Keeping Controlled Drugs Under Control

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One of the most confusing aspects of veterinary hospital management undoubtedly has to be the controlled substance program. What are the requirements? What substances are included on the federal and state registers? 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 those veterinarians who have been "left alone" or who have "never had a problem" are finding themselves in discord with the Drug Enforcement Agency (DEA).

Penalties for infractions and/or non-compliance can range from written warnings to fines and disciplinary action by the state professional board to revocation of state and federal controlled substance certification.

Ask the following questions of the practice's controlled drug program:

1 Can you retrieve the client name, patient name, date and quantity for every instance where a controlled substance was administered or dispensed from the hospital supply?

2 Are all controlled substances, regardless of their designated schedule, secured in an adequate cabinet or safe (see definition below)?

3 Is there a written inventory, signed and dated within two years, of all controlled substances present at the time?

4 Are purchase records for Schedule II controlled substances completed after receipt of the drug?

5 Is there a method that alerts you if any amount of controlled substance is missing or unaccounted for (declining balance on hand method)?

If you answer no to even one question, there may be a significant "hole" in the system that would place the practice at risk. The remainder of this section will help identify exactly which substances are controlled, how to keep adequate security, how to maintain control of the drugs, and what to do if something goes wrong.

Identification

Recognizing a controlled substance is fairly simple; the label contains a large letter "C" with roman numerals depicting the schedule centered within the "C". A current list of controlled substances may be obtained by contacting the Washington DEA office at 800/882-9539; however, this list is marginally useful because it shows the chemical name and not necessarily in the product or combination name. A better way is to actually look for the controlled substance symbol on the labels of all the drugs currently on hand. Some common controlled substances in veterinary hospitals are:

- Anesthetics and analgesics such as pentobarbital, sodium pentothal, telazol and diazepam (Valium), torbutrol, torbugesic, morphine, demerol, talwin, ketamine;
- Diphenoxylate with atropine (Lomotil), Hydrocodone (Hycodan), phenobarbital (except dilantin);
- All forms of euthanasia solution; and
- Anabolic steroids such as stanozol (Winstrol-V), testosterone, nandrolone, mibolerone (Cheque Drops), and boldenone (Equipoise).

Registration

Every veterinarian who orders, dispenses, prescribes or administers a controlled substance must be registered with the DEA. In practices with multiple facilities, there must be at least one veterinarian registered at any location where controlled drugs are stored on the premises. For instance, if there is a central hospital with a satellite clinic, in order to store controlled substances at the satellite office, the veterinarian must be registered at both locations. Of course, the veterinarian can transport the drugs back and forth each day to avoid this requirement, but that is really not practical in most cases. Mobile practitioners should be registered at their "base" of operations; that will allow him or her to prescribe controlled substances from any location; however, storage of the drugs must be at the registered location. Relief veterinarians should be registered at their "office" location, but in most cases, the relief veterinarian would not order or store any controlled substances as part of their license. The relief veterinarian would give verbal prescription orders to the staff of the hiring practice for administration or dispensing from the practice's stock.

Recently, the DEA has changed the rules to allow, in certain situations, associate veterinarians to act as an agent of the registered veterinarian (or practice) and forego the individual registration requirement. In this case, a technician carrying out the order of the veterinarian would not be an agent because he or she is not authorized to order the action, but an associate veterinarian would. Although this appeals to many practices, it isn't such a good idea for most practices. This exception 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 program from ordering to patient administration.

Most veterinary practices do not have the safeguards in place to satisfy the requirements necessary for the exemption. 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 to do this and the ones that do are sometimes surprised by the findings of the check!

Additionally, the "agent" cannot write or phone prescriptions to be filled outside of the practice; only a registered practitioner can execute a prescription. There are also provisions where the registered practitioner must formally review the agent's actions- this means the registered practitioner must "countersign" each medical record entry of the agent where controlled substances were administered or dispensed. Given the nature of the average 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.

Storage

Controlled substances must be kept in a securely locked, substantially constructed cabinet or safe. If a portable lock-box is used, it must be securely affixed to an immovable object such as a cabinet or wall. Similarly, lightweight filing cabinets or fire safes are inappropriate since they can be easily picked up and removed. Cabinets should have hinges that are not exposed. The interspersing of controlled drugs among the entire pharmacy so that thieves would be less likely to "tear up" the cabinet is not allowed under the law. The owner of the substances must make a reasonable attempt to keep them secured from unauthorized persons. Statistically, the overwhelming majority of thefts of controlled drugs from veterinary hospitals comes from employees rather than break-ins. 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 good primary lock are the basic necessities.

Mobile units should be stocked with only enough of each drug for basic operation. Excess supplies should remain in a fixed, secure location. There is 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 in the vehicle and locking the doors is not adequate. If the vehicle is not equipped with locking bins or compartments, a small, lockable box 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 storage.

Ordering

Due to their potential for addiction, Schedule II drugs are afforded a bit more attention during manufacturing, distribution and dispensing. In order to purchase any Schedule II substance (morphine, demerol,, oxymorphone, fentanyl patches) the supplier must receive an accurate DEA Form 222 from the practice. These triplicate forms are usually supplied with the initial registration. Replacements should be requested by calling the DEA at 800/882-9539. The order forms must be used sequentially, with the original and second copy sent to the vendor. The third copy is retained by the practice.

When the shipment is received, that retained copy must be annotated with the quantity and date that the drug is received. All three copies of voided or unusable forms must be retained. Completed forms must be maintained separate from all other documents - they should not be filed with the accounting paperwork.

Aside from Schedule II substances, all other controlled drugs are ordered in the same manner as any other supplies. The supplier will ask for a copy of your current DEA registration to keep on file. There are no special paperwork requirements for Schedule III - V purchases (usage records must still be maintained). It is recommended that a copy of the invoices (or packing lists) be maintained so that reconciliation of discrepancies can be done quickly.

Obtaining controlled substances from a local pharmacy for "in-house" or resale use is prohibited; this circumvents the normal accountability process. Prescriptions filled at local pharmacies should only be for specific patients and should not be retained in the hospital's stock once the patient is discharged. Likewise, "borrowing" or purchasing controlled substances from other practices is not allowed since it also circumvents the normal accountability process.

All records of purchases must be maintained for two years (corresponding with the biennial inventory).

Practices with multiple locations must be especially cautious of ordering the drugs for one location and transferring them to another; the paperwork involved in the transfer usually does not justify any savings in cost. Meticulous records must be kept of each transfer, the second location must also registered with the DEA, there is adequate security at the second location and appropriate usage records (patient-level accountability) are maintained for the drugs transferred. Additionally, whenever schedule II drugs are transferred, 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 2 of the DEA Form 222 to the DEA field office when the transfer is made.

Many veterinary practices help the local humane organization or county impound facility by acting as consultants. It is considered a violation of the Controlled Substances Act for a registered practitioner to order or transfer euthanasia solution to an impound facility for their exclusive use. Recently, the DEA has started issuing permits to these facilities (if they qualify as a legitimate impound facility) so that they can procure their own supply. The DEA has done this because of severe problems with security and record keeping at these facilities, as well as the liability that is placed on the veterinarian. 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; in no circumstances should controlled substances be "issued" to another facility that is not properly licensed to possess them.

Accountability

The accountability of controlled drugs is a major problem in many veterinary practices, but it doesn't have to be. Whenever the practice dispenses or administers a controlled substances to a patient, it must be recorded both on the medical record as well as a "readily retrievable" log (examples are included in the Appendix.) There should be a system in place that gives an accurate "balance on hand" for each controlled drug. Although a perpetual log is not mandated by the Controlled Substance Act, it has been shown to be the most convenient, effective method to manage this program. It's very easy to spot a potential problem when there are only 3 bottles left and the log says we should have four! Without this perpetual reminder system, unless someone takes the time to "balance the books," the loss may never be discovered.

The practice of numbering bottles for accountability is an acceptable means of accountability; however, be careful to establish a clear system for recording the numbers that have already used. Example: Assume 15 bottles were received and numbered consecutively #1 - #15. Someone removed the # 15 bottle. When the next order is received, what system would be in place to identify that the #15 bottle was missing?

Computerized logs are acceptable and very useful to many practices. If you decide to computerize the controlled drug logs, be sure to do periodic spot checks for accuracy. Make sure the computer will be able to produce a report that identifies the date, client, patient, drug and amount. The balance on hand portion need not be present on the report, but should be easily available for verification. Also be sure that all controlled drugs are accounted for in every transaction; 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. Also remember to do the manual things that are necessary (e.g., conduct and document the biennial inventory), as well as generate regular "hard copy" reports for the files.

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. Disposal of the waste is usually by sanitary sewer. Large differences in the amounts on a recurring basis is an indication of a potential problem.

When issuing controlled drugs to mobile units, they should be logged out in the central pharmacy area to a specific truck or veterinarian. The patient and client data is maintained on the truck by means of a mobile vehicle log sheet (see the sample form at the end of this monograph.) When the bottle is empty, the log sheet is totaled and returned to the central pharmacy where a new bottle and log sheet is issued.

There are no special record keeping requirements for writing prescriptions other than an entry in the medical record.

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 you first receive the drugs NOT when you first dispense or administer a substance). They require the inventory to be written and contain certain key elements. It must include the name, address & DEA registration number of the veterinarian, the date and time the inventory is taken and the signature of the person conducting the inventory.

The written inventory must be maintained for two years.

The inventory procedure and documentation must be repeated every two years; this is called a biennial inventory. It should be done as close as possible to the date the previous inventory was conducted. The information necessary is the same as for the initial inventory.

This is a requirement that many hospitals find ridiculous: "Why would I wait for 2 years to do another inventory?" This does not mean that inventories can't be performed more often; most consultants and successful business persons would recommend at least monthly for highly sensitive items. Just remember to complete the documentation in a manner that the DEA requires at least once every two years. This is also a good time to "balance the books", e.g., bottles ordered in the past two years minus quantity which the support documents (log) reflect as being used equals the quantity on hand.

If you use an unbound (loose leaf) inventory system, the first entry on each page should reflect a "balance forward" or an actual "per inventory" balance that matches the last entry on the previous page. Check with your state Board of Pharmacy to ensure that they do not require the use of a bound ledger.

Shortages

If a shortage of a controlled substance is detected, first try to find the source of the shortage. Very often it is a mathematical or record keeping problem. Be sure all the numbers were added or subtracted correctly. Be sure that 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 the problem is located, then an entry to correct the balance is appropriate. If the shortage cannot be explained or if it's obvious that there was a theft, you must make a report to the DEA field office for your area. There is no time limit that must be observed for making this report, but once it is determined that the loss is not accidental or administrative, then do not delay - report it immediately.

Reporting shortages or thefts will not automatically cause an audit by the DEA. Follow the instructions of the agent when making the report, but most often the matter is handled administratively. The DEA agent will send you a form to complete - this will ask for what's missing and for a possible explanation. You do not have to have evidence to support the suspicion; that's their job. If you find the shortage was pilfered from within or if your practice was burglarized, notify the local police immediately, but don't rely on them to notify the DEA - it's your responsibility!

Disposal

Outdated controlled substances present a very unique problem. Many practices don't want to throw them away or dispose of them improperly. On the other hand, they are commonly removed from the working stock. Therein lies the problem; the presence of drugs with laxed accountability presents the ideal situation for theft. When you have controlled drugs expire, you should take immediate steps to dispose of them.

Small amounts (perhaps up to 10% of a full bottle) of schedules III, IV or V substances (such as Telazol that has been reconstituted and has now expired) may be disposed of by flushing it down the sink while the water is running. Remember to keep adequate records like an entry on the log stating date, time, drug, quantity, and method of disposal. In most cases it is not required, but it would be a good idea to have two persons sign the log as witnessing the destruction.

For significant amounts of any controlled drug (more than 10% of a full bottle), or any amount of a schedule II substance, the DEA has started using "Reverse Distributors." As the name implies, the reverse distributors are private companies authorized to receive controlled substances that are no longer wanted or are expired. These companies typically charge a modest fee for the service, but the administrative aspect of the process is greatly reduced. Contact the nearest DEA field office for a list of reverse distributors.

Remember to secure and account for the drugs as usual until they are shipped and confirmation is received from the reverse distributor.

DEA Authorized Reverse Distributors

BFI Pharmaceutical Service
801-N North Blacklawn Rd
Conyers, GA 30207
(800) 777-6565

Capital Returns, Inc.
9600 W Flagg Ave
Milwaukee, WI 53225
(414) 527-9912

Easy Returns Midwest
dba Reverse Management Systems
201 San Augustine St
Center, TX 75935
(800) 797-3837
(409) 598-4100

EXP Pharmaceutical Waste Management
2416 Radley Ct, Ste 9
Hayward, CA 94545
(800) 350-0397
Guaranteed Returns

dba Devos, Ltd.
140 N Bell Mead Rd #3
East Setauket, NY 11733
(800) 473-2138

Pharmaceutical Credit Corp
130 Seaboard Ln, Ste A-6
Franklin, TN 37067
(800) 487-4308

Pharmaceutical Recovery Svcs, Inc
1890 Semoran Blvd, Ste 339
Winter Park, FL 32792
(800) 238-7774

Pharmaceutical Services Group, Inc.
1600 N M291 Highway, Ste 405
Sugar Creek, MO 64056
(816) 257-2677

Pharmaserv
11426-B Kingston Pike
Knoxville, TN
(423) 675-1355

Reverse Distribution Services, Ltd.
4100 Fleetwood Rd
Fort Worth, TX 76155
(817) 868-5300

Rx Returns, Inc.
RD #1 Tollgate Rd
Palm, PA 18020
(215) 679-9418

SAI Transport
3420 Youngs Ridge Rd
Lakeland, FL 33809
(941) 858-7110

Refilling Prescriptions for Controlled Substances

Refills for controlled substances have limitations. Because of their severe potential for addiction, schedule II drugs can not be refilled without a new prescription (either verbal or in writing) every time. Schedule III-V drugs can be refilled up to five times in

6 months before a new prescription order is required. By setting up this system, DEA implies that only up to a 30 day supply of a controlled substance should be dispensed at one time. This means that phenobarbital patients must have the prescription refilled every month and be reevaluated every 6 months. In the context of this regulation, when a new prescription order is required, it is implied that the veterinarian must examine the patient before a prescription can be given, therefore, animals on recurring doses of a schedule II drug must be examined at least every month and animals on prescriptions for schedule III-V drugs must be examined at least every 6 months.

Speaker Information

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