

New Interpretation of the 72-Hour Compounding Rule

The 72-hour compounding rule has long been on the CVMA's radar as a concern for members who are unable to dispense a reasonable supply of a compounded drug for an animal patient. We have been working with the Veterinary Medical Board (VMB) on a number of compounding concerns and positive results have been achieved on the 72-hour rule.

The VMB recently changed its interpretation of California Pharmacy law regarding dispensing compounded medications. The law is the California Code of Regulations, Section 1735.2(c)(2) which defines a "reasonable quantity" of a medication that may be compounded in advance by a pharmacy in anticipation of dispenser needs. Historically, the VMB interpreted the law to limit the amount of compounded medication that veterinarians may dispense to clients from hospital stock to no more than a 72-hour supply. The new interpretation does not limit the quantity that may be dispensed for an individual patient.

Why the Change?

In November 2015, members of the VMB met with the Board of Pharmacy (BOP) Executive Director and Legal Counsel to discuss compounding issues. Among the discussion topics was the 72-hour compounding rule. At the meeting, the VMB learned that the historical interpretation of Section 1735.2 regarding restrictions on dispensing a 72-hour supply of compounded medication to a client/patient was never intended to be applied to veterinarians.

What this Means to Veterinarians

This regulation does not state the exact amount of compounded medication that may be dispensed to clients. Therefore, with the new interpretation, veterinarians are permitted to send home the amount of compounded medication needed for the patient.

There are parameters however regarding the quantity of compounded drugs pharmacists may furnish to a dispenser based on historic and anticipated need. In reviewing an order from a veterinary practice, a pharmacist is bound by "reasonable quantity" restrictions. According to the VMB, "the regulation defines a "reasonable quantity" of a compounded medication that may be furnished by a pharmacy to a veterinarian for in office use, or to dispense to their client/patient. Thus, the "reasonable quantity" is a formula used by pharmacies to supply prescribers and dispensers".

CVMA Requests Amendment to Regulation

Despite the new flexibility provided in the BOP interpretation of the 72-hour compounding rule, the CVMA has requested that the regulation be changed to increase the use estimate to a 120-hour supply to be prepared in advance by compounding pharmacies for veterinary practices. While still in process, the CVMA is hopeful that BOP regulations will soon reflect this amendment. If adopted, it will provide even more ability for pharmacists to compound medications in advance in anticipation of veterinary practice needs. The CVMA will report on changes to this regulation as they continue to develop.