DEPARTMENT OF CONSUMER AFFAIRS
TITLE 16. PROFESSIONAL AND VOCATIONAL REGULATIONS
DIVISION 20. VETERINARY MEDICAL BOARD

VETERINARY DRUG COMPOUNDING

ORDER OF ADOPTION

Amend section 2036.5 of article 4 and sections 2090, 2091, 2092, 2093, and 2094 of article 11 of division 20 of title 16 of the California Code of Regulations as follows:

ARTICLE 4. PRACTICE

§ 2036.5. Animal ~~Hospital~~ Health Care Tasks for Permit Holders and Veterinary Assistants.

(a) Permit holders and veterinary assistants shall be prohibited from performing any of the functions or activities specified in subsections (a), (b), and (c) of ~~S~~section 2036 of these regulations, except that a permit holder under the direct or indirect supervision of a licensed veterinarian may administer a controlled substance.

(b) Subject to the provisions of subsection (a) of this section, permit holders and veterinary assistants in ~~an animal hospital setting~~registered veterinary premises may perform auxiliary animal health care tasks under the direct or indirect supervision of a licensed veterinarian or the direct supervision of an R.V.T. The degree of supervision by a licensed veterinarian over a permit holder or veterinary assistant shall be higher than or equal to the degree of supervision required when an R.V.T. performs the same task and shall be consistent with standards of good veterinary medical practices.

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

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~~who has established the veterinarian-client-patient relationship for the animal patient(s), or an ~~registered veterinary technician~~R.V.T. 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 an ~~registered veterinary technician~~R.V.T. 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.

(2) The sole act of tablet splitting or crushing~~,~~ or capsule opening.

(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) "Immediate use" means administration of a sterile compounded drug preparation to an animal patient beginning within four hours from the time the drug preparation was compounded.

(e~~f~~) "Office stock" means a compounded drug prepared without a patient-specific prescription that may be administered to an animal patient within the registered veterinary premises where the drug preparation was compounded or administered in mobile units and vehicles operated from the registered veterinary premises in accordance with section 4853 of the code, or dispensed only to a client, client's ~~representative~~authorized agent, or other veterinarian at the same veterinary premises.

Note: Authority cited: Sections 4808 and 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, through reliance on drug compounding standards in the profession and in accordance with section 2032.

(b) A veterinarian shall not perform or supervise the performance by an R.V.T. of 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 or supervise the performance by an R.V.T. of 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 is historical documentation of the need, safety, and efficacy of the preparation.

(e) Only sterile drugs approved by the 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: Sections 4808 and 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), (d), ~~and~~ (e), and (f) and sections 2093 and 2094.

(2) Policies and procedures for the training of an ~~registered veterinary technician~~R.V.T. 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~~Except as provided under subsections (d) and (e), a master formula document shall be maintained for each compounded drug preparation and include all of the following:

(1) Name, strength, and quantity of each A~~a~~ctive ingredients to be used.

(2) Equipment to be used.

(3) Calculation of E~~e~~xpiration date of the compounded drug preparation.

(4) Name, strength, and quantity of each I~~i~~nactive ingredients to be used.

(5) Specific compounding steps to be used to prepare the compounded drug preparation.

(6) Instructions for storage, handling, and administration of the compounded drug preparation.

(7) Name assigned to the compounded drug preparation.

(c) The master 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 and a master formula document is not otherwise maintained pursuant to subsection (b), a formula record for the compounded drug preparation ~~may~~ shall be kept in the medical record of the animal patient and shall include all information required in paragraphs (1) through (6) of subsection (b).

(e) Notwithstanding subsections (b) and (d), for intravenous (IV), intramuscular (IM), or subcutaneous (SQ) compounded drug preparations for immediate use on an animal patient that contain a sterile solution, the name and quantity of the sterile solution and the name, strength, and quantity of the ingredient(s) added to the sterile solution shall be recorded in the animal patient's medical record.

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

(1) Name or initials of the veterinarian who made or supervised the making of a compounded drug preparation and the name or initials of the ~~registered veterinary technician~~R.V.T., if any, who made the compounded drug preparation.

(2) Expiration date of the compounded drug preparation.

~~(3) Directions for its storage and administration.~~

(4~~3~~) Name, amount, and strength of the active ingredient(s) in the compounded drug preparation.

(5~~4~~) Date the drug preparation was compounded.

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

(1) Training and supervision of the ~~registered veterinary technician~~R.V.T. who is compounding the drug preparation.

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

Note: Authority cited: Sections 4808 and 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) For a compounded intravenous (IV) or subcutaneous (SQ) drug preparation that does not satisfy the definition of "immediate use," the preparation shall expire up to 72 hours after the preparation is initially compounded.

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

§ 2094. Labeling of Compounded Drug Preparations.

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

(1) Name assigned to the compounded drug preparation.

(~~1~~2) Name, strength, and quantity of each active ingredient.

(~~2~~3) Expiration date.

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

(4) Name or initials of the preparer.

(5) Date of drug preparation.

(b) All intravenous (IV), intramuscular (IM), and subcutaneous (SQ) compounded drug preparations for an animal patient that contain a sterile solution shall be labeled with the following information:

(1) Name, strength, and quantity of the ingredient(s) added to the sterile solution.

(2) Date and time of the initial preparation.

(3) Name or initials of the preparer.

(ac) In addition to the label requirements specified above, Aall labeling of any dispensed compounded drug preparation shall comply with subsection (b) of section 2032.2.

(d) If the label or packaging of a component or ingredient in the compounded drug preparation indicates refrigeration is required, the label of the compounded drug preparation shall state refrigeration is required.

Note: Authority cited: Sections 4808 and 4826.5, Business and Professions Code. Reference: Section 4826.5, Business and Professions Code.