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The legality of using live agents to control disease in Minnesota

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Minnesota Board of Animal Health

Introduction

Two agencies are involved in regulating the sale and distribution of veterinary biological products in Minnesota: the Minnesota Board of Animal Health and USDA's Center for Veterinary Biologics.

The Minnesota Board of Animal Health has rules relative to the sale and distribution of biological products; these include Minnesota Rules Chapter 1720 parts 1720.0580 through 1720.0640. For a full transcript of these rules, see below. These rules state that an active virus or infective agent of any communicable disease of domestic animals can be sold only to veterinarians and pharmacists or companies and corporations engaged in the retail sale of such products. Pharmacists, companies, or corporations are allowed to sell these products only to veterinarians, with the exception that the product can be sold to an animal owner who has a written prescription from a veterinarian. In all cases, the veterinarian involved must be licensed by the state of Minnesota. Finally, no biological products containing the active or infective agent of any communicable, infectious disease of livestock can be sold or distributed unless it is a USDA licensed product.

The USDA's Center for Veterinary Biologics licenses veterinary biological products as well as establishments that deal with veterinary biologics; this is done according to the Code of Federal Regulations, Title 9, Chapter 1, Parts 101 through 130. Part 107 provides for exemptions to the requirements for these licenses. For example, products prepared by a person solely for administration to animals owned by that person are exempt from licensing requirements. Products prepared by a veterinarian solely for administration to animals in the course of a state-licensed, professional practice of veterinary medicine by a veterinarian under a veterinarian-client-patient relationship are exempt from licensing requirements as are establishments in which these products are prepared.

Minnesota rules relating to sale and distribution of biological products and antigens

The following text was taken from *Minnesota Rules 1999*, including amendments adopted through February 16, 2001.

1720.0580 Biologics

No person, persons, pharmacists, companies, or corporations located within or without the state of Minnesota, engaged in the manufacture, wholesale or retail sale, or distribution of biological products containing the active virus or infective agent of any communicable, infectious disease of domestic animals shall sell or distribute these products to any person or persons located within the state of Minnesota except to veterinarians licensed to practice in Minnesota and to pharmacists, companies, and corporations engaged in the retail sale of such products, who shall not sell to persons other than licensed veterinarians except on the written prescription of a veterinarian licensed to practice in Minnesota.

1720.0590 Antigens

No person, persons, pharmacists, companies, or corporations located within or without the state of Minnesota, engaged in the manufacture, wholesale or retail sale, or distribution of antigens and all other biological products used in the detection and diagnosis of communicable, infectious diseases of domestic animals shall sell or distribute these products to any person or persons located within the state of Minnesota except to veterinarians licensed to practice in Minnesota and to pharmacists, companies, and corporations engaged in the retail sale of such products, who shall not sell to persons other than licensed veterinarians.

1720.0600 Prescriptions

Prescriptions shall not be written by veterinarians for *Brucella abortus* vaccine, modified live rabies vaccine, antigens, and all other biological products used in the detection and diagnosis of communicable, infectious diseases of livestock, or other biological products that may be determined by the board to be too dangerous for lay use.

1720.0610 Retention of prescription copies

A copy of all written prescriptions shall be maintained on file by the issuing veterinarian for a period of two years.

1720.0620 Sale or distribution of biological products and antigens

No person, persons, pharmacists, companies, or corporations shall sell or distribute in Minnesota biological products containing the active or infective agent of any communicable, infectious disease of livestock, or antigens

used in the detection and diagnosis of communicable, infectious diseases of domestic animals unless such products are licensed by the United States Department of Agriculture and are in the original unopened container of the manufacturer.

1720.0630 Storage of biological products or antigens

Such products shall at all times be maintained in storage in accordance with the recommendations of the manufacturer.

1720.0640 Sale, distribution, and use of poultry biologicals and antigens

With the exceptions of parts 1720.0620 and 1720.0630 the provisions of these rules shall not apply to biological products and antigens manufactured and sold exclusively for use in poultry; provided, the Board of Animal Health may impose restrictions on the sale, distribution, and use of poultry biologicals and antigens if deemed necessary to protect the health of livestock and poultry in Minnesota.

