Veterinary Medical Board
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MEMORANDUM

DATE	October 12, 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 Proposed Regulatory Amendments to California Code of Regulations (CCR), Title 16, Sections 2036.5, 2090, 2091, 2092, and 2094 Regarding Veterinary Drug Compounding**

Background

The Veterinary Medical Board's (Board) drug compounding regulations became effective on April 1, 2022. During the 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, as well as a courtesy formula form for use by practitioners to comply with CCR, title 16, section 2092, subsection (b).

On April 19, 2022, the MDC reviewed and approved the Subcommittee's Guidance on Veterinary Drug Compounding (Guidance) and a courtesy formula form (Compounded Drug Preparation Formula Form). On July 20, 2022, the Board reviewed, revised, and approved the Guidance and Compounded Drug Preparation Formula Form.

During the development of the Guidance, the Subcommittee identified several gaps 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 its April 19, 2022 meeting that raised concerns about the efficiency of the process and lack of registered veterinary technicians (RVTs) in the workforce. A second issue was the use of intravenous (IV) compounded fluid preparations that are frequently changed during their administration.

During the July 19, 2022 MDC meeting, the Subcommittee presented two ways, a legislative proposal and a regulatory proposal, to resolve the gaps in the regulations and the practical inefficiencies. At that meeting, the MDC approved a recommendation to the Board to submit to the California State Legislature an amendment to Business and Professions Code section 4826.5 to authorize a veterinary assistant control substance permit (VACSP) holder to compound preparations under the direct supervision of a veterinarian. This amendment is intended to help resolve the bottle neck of the compounding process that has arisen from veterinary workforce issues, but still has the consumer protection of requiring veterinarian supervision of a "licensed" person. The Board will review that legislative

proposal at its October 19-20, 2022 meeting.

With respect to the regulatory proposal, discussion and public comment during the July 19, 2022 MDC meeting revealed that additional changes to the medical recordkeeping requirements for compounding drug preparations were needed.

Regulatory Amendments

With the comments from the stakeholders and staff, the Subcommittee took another approach to streamline the medical recordkeeping process. The discussion below includes regulatory amendments previously proposed during the July 19, 2022 MDC meeting and revisions to the medical recordkeeping process.

This regulatory proposal would 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

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 the 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 the abbreviation "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 Oct. 7, 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" to include that such compounded drugs may be "used within the registered veterinary premises where the drug preparation was compounded, in mobile units and vehicles operated from the registered premises" to accommodate the preparation of office stock compounded drugs that are used on animal patients while at the veterinary premises or from mobile units. (Prop. CCR, tit. 16, § 2090, subs. (g).)

Section 2090 should also be amended to define the term "Unique Formula Code," which would be the designation given to a compounded drug formula listed on the Master Formula Form. (Prop. CCR, tit. 16, § 2090, subs. (h).) The "Unique Formula Code" is necessary to identify the formula that is compounded especially for office stock. It is possible to have preparations with the same ingredients, but different concentrations of the ingredients, and the unique code will identify which drug preparation is being referred to.

In CCR, title 16, section 2091, the phrase "or supervise the performance by an R.V.T or permit holder" would be added to subsections (b) and (c) to prohibit a veterinarian from supervising drug compounding by an RVT or VACSP holder when the complexity of the drug compounding exceeds the veterinarian's knowledge, skill, facilities, or available equipment. In the same way that prohibiting a veterinarian from drug compounding that exceeds his or her knowledge and skills protects consumers, the addition of this common-sense provision would further protect consumers.

As discussed above, in CCR, title 16, section 2092, subsection (a)(2), "or permit holder" would be added to the training requirement to provide for the proposed statutory amendment to BPC section 4826.5 authorizing VACSP holders to prepare compounded drugs.

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, which would be defined under section 2090, new subsection (h), 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), (5).)
c. Renumber current subsection (b)(2) and new (b)(3) to accommodate new subsection (b)(1).
d. Clarify the expiration date of a compounded preparation by documenting its calculation method. This amendment addresses the problem that the exact expiration date for a

compounded drug preparation cannot be specified on the Master Formula Form; the exact expiration date can only be determined at the end of the compounding procedure. The actual expiration date of the compounded drug preparation is determined by other criteria and would be documented pursuant to subsection (e)(2).

e. For consistency and clarity, add the words “compounded” and “preparation” to the word “drug” used in renumbered subsection (b)(6)
f. For consistency and clarity, add the term “drug” to the term “compounded preparation” used in renumbered subsection (b)(7).

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.

In CCR, title 16, section 2092, subsection (d), the Subcommittee proposes to clarify documentation of infrequently compounded drug preparations in the animal patient medical record.

For intravenous (IV) solutions prepared for immediate use on an animal patient, the Subcommittee proposes the compounded drug preparation need only be documented in the animal patient medical record and indicate the name, strength, and quantity of the sterile solution, that is not otherwise compounded at the veterinary premises, and the ingredients added to the sterile solution, which is common practice now, and provides efficient and sufficient documentation of the compounded drug preparation administered to the animal patient. (Prop. CCR, tit. 16, § 2092, subs. (e).) In these circumstances, the sterile solution is purchased from another source and itself is not compounded at the veterinary premises. Since the sterile solution may contain a long list of active and inactive ingredients, only documentation of the name, strength, and quantity of the sterile solution and those ingredients added to the sterile solution at the veterinary premises should be necessary.

In CCR, title 16, section 2092, subsection (e), the Subcommittee proposes to clarify and reduce the information required to be maintained in the animal patient’s medical record. The proposed amendments would renumber the subsection, include minor conforming text revisions. (Prop. CCR, tit. 16, § 2092, subs. (f)(1)-(4).) 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 proposal also would add a requirement to document the name of the compounded drug preparation and/or the Unique Formula Code to better identify the compounded drug preparation in the medical record.

The Subcommittee also recommends clarifying CCR, title 16, section 2094, subsection (b), to eliminate unnecessary information and require that all office stock be labelled and include the Unique Formula Code (as listed on the Master Formula Form), an expiration date, and name or initials of the preparer and date of drug preparation. The regulatory proposal would delete the existing requirements in subsection (b)(1) and (3) (name, strength, and quantity of each ingredient and lot number or control number assigned by the preparer) 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 for the compounded drug preparation in accordance with proposed subsection (b)(1), which separately would require the name, strength, and quantity of each ingredient, there is

no need to include that information on the label.

In addition, the Subcommittee is recommending deleting “lot number” in section 2094, subsection (b)(3), regarding labelling of office stock. The proposed regulations would use the Unique Formula Code in place of the lot number; so whatever the new compounded drug preparation is, it will have a Unique Formula Code that will identify the preparation and the "lot number or control number" is not necessary. The Unique Formula Code is essential for the business part of the practice because the client would be charged a fee for that product based on its identification.

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 and discuss the attached regulatory proposals. If the MDC agrees with the Subcommittee’s recommendations, please entertain 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.

Attachment

1. Regulatory Proposal to Amend California Code of Regulations, Title 16, Sections 2036.5, 2090, 2091, 2092, and 2094 Regarding Veterinary Drug Compounding

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 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 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.

§ 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 R.V.T. ~~registered veterinary technician~~ or a 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 beginning 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.

(g~~e~~) “Office stock” means a compounded drug prepared without a patient-specific prescription that may be used within the registered veterinary premises where the drug preparation was compounded, in mobile units and vehicles operated from the registered veterinary premises, 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.

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 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. or permit holder 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: 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~~ may be maintained on a 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~~4) Calculation of e~~E~~xpiration date of the compounded drug preparation.

(~~4~~5) Name, strength, and quantity of each i~~I~~nactive ingredient~~s~~ to be used.

(~~5~~6) Specific compounding steps to be used to prepare the compounded drug preparation.

(~~6~~7) 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 a Master Formula Form is not maintained, ~~the compounded drug preparation is not routinely compounded,~~ 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 (2) through (7) of subsection (b).

(e) Notwithstanding subsection (d), for intravenous (IV) compounded drug preparations for immediate use on an animal patient that contain a sterile solution that is not otherwise compounded at the veterinary premises, the name, strength, and quantity of the sterile solution and the ingredient(s) added to the sterile solution shall be documented 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 R.V.T.~~registered veterinary technician~~ or permit holder, 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.~~
(3~~5~~) Date the drug preparation was compounded.
(4) Name of the compounded drug preparation and/or the Unique Formula Code, ~~if any.~~

(~~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~~shall be labeled with the following information:

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

(2) Expiration date.

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

(3~~4~~) Name or initials of the preparer.

(4~~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.