

# Veterinary Medical Board

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## MEMORANDUM

<b>DATE</b>	November 14, 2018
<b>TO</b>	Veterinary Medical Board
<b>FROM</b>	Amanda Drummond, Administrative Programs Coordinator
<b>SUBJECT</b>	<b>Agenda Item 8C. Section <a href="#">2036</a>, Article 4, Division 20, Title 16 of the CCR Regarding Animal Health Care Tasks for a Registered Veterinary Technician (RVT) and Sections 2090-2096, Article 11, Division 20, Title 16 of the California Code of Regulations (CCR) Regarding Drug Compounding</b>

### **Background:**

The Veterinary Medical Board (Board) approved the Drug Compounding language at the [October 2017](#) Board meeting, which included a new CCR section 2092(f)(1) authorizing RVTs to compound drugs under veterinarian supervision. At the [February 2018](#) and [May 2018](#) Board meetings, the Board discussed CCR section [2036](#) regarding RVT Tasks Under Indirect Supervision; RVT Drug Compounding was tabled for a future discussion.

The proposed Drug Compounding language holds the supervising veterinarian responsible for the RVT's training and supervision prior to the RVT providing drug compounding services.

The proposed language for Drug Compounding and RVT Tasks for Indirect Supervision are before the Board for discussion and consideration.

### **Attachments:**

- Proposed language for CCR sections 2090-2096 (Board approved [October 2017](#))
- Proposed amendments to CCR section [2036](#) (Board approved [May 2018](#))

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

PROPOSED LANGUAGE

Proposed amendments to the regulatory language are shown in single underline for new text and ~~single 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 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 or bulk substances.

(b) "Compounding" does not include reconstitution of a drug pursuant to a manufacturer's direction(s) for oral, rectal, topical, or injectable administration, nor does it include the sole act of tablet splitting or crushing, capsule opening, or the addition of flavoring agent(s) to enhance palatability.

(c) "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.

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.

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

(c) Sterile 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 of this preparation.

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

**Commented [WT1]:** This change was in my notes but I'm not sure where it came up. May have been a Grant Miller request to correct all VCPR mentions. If you can't find this change as approved by Board, then describe as EO minor/technical change.

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

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 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.

**Commented [WT2]:** For consistency with other regs being promulgated. EO minor/technical change under delegated authority.

**Commented [WT3]:** For consistency with other regs being promulgated. EO minor/technical change under delegated authority.

**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.**

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

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

**Commented [WT4]:** For consistency with other regs being promulgated. EO minor/technical change under delegated authority.

**2095. Quality Assurance.**

(a) A veterinary premises that engages in compounding drug preparations shall establish a quality assurance program which 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 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) 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 or the California State Board of Pharmacy 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.

**Commented [WT5]:** Revision made at meeting.

**2096. Inspection Authority and Enforcement.**

(a) The California State Board of Pharmacy and the Veterinary Medical Board shall have authority to inspect any veterinary premises engaged in compounding to ensure compliance.

(b) The Veterinary Medical Board is charged with enforcing the provisions of this Article.  
Note: Authority cited: Section 4826.5, Business and Professions Code. Reference: Section 4826.5, Business and Professions Code.

**Commented [WT6]:** Revision made at meeting.

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

PROPOSED LANGUAGE

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

Amend Section 2036 of Article 4 of Division 20 of Title 16 of the California Code of Regulations to read as follows:

**2036. Animal Health Care Tasks for R.V.T.**

(a) Unless specifically so provided by regulation, an R.V.T. shall not perform the following functions or any other activity which represents the practice of veterinary medicine or requires the knowledge, skill and training of a licensed veterinarian:

**Commented [WT1]:** Technical revision by EO under delegated authority in Board motion; necessary for consistency with use of "an R.V.T." in subsections (b) and (c).

- (1) Surgery;
- (2) Diagnosis and prognosis of animal diseases;
- (3) Prescription of drugs, medicines or appliances.

(b) An R.V.T. may perform the following procedures only under the direct supervision of a licensed veterinarian:

- (1) Induce anesthesia;
- (2) ~~Perform casts and splints;~~
- ~~(3) Perform dental extractions;~~
- (4) Suture cutaneous and subcutaneous tissues, gingiva and oral mucous membranes;

**Commented [WT2]:** Technical revision by EO under delegated authority in Board motion.

~~(5) Create a relief hole in the skin to facilitate placement of an intravascular catheter;~~

**Commented [WT3]:** Technical revision by EO under delegated authority in Board motion.

(c) An R.V.T. may perform the following procedures under indirect supervision of a licensed veterinarian:

**Commented [WT4]:** Technical revision by EO under delegated authority in Board motion.

- (1) Administer controlled substances;
- (2) Apply casts and splints.

(d) Subject to the provisions of subsection(s) (a), (b) and (c) of this section, an R.V.T. may perform animal health care tasks under the direct or indirect supervision of a licensed veterinarian. The degree of supervision by a licensed veterinarian over an R.V.T. shall be consistent with standards of good veterinary medical practices.

**Commented [WT5]:** Technical revision by EO under delegated authority in Board motion.

Authority cited: Sections 4808, 4826 and 4836, Business and Professions Code. Reference: Sections 4836, 4840 and 4840.2, Business and Professions Code.