BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY • GAVIN NEWSOM, GOVERNOR
DEPARTMENT OF CONSUMER AFFAIRS • VETERINARY MEDICAL BOARD
1747 North Market Blvd., Suite 230, Sacramento, CA 95834-2987
P (916) 515-5520 | Toll-Free (866) 229-6849 | www.vmb.ca.gov

MEMORANDUM

DATE	July 11, 2022
TO	Multidisciplinary Advisory Committee (MDC)
FROM	Drug Compounding Subcommittee (Subcommittee) Richard Sullivan, DVM, Chair Marie Ussery, RVT
SUBJECT	**Agenda Item 6. Update, Discussion, and Potential Recommendation to the Board on Legislative Proposal to Amend Business and Professions Code Section 4826.5 and Regulatory Proposal to Amend CCR, Title 16, Sections 2036.5, 2090, 2091, 2092, and 2094 Regarding Veterinary Drug Compounding**

Background

Business and Professions Code section 4826.5 authorizes licensed veterinarians and registered veterinary technicians (RVTs) supervised by licensed veterinarians to compound drugs for animal use, as specified. In accordance with BPC section 4826.5, the Veterinary Medical Board (Board) promulgated drug compounding regulations, which became effective on April 1, 2022. In addition, the Board amended California Code of Regulations (CCR), title 16, section 2036 to authorize RVTs to perform drug compounding from bulk substances under direct supervision of a licensed veterinarian and drug compounding from non-bulk substances under indirect supervision.

During the Board's January 2022 meeting, the Board directed the MDC to create a guidance document to assist licensees and registrants in complying with the new regulations. Dr. Sullivan and Ms. Ussery formed the Subcommittee to draft the guidance for MDC discussion and consideration.

During the development of the guidance document several gaps were discovered in the paper trail that is necessary to document the process of compounding a preparation for a client or for office stock. In addition, the MDC received comments from stakeholders at the April 19, 2022 meeting that raised concerns about the efficiency of the process, especially during this period of veterinary professional workforce issues. One such issue raised was the workforce issue of not having enough registered veterinary technicians. A second issue was the use of intravenous (IV) compounded fluid preparations that are frequently changed during their administration.

Discussion

The Subcommittee has identified ways to resolve both the gaps in the regulations and the practical inefficiencies of the regulations raised by the stakeholders. The Subcommittee is proposing amendments to Business and Professions Code (BPC) section 4826.5 and California Code of Regulations (CCR), title 16, sections 2036.5, 2090, 2091, 2092, and 2094.

A. Legislative Proposal

The first recommendation is a legislative proposal to amend BPC section 4826.5 to allow a VACSP holder to compound drug preparations under the supervision of a veterinarian. This will increase access to care, which is restricted at present by workforce issues, but still has the consumer protection of requiring veterinarian supervision of a "licensed" person.

B. Regulatory Proposal

The second recommendation is a regulatory proposal to amend the VACSP practice regulation and veterinary drug compounding regulations to increase consumer and animal patient access to compounded drug preparations prepared by trained and supervised VACSP holders. CCR, title 16, section 2036.5, among other things, establishes the animal hospital health care tasks that may be performed by VACSP holders. Once BPC section 4826.5 is amended to authorize VACSP holders to perform drug compounding, CCR, title 16, section 2036.5 should be amended to authorize a VACSP holder to perform drug compounding under veterinarian supervision.

1. Increasing Access to Care Using VACSP Holders

As noted above, an RVT may perform drug compounding from bulk substances under direct veterinarian supervision and perform drug compounding from non-bulk substances under indirect supervision. (CCR, tit. 16, § 2036, subs. (b)(5), (c)(3).) Using the term "permit holder," which is defined in CCR, title 16, 2034, subsection (k), the proposal similarly would add to section 2036.5 a new subsection (c) to authorize a VACSP holder to perform drug compounding from bulk substances under the direct supervision of a licensed veterinarian, and a new subsection (d) to authorize a VACSP holder to perform drug compounding from non-bulk substances under the direct or indirect supervision of a licensed veterinarian or the direct supervision of an R.V.T.

VACSP holders also would be added to the drug compounding regulations, including requiring the veterinarian supervising the compounding of drug preparations to be responsible for the training and supervision of a VACSP holder who is compounding the drug preparation. (Prop. CCR, tit. 16, §§ 2090, subs. (a), (b), 2091, subs. (b), (c), 2092, subs. (a)(2), (f)(7), (g)(1).) The proposal also would revise the term "registered veterinary technician" used in the drug compounding regulations to conform to the use of "R.V.T.," as defined in CCR, title 16, section 2034, subsection (b). (Prop. CCR, tit. 16, §§ 2090, subs. (a), (b), 2091, subs. (b), (c), 2092, subs. (a)(2), (f)(7), (g)(1).)

2. Correcting Drug Compounding Regulations

As noted above, there are several corrections that should be made to close gaps and increase efficiencies. The Subcommittee recommends making several additional amendments to the drug compounding regulations, discussed further below.

CCR, title16, section 2090 should be amended to define “immediate use,” which is currently used in section 2091, subsection (d). The Subcommittee proposes immediate use should mean administration of a sterile compounded drug preparation on an animal patient within four hours from the time the drug preparation was compounded. (Prop. CCR, tit. 16, § 2090, subs. (e).) This definition is consistent with standard veterinary drug compounding practice and is proposed to be added to the U.S. Pharmacopeia 797, section 1.3 (USPC – 797 Pharmaceutical Compounding Sterile Preparations, Aug. 31, 2021, p. 3, as of July 8, 2022).

Section 2090 should be amended to define a Master Formula Form, which would list the formulas for all compounded drug preparations compounded at the veterinary premises on a regular basis, and contain the information specified in section 2092, subsection (b). (Prop. CCR, tit. 16, § 2090, subs. (f).) This would clarify the formula list requirements for practitioners.

Section 2090 should be amended to renumber and clarify the definition of “office stock” by adding that such compounded drugs may be “used within the practice” to accommodate the preparation of office stock compounded drugs that are used on animal patients while at the veterinary premises. (Prop. CCR, tit. 16, § 2090, subs. (g).)

Section 2090 should also be amended to define the terms “unique formula code” and “unique compounded drug preparation number,” which are new identifying numbers that would be included in the formula and compounded drug preparation documents discussed further below. (Prop. CCR, tit. 16, § 2090, subs. (h), (i).)

Next, the Subcommittee proposes amending CCR, title 16, section 2092, subsection (b), to clarify the information required in the formula document (titled Master Formula Form) maintained for each compounded drug preparation compounded at the veterinary premises on a regular basis as follows:

a. As new subsection (b)(1), require each compounded drug formula to be assigned a unique formula code that identifies the preparation.

b. Clarify the information required to be documented in the Master Formula Form for active and inactive ingredients. The information should include the name, strength, and quantity of each of ingredient to provide specificity of the drug preparations being compounded. (Prop. CCR, tit. 16, § 2092, subs. (b)(2), (4).)

c. Delete subsection (b)(3). The expiration date of a compounded preparation cannot be determined in the formula; it can only be determined at the end of the compounding procedure. The expiration date of the compounded drug preparation is determined by other criteria and would be included in subsection (e)(4).

d. For consistency and clarity, add the words “compounded” and “preparation” to the word “drug” used in subsection (b)(5)

e. For consistency and clarity, add the term “drug” to the term “compounded preparation” used in subsection (b)(6).

For consistency, the Subcommittee recommends revising subsection (c) to change the term

“formula document” to “Master Formula Form,” and revising subsection (d) to add the term “animal” into the phrase “the medical record of the patient” for consistency and clarity.

Further, the Subcommittee recommends adding a new subsection (e) to section 2092 to exempt from the formula documentation requirements on the Master Formula Form all IV fluids and sterile drug preparations for immediate use because those preparations are ever-changing during the treatment and modified for the needs of the individual animal patient, especially during the treatment of critical care patients. IV fluids and any immediate use sterile drug preparations administration along with any changes in their administration, are documented in the animal patient medical records, so exempting IV fluids and immediate use sterile drug preparations from the formula documentation requirements on the Master Formula Form would eliminate maintenance of formula records and improve veterinary practice efficiency. To improve clarity in the medical records, the Subcommittee proposes that the name, strength, and quantity of the components or ingredients added to a sterile solution are documented.

The Subcommittee also proposes to clarify the information required to be maintained in the patient’s medical record by specifying that a compounded drug preparation document must be maintained and include all of the following information: the unique formula code, if one exists; the date each preparation was compounded; the unique compounded drug preparation number; the name of each active and inactive ingredient; the expiration date of each active and inactive ingredient; as applicable, the client number and animal patient name or herd identification or “office stock.” (Prop. CCR, tit. 16, § 2092, subs. (f)(1)-(8).)

The regulatory proposal would also delete the requirements in CCR, title 16, section 2092, subsection (e)(3)-(4) (directions for drug preparation storage and administration, and name, amount, and strength of the compounded drug preparation) from the compounded drug preparation document as this information would already be provided on the Master Formula Form required under subsection (b).

The Subcommittee also recommends clarifying CCR, title 16, section 2094 by requiring that all office stock be labelled and include the unique formula code as listed on the Master Formula Form, the unique compounded drug preparation number, an expiration date, and name or initials of the preparer. The regulatory proposal also would delete the requirements in CCR, title 16, section 2094, subsection (b)(1), (3), and (5) (name, strength, and quantity of each ingredient and lot number or control number assigned by the preparer, and date of drug preparation) from the compounded drug preparation label. Most of the time, these preparations are in small bottles and used in house. As such, only a minimal amount of information can be included on the small labels for these bottles. Since the label would reference the unique formula code and unique compounded drug preparation number for the compounded drug preparation in accordance with proposed subsection (b), paragraphs (1) and (2), which separately would require the name, strength, and quantity of each ingredient, there is no need to include that information on the label. Further, the lot number or control number required in subsection (b)(3) is proposed to be renamed as the Unique Compounded Drug Preparation Number, included in the proposal as new subsection (b)(2). In addition, the date of drug preparation in subsection (b)(5) would be reflected in the compounded drug preparation document required to be maintained under CCR, title 16, section 2092, subsection (f)(5).

Further, the Subcommittee recommends adding to section 2094 a new subsection (c) to clarify that if the drug label or packaging of a component or ingredient of the compounded drug preparation indicates the component or ingredient must be refrigerated, the compounded drug preparation also shall be labelled as refrigeration required. All medications that need to be refrigerated shall require a warning on their label.

Action Requested

Please review the attached legislative and regulatory proposals. If the Committee agrees with the Subcommittee's recommendations, please consider:

1. A motion to recommend to the Board the legislative proposal to amend Business and Professions Code section 4826.5 to authorize a veterinary assistant controlled substance permit holder to perform drug compounding.
2. A motion to recommend to the Board the regulatory proposal to amend California Code of Regulations, title 16, sections 2036.5, 2090, 2091, 2092, and 2094 related to veterinary drug compounding.

Attachments

1. Legislative Proposal to Amend Business and Professions Code Section 4826.5
2. Regulatory Proposal to Amend California Code of Regulations, Title 16, Sections 2036.5, 2090, 2091, 2092, and 2094

VETERINARY MEDICAL BOARD
LEGISLATIVE PROPOSAL TO AMEND
BUSINESS AND PROFESSIONS CODE SECTION 4826.5

Additions are indicated in single underline.

Deletions are indicated in ~~single strikethrough~~.

Amend Business and Professions Code section 4826.5 as follows:

4826.5. Notwithstanding any other law, a licensed veterinarian or a registered veterinary technician or veterinary assistant controlled substance permit holder under the supervision of a licensed veterinarian may compound drugs for animal use pursuant to Section 530 of Title 21 of the Code of Federal Regulations and in accordance with regulations promulgated by the board. The regulations promulgated by the board shall, at a minimum, address the storage of drugs, the level and type of supervision required for compounding drugs by a registered veterinary technician or a veterinary assistant controlled substance permit holder, and the equipment necessary for the safe compounding of drugs. Any violation of the regulations adopted by the board pursuant to this section shall constitute grounds for an enforcement or disciplinary action.

VETERINARY MEDICAL BOARD
REGULATORY PROPOSAL TO AMEND
CALIFORNIA CODE OF REGULATIONS, TITLE 16,
SECTIONS 2036.5, 2090, 2091, 2092, AND 2094

Additions are indicated in single underline.

Deletions are indicated in ~~single strikethrough~~.

Amend section 2036.5 of article 4 and sections 2090, 2091, 2092, and 2094 of article 11 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 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 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.

(c) Notwithstanding subsection (a), permit holders in an animal hospital setting may perform drug compounding from bulk substances under the direct supervision of a licensed veterinarian.

(d) Notwithstanding subsection (a), permit holders in an animal hospital setting may perform drug compounding from non-bulk substances under the direct or indirect supervision of a licensed veterinarian or the direct supervision of an R.V.T.

Note: Authority cited: Sections 4808 and 4836, Business and Professions Code. Reference: Sections 4826.5, 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 has established the veterinarian-client-patient relationship for the animal patient(s) or an R.V.T. ~~registered veterinary technician~~ or permit holder 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 R.V.T. or permit holder ~~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.

(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 on an animal patient within four hours from the time the drug preparation was compounded.

(f) “Master Formula Form” is a list of all drug preparations compounded at the veterinary premises on a regular basis and contains the information specified in subsection (b) of section 2092.

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

(h) “Unique Formula Code” is the designation given to a formula that is listed on the Master Formula Form created pursuant to subsection (b) of section 2092.

(i) “Unique Compounded Drug Preparation Number” is a unique number given to each compounded drug preparation prepared for an animal patient or for office stock.

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, 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. or permit holder, 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. or permit holder, 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: 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 an R.V.T. ~~registered veterinary technician~~ or permit holder 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 master formula ~~document~~ shall be maintained on the Master Formula Form and include all of the following:

(1) Unique Formula Code.

(~~1~~2) Name, strength, and quantity of each a~~A~~ctive ingredient~~s~~ to be used.

(~~2~~3) Equipment to be used.

~~(3) Expiration date of the preparation.~~

(4) Name, strength, and quantity of each i~~I~~nactive ingredient~~s~~ 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.

(c) The Master Formula Form~~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 animal patient.

(e) All intravenous fluid preparations administered to animal patients for treatment of the animal patient's fluid and electrolyte imbalance and sterile drug preparations for immediate use are exempt from the requirements of subsection (b) if the name, strength, and quantity of the components or ingredients added to a sterile solution are documented in the patient's medical record.

(~~e~~f) For ~~each~~ all compounded drug preparations prepared for an animal patient or for office stock, a compounded drug preparation document shall be maintained and include all of the following ~~information shall be recorded in the patient's medical record~~:

(1) Unique Formula Code, if one exists.

(2) Date each preparation was compounded.

(3) Unique Compounded Drug Preparation Number.

(4) Name of each active and inactive ingredient in each compounded drug preparation.

(5) Expiration date of each active and inactive ingredient in each compounded drug preparation.

(6) As applicable, client identification number and animal patient name or herd identification or "Office Stock."

(~~1~~7) Name or initials of the veterinarian who made or supervised the making of a compounded drug preparation and the name or initials of the R.V.T.~~registered veterinary technician~~ or permit holder, if any, who made the compounded drug preparation.

(~~2~~8) 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~~.

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

(1) Training and supervision of the R.V.T.~~registered veterinary technician~~ or permit holder 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.

§ 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 office stock ~~other~~ compounded drug preparations shall be labeled with the following information:

(1) ~~Name, strength, and quantity of each ingredient.~~ Unique Formula Code.

(2) Unique Compounded Drug Preparation Number.

(~~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.~~

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

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