BEST PRACTICES FOR THE PRESCRIBING OF COMPOUNDED CONTROLLED SUBSTANCES TO CERVID PRODUCERS

Summary of Issue:

The Board is aware of the increased use of "BAM" and "MK" kits for practitioners, particularly in working with deer herds. However, because these kits use controlled substances, many common practices around the prescribing of these medications violate both Board rule and statute, as well as federal regulations. To ensure compliance, the Board is issuing the following guidance and some additional helpful information below.

Compliance:

Even following these guidelines cannot prevent complaints from being generated. TBVME has a statutory responsibility to investigate all complaints brought before it. We will take into account following these guidelines on any relevant complaints that the agency reviews.

There are several federal rules and regulations involved in the prescribing and dispensing of controlled substances. Please consult your local DEA field office for further information.

What is "BAM" and "MK"?

"BAM"

Butorphanol (butorphanol tartrate) is a synthetically derived opioid agonist-antagonist analgesic of the phenanthrene series.

Butorphanol is a U.S. Drug Enforcement Administration (DEA) class IV controlled substance.

Azaperone is a butyrophenone tranquilizer that causes tranquilization and sedation, antiemetic activity, reduced motor activity, and inhibition of CNS catecholamines.

Medetomidine (medetomidine hydrochloride), used alone and in combination with other drugs, has been shown to be useful for anesthesia and immobilization in zoo animals.[1] Medetomidine is an α-2-adrenoreceptor agonist with sedative and analgesic properties.

"MK"

Medetomidine (5mg/ml) provides α-2 adrenergic agonists, with Ketamine HCL (150 mg/ml) supplying an effective paralytic.

Atipamezole, a synthetic α2-adrenergic antagonist, is provided in the MK Kit as a reversal agent.

Ketamine is a U.S. Drug Enforcement Administration (DEA) class III controlled substance.

Veterinarian Use

Reasons that a deer may need to be sedated/anesthetized include:

- Regulatory testing (e.g., CWD, TB and Brucellosis)
- Semen collection
- Artificial insemination
- Antler Removal
- Illness or injury

Best Practices:

1. Ensure that you have a valid veterinarian-client-patient relationship (VCPR) with the animal or herd.

2. While there's not a specific rule or statute, best practices are seeing the animal or herd at least once annually to maintain that valid VCPR.

3. Ensure that you have a valid medical reason to prescribe the controlled drugs and have determined that such prescription drug is therapeutically indicated for the health and/or well-being of the animal.

4. Only prescribe the amount of controlled drug not to exceed the established need for the specific occurrence of a disease or condition for the patient for whom the compounded drugs are intended.

5. Ensure to inform & educate cervid producers that compounded/prescription drugs are being prescribed for their cervid herd only & must not be used on another herd, or sold / redistributed to other cervid producers.

6. Ensure the client understands withdrawal periods for the controlled drugs if the animals are being harvested.

7. Consider using a form stating the provisions above, signed by receiving cervid producer and kept by prescribing veterinarian in cervid producers patient records.

8. Patient records should document – herd/animal, VCPR, farm calls, exams, diagnosis, treatments, and drugs prescribed.

Applicable Statutes and Rules;

TEXAS HEALTH AND SAFETY CODE TITLE 6. FOOD, DRUGS, ALCOHOL, AND HAZARDOUS SUBSTANCES SUBTITLE C. SUBSTANCE ABUSE REGULATION AND CRIMESCHAPTER 481. TEXAS CONTROLLED SUBSTANCES ACT

5) "Controlled substance" means a substance, including a drug, an adulterant, and a dilutant, listed in Schedules I through V or Penalty Group 1, 1-A, 1-B, 2, 2-A, 3, or 4. The term includes the aggregate weight of any mixture, solution, or other substance containing a controlled substance. The term does not include hemp, as defined by Section 121.001, Agriculture Code, or the tetrahydrocannabinols in hemp.

(27) "Medical purpose" means the use of a controlled substance for relieving or curing a mental or physical disease or infirmity.

(39) "Practitioner" means:
(A) a physician, dentist, veterinarian, podiatrist, scientific investigator, or other person licensed, registered, or otherwise permitted to distribute, dispense, analyze, conduct research with respect to, or administer a controlled substance in the course of professional practice or research in this state;

Sec. 481.071. MEDICAL PURPOSE REQUIRED BEFORE PRESCRIBING, DISPENSING, DELIVERING, OR ADMINISTERING CONTROLLED SUBSTANCE.

(a) A practitioner defined by Section 481.002(39)(A) may not prescribe, dispense, deliver, or administer a controlled substance or cause a controlled substance to be administered under the practitioner's direction and supervision except for a valid medical purpose and in the course of medical practice.

Texas Occupations Code Title 4 Chapter 801 Sec. 801.351. EXISTENCE OF VETERINARIAN-CLIENT-PATIENT RELATIONSHIP.
(a) A person may not practice veterinary medicine unless a veterinarian-client-patient relationship exists. A veterinarian-client-patient relationship exists if the veterinarian:
(1) assumes responsibility for medical judgments regarding the health of an animal and a client, who is the owner or other caretaker of the animal, agrees to follow the veterinarian's instructions;
(2) possesses sufficient knowledge of the animal to initiate at least a general or preliminary diagnosis of the animal's medical condition; and
(3) is readily available to provide, or has provided, follow-up medical care in the event of an adverse reaction to, or a failure of, the regimen of therapy provided by the veterinarian.

(b) A veterinarian possesses sufficient knowledge of the animal for purposes of Subsection (a)(2) if the veterinarian has recently seen, or is personally acquainted with, the keeping and care of the animal by:
(1) examining the animal; or
(2) making medically appropriate and timely visits to the premises on which the animal is kept.
(c) A veterinarian-client-patient relationship may not be established solely by telephone or electronic means.

Texas Administrative Code Title 22
Rule 573.41 Use of Prescription Drugs
(a) It is unprofessional conduct for a licensed veterinarian to prescribe, administer, dispense, deliver, or order delivered any prescription drug without first having established a veterinarian-client-patient relationship and determined that such prescription drug is therapeutically indicated for the health and/or well-being of the animal(s). Prescription drugs include all controlled substances in Schedules I - V and legend drugs which bear the federal legends, recognized as such by any law of the State of Texas or of the United States.
(b) It shall be unprofessional conduct and a violation of the rules of professional conduct for a licensed veterinarian to prescribe, provide, obtain, order, administer, possess, dispense, give, or deliver to or for any person prescription drugs that are not necessary or required for the medical care of animals, or where the use or possession of such drugs would promote addiction thereto. Prescription drugs are defined in subsection (a) of this section.
(c) A licensed veterinarian prescribing, administering, dispensing, delivering, or ordering delivered any prescription drug must comply with the laws, including all rules, of both the United States and the State of Texas, including but not limited to Chapter 483 of the Texas Health and Safety Code.

RULE §573.44 Compounding Drugs
(a) A veterinarian may only compound drugs for a specific animal or herd with which the veterinarian has established and maintained a valid veterinarian-client-patient relationship.
(b) A veterinarian may only prescribe, administer, or dispense compounded drugs to treat a specific occurrence of a disease or condition, which threatens the health of the animal or will cause suffering or death if left untreated, that the veterinarian has observed and diagnosed in the particular patient for whom the compounded drugs are intended. The amount of a drug that a veterinarian compounds or orders compounded for dispensing or office use must not exceed the established need for specific compounded drugs for patients with which the veterinarian has established and maintained a valid veterinarian-client-patient relationship.
(c) Labeling Requirements.
(1) All compounded drugs must bear the labeling information required under §573.40 of this title (relating to Labeling of Medications Dispensed), as well as the following information:
(A) date on which the drug was compounded;
(B) name and strength of medically active ingredients;
(C) identity of treated animals;
(D) withdrawal/withholding times if needed; and
(E) condition or disease to be treated.
(2) In addition to the information listed in paragraph (1) of this subsection, compounded drugs dispensed to the client must also state a date dispensed and an expiration date, which should not exceed the length of the prescribed treatment.

(d) Limitations on Compounded Products.

(1) A veterinarian shall not compound or order a drug compounded if there is a FDA approved, commercially available animal or human drug that, when used as labeled or in an extra-label fashion in its available dosage form and concentration, will appropriately treat the patient.

(2) A veterinarian shall only compound or order compounded products with FDA-approved commercially available animal or human drugs as the active ingredients.

(3) A veterinarian shall not promote and/or distribute compounded drugs that are essentially similar to FDA-approved products.

(4) A veterinarian must ensure the safety and efficacy of a compounded drug, including but not limited to avoiding known drug incompatibilities and inappropriate combinations, and must use a pharmacist to perform drug compounding when the complexity of the compounding exceeds the veterinarian's knowledge, skill, facilities, or available equipment.

(e) Compounding for Food-Producing Animals.

(1) For animals intended for human consumption, a veterinarian must establish an extended withdrawal interval for the compounded product sufficient to ensure food safety and may not compound from any drugs prohibited for use in food-producing animals. The withdrawal period must be supported by scientific information, and the veterinarian shall note the method used to determine the withdrawal interval in the patient records.

(2) A veterinarian shall not compound or order a drug compounded if the compounded drug results in violative food residue, or any residue that may present a risk to public health.

(3) Compounding from a human drug for use in food-producing animals is not permitted if an approved animal drug can be used for compounding.

(4) Veterinarians shall ensure that procedures are in place to maintain the identity of treated animals and shall note those procedures in the patient records.

(f) Limitations on Promotion and Sale of Compounded Drugs.

(1) A veterinarian shall not prepare for sale any compounded drugs which employ fanciful names or trade names, colorings or other additives, or that in any way imply that the compounds have some unique effectiveness or composition.

(2) A veterinarian shall not advertise, promote, display, resell, or in any other way market prepared compounded drugs.

(3) A veterinarian shall not offer compounded drugs to other state licensed veterinarians, pharmacists or other commercial entities for resale.

RULE §573.52 Veterinarian Patient Record Keeping

(a) A veterinarian performing a physical examination, diagnosis, treatment or surgery on an animal or group of animals shall prepare a legible written record or computer record concerning the animals containing, at a minimum, the following information:

(1) name, address, and telephone number of the owner;

(2) identity of the species, animal, herd, or flock;

(3) except for herds or flocks, the age, sex, color, and breed;

(4) dates of examination, treatment and surgery;

(5) brief history of the condition of each animal, litter, herd, or flock;

(6) examination findings, if required for diagnosis or treatment and is not difficult to obtain:

- **(A)** weight - actual or estimated;
- **(B)** temperature;
- **(C)** pulse;

(D) respiration; and
(E) any additional findings needed for diagnosis;
(7) laboratory and radiographic tests performed and reports;
(8) differential diagnosis; referrals/consultations; to/with specialists and the client's response;
(9) procedures performed/treatment given and results;
(10) drugs (and their dosages) administered, dispensed, or prescribed;
(11) surgical procedures shall include a description of the procedure, the name of the surgeon, the type of sedative/anesthetic agent used, the route of administration and the dosage; and
(12) anesthesia monitoring performed during surgical procedures.
(b) Individual records must be maintained on each patient, except that records on livestock or litters of animals may be maintained on a per-client basis. Records pertaining to these animals may be kept in a daily log or billing records, provided that the treatment information is substantial enough to identify these animals and the medical care provided.
(c) Medical records and radiographs are the physical property of the hospital or the proprietor of the practice that prepared them. Records, including radiographs, must be maintained for a minimum of three years after the last visit.
(d) Medical records shall be released upon request from a treating veterinarian with a legitimate interest, and shall be returned to the originating practice within a reasonable time if requested. Copies of records must be made available upon request from the owner of an animal at a reasonable cost to the owner and within a reasonable time. A veterinarian may not withhold the release of veterinary medical records for nonpayment of a professional fee.
(e) All regulated substances shall be recorded as required by federal and/or state regulations.
(f) Any signed acknowledgement required by §§573.14 and 573.16 - 573.18 (relating to all complementary therapies).

RULE §573.43 Controlled Substances Registration
(a) A licensed veterinarian shall comply with all requirements of the federal Drug Enforcement Administration (DEA) regarding controlled substance registration.
(b) A licensed veterinarian registered with the DEA must comply with all relevant state and federal statutes and rules, including but not limited to Chapter 481 of the Texas Health and Safety Code, Chapter 13 of Part 1 of Title 37 of the Texas Administrative Code, and Chapter 13 of Title 21 of United States Code.

CFR § 1306.04 Purpose of issue of prescription.
(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.
(b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

(c) A prescription may not be issued for "detoxification treatment" or "maintenance treatment," unless the prescription is for a Schedule III, IV, or V narcotic drug approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment and the practitioner is in compliance with requirements in § 1301.28 of this chapter.
(d) A prescription may be issued by a qualifying practitioner, as defined in section 303(g)(2)G)(iii) of the Act (21 U.S.C. 823(g)(2)(G)(iii), in accordance with § 1306.05 for a Schedule III, IV, or V controlled substance for the purpose of maintenance or detoxification treatment for the purposes of administration in accordance with section 309A of the Act (21 U.S.C. 829a) and § 1306.07(f). Such prescription issued by a qualifying practitioner shall not be used to supply any practitioner with a stock of controlled substances for the purpose of general dispensing to patients.

CFR Title 21 §530.5 Veterinary records
(a) As a condition of extralabel use permitted under this part, to permit FDA to ascertain any extralabel use or intended extralabel use of drugs that the agency has determined may present a risk to the public health, veterinarians shall maintain the following records of extralabel uses. Such records shall be legible, documented in an accurate and timely manner, and be readily accessible to permit prompt retrieval of information. Such records shall be adequate to substantiate the identification of the animals and shall be maintained either as individual records or, in food animal practices, on a group, herd, flock, or per-client basis. Records shall be adequate to provide the following information:
(1) The established name of the drug and its active ingredient, or if formulated from more than one ingredient, the established name of each ingredient;
(2) The condition treated;
(3) The species of the treated animal(s);
(4) The dosage administered;
(5) The duration of treatment;
(6) The numbers of animals treated; and
(7) The specified withdrawal, withholding, or discard time(s), if applicable, for meat, milk, eggs, or any food which might be derived from any food animals treated.
(b) A veterinarian shall keep all required records for 2 years or as otherwise required by Federal or State law, whichever is greater.
(c) Any person who is in charge, control, or custody of such records shall, upon request of a person designated by FDA, permit such person designated by FDA to, at all reasonable times, have access to, permit copying, and verify such records.

CFR Title 21 §530.20 Conditions for permitted extra label animal and human drug use in food-producing animals.
(a) The following conditions must be met for a permitted extralabel use in food-producing animals of approved new animal and human drugs:
(1) There is no approved new animal drug that is labeled for such use and that contains the same active ingredient which is in the required dosage form and concentration, except where a veterinarian finds, within the context of a valid veterinarian-client-patient relationship, that the approved new animal drug is clinically ineffective for its intended use.
(2) Prior to prescribing or dispensing an approved new animal or human drug for an extralabel use in food animals, the veterinarian must:

(i) Make a careful diagnosis and evaluation of the conditions for which the drug is to be used;
(ii) Establish a substantially extended withdrawal period prior to marketing of milk, meat, eggs, or other edible products supported by appropriate scientific information, if applicable;
(iii) Institute procedures to assure that the identity of the treated animal or animals is carefully maintained; and
(iv) Take appropriate measures to assure that assigned timeframes for withdrawal are met and no illegal drug residues occur in any food-producing animal subjected to extralabel treatment.
(b) The following additional conditions must be met for a permitted extralabel use of in food-producing animals an approved human drug, or of an animal drug approved only for use in animals not intended for human consumption:
(1) Such use must be accomplished in accordance with an appropriate medical rationale; and
(2) If scientific information on the human food safety aspect of the use of the drug in food-producing animals is not available, the veterinarian must take appropriate measures to assure that the animal and its food products will not enter the human food supply.
(c) Extralabel use of an approved human drug in a food-producing animal is not permitted under this part if an animal drug approved for use in food-producing animals can be used in an extralabel manner for the particular use.

RULE §573.45 Extra-Label or Off-Label Use of Drugs
(d) Extra-Label Drug Use in Food-Producing Animals.
(1) For animals intended for human consumption, a veterinarian must establish an extended withdrawal interval sufficient to ensure food safety. The withdrawal period must be supported by scientific information, and the veterinarian shall note the method used to determine the withdrawal interval in the patient records.
(2) A veterinarian shall not prescribe an extra-label drug in a manner that will result in violative food residue, or any residue that may present a risk to public health.
(3) Veterinarians shall ensure that procedures are in place to maintain the identity of treated animals, and shall note those procedures in the patient records.