

# Minnesota Board of Veterinary Medicine

## BVM BITS



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Veterinary Practice Act

## Client Financial Constraints

In clinical practice, veterinarians are very frequently limited in both diagnostic and treatment options by the owner's ability or willingness to pay for those services. When care of the animal is constrained and the animal does not do well, the owner may seek to blame the veterinarian. This may take the form of a complaint to the Board, particularly if the animal dies or subsequently needs to be euthanized.

How can this type of scenario be avoided to limit the likelihood of an unwarranted complaint to the Board? Excellent client communication is the best preventive and defensive practice, albeit time consuming. Options for payment, diagnosis and treatment should be clearly explained, seeking acknowledgement by the owner that she or he understands. Those conversations, phone calls and/or emails should be documented in the medical record, and/or on a consent form if a procedure or treatment is recommended but not elected by the owner. These entries should include the owner's conversations with staff. If there is a concern that the owner may become contentious, any witnesses to such conversation could be noted. Board members reviewing a complaint can more quickly discern what transpired within the veterinarian-client patient relationship when that client communication is well documented in the medical record.

Referral should be offered if the veterinarian believes more effective diagnostic or treatment options are available, even if the client is likely to decline. Although not required by law, options for referral to a non-profit veterinary clinic may exist.

If the owner declines treatment and the animal is clearly suffering from a treatable condition, a conversation about humane euthanasia or surrender to a humane society should occur and be noted in the record. In some circumstances, an owner may be able to make a more humane decision for the animal after speaking with a staff member or grief counselor if available. Such assistance may also help the owner understand that the need to blame someone other than oneself is a common component of regret and grief. If the owner insists on no treatment or no euthanasia, this could be considered animal cruelty, which must be reported to a humane agent or law enforcement.

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.



## MN Regulations and Veterinary Feed Directive Changes

Veterinary Feed Directives (VFD's) are a form of prescription. Minnesota government regulations pertaining to prescription writing apply to VFD's. The Center for Veterinary Medicine of the FDA has provided the following summary to guide food animal veterinarians as the new federal regulations go in to effect (emphasis added). Please note that Minnesota's definition of a valid VCPR includes the phrase, "timely visits to the premises". **"Timely" is interpreted as within the last 12 months to the premises housing the animals that will receive the prescription medication.**

**From the FDA:** FDA intends to use a phased enforcement strategy for implementation of this final rule as OTC drugs become VFD drugs under GFI #213. FDA first intends to provide education and training for stakeholders subject to this final rule such as veterinarians, clients (animal producers), feed mill distributors and other distributors. FDA will then engage in risk-based general surveillance, as well as for-cause inspection assignments. FDA intends to work closely with **state regulatory partners and state boards of veterinary medicine in their enforcement strategy**. In instances where a state VCPR applies the state may also pursue enforcement. FDA typically issues advisory actions such as untitled or warning letters prior to pursuing enforcement actions such as injunctions, seizures, monetary penalties, or criminal actions. Particularly egregious violations might warrant immediate enforcement action.

In the preamble to the final rule, we stated our expectations for the shared responsibilities of feed mills, veterinarians and clients in determining the appropriate amount of feed to be manufactured for the approximate number of animals authorized by the VFD. When investigating situations where there has been a violation in the authorization or use of a drug, we intend to hold parties responsible for their actions that violate the legal requirements. For example, if a feed mill appropriately fills a valid VFD, but it is used in a manner contrary to the regulation, we would pursue enforcement against the individual or individuals responsible for such use. Conversely, if a feed mill does not distribute an amount of VFD feed that is commensurate with the approximate number of animals specified by the veterinarian on the VFD, we would pursue enforcement against the feed mill.

We intend to inspect for veterinarian, distributor, and client compliance with the VFD requirements. Typically, we intend to inspect a distributor and then inspect a subset of the veterinarians and clients associated with the VFDs the distributor has received. Inspections will be focused on compliance with all of the requirements of the VFD regulation.

### ***When can a veterinarian issue a VFD order?***

We would find it acceptable for a veterinarian to issue a VFD prior to January 1, 2017 for a medicated feed that is expected to transition from OTC to VFD **if** all of the following conditions are met:

- (1) The VFD Blue Bird labeling is available for the VFD feed. The veterinarian needs to know the conditions of use and other information that appears on the labeling in order to correctly fill out the VFD according to the approval. We expect that Blue Bird labeling will begin to be made available on FDA's website beginning the week of December 6, 2016.

## MN Regulations and Veterinary Feed Directive Changes Cont.

- (2) The course of treatment authorized by the VFD is able to be completed before the VFD's expiration date or June 30, 2017 whichever is shorter. The expiration date is expected to be up to 6 months for the drugs that are transitioning from OTC to VFD. The expiration date is counted from the date of issuance, which is the date the veterinarian authorizes the VFD, not the date the drugs transition to VFD marketing status.
- (3) The veterinarian has a VCPR with the client that meets the requirements in the 2015 VFD regulation. For states in which the federal VCPR applies, if the veterinarian has established a VCPR with the client and that VCPR meets the requirements necessary for the VFD rule, the veterinarian can authorize the VFD under that established relationship. The veterinarian should also check state authority, particularly in states in which the state VCPR applies.

### *When does this take effect?*

FDA's Guidance for Industry (GFI) #213, issued in December 2013, sets out FDA's judicious use strategy. GFI #213 requests that animal drug sponsors of approved medically important antimicrobials administered through medicated feed or water:

- (1) Voluntarily remove from their product labels indications for use related to growth promotion, and
- (2) Bring the remaining therapeutic uses of these products under a veterinarian's oversight by changing their marketing status from over-the-counter to veterinary feed directive (VFD) for drugs administered through feed, or to prescription (Rx) for drugs administered through drinking water. This transition is expected to be accomplished by December 2016.

As a result of this transition, animal producers will need to obtain a prescription for any affected drugs administered through drinking water, or a VFD for any affected drugs administered through medicated feed.

GFI #213 affects medically important antimicrobials administered through medicated feed or water. Therefore, we expect that after January 1, 2017, the drugs affected by GFI #213 will only be labeled with therapeutic claims and they will be marketed as VFD drugs if administered through feed and Rx drugs if administered through drinking water.

What will the specific ruling be for feed that is in the bins on January 1, 2017? This inventory will often last for 1 to 2 weeks and producers are concerned on usage when the program starts.

On January 1, 2017, the marketing status of the affected drugs will change from over-the-counter (OTC) to prescription (Rx) status for drugs administered through medicated drinking water, or to veterinary feed directive (VFD) for drugs administered in medicated feeds. At the time of transitioning from OTC to VFD marketing status, these products will fall under the 2015 VFD rule that went into effect on October 1, 2015.

On January 1, 2017, the client must have a VFD to authorize the feeding of any VFD feed. If the client already has VFD feed on site, they must receive a VFD authorizing the use of the VFD feed prior to feeding that VFD feed. If they have Type A medicated article on site they must have a VFD prior to feeding any of the resulting VFD feed mixed from that Type A medicated article.

## Veterinary Facility Inspection

Unlike a number of other states, the Minnesota Board of Veterinary Medicine does not routinely inspect veterinary clinics or mobile veterinary units but has the authority to do so in response to a complaint (MN Statute 156.121) or allegations of violations of statutes pertaining to prescription medications (MN Statute 156.20)

(<https://www.revisor.mn.gov/statutes/?id=156>). An inspection by the Board can be unannounced but must be made at a reasonable time, such as when the facility is open. The Minnesota Board of Pharmacy has authority to inspect veterinary facilities where prescription medications and biologicals are stored for distribution in Minnesota. Other federal, state, county and city agencies also have authority to inspect veterinary practices.

During an inspection, the Board representative(s) may inspect pertinent records, equipment, materials, containers, and facilities bearing on whether veterinary drugs are in compliance with the statutes, as well as the cleanliness and sanitation. Samples and photographs are often taken.



Several rules describe the expected standards for premises and facilities. A veterinary facility is defined as a building, shelter, structure, or mobile unit in which licensed veterinarians routinely engage in the practice of veterinary medicine. A housing facility is defined as a structure, cage, building, or other facility used for housing animals under veterinary care. Expected standards in a veterinary facility are detailed in MN Rule [9100.0200](#) and [9100.0300](#). The categories in 9100.0200 include biologics and other drugs, cages, communicable or contagious diseases, equipment, food and water, pest control, sanitation, storage, waste disposal, water, and electric power. In 9100.0300, the categories include cleaning and disinfecting, drainage, heating, interior surfaces, lighting, outdoor housing facilities, structural strength and ventilation.

Other regulations may be considered during an inspection as well to determine if a veterinary facility meets minimum standards ([9100.0800](#)). One of these regulations that few veterinarians are aware of is that drugs and biologics must be stored, prescribed, and dispensed in compliance with the Minnesota Board of Pharmacy's statute 151.35 Drugs, Adulteration (<https://www.revisor.mn.gov/statutes/?id=151.35>) and the United States Pharmacopeia - National Formulary. Board of Pharmacy statute governs many aspects of medications that a veterinary clinic routinely handles, including opened bottles, drug combinations, returned drugs, and expired medications. The USP website is complex, but does provide guidance on many topics, including common practices such as repackaging medication, expiration dates, and compounding. (<http://www.usp.org/usp-nf/harmonization/general-chapters/general-methods>). Compliance with requirements for labels for dispensed drugs is another area that an inspection might investigate, as well as prescription records, particularly for controlled substances.

If an inspection finds that a veterinary facility fails to meet the requirements, the owners of the veterinary practice would potentially face allegations of unprofessional conduct by the Board and would be expected to remedy the problems that were identified within a specified time period.

## Board Open Appointments

The position of a public member to serve on the Large Animal Complaint Committee will be open in 2017. Applicants may not or never have been, a member of the veterinary profession, the spouse of any such person, or have a material financial interest in either the provision of veterinary service or an activity directly related to the profession.

Board members are considered volunteers. However, a member does receive a modest per diem for time spent on the work of the Board and travel to the meetings. The time commitment for a veterinarian on the Large Animal Complaint Review Committee and a public member are: 3 - 6 Board meetings/year for an entire afternoon; 10 - 20 complaint review conferences of 2 hours each/year; and 1-2 hours a week reviewing complaint files. The terms are for 4 years, and members can reapply for 2nd and 3rd terms.

The Secretary of State's Office will begin accepting applications for the open position soon. These will be reviewed by the Governor who will make the appointments. The new Board member's term will begin January 1, 2017. Applications will be accepted until the position is filled.

Once the open position is announced, the Secretary of State's link to online applications or a downloadable application will be found on this page: <http://www.sos.state.mn.us/boards-commissions/current-vacancies/>

Please contact Dr. Wilson at the Board of Veterinary Medicine if you have questions about the positions: (651) 201-2844 or [julia.wilson@state.mn.us](mailto:julia.wilson@state.mn.us)



## Professional Firm Renewal Reminder

Annual professional firm renewals will be sent out by the Board in November to each professional firm. Renewal forms and a \$25.00 annual registration fee are due by January 1.

If you need to update your firm's contact information, please contact the Board at [vet.med@state.mn.us](mailto:vet.med@state.mn.us)

## License Verification

If you are applying for licensure in another state, you may need to contact the Board for a document stating you are in good standing with the Minnesota Board of Veterinary Medicine. The Board will generate a form that contains your license history in Minnesota and will send this form directly to the state in which you are seeking licensure. There is a \$25.00 fee associated with this request.

You can request a license verification document two different ways:

1. Fill out the request online using our online license verification form. You may pay with credit card online.
2. Fill out a paper copy of the request form. The form can be downloaded on our website or you can email [vet.med@state.mn.us](mailto:vet.med@state.mn.us) or call us to request this form. A \$25.00 check written to the Minnesota Board of Veterinary Medicine must accompany the paper form.

License verifications requests are completed within 1-2 business days of the request and are sent directly to the specified state. Special accommodations to this request can be made by contacting the Board at [vet.med@state.mn.us](mailto:vet.med@state.mn.us).



## License Renewal & CE Extensions

Odd-numbered licenses expire on February 28, 2017. Renewal notices will be sent by email on 11/28/16 and by postcard 12/29/16. Online renewals begin in November.

Please remember that you need a total of 40 hours of continuing education credits from March 1, 2015 through February 28, 2017. Thirty of these hours must be interactive. It takes 30 actual hours of self-study to claim the maximum of 10 hours of non-interactive CE. Most on-line courses are non-interactive. There is a maximum of 10 hours allowed for practice management topics. If you will not have 40 hours prior to the renewal period, please contact the Board.



## Board Member Contact Information

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## Tips: Who Else to Call?

**DEA:** controlled substances, DEA registration

**MVMA:** veterinary technician credentials and CE

**USDA/APHIS:** federal accreditation, health certificate requirements

**DNR:** wildlife questions

**FDA:** Veterinary feed directives, AMDUCA

**Board of Animal Health:** reportable diseases, rabies certificates, MN health certificates, animal identification

**Board of Chiropractic Examiners:** human chiropractors working on animals

**Board of Pharmacy:** compounding, drug label requirements, pharmacy or pharmacist complaints, pharmacy license verification

## 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](http://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:

2829 University Avenue SE, Suite 530

Minneapolis, MN 55414

<http://www.pharmacy.state.mn.us/>

Phone: (651) 201-2825 Fax: (651) 210-2837

### Minnesota Department of Health:

Joni Scheftel, DVM, MPH, DACVPM State Public Health Veterinarian,

625 Robert St. North St. Paul, MN 55155-2538 651-201-5107

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### FDA Minneapolis State Liaison:

Ryan Benedict 612-758-7191 [ryan.benedict@fda.gov](mailto:ryan.benedict@fda.gov)

