosage form and concentration, appropriately treat the condition diagnosed.
10. Compounding from a human drug for use in food-producing animals if an approved animal drug can be used for the compounding.
11. Instances where illegal residues occur in meat, milk, eggs, honey, aquaculture, or other food-producing animal products, and such residues were caused by the use of a compounded drug.
12. Labeling a compounded drug with a withdrawal time established by the pharmacist instead of the prescribing veterinarian.
13. Labeling of compounded drugs without sufficient information, such as withdrawal times for drugs for food-producing animals or other categories of information that are described in 21 CFR 530.12.

The foregoing list of factors is not intended to be all inclusive. Other factors may be appropriate for consideration in a particular case.

Bulk drug substances for compounding and subsequent use in animals to which CVM would not ordinarily object:
- Ammonium molybdate.
- Ammonium tetrathiomolybdate.
- Ferric ferrocyanide.
- Methylene blue.
- Picrotoxin.
- Pilocarpine.
- Sodium nitrite.
- Sodium thiosulfate.
- Tannic acid.

FDA vs. EPA Dispensing

Germicidal preparations for use on inanimate objects, as well as rodenticides, and most insecticides are subject to the Federal Insecticide, Fungicide, and Rodenticide Act, administered by the Pesticide Regulation Division of the Environmental Protection Agency (EPA), Washington, D.C. 20460. However, some products used to control external pests are intended to act systemically and, therefore, are regulated as drugs by the FDA and not as pesticides by the EPA. For example, topically applied flea control products are usually regulated by EPA, whereas orally administered flea control products generally fall under FDA's jurisdiction. In those situations where violative residues of pesticides are detected in animal-derived human food products, FDA has the responsibility for regulatory enforcement.

EPA has issued a notice to remind retailers of a Dec. 31, 2004, stop-sale date for all outdoor diazinon home, lawn, and garden products. It is now unlawful to sell diazinon outdoor non-agricultural use products in the United States. This is part of an agreement between EPA and diazinon registrants to phase out and eliminate all residential uses of the insecticide diazinon.

Off Label Drug Use

AMDUCA

The Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA) was passed by congress to alleviate some of the barriers veterinarians faced when they must prescribe human drugs for patients, and when they must use a drug that was not approved for a particular species of patient. Although these rules seem "common-sense" to many people, until now, veterinarians have been breaking the law every time they used a drug in either of these two ways. The Act has not changed the drug approval process, but has simply made it legal to prescribe a human drug (like insulin) for a veterinary patient. It has also made it acceptable to use a veterinary-specific drug on a species of animal for which it has not been approved by the FDA when no other veterinary
drug for the same condition is available. It does not make it acceptable to use a non-approved drug in any species of animal for a condition when there is a drug licensed for that species.

From a regulatory standpoint, a companion animal veterinarian stands little risk of problems from extra-label drug use; however, many attorneys and practice consultants recommend obtaining an "informed consent" signature from the client. This does not mean the client waives his or her rights in any future actions against the practice, but it does prove that he/she was informed of the off-label use and granted their permission to proceed.

Food animal practitioners must be more conservative in their off-label use of medications. Since the FDA is seriously concerned with protecting the nation's food supply, there is definitely the chance of regulatory "scrutiny" if a drug residue was found in an animal at slaughter and was traced back to a veterinary practice. Specific guidance for the extra-label use of any medication in food animals should be obtained from the FDA's Center for Veterinary Medicine or the state veterinarian. Additionally, records should be maintained that clearly show the practice has informed the client of required milk and slaughter withholding times.

The following drugs are prohibited for extra-label animal and human drug uses in food-producing animals:

- Chloramphenicol.
- Clenbuterol.
- Diethylstilbestrol (DES).
- Dimetridazole.
- Ipronidazole.
- Other nitroimidazoles.
- Furazolidone (except for approved topical use).
- Nitrofurazone (except for approved topical use).
- Sulfonamide drugs in lactating dairy cattle (except approved use of sulfadimethoxine, sulfabromomethazine, and sulfaethoxypyridazine).
- Fluoroquinolones.
- Glycopeptides.

Extra-label use of drugs in treating food-producing animals for improving rate of weight gain, feed efficiency, or other production purposes, or for routine disease prevention is prohibited under AMDUCA. A drug (including a bulk drug) may not be mixed into feed for any use or at a potency level not specifically permitted by the regulations in 21 CFR Part 558, even if prescribed by a veterinarian.

In addition to uses which do not comply with the general provisions above, the following specific extra-label uses are not permitted:

1. Extra-label use in an animal of an approved new animal drug or human drug by a lay person (except when under the supervision of a licensed veterinarian).
2. Extra-label use of an approved new animal drug or human drug in or on an animal feed.
3. Extra-label use resulting in any residue which may present a risk to the public health.
4. Extra-label use resulting in any residue above an established safe level, safe concentration, or tolerance.
Veterinary Use of Approved Human Drugs

Most veterinary use of human-labeled drug products occurs in non-food animal practice (companion, sporting, exotic, etc.). Many diseases of pets and other non-food animals cannot be treated in accordance with current standards of veterinary practice without the use of human-labeled drugs because approved drug products bearing veterinary labeling often do not exist. FDA has generally refrained from taking enforcement actions in this area because there is no expected adverse impact upon the public health. In rare circumstances, when the health of the treated animals is harmed, regulatory attention by FDA would be considered or, preferably, referred to the state veterinary licensing authority for investigation.

Use of human-labeled drug products in food-producing animals should be limited to those cases where appropriate veterinary-labeled therapy does not exist. It is unacceptable to use a human-labeled product for common disease conditions in food animals because approved veterinary-labeled drug products, e.g., antibacterials, anti-inflammatory agents, etc., are available. The food animal veterinarian assumes greater responsibility when he or she uses a human-labeled drug rather than a veterinary drug. Use of human-labeled drugs may be considered by food animal veterinarians only when they have made a careful and definitive diagnosis and evaluation of the condition for which the drug is to be used, and they are operating within the confines of a valid veterinary/client/patient relationship; made a deliberate determination that there is no other appropriate veterinary-labeled therapy (i.e., there is no marketed veterinary-labeled drug product specifically labeled for the disease condition to be treated or the veterinary drug has been found clinically ineffective by the veterinarian in the animals to be treated) and they have taken adequate steps to prevent the occurrence of illegal residues in edible animal products. This should include a review of the best available toxicological and tissue distribution and tissue residue depletion data and establishment of an extra long drug withdrawal period prior to marketing meat, milk, or eggs. The animal owner or manager should be given explicit written withdrawal instructions. The practitioner should have a high degree of confidence that the client will follow the drug withdrawal instructions.

Regulatory action will be considered when an illegal residue occurs even if the veterinarian followed the foregoing precautions. Lay persons (e.g., owners) who administer human-labeled drugs either to food-producing or non-food animals without the supervision of a licensed veterinarian operating within the framework of a valid veterinarian/client/patient relationship will be subject to regulatory action.

MUMSA

Minor use drugs are drugs for use in major species (cattle, horses, swine, chickens, turkeys, dogs, and cats) that are needed for diseases that have a limited geographic range or affect a small number of animals. Minor species are all animals other than the major species, which includes zoo animals, ornamental fish, parrots, ferrets, and guinea pigs. Some animals of agricultural importance are also minor species. These include sheep, goats, catfish, and honeybees.

The University of Florida CVM maintains an extensive database of drugs and dosages for minor species on the Internet at http://www.nrsp-7.org/mumsrx/.
Internet Pharmacies

With the proliferation of Internet pharmacies and chain stores getting into the veterinary pharmaceutical market, the veterinary practice may receive requests from clients for medications to be filled by these "outside pharmacies." If a medication would otherwise be prescribed for a patient, a veterinarian cannot force a client to purchase needed medication from any specific source, including the in-house pharmacy. If the client requests a written or verbal prescription for medication, the veterinarian must provide that prescription if he/she would have otherwise dispensed the medication from the in-house pharmacy. This implies that a veterinary/patient/client relationship exists and that the veterinarian assumes the primary medical responsibility for the medical case.

It is certainly allowable for the practice to charge a reasonable fee for the execution of the prescription. Furthermore, attempting to educate the client on the hazards associated with Internet drug purchases is certainly acceptable, including matching prices as a client courtesy. However, the prescription cannot be withheld simply because the client chooses to have it filled somewhere other than the veterinary practice.

It is also acceptable for a veterinary practice to take refill orders from a client via the telephone, e-mail, or other means of communication and ship the medication to the client's home or business as long as the refill would have been approved and dispensed if the client were present in the practice. If the medication to be refilled is a controlled substance, it must be shipped via a secure means with an adult signature obtained to confirm delivery.

There are many states Attorney's General that are trying to regulate the Internet pharmacy industry, but that's a different issue...the practice can assist those law enforcement agencies but the veterinarian must still give a prescription to the client if he/she asks for it.

Keeping Controlled Drugs Under Control

The whole issue of ordering, storing, dispensing, and recording controlled drugs can be of the most confusing in the veterinary practice. Since it’s inception in 1970, the Controlled Substance Act has placed specific mandates on those who manufacture, distribute, administer, or dispense drugs that are deemed addictive or abusive. The Act established the federal Drug Enforcement Agency (DEA) to formulate and enforce regulations. In addition, many states have enacted supplemental regulations that apply in those jurisdictions.

Penalties for violating those regulations can include written warnings, fines, disciplinary action by the state professional board, and even revocation of state and federal controlled substance certification.

There are five categories, or schedules, of controlled substances but, in a clinical veterinary practice, schedule I drugs are rarely used. Recognizing a controlled substance and it’s schedule is fairly simple - the label contains a large letter "C" with roman numerals depicting the schedule centered within the "C." This list is not all inclusive, but some common controlled substances in veterinary hospitals are:

- Anesthetics such as pentobarbital, sodium thiopental (Pentothal), Telazol, ketamine and diazepam (Valium).
• Diphenoxylate with atropine (Lomotil), Hydrocodone (Hycodan), phenobarbital (except dilantin).
• All forms of euthanasia solution.
• Anabolic steroids such as stanozol (Winstrol-V), testosterone, nandrolone, mibolerone (Cheque Drops), and boldenone (Equipoise).
• Pain medications such as butorphenol (Torbutrol, Torbugesic), oxycodone, buprenorphine (Buprenex), fentanyl (Duragesic).

A complete list of controlled substances can be obtained on the DEA's Web site at http://www.deadiversion.usdoj.gov/schedules/schedules.htm.

With the increased emphasis by governments to curb America's drug problems, health care providers are enduring the results of more frequent audits and reviews by federal and state regulatory agencies. Even veterinarians who have been "left alone" or who have "never had a problem" are finding themselves in discord with the DEA.

**Registering With the DEA**

Every veterinarian who orders, dispenses, prescribes, or administers a controlled substance must be registered with the federal DEA and, in some cases, the state agency that regulates controlled substance activity. In most cases, the registration classification is for a “practitioner.”

Recently, the federal DEA has changed the rules to allow, in certain situations, associate veterinarians to act as “an agent” of another veterinarian (or practice) and forego the individual registration requirement. Although this idea has appeal because of the cost savings, it's not really suitable for most veterinary practices. This type of registration was designed for the large medical facility with hundreds of residents, interns, or attending physicians. In these instances, the institution would routinely do background checks into each provider and would have a central pharmacist overseeing the entire controlled drug program from ordering to patient administration.

Furthermore, in this type of registration, an "agent" cannot write or phone prescriptions to be filled outside of the practice; only a registered practitioner can execute a prescription.

Most veterinary practices just do not have the safeguards in place to satisfy the requirements of this type of registration. For instance, each registered practitioner must conduct a background check of any person they authorize to prescribe, dispense, or administer controlled drugs as their agent. Few practices are willing go through the effort to accomplish these background checks and the ones that do are sometimes surprised by what they find out!

In these “agent” situations, there is also an expectation that the registered veterinarian would formally review the “agent veterinarian’s” actions on a given schedule (comparable to a peer review process). Given the nature of the average veterinary practice, these requirements would be difficult to meet. Finally, remember that the registered practitioner's license would be at risk if the agent were to misuse or divert controlled substances and the registered practitioner did not have the safeguards in place to recognize or prevent the action.

A technician carrying out the order of the registered veterinarian would not normally be considered an “agent” because he or she is not authorized to order the action. However, it is
expected that appropriate internal controls and record keeping procedures are instituted to minimize unauthorized access and detect inappropriate activity.

Multiple Facilities

If there is more than one physical location in the practice, at least one veterinarian must be registered at each location where controlled substance activity will take place. For instance, in order for controlled substances to be stored and dispensed from a satellite location, the main hospital and the satellite location must be registered individually.

A veterinarian may be registered at more than one location when necessary or practices with multiple veterinarians can have a different one registered at each location in order to meet this requirement.

Relief veterinarians and mobile practitioners should obtain their own DEA registration at their "base of operations" address. This will allow them to issue verbal and written prescription orders at any location where they are licensed to practice, and to use the supplies of the “host practice.” A relief veterinarian who orders controlled substances with their DEA number, would be responsible for the record keeping and security of those drugs, regardless of their ultimate place of use.

A controlled substance registration is valid for three years. For new applications, or if the renewal form has not been received at least 45 days prior to a registrant’s expiration date, contact the DEA at 1-800-882-9539. Registration forms and an interactive application are also available on the DEA's Web site (www.deadiversion.usdoj.gov)

Security and Staff Access

Controlled substances must be kept in a “securely locked, substantially constructed cabinet or safe.” A common myth in the veterinary profession is the requirement for double locks; this is not a bad idea, but it is not a requirement. A substantial container and a significant primary lock are the basic necessities.

The owner of the controlled substances must make a reasonable attempt to keep them secured from unauthorized persons, so the interspersing of controlled substances among the entire pharmacy so that thieves would be less likely to "tear up" the cabinet is not allowed unless the entire pharmacy area has security adequate to meet the definitions of the Controlled Substances Act. Portable lock boxes must be securely affixed to an immovable object such as a cabinet or wall or locked inside of an immovable safe or cabinet when not in use. Similarly, lightweight filing cabinets or fire safes are inappropriate since they can be easily picked up and removed.

Mobile units should be stocked with only enough of each drug for basic operation. Excessive supplies should remain in a fixed, secure location. There are no additional security requirements for vehicles other than a substantial container be used if the vehicle is ever unsupervised (like in the parking lot of a store). The container must be locked when unsupervised. Simply keeping the drugs in a box or bag and locking the vehicle's doors is not adequate. If the vehicle is not equipped with locking bins or compartments, a small, lockable safe should be mounted to the vehicle for storage of controlled drugs (the box should be in an "out-of-sight" location if possible). If these security measures are followed, it is not necessary to remove the drugs from the vehicle for short-term storage.
Situations where the drug cabinet is left open during the day, the key to the cabinet is “hidden” where everyone knows it’s locations, and “on-the-shelf storage” have also contributed to pilfering and diversion of controlled substances by staff and visitors.

In one recent incident in Tennessee, a veterinary assistant without specific authority to access the drugs stole 30cc of euthanasia solution and attempted to kill her ex-husband. During the investigation, it was revealed that the staff member gained access on a weekend when she was cleaning kennels because the location of the “hidden key” was common knowledge among the staff. The woman was arrested and is now in jail, but the end result for the practice is still undetermined. It is likely they will not only be cited for laxed security, but they may even be open to liability for negligence in a civil case brought by the victim.

In most cases, a combination-style lock is a better choice than a key style for the “working supply” of controlled substances in a veterinary practice. Locks like the one pictured below are inexpensive (about $60) and can be installed on wood or metal doors. Most styles lock automatically when the door is closed. If a combination lock is used, the combination should be changed on a regular basis and whenever someone with a knowledge of the combination leaves.

On a similar note, when using a cabinet or drawer for controlled drug storage:
  • It must be sturdy enough to be a reasonable deterrent.
  • The hinges should be internal to the door or at least a style that can’t be easily removed.
  • All sides of the cabinet and drawer must be enclosed so that access cannot be gained by removing the drawer above or opening the cabinet to the side of the locked one.

In the end, veterinary hospitals must take whatever precautions are necessary to protect controlled substances from break-ins as well as pilfering by staff or visitors.

**Ordering Controlled Substances**

In most aspects, ordering controlled substances in Schedules III through V is done much the same way as any other product in our 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, but it is highly recommended that copies of the invoices or packing lists be maintained in a special file so that reconciliation of discrepancies can be done quickly.

Ordering Schedule II substances (morphine, demerol, oxymorphone, fentanyl) does take a little more work. The practice must prepare and send an accurate DEA Form 222 to the supplier. These triplicate forms are supplied by the DEA; replacements can be requested on the DEA's Web site or via telephone at (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.

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 substances inventory records.
All records related to the purchase and use of controlled substances must be maintained for at least two years (usually corresponding with the biennial inventory).

**Special Situations**

Obtaining controlled substances from a local pharmacy by writing a prescription for "in-house" or resale use is usually prohibited because it circumvents the normal accountability process at the DEA. Prescriptions filled at local pharmacies for controlled drugs should only be for specific patients and not to replenish hospital supplies unless the pharmacy possesses a wholesale distributor DEA registration.

Practices with multiple physical locations must be especially cautious of ordering the drugs for one location and transferring them to another. This could be an acceptable practice if meticulous records are kept of each transfer, every location, is registered with the DEA, there is adequate security at every location and appropriate usage records (patient-level accountability) are maintained for the drugs transferred.

Additionally, when schedule II drugs are transferred from one location to another, the receiving facility must prepare and submit a completed DEA Form 222 to the issuing facility, just as if the issuing facility were a supply company. The issuing facility must annotate and submit copy two of the DEA Form 222 to the DEA field office when the transfer is made. In the end, most practices with multiple locations find it easier and more accurate to order controlled drugs for each location using the different DEA numbers for that respective location.

Many practices help the local humane organization or county impound facility by acting as consultants. Because of the severe problems associated with security and record keeping at these facilities, as well as the liability that is placed on the veterinarian, it's not a good idea for a veterinary practice to order or transfer controlled substances (such as euthanasia solution) to an impound facility for their exclusive use.

In most states, if they qualify as a legitimate impound facility, the DEA will issue controlled substance licenses to these organizations directly so they can procure their own supply of euthanasia solution. If the impound facility is unable to obtain a DEA permit of their own, then the veterinarian could agree to euthanasia (or supervise the euthanasia) of animals with drugs from his or her supply on a case-by-case basis, but it is unlawful to transfer controlled substances to another facility or person not properly licensed to possess them.

**Dispensing and Administering**

Each time the practice dispenses or administers a controlled substance, it must be recorded both on the medical record and a "readily retrievable" record. Sometimes this becomes a problem because the record keeping system doesn't fit the practice style. For instance, many practices appoint a specific person to log all controlled drugs regardless of who actually performed the transaction. In some practices, staff members must rely on medical record “reviews” to complete logs later in the day. These “second person” formats usually result in less accuracy and more frustration for everyone concerned.

Although there are other methods of compliance and a perpetual log is not specifically mandated by the Controlled Substance Act, it has been shown to be the most convenient, effective method to manage this program in most practices.
The logs should contain:
  • The date of the transaction.
  • The client and patient's name (other details should be available on the medical record).
  • The name of the drug (unless the log is for a specific drug).
  • The quantity of the substance administered or dispensed.
  • An accurate "balance on hand".
  • The name of the prescribing veterinarian if there is more than one in the practice.
  • The initials of the staff member who dispensed or administered the drug.

With this system, it’s usually better to have the person performing the transaction make the entry in the log rather than “telling someone else to do it.” Somehow, when a person puts their initials on the form, pride and professionalism play a large part in the process and the result is usually better accuracy.

Since a perpetual log has a “balance on hand” component, it’s very easy to spot a potential problem when there are only three bottles left in the safe and the log says there should be four! Without this perpetual log system, it takes an overt “balancing of the books” to discover problems.

It's also acceptable to have more than one "log book" in the practice. In most instances, a "Central Pharmacy/End User Accountability System" is the most practical for a veterinary practice, but the end result is that each time a controlled drug is administered to a patient or dispensed to a desired client, it is recorded in some format.

Computerized logs are acceptable and very useful to many practices, if the accuracy of the entries are verified periodically and the computer is able to produce a report that identifies the date, client, patient, drug, and amount used or dispensed for every single transaction. The balance on hand portion need not be present on the report but should be easy to verify.

Also be sure that all controlled drugs that are used are accounted for in every transaction. For instance, it does no good to produce a computer report that gives the names of all patients who were given "injectable anesthesia" when the hospital uses three different drugs for this purpose and different quantities for each patient.

For drugs that are prepared by a formula (e.g., weight of the patient) but given to effect, there are two considerations that must be addressed. First, the accountability of the substance is necessary, so the amount drawn must be indicated. Secondly, the forensic and quality of care issues mandate the demonstration of how much the patient actually received - the term "to effect" is no longer acceptable in most cases. Hence, the easiest way to satisfy both requirements is to use the "drawn/given" method of documentation. The name of the drug is followed by two numbers separated by a slash (e.g., Pentothal 10/8). This indicates that 10 ml were drawn up and allocated to this patient, but only 8 ml were actually injected. The wasted amount is the difference.

Controlled substances dispensed to clients for administration to animals must follow the guidelines for packaging and labeling of prescription drugs discussed earlier.

There are no special record keeping requirements for issuing prescriptions to be filled by a retail pharmacy other than an entry in the medical record.
The Preferred Record keeping System

The most practical controlled drug documentation program for a veterinary practice seems to be the "Central Pharmacy/End User" system. In this system, the bulk supply of drugs are received into a central pharmacy and then "issued" to the various sections of the hospital where they are actually used in operations. What makes the Central Pharmacy/End User system different from the traditional methods is the presence of multiple drug logs which are maintained where the drug is actually used or dispensed instead of one centrally-located log. In this case, the term “user” is not an individual person but the section of the hospital where the activity takes place, such as surgery, outpatient pharmacy, etc.

Here's an explanation of how this type of system works:

• When bottles of a controlled drug are received from the supplier, the unopened bottles are placed in the central pharmacy safe (usually a place with limited access such as a storage room or doctor’s office). The receipt is logged (in full bottle quantities) on the central pharmacy log using the invoice number and supplier in the "client ID" section. The balance on hand is updated to reflect the new quantity and the actual amount of the drug in the safe should match the new balance on hand.

• When drugs are needed for a procedure, a single bottle is taken out of the safe and "transferred" to another area of the practice, such as the surgery department or maybe an ambulatory truck. The central pharmacy log is annotated with the place where the drug is being "issued" (e.g., surgery or truck #1). The balance on hand is updated and the actual quantity of the drug in the safe is verified to match the balance on hand.

• The bottle is then taken to the appropriate activity center (e.g., surgery) and immediately entered on the "user level" drug log as received from the central pharmacy, only this time the drug is entered in the dispensing quantities (such as ml or tablet). The balance on hand of the user level log is updated and verified. As the drug is used, each patient's dose is recorded on the user level log. When the bottle is empty, the log's balance on hand should be zero and another bottle is obtained from the central pharmacy.

This process takes place for several activity centers simultaneously. For instance, on a single day, the central pharmacy may issue a bottle of a drug to the surgery department, the outpatient pharmacy, and the ambulatory unit. Each of those activity centers will keep track of their individual activities on their log. Each activity center's log is balanced individually, but each issue of a drug can be verified against the central pharmacy log.

In a perfect system, the central pharmacy and each individual activity center would have separate safes or lock boxes. If this isn't practical, it's best to use a small box, tray, or basket in the community safe for each activity center so that supplies for each center can be maintained separately.

If at any time in the process, the balance on hand of any log does not match the actual amount of drug present, either an investigation into the shortage is initiated or an "adjustment" is made to the log. If the shortage is significant, an internal investigation is initiated (see Shortages section), but if the shortage is very small and insignificant, such as happens when using multiple dose vials of injectable medications, an “administrative adjustment” entry is made on the log with the
date, initials of the person making the adjustment, and an amount necessary to bring the balance to zero at the end of the bottle.

The layout or format of the log is less important than actually entering the information. In some instances (e.g., an ambulatory unit), a single page log for each bottle of drug is the best way to keep track and, in other instances (e.g., the central pharmacy), a "column style" log with multiple drugs on the same sheet is more practical.

**Shortages**

If a shortage of a controlled substance is detected, an investigation into the problem is warranted. The first step in an investigation is to ensure that there is not a mathematical or record keeping problem rather than an actual shortage. Check the arithmetic to be sure all the numbers were added or subtracted correctly.

Make sure that all entries are posted to the correct drug and strength (e.g., Rx for phenobarbital 15 mg tablets was incorrectly entered on the phenobarbital 30 mg log). Compare computer or sales records with the logs to determine if a prescription was filled and not entered on the log.

If a record keeping problem is identified, then an entry on the log to correct the balance is the appropriate solution. DO NOT rewrite the log or attempt to alter previous entries; simply make an entry on the next available line in the log using the current date and explaining the correction.

If the shortage cannot be explained with a mathematical or record keeping error, or if it's obvious that there was a theft, a report to the DEA field office is required. There is no time limit that must be observed (i.e., within xx hours of the discovery), but once it is determined that the loss is not accidental or administrative, then do not delay-report it immediately. Follow the instructions of the agent when making the report, but most often the matter is handled administratively. The DEA agent will provide a form to complete-this will ask for what's missing and for a possible explanation. If the shortage was pilfered from within or if the practice was burglarized, the local police should also be contacted, but don't rely on them to notify the DEA-it's the practice owner's responsibility!

Reporting shortages or thefts will not automatically cause an audit by the DEA and is normally not “held against” the practice unless there has been a serious, willful violation of the rules by the practice.

**Refills**

In the context of the veterinary/client/patient relationship as it applies to controlled substances, when a prescription order is issued, it is expected that the veterinarian has examined the patient at least some time in the recent past. Although it's not specifically mandated, it is highly recommended that patients on long-term treatment plans including controlled substances be re-examined prior to issuing a refill prescription order.

Because of their severe potential for addiction, Schedule II drugs cannot be refilled without the clinician issuing a new prescription (either verbal or in writing) each time a refill is necessary. A veterinarian may authorize Schedule III-V drugs to be refilled up to five times within a six month period before a new prescription order is required. At the federal level, this limitation implies that only a 30 day supply of a controlled substance should be dispensed at one time. Some
states, such as New York, have formalized this limitation in writing by making it a specific violation to dispense controlled substances in any manner that would allow the client to obtain more drugs than would actually be used for the patient in that six month period.

Therefore, under these guidelines, it is implied that animals on recurring doses of a Schedule II drug would be examined at least every month and animals on Schedule III through V drugs would be examined at least every six months.

**Inventories**

As with any other aspect of inventory control, regular physical counts are essential to any control program. The DEA requires at a minimum, an initial inventory must be taken on the day the practice first conducts any controlled substance activity (that's when the first drugs are received NOT when they are first dispensed or administered). This inventory must be in writing and contain the following key elements:

- The name, address, and DEA registration number of the veterinarian.
- The date and time the inventory is taken.
- The actual amount of each controlled substance physically on hand.
- The signature of the person conducting the inventory.

The inventory procedure and documentation must be repeated every two years; this is called a biennial inventory. These written inventories must be maintained for at least two years.

Of course, this does not mean that inventories can't be conducted more often. Most consultants and inventory professionals recommend, at least, monthly inventories for highly sensitive items. Just remember to complete the documentation that the DEA requires at least once every two years.

Some practices find it easier to maintain the system when “end-of-bottle inventories” are performed along with the scheduled counting ones. An end-of-bottle inventory is simply comparing the quantity on hand in the log or computer to the actual amounts on the shelf whenever a bottle is empty. By using this method, counting hundreds of pills or estimating liquids isn’t required. When each bottle is empty, the remaining full bottles are counted and compared to the log with adjustments made to the log to make it current. Of course, that entry is made assuming the shortages or overages are the result of “shrinkage” (an inventory term related to counting or packaging variances) and not loss related to pilfering or theft.

When an unbound (or loose leaf) inventory system is used, pages should be numbered and the first entry on each page should reflect the "balance forward" or an actual "per inventory" amount that matches the last entry on the previous page.

**Disposal of Controlled Substances**

The DEA has specific rules that must be followed for disposing of expired or no-longer-needed controlled substances. 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 substance that was removed from the supply for a particular patient, but 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 squirited into absorbent material for disposal in the regular trash or even flushed down the drain. If the unused dose was already logged out of the hospital’s system using the "drawn/given" method described above, there are no special record keeping rules except to note the wasted amount on the medical record.

Similarly, drugs that may have been dispensed to a client and subsequently returned cannot be used again because there is no way to guarantee they have not been adulterated. In most cases where no invoice adjustment is expected, the client should dispose of the drugs by flushing them down the drain or toilet. If the drugs are returned “for credit,” an annotation should be made on the patient’s medical record explaining the situation but the drugs are not logged back into the practice’s controlled drug system. Remember, the DEA doesn’t care what or how you charge the client, only that the drugs are accounted for until they are dispensed to the “end user.” In these situations, most practices will issue a credit to the client but destroy the remaining drugs as outlined above.

Unused stocks are quantities of controlled substances 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 Telazol® that has been reconstituted and has now expired or Pentothal® 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 a good idea to have two persons initial or sign the log as witnessing the destruction.

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 substances is usually accomplished using “Reverse Distributors." The DEA will no longer accept drugs for disposal but has licensed private companies to receive controlled substances 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. We’ve also compiled a short list of reverse distributors and made it available on our Web site. Just click on the Suggested Source Sheets link from our home page (www.safetyvet.com.)

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