UNDER REVIEW Practice owners and managers should actively look for gaps in their controlled substance policies to identify risk.

FOCUS ON

Safeguarding Controlled Substances in the Practice

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Controlled substances are essential to providing patient care in most veterinary practice settings; however, they are also highly addictive and subject to abuse by humans. Human drug overdose deaths have been steadily climbing since the early 2000s. In 2020, almost 92 000 people in the United States died from drug overdose, with 56 516 of those deaths resulting from synthetic opioids other than methadone (primarily fentanyl).[1]

Owing to the risks associated with abuse of controlled substances, The U.S. Department of Justice (DOJ) and state governments implement and enforce regulations pertaining to the oversight of these drugs. This article provides some insight into what the regulations are trying to accomplish as well as tips for compliance in veterinary practices.

REGULATORY LANDSCAPE

The Controlled Substances Act is part of Title 21 of the United States Code. This act includes a list of all scheduled drugs, and any drug or chemical included on this list is considered a controlled substance (**BOX 1**).[2] If something is a controlled substance in the United States Code, then it is federally controlled. However, each state has its own controlled substance acts that may include additional drugs/chemicals, making those controlled substances at the state level. If there is a conflict between the federal and state acts, the more stringent prevails. Practice owners and managers need to review both state and federal regulations for the complete details of laws applying to veterinary practices.

To add to this, gabapentin is well known for its ability to potentiate the effects of opioids, making it a highly diverted drug. Although gabapentin remains a noncontrolled drug at the federal level, states are starting to implement their own requirements for increased gabapentin oversight compared with other noncontrolled medications.[3]

Owing to their public health importance, these regulations are strictly enforced, with large fines for noted violations. While veterinarians strive to comply with all regulations, the number of regulations, their variation between states, and their application in the veterinary setting make compliance a challenge.

IMPORTANCE OF COMPLIANCE

In human health care, it is estimated that 10% to 15% of healthcare workers will abuse drugs at some point in their career and that 80% to 93% of diversion goes

undetected.[4] In a human healthcare study, 98% of providers indicated that they were concerned about hospital drug diversion and 70% strongly believed that most diversion goes undetected. However, only 36% believed that undetected drug diversion was a problem at their facility.[5] These studies indicate that although healthcare professionals are aware that drug diversion is a significant problem, there is often an impression that it's "over there and not here."

Similar data do not yet appear to be readily available in veterinary medicine. However, similar trends are likely, and several recent reports of drug diversion in veterinary practices have been published.[6-9] These occurred throughout the United States, with the diverting employees including veterinarians, veterinary nurses/technicians, and receptionists. With fines up to $14 502 per recordkeeping violation,[10] these cases resulted in significant monetary consequences for the practice well beyond those of the lost drugs.

AREAS OF RISK IN VETERINARY PRACTICES

To understand how to comply with controlled substance regulations, it is important to identify what they are trying to prevent: not only diversion, but also various opportunities for diversion. The goal of controlled substance regulations is therefore to make it sufficiently difficult for anyone to divert drugs at any point in a drug's life cycle. For veterinary practices, the period from procurement through when the drug is administered, dispensed, or disposed of is the focus of concern.

Depending on the required and optional safeguards that are in place, some tasks during this period may represent an increased risk for diversion, such as:

- **Procurement activities.** Drugs may be deliberately ordered or inventoried incorrectly.
- **Preparation and dispensing activities.** Drugs may be replaced with a similar-looking product (e.g., replacing methadone with saline).
- **Prescribing activities.** Prescriptions may be altered or written for unnecessary drugs.
- **Administration activities.** A drug may be falsely documented as being given when it was not.
- **Disposal activities.** A medication may be falsely documented as being wasted when it was not.

Practice owners and managers should analyze how each of these activities is overseen in their practice, asking the following questions:

- During which of these activities could someone feasibly pocket a controlled substance with low likelihood of being caught?
- How much could they divert before being caught?

When implementing strategies surrounding controlled substances, the answers to these questions can help inform decisions about whether the minimum legal requirements are sufficient or whether additional measures are needed.

BOX 1 Federal Drug Schedules[2]

Schedule I: Drugs/substances with no established medical use and a high potential for abuse.

Schedule II: Drugs/substances with a high potential for abuse but an established medical use. Use of these drugs may result in severe psychological or physical dependence.

Schedule III: Drugs/substances with a moderate to low potential for physical and psychological dependence.

Schedule IV: Drugs/substances with a low potential for abuse and low risk of dependence.

Schedule V: Drugs/substances with a lower potential for abuse compared with Schedule IV.

STRATEGIES FOR RECORDKEEPING AND STORAGE/ACCESS

Controlled substance regulations can generally be grouped into those governing recordkeeping and storage/access. This section provides tips and compliance ideas for these activities in the veterinary practice setting.

Recordkeeping

When considering recordkeeping requirements, the goal is to be able to track the current location of every controlled substance and the people who have been involved with it up to its current location or ultimate use or disposal. Remembering that goal can often help determine how to address "gray areas" that may not be clearly stated in regulations, such as what constitutes secure storage for ambulatory practice and who in the practice should be allowed access to controlled drugs.

Verifying the accuracy of running inventory on a weekly, biweekly, or monthly basis will greatly decrease the amount of data to sort through when evaluating discrepancies.

Also, federal law mandates that a healthcare organization and its employees report any incident of drug diversion within the organization.[11] Complying with this law requires sufficient recordkeeping to be able to determine if drug diversion is occurring.

The following suggestions are beyond minimum federal requirements and may be beyond the minimum recordkeeping requirements for individual states; however, they can still be valuable in decreasing the potential for diversion.

Keep running counts of all controlled substances.

A running inventory may be required for Schedule II medications, but may be optional for Schedule III, IV, or V medications. However, without a running inventory for Schedule III, IV, or V medications, it may be impossible to determine whether any are missing, unless the practice keeps only a few vials on hand with very limited access and use. For larger stocks, a vial missing may not be noticed for quite some time.

Automated dispensing cabinets or software can help with running inventory, especially in high-volume practices, but paper records still have a place in many practice settings. Well-managed paper records can be a better option than a poorly managed high-tech system.

Regularly verify that your running inventory is correct.

State laws require practices to do a full inventory with actual counts of all Schedule II medications at least every other year. However, if the count is off by a significant amount at these audits, it will likely take reviewing piles of records to determine what happened to those missing drugs. Verifying the accuracy of running inventory on a weekly, biweekly, or monthly basis will greatly decrease the amount of data to sort through when evaluating discrepancies. In general, the more often a medication is used, the more often the accuracy of the current count should be confirmed.

Institute documentation confirmation processes.

Who verifies that the correct amount of drug was dispensed, that a drug made it into the patient versus someone's pocket, or that a drug logged as wasted really was destroyed? If the answer is only the employee who recorded it, then it may be worth considering a process that requires a second person to verify the quantity of medication dispensed or to witness drug administration and wasting. These changes may result in extra documentation and workflow adjustments, but they can also greatly decrease the ability to divert drugs without anyone noticing, especially as veterinary patients cannot talk.

Storage/Access

Federal regulations require storing controlled substances in a secure manner, but they provide very little detail beyond that. State laws may add a few additional requirements, but there are still a variety of ways to meet them. The following recommendations apply to all controlled substances in all states.

- If drugs are stored behind a key lock, limit access to the key to only those authorized to access the medications. This could be done with a key storage box that is accessed by a combination lock.
- If a combination lock is used to secure controlled substances (or the key to the controls), give the combination only to those authorized to access the drugs and change it when any of those personnel terminate their employment.
- Secure locked ambulatory boxes to the vehicle in some manner, such as with a cable lock, so that it is not possible for a passerby to smash a window and walk off with the box.
- Relock controlled substance storage immediately after access. Storage should not be left unlocked, or drugs left out of the storage area, for convenience.
- Limit access to controlled substances only to those who need it. Depending on the practice, this may include only doctors, doctors and some veterinary nurses, or doctors and all veterinary nurses. Keep in mind that the more people who have access, the more

likely it is that errors will occur and the more difficult it becomes to detect diversion.

DOCUMENTATION OF PROCESSES

Setting clear expectations for how controlled substances are to be handled is important to ensuring compliance. Therefore, all controlled substance recordkeeping and storage/access security processes should be documented in either a policy or a standard operating procedure (SOP). Ideally, this documentation includes how the practice complies with each state and federal regulatory requirement as well as any additional processes in place. When changes to processes are made—for example, application of any of the recommendations in this article—those changes should be reflected in the policy or SOP. This way, they can be easily communicated and referred to by everyone in the practice.

SUMMARY

It is impossible to eliminate all potential for drug diversion. However, understanding why controlled substance regulations are in place and acknowledging the natural bias that diversion will not happen in "our" practice can provide a new lens for reviewing and determining how to comply with the regulations. After reviewing the minimum requirements in state and federal controlled substances acts, practice owners and managers should look critically at potential opportunities for diversion in their practice and make policy and procedure decisions to minimize any identified gaps, thereby decreasing risk and increasing the ability to identify it if it happens. TVP

To see the references for this article, please visit **todaysveterinarypractice.com**.

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