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

INITIAL STATEMENT OF REASONS

Veterinary Drug Compounding

HEARING DATE: No hearing has been scheduled for the proposed action.

SUBJECT MATTER OF PROPOSED REGULATIONS: Veterinary Drug Compounding

SECTIONS AFFECTED: 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

BACKGROUND AND STATEMENT OF THE PROBLEM:

The California Veterinary Medical Board (Board)'s mission is to protect consumers and animals by regulating licensees, promoting professional standards, and diligently enforcing the Veterinary Medicine Practice Act (Practice Act). The Board regulates over 47,000 veterinarians, registered veterinary technicians (RVTs), veterinary assistant controlled substance permit (VACSP) holders, and veterinary premises. The Board is authorized to establish reasonably necessary regulations for the enforcement of the Practice Act (BPC section 4808).

BPC section 4826.5 authorizes veterinarians and RVTs (under the supervision of a veterinarian) to 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. On April 1, 2022, article 11 (Compounding in Veterinary Premises) of division 20 of title 16 of the CCR (sections 2090 through 2095) became operative. These regulations: define drug compounding in veterinary premises and the parameters of a veterinarian or RVT providing drug compounding services; mandate that veterinary premises develop policies and procedures regarding drug compounding services; establish requirements for expiration dates for sterile and non-sterile drugs; enforce labeling requirements for compounded drugs; and require quality assurance protocols for drug compounding.

During the January 2022 meeting, the Board directed the Multidisciplinary Committee (MDC) to create a guidance document to assist licensees and registrants in complying with the new regulations and formed a 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 drug

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 cumbersome documentation requirements for compounded intravenous (IV) fluids administered on a continuous basis to an animal patient. After several additional stakeholder meetings, including outreach and coordination with the California State Board of Pharmacy, as well as Subcommittee, MDC and Board meetings, the Board approved this proposal on April 17, 2024.

By adopting the proposed regulations, the Board seeks to further update and clarify veterinary drug compounding requirements. The regulations ensure that veterinarians and RVTs are adhering to developed policies and quality assurance standards. The Board anticipates that California consumers and their animals will be better protected through properly compounded drugs.

More specifically, this regulatory proposal would:

- Change instances of “animal hospital” to the standardized term “registered veterinary premises”;
- Add a definition for “immediate use” to clarify the timeframe for when a sterile compounded drug preparation is to be used;
- Clarify the definition of “office stock” by indicating the locations where the compounded drug may be administered;
- Change the term “client’s representative” to “client’s authorized agent” to conform with statutory terminology;
- Clarify the parameters of a veterinarian or RVT performing drug compounding;
- Update language to reflect new documentation/record keeping requirements;
- Clarify master formula document requirements;
- Clarify documentation requirements for immediate use compounded drug preparations;
- Clarify documentation requirements for animal patient-specific compounded drug preparations;
- Clarify the expiration of compounded IV or subcutaneous (SQ) drug preparations;
- Clarify and further define labeling requirements for compounded drug preparations;
- Update the regulatory authority cited to include BPC section 4808; and
- Make other nonsubstantive changes (i.e., changing instances of “registered veterinary technician” to “R.V.T.”).

ANTICIPATED BENEFITS FROM THIS REGULATORY ACTION:

This regulatory proposal focuses on updating and clarifying a reliable set of minimum standards for providing drug compounding services in veterinary premises, as mandated by BPC section 4826.5. The regulatory proposal would benefit the health, safety, and

welfare of California consumers and their animals by ensuring compounded drugs for animal use are properly prepared. The regulatory proposal may benefit worker safety in veterinary premises, as it establishes requirements, policies, and procedures to be followed by veterinarians and supervised RVTs when making compounded drugs.

SPECIFIC PURPOSE OF, AND RATIONALE FOR, EACH ADOPTION, AMENDMENT, OR REPEAL:

1. Amend Section 2036.5 Title

Purpose: The purpose of the proposed amendment is to remove the word "hospital" from the title of the regulation.

Rationale: The subject matter of the regulation pertains to health care tasks, functions, or activities of permit holders and veterinary assistants. Additionally, the Board is moving to strike instances of the term "hospital" and instead use the more appropriate and standardized term "registered veterinary premises" when referring to locations of operation where veterinary medicine, veterinary dentistry, veterinary surgery, and the various branches thereof is being practiced. Per BPC section 4853, all veterinary premises are required to be registered with the Board.

2. Amend Section 2036.5 Subsection (a)

Purpose: The purpose of the proposed amendment is to add commas and change the "S" in the word "Section" to a lowercase "s."

Rationale: This proposed change provides a grammatical correction and conforms the word "section" (with a lowercase "s") with other instances of the word in the Board's regulations.

3. Amend Section 2036.5 Subsection (b)

Purpose: The purpose of the proposed amendment is to change "animal hospital setting" to "registered veterinary premises."

Rationale: As noted above, the Board is moving to strike instances of the term "hospital" and instead use the more appropriate and standardized term "registered veterinary premises" when referring to locations of operation where veterinary medicine, veterinary dentistry, veterinary surgery, and the various branches thereof is being practiced.

4. Amend Section 2090 Subsection (a)

Purpose: The purpose of the proposed amendment is to change the word "that" to "who" and change "registered veterinary technician" to "R.V.T."

Rationale: This proposed change provides a grammatical correction and provides consistency within the regulations by using the acronym "R.V.T."

5. Amend Section 2090 Subsection (b)

Purpose: The purpose of the proposed amendment is to change "registered veterinary technician" to "R.V.T."

Rationale: See rationale in number 4 above.

6. Amend Section 2090 Subsection (c)(2)

Purpose: The purpose of the proposed amendment is to add the word “or.”

Rationale: This proposed change provides a grammatical/clarifying amendment.

7. Adopt Section 2090 Subsection (e) - new

Purpose: The purpose of the proposed addition is to add a definition for “immediate use”, as it pertains to the administration of a sterile compounded drug preparation.

Rationale: This proposed addition provides the definition for “immediate use” to clarify the timeframe for when a sterile compounded drug preparation is to be used (within four hours from the time the drug preparation was compounded). This timeframe aligns with the United States Pharmacopeia (USP) Chapter 797 Immediate Use Standards.

8. Amend Section 2090 Subsection (f)

Purpose: The purpose of the proposed amendment is to clarify the definition of “office stock.”

Rationale: This proposed change clarifies the definition of “office stock” by indicating the locations where the compounded drug may be administered (within the registered veterinary premises or in mobile units and vehicles operated from the registered veterinary premises in accordance with BPC section 4853). The proposed change also more clearly defines the use proposed for office stock consistent with Federal Food and Drug Administration (FDA) guidance in this area and other state compounding laws and regulations. Additionally, the proposed change maintains consistency with the statutory use of the term “authorized agent of the client.”

9. Amend Section 2090 Note

Purpose: The purpose of the proposed amendment is to add BPC section 4808 to the Note / Authority cited.

Rationale: BPC section 4808 should be added to the Note, as it is the statute that gives the Board authority to adopt, amend, or repeal rules and regulations.

10. Amend Section 2091 Subsections (b) and (c)

Purpose: The purpose of the proposed amendment is to clarify the parameters of a veterinarian or RVT performing drug compounding.

Rationale: This proposed change also clarifies that a veterinarian cannot supervise the performance by an RVT of sterile or non-sterile drug compounding under the circumstances discussed in those subsections.

11. Amend Section 2091 Note

Purpose: The purpose of the proposed amendment is to add BPC section 4808 to the Note / Authority cited.

Rationale: BPC section 4808 should be added to the Note, as it is the statute that gives

the Board authority to adopt, amend, or repeal rules and regulations.

12. Amend Section 2092 Subsection (a)(1)

Purpose: The purpose of the proposed amendment is to update and reference revisions and new documentation/record keeping requirements as it pertains to veterinary premises that engage in compounding drug preparations.

Rationale: This proposed change references updated and new documentation/record keeping requirements.

13. Amend Section 2092 Subsection (a)(2)

Purpose: The purpose of the proposed amendment is to change "registered veterinary technician" to "R.V.T."

Rationale: As noted above, this proposed change provides consistency within the regulations by using the acronym "R.V.T."

14. Amend Section 2092 Subsection (b) and (b)(1), (b)(3), (b)(4), (b)(5), and (b)(7)

Purpose: The purpose of the proposed amendment is to add "master" to the term "formula document" to be consistent with industry terminology and to provide clarity to the regulated public. Additionally, the proposed amendment clarifies the master formula document requirements and clarifies that a master formula document shall be maintained for each compounded drug preparation.

Rationale: These proposed changes add the "master" to the term "formula document" to be consistent with industry terminology and to provide clarity to the regulated public. This term is also used by the California Board of Pharmacy.

15. Amend Section 2092 Subsection (c)

Purpose: The purpose of the proposed amendment is to add the word "master" in front of "formula document."

Rationale: The proposed change standardizes drug compounding terminology.

16. Amend Section 2092 Subsection (d)

Purpose: The purpose of the proposed amendment is to clarify documentation requirements for animal patient specific compounded drug preparations.

Rationale: The proposed changes provide additional clarity to the requirements for animal patient specific compounded drug preparations by outlining what must be included for situations where a compounded drug has not been routinely compounded and a master formula document is not otherwise maintained. More specifically, the proposed changes require that the medical record for each individual animal patient include all the information listed in paragraphs (1) through (6) of subsection (b) of Section 2092.

17. Adopt Section 2092 Subsection (e) - new

Purpose: The purpose of the proposed addition is to provide documentation

requirements for immediate use IV, intramuscular (IM), and subcutaneous (SQ) compounded drug preparations that contain a sterile solution.

Rationale: The proposed addition ensures that documentation requirements for specified immediate use compounded drug preparations that contain a sterile solution are also provided in the Board's regulations.

18. Amend Section 2092 Subsection (f) *(previously subsection (e))*

Purpose: The purpose of the proposed amendment is to add the word "animal" in front of "patient."

Rationale: This proposed change is being made throughout the regulations to specify when the regulations are meant to be applied to an animal patient, as opposed to references to the human client.

19. Amend Section 2092 Subsection (f)(1)

Purpose: The purpose of the proposed amendment is to change "registered veterinary technician" to "R.V.T."

Rationale: As noted above, this proposed change provides consistency within the regulations by using the acronym "R.V.T."

20. Repeal Existing Section 2092 Subsection (f)(3) *(old)*

Purpose: The purpose of the proposed changes is to repeal what was previously (e)(3) before the proposed revisions.

Rationale: The proposed change deletes the words "Directions for its storage and administration" in this list since that can be found in Section 2092 (b)(6) and is unnecessary to be kept in every animal patient medical record.

21. Amend and Renumber Section 2092 Subsection (f)(3) *(new)* and (f)(4)

Purpose: The purpose of the proposed change is to renumber the provisions and to add the words "active ingredient(s)" in front of compounded drug preparation.

Rationale: The proposed change adds the term "active ingredients" for circumstances where a veterinarian may either, take over a patient, or receive a new patient as a referral, and the veterinarian needs information on the medication that was compounded by another veterinarian. In these situations, the veterinarian only needs the essential information of name, amount, and strength of the active ingredient.

They do not need to know the inactive ingredients or any other information about the compounded drug preparation. Further, the veterinarian may not have access to the Master Formula if this animal patient was referred from a different hospital. Even if they do have access to the Master Formula, it is very inefficient to have to find it and look up the active ingredient(s) when the information needs to be in the medical record anyway.

22. Amend Section 2092 Subsection (g)(1)

Purpose: The purpose of the proposed amendment is to change "registered veterinary

technician" to "R.V.T."

Rationale: As noted above, this proposed change provides consistency within the regulations by using the acronym "R.V.T."

23. Amend Section 2092 Note

Purpose: The purpose of the proposed amendment is to add BPC section 4808 to the Note / Authority cited.

Rationale: BPC section 4808 should be added to the Note, as it is the statute that gives the Board authority to adopt, amend, or repeal rules and regulations.

24. Adopt Section 2093 Subsection (c) - new

Purpose: The purpose of the proposed addition is to clarify when a compounded IV or SQ drug preparation expires.

Rationale: Because it is currently unclear when compounded IV and SQ drug preparations that do not meet the definition of "immediate use" expire, the proposed addition provides a safe expiration timeframe (up to 72 hours) for compounded IV or SQ drug preparations.

25. Adopt Section 2094 Title

Purpose: The purpose of the proposed change is to add the word "Drug" to the title of the regulation.

Rationale: The proposed change standardizes terminology in the regulations.

26. Amend Section 2094 Subsections (a)

Purpose: The purpose of the proposed changes is to clarify labeling requirements for office stock.

Rationale: "Office stock" is defined under Section 2090 (f) and the proposed change provides clarity to labeling requirements for office stock.

27. Adopt Section 2094 Subsection (b) and (b)(1)-(3) - new

Purpose: The purpose of the proposed change is to add labeling requirements for IV, IM, and SQ compounded drug preparations.

Rationale: During the October 2023 Board meeting, a concern was raised that there are no labeling requirements for IV/SQ compounded drug preparations being administered within a veterinary premises. This is a safety concern, as no one other than the preparer knows what is in the hanging bag of IV/SQ fluids or when it was prepared.

28. Adopt Section 2094 Subsection (c)

Purpose: The purpose of the proposed change is to move existing subsection (a) to a new subsection (c) to clearly reference both the labeling requirements in Section 2032.2 and Section 2094 (a) and (b).

Rationale: The proposed change is being made for ease of reading and to clarify that

labeling requirements for dispensed compounded drug preparations are found under Section 2032.2 (b) and Section 2094 (a) and (b).

29. Adopt Section 2094 new Subsection (d)

Purpose: The purpose of the proposed change is to add a labeling requirement for compounded drug preparations that require refrigeration.

Rationale: The proposed addition provides an additional safety requirement.

30. Amend Section 2094 Note

Purpose: The purpose of the proposed amendment is to add BPC section 4808 to the Note / Authority cited.

Rationale: BPC section 4808 should be added to the Note, as it is the statute that gives the Board authority to adopt, amend, or repeal rules and regulations.

UNDERLYING DATA:

- January 20-21, 2022 Board Meeting Agenda, Relevant Materials, and Minutes
- April 19, 2022 MDC Meeting Agenda, Relevant Materials, and Minutes
- July 19, 2022 MDC Meeting Agenda, Relevant Materials, and Minutes
- October 18, 2022 MDC Meeting Agenda, Relevant Materials, and Minutes
- October 19-20, 2022 Board Meeting Agenda, Relevant Materials, and Minutes
- January 25-26, 2023 Board Meeting Agenda, Relevant Materials, and Minutes
- October 18-19, 2023 Board Meeting Agenda, Relevant Materials, and Minutes
- January 16, 2024 MDC Meeting Agenda, Relevant Materials, and Minutes
- April 17-19, 2024 Board Meeting Agenda, Relevant Materials, and Minutes

BUSINESS IMPACT:

The Board has made the initial determination that the proposed regulations will not have a significant statewide adverse economic impact directly affecting businesses including the inability of California businesses to compete with businesses in other states.

This initial determination is based on the following facts:

The Board has determined that this regulatory proposal will not have any impact on the creation of jobs or new businesses, the elimination of jobs or existing businesses, or the expansion of businesses in the State of California. The regulatory proposal would update and clarify minimum standards for drug compounding in the limited setting of a veterinary premises.

ECONOMIC IMPACT ASSESSMENT:

This Board has determined that this regulatory proposal will have the following effects:

- It will not create or eliminate jobs within the State of California because the proposed regulations apply to veterinary premises where drug compounding occurs. The regulatory proposal benefits veterinary premises by providing drug compounding

provisions specific to veterinary premises and eliminates the need for these veterinary premises to attempt to conform to the drug compounding provisions already established under the pharmacy law.

- It will not create new businesses or eliminate existing businesses within the State of California because the regulations are not requirements for all veterinarians or veterinary premises, but only apply to veterinary premises where drug compounding already occurs. The regulatory proposal benefits veterinary premises by providing drug compounding provisions specific to veterinary premises and eliminates the need for these veterinary premises to attempt to conform to the drug compounding provisions already established under the pharmacy law.
- It will not affect the expansion of businesses currently doing business within the State of California because it only applies to veterinary premises where drug compounding is performed. The regulatory proposal benefits veterinary premises by providing drug compounding provisions specific to veterinary premises and eliminates the need for these veterinary premises to attempt to conform to the drug compounding provisions already established under the pharmacy law.
- It would benefit the health, safety, and welfare of California residents and their animals because it provides Board oversight over veterinarians, RVTs, and veterinary premises that provide drug compounding preparations for use on animal patients and specifies requirements for safe, effective drug compounding.
- It may benefit worker safety at veterinary premises as it establishes requirements, policies, and procedures to be followed by veterinarians and supervised RVTs when making a compounded drug preparation.
- It does not affect the State's environment because it regulates drug compounding performed inside veterinary premises.

SPECIFIC TECHNOLOGIES OR EQUIPMENT:

This regulatory proposal does not mandate the use of specific technologies or equipment.

CONSIDERATION OF ALTERNATIVES:

No reasonable alternative to the regulatory proposal would be either more effective in carrying out the purpose for which the action is proposed or would be as effective or less burdensome to affected private persons and equally effective in achieving the purposes of the regulation in a manner that ensures full compliance with the law being implemented or made specific.

No such alternatives have been proposed, however, the Board welcomes comments from the public.

DESCRIPTION OF REASONABLE ALTERNATIVES TO THE REGULATION THAT WOULD LESSEN ANY ADVERSE IMPACT ON SMALL BUSINESS:

No such alternatives have been proposed, however, the Board welcomes comments from the public.