**811—12.2(169) Controlled substances, drugs, prescription medications and restricted immunization products.** When state or federal law restricts a drug, medication or immunization product intended for use by or on the order of a licensed veterinarian, the licensed veterinarian shall sell, distribute, or order the drug or medication only in the course of the licensed veterinarian's professional practice. A prescription veterinary drug, medication or immunization product shall not be deemed to be used "in the course of the licensed veterinarian's professional practice" unless a valid veterinarian/client/patient relationship exists.

**12.2(1)** *Prescriptions.* The order for all such drugs, medications or immunization products shall be accompanied by the licensed veterinarian's original prescription that shows the following:

*a.* Licensed veterinarian's name, address and telephone number;

*b.* Client's name;

*c.* Patient's name or identification;

*d.* Date issued;

*e.* Drug, medication or product name, strength, and quantity;

*f.* Directions for use;

*g.* Number of times the prescription may be refilled;

*h.* Expiration date of the drug, medication or product; and

*i.* Applicable withdrawal period (paragraph 12.2(2)*"d"*) for livestock and poultry.

**12.2(2)** *Extra-label use of veterinary drugs, medications, and immunization products.* Any extra-label use of veterinary drugs, medications or immunization products shall be by or under the order of a licensed veterinarian only and shall be subject to the following criteria:

*a.* There shall be a veterinarian/client/patient relationship as defined in subrule 12.1(1).

*b.* For drugs or medications used in patients not intended for food, one of the following applies:

(1) There are no marketed drugs, medications and immunization products specifically labeled for the condition(s) diagnosed;

(2) The approved product is clinically ineffective; or

(3) In the licensed veterinarian's clinical judgment, the labeled dosage is inappropriate for the condition or the extra-label use should result in a better outcome for the patient.

*c.* The health of the treated patient is immediately threatened, or suffering or death would result from a failure to treat the affected patient.

*d.* Appropriate withdrawal period shall be specified when the drugs, medications or immunization products are used in animals intended as food. Extra-label drug use in food-producing animals must follow Food and Drug Administration - Animal Medicinal Drug Use Clarification Act regulations (21 Code of Federal Regulations 530). Licensed veterinarians are encouraged to consult the Food Animal Residue Avoidance Databank (FARAD) or public peer-reviewed documents when determining appropriate withdrawal period.

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