

**California Code of Regulations
Title 16. Professional and Vocational Regulations
Division 20. Veterinary Medical Board**

SECOND MODIFIED TEXT

Proposed amendments to the regulatory language are shown in single underline for new text and ~~single strikethrough~~ for deleted text.

Modifications to the proposed regulatory language are shown in double underline for new text and ~~double strikethrough~~ for deleted text.

Second Modifications to the proposed regulation text are shown in *italicized double underline* for new text and ~~*italicized double strikethrough*~~ for deleted text.

Add Article 11 (commencing with Section 2090) to Division 20 of Title 16 of the California Code of Regulations to read as follows:

Article 11. Compounding in a Veterinary Premises.

2090. Definitions.

(a) "Compounding" means any of the following activities performed in a registered veterinary premises by a licensed veterinarian that has established the veterinarian-client-patient relationship for the animal patient(s) or a registered veterinary technician under the direct or indirect supervision of that veterinarian:

- (1) Altering the dosage form or delivery system of a drug.
- (2) Altering the strength of a drug.
- (3) Combining components or active ingredients.
- (4) Preparing a compounded drug preparation from chemicals.

(b) "Compounding" also means preparing a compounded drug preparation from bulk substances by a licensed veterinarian, who has established a veterinarian-client-patient relationship for the animal patient or prepares the compounded drug preparation for office stock, or by a registered veterinary technician under the direct supervision of that veterinarian.

(c) "Compounding" does not include:

- (1) Reconstitution of a drug pursuant to a manufacturer's direction(s) for oral, rectal, topical, or injectable administration, ~~nor does it include~~
- (2) The sole act of tablet splitting or crushing, capsule opening, ~~or the~~
- (3) Addition of flavoring agent(s) to enhance palatability.;

(d) "Expiration date" means the date, or date and time, determined from the date the preparation is compounded, after which administration of a compounded drug preparation

shall not begin, the preparation shall not be dispensed, and the preparation shall not be stored other than for quarantine purposes.

(e) "Office stock" means a compounded drug prepared without a patient-specific prescription that may be dispensed only to a client, client's representative, or other veterinarian at the same veterinary premises.

Note: Authority cited: Section 4826.5, Business and Professions Code. Reference: Section 4826.5, Business and Professions Code.

2091. Veterinary Drug Compounding.

(a) A veterinarian shall ensure the safety and efficacy of a compounded drug preparation, including, but not limited to, avoiding known drug incompatibilities and inappropriate complications, through reliance on drug compounding standards in the profession and in accordance with section 2032.

(b) A veterinarian shall not perform either sterile or non-sterile drug compounding when the complexity of the drug compounding exceeds the veterinarian's knowledge, skill, facilities, or available equipment.

(c) A veterinarian shall not perform either sterile or non-sterile drug compounding unless there are no other human or animal drugs approved by the United States Food and Drug Administration (FDA) and available that satisfy the need for this preparation.

(d) Sterile drug compounding shall be for immediate use except in the following conditions:

(1) A dilution of the ingredients is essential for the safe administration of the preparation.

~~(2) There are no other human or animal drugs that satisfy the need for this preparation.~~

~~(3) There is historical documentation of the need, safety, and efficacy of the preparation.~~

~~(e) Only sterile drugs approved by the United States Food and Drug Administration FDA shall be used as the ingredients in a sterile compounded drug preparation.~~

(f) For non-sterile compounded drug preparations, active pharmaceutical ingredients (APIs) shall be purchased from an FDA-registered facility, and all records of such purchases shall be maintained for three (3) years to prove the origin of the APIs.

Note: Authority cited: Section 4826.5, Business and Professions Code. Reference: Section 4826.5, Business and Professions Code.

2092. Policies and Procedures.

(a) A veterinary premises that engages in compounding drug preparations shall develop and maintain a written policies and procedures manual, which shall include:

- (1) A list of each of the requirements of subsections (b) and (e) and sections 2093 and 2094.
- (2) Policies and procedures for the training of a registered veterinary technician who may perform compounded drug preparations.
- (3) Policies and procedures for a quality assurance program established pursuant to section 2095.

(b) For each compounded drug preparation, a formula document shall be maintained and include all of the following:

- (1) Active ingredients to be used.
- (2) Equipment to be used.
- (3) Expiration date of the preparation.
- (4) Inactive ingredients to be used.
- (5) Specific compounding steps to be used to prepare the drug.
- (6) Instructions for storage, handling, and administration of the compounded preparation.

(c) The formula document may be included in the policies and procedures manual maintained pursuant to subsection (a).

(d) If the compounded drug preparation is not routinely compounded, a formula record for the preparation may be kept in the medical record of the patient.

(e) For each compounded drug preparation prepared for a patient, the following information shall be recorded in the patient's medical record:

- (1) Name or initials of the veterinarian ~~that~~ who made or supervised the making of a compounded drug preparation and the name or initials of the registered veterinary technician, if any, who made the compounded drug preparation.
- (2) Expiration date of the compounded drug preparation.
- (3) Directions for its storage and administration.
- (4) Name, amount, and strength of the compounded drug preparation.
- (5) Date the drug preparation was compounded.
- ~~(6) Proper storage of the compounded drug preparation.~~

(f) The veterinarian performing or supervising the compounding of drug preparations is responsible for the following:

- (1) Training and supervision of the registered veterinary technician who is compounding the drug preparation.

(2) Proper storage of the drugs used in compounding and the compounded drug preparations.

Note: Authority cited: Section 4826.5, Business and Professions Code. Reference: Section 4826.5, Business and Professions Code.

2093. Expiration Dates.

(a) For non-sterile compounding, the expiration date shall not exceed either of the following:

(1) 180 days from the date the preparation is compounded.

(2) The shortest expiration date of any ingredient in the non-sterile compounded drug preparation.

(b) For sterile compounding, the expiration date shall not exceed either of the following:

(1) 30 days from the date the preparation is compounded.

(2) The shortest expiration date or beyond use date of any ingredient in the sterile compounded drug preparation.

~~(c) The expiration date may be extended if the product's integrity, potency, and quality are measurable and demonstrable.~~

Note: Authority cited: Section 4826.5, Business and Professions Code. Reference: Section 4826.5, Business and Professions Code.

2094. Labeling of Compounded Preparations.

(a) All labeling of any dispensed compounded drug preparation shall comply with subsection (b) of section 2032.2.

(b) All other compounded drug preparations shall be labeled with the following information:

(1) Name, strength, and quantity of each ingredient.

(2) Expiration date.

(3) Lot number or control number assigned by the preparer.

(4) Name or initials of the preparer.

(5) Date of drug preparation.

Note: Authority cited: Section 4826.5, Business and Professions Code. Reference: Section 4826.5, Business and Professions Code.

2095. Quality Assurance.

(a) A veterinary premises that engages in compounding drug preparations shall establish a quality assurance program that documents and assesses medication errors to determine cause and an appropriate response.

(b) The purpose of the quality assurance program shall be to assess errors that occur in the compounding of drug preparations, as well as to evaluate and document adverse reactions of animal patients to compounded drug preparations.

(c) When a veterinarian determines that a medication error has occurred, the veterinarian shall ~~immediately as soon as possible~~ communicate to the client or the client's representative the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.

(d) ~~The board may review R~~ records generated for and maintained as a component of the ongoing quality assurance program ~~shall be considered peer review documents and not subject to discovery in any arbitration, civil, or other proceeding, except as provided hereafter. That privilege shall not prevent review of a veterinary premises's quality assurance program and records maintained as part of that system by the board~~ as necessary to protect the public health and safety or if fraud is alleged by a government agency with jurisdiction over the veterinary premises. Nothing in this section shall be construed to prohibit a client or client's representative from accessing records of the animal patient pursuant to subsection (b) of section 2032.3.

(e) Reports of drug contraindications and adverse reactions may be included in the quality assurance documentation.

Note: Authority cited: Section 4826.5, Business and Professions Code. Reference: Section 4826.5, Business and Professions Code.