

Compounded Medications and Veterinary Practice: Important Laws

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Many veterinary practices use compounded medications in place of generic or legend brands in their day-to-day operations. Compounded medications refer to FDA-approved medications (generic or legend) that have been altered to meet the needs of a particular patient. FDA rules state that compounded medications must be formulated directly from approved generic or legend products, when such products are available. The use of bulk products or raw active ingredients during the compounding process is prohibited. Furthermore, if an FDA-approved formulation of equal strength and form exists, compounding of the product is prohibited.

Compounding pharmacies must carry current licenses with the Board of Pharmacy in each state where medications are compounded. In addition, the compounding pharmacy must be registered in each state to which it ships products. Therefore, if a practice uses a compounding pharmacy in New Jersey, that pharmacy must be registered with the California Board of Pharmacy. To check the status of a pharmacy license with the California Board of Pharmacy, visit: http://www.pharmacy.ca.gov/online/verify_lic.shtml and select either “sterile compounding” or “non-resident sterile compounding.” While these rules are primarily applicable to the compounding pharmacies, they do impact the veterinarian because veterinarians are liable for medications used or dispensed in their practice. Therefore, veterinary practices that use compounded medications should consult with the compounding pharmacy to determine how the medications are being manufactured and whether or not proper licensing exists.

In addition, should a practice regularly use compounded products in their hospital stock, the following California laws must be considered:

Compounding Defined

According to the California Code of Regulations, Title 16, Section 1735(a): compounding means:

- Altering the dosage form or delivery system of a drug
- Altering the strength of a drug
- Combining components or active ingredients
- Preparing a drug product from chemicals or bulk drug substances

Examples of compounding would include: making a paste or oral suspension from crushed or melted

pill, or combining two injectable medications in one vial or syringe.

Compounding Exceptions

According to the same code listed above, compounding does not include:

- Reconstituting a drug pursuant to manufacturer’s directions
- Tablet splitting
- Adding flavoring agents to enhance palatability

The 72-Hour Compounding Rule

It is unlawful for a practice to dispense compounded medications to clients out of stock. The law states that practitioners must provide a written or oral prescription for a compounded product, to be filled by the client for the animal patient. Therefore, while a veterinary practice may use compounded medications for administration in house, it must not send clients home with medication from this stock.

One exception to this rule exists: the 72-hour compounding rule. California Code of Regulations Title 16, Section 1735.2 (b) states that a practice may prepare and store a limited quantity of a compounded product in advance of a patient-specific prescription where such a quantity is necessary to ensure continuity of care. The law goes on to define a reasonable quantity as not more than a 72-hour (i.e., three-day) supply, which is distributed to a client upon patient discharge.

The 72-hour rule, which is enforced by the California Veterinary Medical Board, is based on the scenario of the Friday afternoon appointment. If a veterinarian sees a patient on Friday at 4:30 and determines the need for a compounded medication to suit that patient’s specific needs, it may be impossible to obtain that medication until Monday. Therefore, the law allows for a 72-hour supply to be sent home with the client from the practice’s stock.

Veterinary practices may use compounded medications in house, provided that the source that they are obtaining the medications from is following FDA compounding rules. If a practice dispenses a compounded medication, the practice must observe the 72-hour limit on dispensed medication and in turn provide clients with a prescription to be filled at a compounding pharmacy once the three-day supply is finished.