**Veterinary Drug Compounding — Legal Requirements, Inspection Findings, and Best Practices**

This document summarizes current California law and regulatory requirements concerning veterinary compounding and outlines the steps to take to ensure compliance.

1. **Compounding Is Permitted Under California Law**

Veterinary compounding is allowed in California under:

* **Business and Professions Code (BPC) § 4826.5**, which states:

“A veterinarian may compound drugs pursuant to a prescription or for office use in accordance with applicable federal and state laws and regulations.”

* **California Code of Regulations (CCR), Title 16, §§ 2091–2095**, which outlines procedures, personnel, labeling, and sterility requirements for veterinary drug compounding.
	+ Sterile drug compounding shall be for immediate use except in the following conditions:
		- A dilution of the ingredients is essential for the safe administration of the preparation.
		- There is historical documentation of the need, safety, and efficacy of the preparation.

The facility may prepare compounded medications for:

* **Specific patients** - compounded drugs may only be administered or dispensed within the context of a valid Veterinarian-Client-Patient Relationship (VCPR), as required under BPC § 4826.5(a) and CCR § 2032.1.
* **Office stock** for medications prepared in advance under the care of the veterinarian, including but not limited to drugs compounded for sterilization surgeries, and other preoperative sedation, pursuant to BPC § 4826.5(a) and VMB guidance. (These preparations must not be dispensed to private patients but can and must be used only within the facility under a valid VCPR.)
1. **Labeling Requirements for Compounded Drugs**

Per 16 CCR § 2094, all compounded medications must be labeled with all of the following on the label affixed to the container holding the compounded drugs:

1. **Name, strength, and quantity of each active ingredient**
2. **Date of compounding**
3. **Beyond-use/expiration date**
4. **Storage instructions**
5. **Lot or batch number**
6. **Name/initials of the person who prepared it**
7. **Name, address, and phone of the facility**
8. **Statement**: “*Compounded by veterinary facility*”
9. **Directions for use**, if dispensed to clients
10. **Multi-Use Bottles/“Office Stock”**

Per CCR §§ 2091–2095, multi-use compounded drugs (e.g., TTDex) are allowed if:

* Properly compounded and documented.
* Used only in-house.
* Labeled per the requirements above.
* Assigned an appropriate “beyond-use date”(to ensure safety and efficacy):
	+ **Sterile**: up to 30 days
	+ **Non-sterile**: up to 180 days

Batch records must be maintained and include formulas, ingredients, preparation method, and staff initials.

**Key References**

* California Business & Professions Code § 4826.5
* California Code of Regulations, Title 16, §§ 2091–2095