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MINNESOTA BOARD OF VETERINARY MEDICINE

BVM Bits

MINNESOTA

In This Issue…

Minnesota Board of Veterinary Medicine
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Veterinary Practice Act

Timing for VCPR Reverts to 12 Months on July 1, 2022

As the pandemic subsides, the Board's extension of time allowed for a valid veterinarian-client-patient relationship will cease as of July 1, 2022. Once again, a valid VCPR will require a physical examination or visit to the premises within the preceding 12 months. Please contact the Board with any questions.

VCPR Cannot Be Established Virtually

The Board of Veterinary Medicine continues to interpret the definition of a valid veterinarian-client-patient relationship as requiring a physical examination, many components of which cannot be completed accurately by virtual means. This contrasts with a subset of states that allow a veterinarian to use their professional judgement to determine when the animal's chief complaints can be accurately assessed virtually.

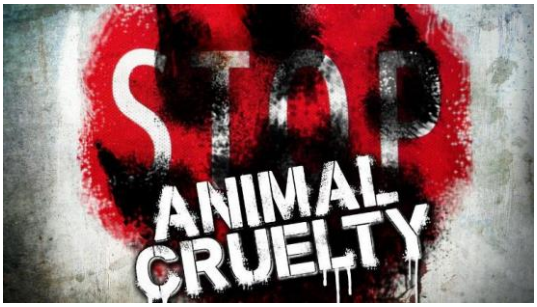
Although multiple telemedicine providers suggest that a patient-specific diagnosis and even treatment recommendations can be made without an office visit, this cannot be legally done in Minnesota.

The mission of the Minnesota Board of Veterinary Medicine is to promote, preserve, and protect the health, safety and welfare of the public and animals through the effective control and regulation of the practice of veterinary medicine.

Recognize and Document Animal Cruelty Well with a Practice Policy and Training

Veterinarians and their staff are often the first persons to recognize potential animal cruelty. Veterinarians are mandatory reporters of animal cruelty in all species as well as suspicions of animal cruelty in companion animals. 9100.0700 Subpart 1 (S); 346.37 Subd. 6. Cruelty is broadly defined in Minnesota law as every act, omission, or neglect which causes or permits unnecessary or unjustifiable pain, suffering, or death. Also, cruelty may be a flag for domestic violence that may warrant investigation by social services or law enforcement. Statute 343. 215 provides immunity to a licensed veterinarian acting in good faith and the in the normal course of business from civil and criminal liability in any action arising in connection with the report of a suspected incident of animal cruelty.

Any veterinarian can support a suspected cruelty investigation when requested by a humane agent or law enforcement but should consider a potential conflict of interest if the animal owner is a client. The veterinarian does not have to make the actual determination of whether clinical findings and observations constitute cruelty or abuse. That is a determination to be made by a humane agent and the courts.



A clinic protocol and training for documenting suspicions or clinical abnormalities that may constitute cruelty are timely choices. With a well thought out plan, training and templates, a practice will provide much needed documentation when reporting cruelty to law enforcement and humane officers. This documentation can be extremely helpful in the prosecution of the perpetrators and would also become part of the animal(s) medical records.

Recently, a Minnesota hospital's excellent model for training staff and documenting cruelty was lauded by The Link Letter. This monthly free electronic newsletter tracks information pertaining to the link between human abuse and abuse of animals. It includes new legislation and laws as well as educational resources for many professions, including health care providers and veterinarians. Please see page 3 on this Link website to see the full details developed at the Animal Emergency Referral Center: Vets-Hospital-reporting-policies-COMPILED-2022.pdf (nationallinkcoalition.org). A free download is available there.

Colleen Crockford, AERC Director of Social Work Services, developed this practice-specific model, which includes the pertinent legal citations for both Minnesota and Wisconsin:

- a protocol, specific to its clients in Minnesota and neighboring Wisconsin;
- a collection of animal abuse definitions and resources, including a city-by-city list of animal control and police contacts;
- a form for reporting suspected animal abuse, which includes: information about the pet owner and the person suspected of abuse; reasons for the report; photos of any injuries; results of the animal's physical exam; the name of the agency in Minnesota or Wisconsin where the report was sent; and who completed the report.

Ms. Crockford can be contacted via email at AERC for additional information: CECrockford@aerc.com.

Compounding Animal Drugs from Bulk Substances

Information Regarding Final Federal Guidance Issued April, 2022

A myriad of federal and state regulations apply to compounding medications for animal use. Veterinarians licensed in Minnesota may, in the course of professional practice and an existing Veterinarian-Client-Patient Relationship (VCPR), prepare medicaments that combine drugs approved by the Food and Drug Administration (FDA) as described in Statute 156.18 Subd. 1 (e).

Law permits compounding of an animal drug when the source(s) of the active ingredient(s) for compounding is a finished FDA-approved drug(s) and not a bulk drug substance. Law prohibits compounding copies of a marketed FDA-approved drug from bulk substances. A drug compounded from bulk drug substance is a copy if it has the same active ingredient and can be given by the same route of administration as the FDA approved drug.

While FDA-approved animal or human drugs can be used to treat an animal under extra-label use and related provisions, there are scenarios for the treatment of animals where no FDA-approved or indexed drug may be available. Under these limited circumstances, animal drugs compounded from bulk drug substances may be an appropriate treatment.

The Center for Veterinary Medicine (CVM) division within the FDA has released final guidance for compounding drugs from bulk substances for the animal industry, GFI #256. GFI #256 - Compounding Animal Drugs from Bulk Drug Substances (fda.gov) This document outlines CVM's recommendations for compounding drugs from bulk substances, when it may be justified, and what enforcement actions, if any, FDA might take if informed of violations. The document also addresses recommendations on compounding for office stock versus within a valid VCPR and what constitutes a copy of an approved medication.

Medications compounded from bulk drug substances do not have the same assurances of safety, efficacy, and quality as FDA-approved and indexed products and their use may result in serious harm, including death. Additional concerns for these products specific to animal use also include the presence of food residues and considerations for regulated sports.

CVM and the Minnesota Board of Veterinary Medicine expect practitioners to be aware of and comply with the requirements of the guidance. Specifically, the board advises practitioners of the following practice considerations when utilizing drugs compounded from bulk substances:

Patient medical records: The patient medical record should include the medical rationale for a medication compounded from bulk drug substances. A compounding pharmacy should also maintain the rationale provided by the practitioner on the prescription or a document maintained with the prescription. Multiple examples of justification are discussed in the guidance document.

Adverse effects of compounded medications: Adverse effects of compounded medications must be reported to the FDA by the pharmacist or veterinarian within 15 business days using Form FDA 1932a which is available online. How to Report Animal Drug and Device Side Effects and Product Problems | FDA.

Continued…

Compounding Animal Drugs from Bulk Substances Continued…

FDA Recommended Labeling for veterinary drugs compounded from bulk substances:

- Name and strength of drug
- Patient identification
- Species and indication for the drug's use
- Name, address and contact information of the compounding pharmacy or compounding veterinarian
- The Beyond Use Date of the product, after which it should no longer be used
- Name, address, and contact information for the veterinarian ordering the medication
- Either "*not for use in food animals*" or *withdrawal time*
- Adequate directions for use and appropriate auxiliary labels
- The following warning and cautionary statements:
    - *"This is a compounded drug. Not an FDA approved or indexed drug."*
    - *"Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian."*
    - *"Report suspected adverse reactions to the [pharmacist or veterinarian who compounded the drug] and the FDA using online Form FDA 1932a."*
- Additional label requirements must be observed for **office stock of compounded medication**:
    - Species of the patient(s)and indication(s) for which the drug will be used

Minnesota-specific labeling requirements are outlined in the Rules of the Board of Pharmacy, *Chapter 6800.3400 Subp. 1 and Subp. 4* and Board of Veterinary Medicine Statutes 156.18, Subd. 2 and 156.19. These regulations apply where stricter than the federal guidance. The veterinary statutes take precedent over the pharmacy rules.

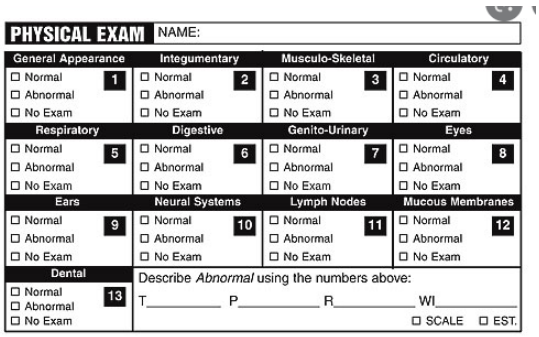
Office stock of compounded medications: Guidance provided by the Minnesota Board of Pharmacy allows veterinarians to maintain a 10-day office supply of urgently needed compounded medications to use and dispense to cover the time needed to have a patient-specific prescription filled. This Minnesota-specific guidance applies to medications compounded from FDA-approved sources and from bulk substances when FDA-approved drugs are unavailable. In nonfood-producing animals, drugs compounded from bulk substances for office stock may be less likely to prompt federal action. The guidance document includes a reference list of bulk drug substances for compounding office stock drugs. A veterinarian who stocks these drugs can only dispense it to the owner of the animal or to another veterinarian **in the same practice.**

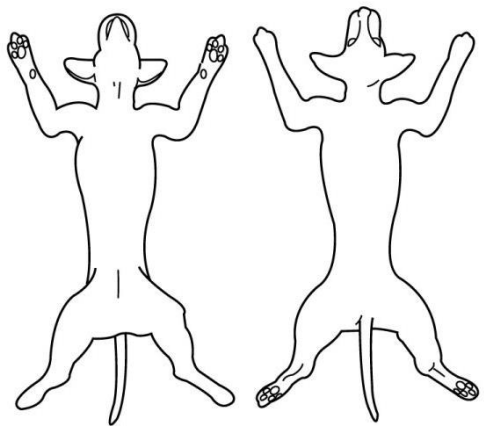
FDA enforcement action is most likely when the drug presents a significant safety concern for animals or humans that may handle the compounded product. This includes products that create unsafe residues in food animals. The prescribing veterinarian must have a valid VCPR and must ensure that the animal does not enter the food supply until science-based withdrawal times are established and included in the record. If the compounded medication is for anesthesia of wildlife, a tag should be placed on the animal with a withdrawal date and "Do Not Consume" warning.

Value of Templates for Medical Records

Data capture from physical examinations and procedures can be challenging during hectic workdays. Information in medical records reviewed by the Board as part of complaint investigations too often fail to meet minimum standards for record keeping. Nine categories of required data are listed in Rule 9100.0800 Subpart 4 A. To reduce the risk of missing expected data, templates can provide a timesaving means of documenting clinical findings, especially for handwritten records. Three templates that are often recommended are to veterinarians with deficient medical records are:

1. Physical examination stickers that list body systems or parts that allow a veterinarian to tick a box noting "normal" or abnormal". Any box that is ticked demonstrates that the system or body part was examined. Abnormalities would then be described in detail. Obligatory fields can be set up in most electronic medical records systems for the same purpose.
2. Dental charts that diagram both maxillary and mandibular teeth provide a quick way for documenting tooth abnormalities, extractions and other dental procedures. These are readily available for dogs, cats, and horses.
3. Anesthesia monitoring templates provide many fields to document not only medications administered but also vital signs, pulse oximetry, blood pressure, duration of anesthesia and surgery, and fluids administered. Use of this type of template provides evidence that the animal was actually monitored, and whether the peri-anesthetic management meets minimum standards.





Other potentially useful templates include:

- Summary for routine surgical procedures which describe where the incision was made, what was done, and type of suture and suture pattern for closure.
- Discharge instructions for routine procedures such as spays, neuters, and catheter sites
- Charts to track parameters and treatments for monitoring hospitalized patients
- In house laboratory testing such as hemograms and urinalyses
- Dermatology templates for marking location of skin abnormalities

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Tips: Who Else to Call?

Board of Animal Health: reportable diseases, rabies certificates, MN health certificates, animal identification, commercial dog and cat breeders
Board of Chiropractic Examiners: human chiropractors working on animals
Board of Pharmacy: compounding, drug label requirements, pharmacy or pharmacist complaints, license verification, prescription monitoring program
DEA: controlled substances, DEA registration
MVMA: veterinary technician credentials and CE
USDA/APHIS: federal accreditation, heath certificate requirements
DNR: wildlife questions
FDA: Veterinary feed directives, AMDUCA
MN Pollution Control Agency: disposal of medications and other substances from a veterinary practice

Contact Information for Related Agencies

Minnesota Board of Animal Health:
625 Robert Street North, St. Paul, MN 55155
http://mn.gov/bah/
Phone: (651) 296-2942 Fax: (651) 296-7417

Drug Enforcement Agency:
100 Washington Avenue South, Suite 800 Minneapolis, MN 55401
www.deadiversion.usdoj.gov/index.html
DEA Regional Field Office at (612) 344-4136
National Office toll free 1-800-882-9539

Minnesota Board of Pharmacy:
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Joni Scheftel, DVM, MPH, DACVPM State Public Health Veterinarian, 625 Robert St. North St. Paul, MN 55155-2538 651-201-5107 joni.scheftel@state.mn.us

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USDA APHIS Veterinary Services:
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