Compounding Drugs

Compounding is a challenging topic for many veterinarians. As a profession, we are striving to practice a high standard of medicine but too frequently face a backorder of an approved medication, a need for a flavored or diluted medication to keep in stock in a practice, or dire economic restrictions. Regulations pertaining to compounding are the domain of the Food and Drug Administration federally, the Minnesota Board of Pharmacy and this Board.

The good news is that the Minnesota Board of Pharmacy has recognized that current state laws and regulations need to be changed to increase accountability for product safety yet be less restrictive for legitimate medical use. A bill designed to align state law with a new federal law called the Drug Quality and Security Act (DQSA) will be introduced in the Minnesota Legislature. The new state law would allow the Board of Pharmacy to develop rules that would permit practitioners, including veterinarians, to purchase a limited stock of a legally compounded medication that could be utilized in their clinic or dispensed to clients, for use in their animals, but only if the veterinarian has a valid client-patient relationship (VCPR). The Minnesota Pharmacy Board intends to have the rules apply to veterinarians even though the federal DQSA does not apply to veterinary compounding.

The interpretation of what constitutes compounding can be unclear. By definition, drug compounding is a practice in which a licensed health professional, or a person under their supervision, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. If there is a valid VCPR, the Veterinary Practice Act allows a veterinarian to add a flavoring agent or vehicle to a prescription drug, dilute a prescription medication, and combine two or more FDA approved prescription medications and/or over the counter drugs, for use in patients. (Minnesota Statutes 156.16 Definitions and 156.18 Veterinary Prescription Drugs) A veterinarian should not prescribe a compounded drug when there is an FDA-approved formulation unless that formulation cannot be safely administered or dosed in that formulation. Ideally, whenever a veterinarian writes a prescription for a medication from a compounding pharmacy, he or she should check that the pharmacy is licensed as a compounder by the FDA and Minnesota. The license of a pharmacy selling medications in or to Minnesota can be verified on the MN Pharmacy Board website: www.pharmacy.state.mn.us

All compounding pharmacies and veterinarians that dispense compounded products are required to follow pharmacy and veterinary regulations on product labeling. The fact that the dispensed medication is compounded should be noted on the label, as compounded medications may have a slightly increased risk of contamination or misformulation. When this risk is discussed with a client, this communication should be recorded in the medical record.