Veterinary Pharmacy Law Review- Opioid Crisis and Aid in Prevention of Diversion.

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- **Objectives:**
- **The Current Opioid Crisis and Epidemic, how the veterinarian can reduce diversion from clients and staff. Fentanyl toxicity and Naloxone training for the staff.**

  Discuss all aspects of handling and storage of tranquilizers and sedatives that are not controlled, but may be abused.
- **Explains current U.S. Drug Enforcement Administration laws for purchasing, documentation, dispensing, and storage and disposal of outdated controlled substances used in veterinary medical practices.**
- **Security is a major prevention measure for diversion to include cameras, educational training for all staff and proper locked CS cabinets or automated dispensers with constant tracking of all staff and use of CS's.**
- **Describes in detail the current compounding regulations and extra-label use of medications that are laws through the U.S. Food and Drug Administration.**
- **Explains devices, policies, and procedures for documentation of training and guidelines for occupational employee safety are included.**
- **Change of OTC antimicrobials to prescription only.**

Compounding – review of the FDA GFR 256 Guidelines for legal compounding of bulk drugs for animals.

According to the FDA, compounding is defined as the "preparation, mixing, assembling, packaging, repackaging, production, propagation, conversion, processing, labeling, or re-labeling of a drug or device in a manner that is not consistent with the approval use of that drug or device. Pharmacies that compounding from an individual prescription (503a) may use bulk drugs for a need of items such as transdermal medicines or products that are not an approved FDA medicine and is needed to treat an animal. 503B pharmacies must follow the FDA guidelines for what may be compounded for office use.

GFI #256 - Compounding Animal Drugs from Bulk Drug Substances (fda.gov)

Controlled substances (CS)

The Comprehensive Drug Abuse Prevention and Control Act of 1970 (The Controlled Substances Act)

This act divides drugs into two broad categories, controlled substances and non-controlled substances. This division has nothing to do with the distinction between prescription drugs and over-the-counter (OTC) drugs. The FDA decides whether a drug is considered prescription of OTC based on whether or not they believe the drug can be packaged with "adequate directions for use under which a layperson can use the drug safely and effectively".

A drug is considered controlled substances if there is significant potential for abuse, or if the drug produces physical or psychological addiction. The decision of whether or not a drug is controlled substances, but individual states have the right to add addition drugs to the list. It is important to know which drugs are considered controlled substances in the state in which you are practicing. The current opioid crisis has a devastating impact on the US, over 100,000 deaths already this year in the US from opioid overdoses.

Controlled substances are divided into five classes or "schedules"

Schedule I: Have a very high abuse potential and no accepted medical use in the United States. Examples include LSD, PCP, and heroin.

Schedule II: Have a high abuse potential with severe risk of physical or psychological addiction, but also have legitimate therapeutic uses. Examples include morphine, codeine, fentanyl, oxymorphone, and Pentobarbital

Schedule III: Have an abuse potential which is significant, but less than schedule I or II. Examples include, and most anabolic steroids.

Schedule IV: Abuse potential is less than that of schedule III drugs. Examples include Phenobarbital, chloral hydrate, and most benzodiazepine tranquilizers (diazepam, oxazepam, etc.) Tramadol, federally controlled as of August 18, 2014, Propofol is controlled in many states, not federally a schedule drug, and however abuse advises strict storage by veterinarians.

Schedule V: Drugs with limited abuse potential or preparations which contain only very small amounts of schedule II-IV drugs.

Some drugs may be controlled in States, but not federally controlled. Check each state.

Record keeping

According to the Drug Enforcement Administration (DEA), records of controlled substances use should be complete enough so that it is "possible to trace the flow of any drug from the time it is…. manufactured….to the pharmacy or hospital that dispensed it, and then to the actual patient who received the drug." The DEA keeps track of the total amount of controlled substances a clinical or practice purchases, and perform an inventory at least once every two years. It is the responsibility of the veterinarian to be able to demonstrate exactly how and when the controlled substances were used.

Storage- Controlled substances should be locked in a secure area or kept in an automated dispenser with a tight control by the authorized DEA and state veterinarian. All uses must have documentation to the animals that are treated and perpetual inventory with all aspects of the drug being secure from receiving the drug, locked in the controlled cabinet and administration only by the authorized prescriber, clinician or technician. No other staff should handle or have any access to this drug.

Drugs that are specific state regulated should be stored on a different shelf in the CS cabinet and labeled, example propofol.

The other category that needs careful control include sedatives and tranquillizer such as alpha 2 antagonists, **xylazine, detomidine, acepromazine**, but needs to be on a separate storage shelf that is closed access.

The veterinarian needs to make sure all staff are aware of the rules and diversion WILL NOT Be Tolerated. Cameras should be placed in all areas where CS are stored and used.
If you require drug testing, seek legal counsel as to the proper way to publish and conduct the drug testing, particularly if a theft occurs. Signature of all employees must be on file
Notify the police department and the DEA of any theft or diversion.

Any CS's sent home should be properly labeled, in small quantities and owners must be counseled on where to store the items in a locked safe space and how to destroy them properly if outdated or not needed.
Home | DEA.gov

Veterinarians should have on stock a Narcan (naloxone) intranasal product for a rapid reversible of an opioid overdose. Available for human use at no-charge in Alabama.
Naloxone – Narcan Nasal Spray – Alabama Department of Mental Health
Training is required.

GFI 263: FDA limits Antibiotics in Livestock will end June 11, 2023 as OTC and become prescription. The FDA intends to allow inventory remaining in distribution to be depleted rather than recalled. This will require a VCPR and visits to the farms to diagnosis and prescribe the best antimicrobial. Monessen is still available.

Extra label Use and Antimicrobials | FDA
CFR: 21 GFR Part 530 -- Extra label Drug Use in Animals

USP 800- Handling of Hazardous Drugs

NIOSH Publications on Hazardous Drugs | Healthcare Workers | CDC