BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY • GAVIN NEWSOM, GOVERNOR
DEPARTMENT OF CONSUMER AFFAIRS • VETERINARY MEDICAL BOARD
1747 North Market Blvd., Suite 230, Sacramento, CA 95834-2978
P (916) 515-5220 | Toll-Free (866) 229-0170 | www.vmb.ca.gov

MEMORANDUM

DATE	October 21, 2021
TO	Veterinary Medical Board (Board)
FROM	Karen Halbo, Regulatory Counsel, Attorney III Legal Affairs Division, Department of Consumer Affairs
SUBJECT	**Agenda Item 11.E. Sections 2090-2095, Article 11, Division 20, Title 16 of the CCR Regarding Drug Compounding**

Background

The Drug Compounding regulatory proposal was originally approved by the Board in October 2017. The language was revised and approved again on October 10, 2019, and January 30, 2020. The package was published by the Office of Administrative Law (OAL) on July 17, 2020, and the 45-day public comment period closed on August 31, 2020.

On October 22, 2020, the Board approved responses to the three written comments received and approved Modified Text to resolve the concerns raised. The 15-day public comment period on the Modified Text closed on December 4, 2020. On January 28, 2021, the Board voted to adopt the response to the one written comment received. Staff then incorporated the Board's responses into the Final Statement of Reasons (FSR) and submitted the final rulemaking package documents for Legal Affairs Division (LAD), DCA Director, and Agency review.

LAD raised concerns about portions of the Modified Text, and in response, on July 22, 2021, the Board approved the Second Modified Text to resolve the concerns LAD raised. The 15-day public comment period on the Second Modified Text closed on August 12, 2021. Two written comments were received, discussed below.

Summary of Comments with Recommendations Regarding the Second Modified Text and Proposed Responses

In accordance with Government Code section 11346.9, subdivision (a)(3), the Board, in its FSR supporting the Drug Compounding rulemaking, must summarize each objection or recommendation made regarding the specific adoption, amendment, or repeal proposed, together with an explanation of how the proposed action has been changed to accommodate each objection or recommendation, or the reasons for making no change. This requirement only applies to objections or recommendations specifically

directed at the specific adoption, amendment or repeal proposed in the Second Modified Text or to the procedures followed by the Board in proposing the adoption, amendment, or repeal. A comment is considered "irrelevant" if it is not specifically directed at the Board's proposed action or to the procedures followed by the Board in proposing the action. (*Id*.)

In the first written comment (Attachment 1), Philip C. Tillman, DVM, articulated strong disapproval of the use of the term "shall" in the proposed regulatory language and recommended the proposed regulations be edited to eliminate every use of the word "shall." As none of the proposed additions or deletions made in the Second Modified Text contained the term "shall," Dr. Tillman's comment was irrelevant because it was outside the scope of the specific adoption, amendment, or repeal being proposed in the Second Modified Text. Accordingly, the Board will not modify the proposed regulations to accommodate the recommendation.

In the second written comment from Kelly O'Brien, Director of Public Affairs for MARS Veterinary Health (MVH) (Attachment 2), MVH made recommendations for the Second Modified Text. The Board is asked to review the recommendations and proposed responses thereto for inclusion in the Board's FSR for this rulemaking.

Recommendations: Summarized below are the recommendations provided by MVH during the 15-day comment period and the proposed Board responses:

1. **California Code of Regulations (CCR), title 16, section 2091, subsection (a)**. In reference to proposed CCR, title 16, section 2091, subsection (a), MVH asserts there are no adequate standards for compounding veterinary drugs, and it is unclear if the Board's intention is to comply with state standards, U.S. Food and Drug Administration (FDA) Guidance, and/or United States Pharmacopeia (USP) standards. MVH asserts veterinarians do not have sufficient guidance to be responsible for the safety and efficacy of compounded medications. MVH recommends the Board wait until such standards are finalized or clarify that veterinarians are responsible for meeting USP standards once they are developed.

   Proposed Response: The proposed regulations are intended to allow veterinarians to do the basic compounding they have done for years. As noted in the Initial Statement of Reasons (ISR) for this rulemaking, the conversation regarding drug compounding in veterinary premises originated at the October 20, 2014 Multidisciplinary Advisory Committee (MDC) meeting. The conversation evolved due to a concern in the veterinary community about the ability to compound drugs and the quality of the drugs from existing compounding facilities. During that meeting, it was noted that the current authority for veterinarians to compound drugs was incomplete, and there was a need for further clarification. Previously, veterinarians could compound medications through a limited exemption identified in the Pharmacy Law (Business and Professions Code (BPC) sections 4051, 4052, and 4127 and CCR sections

1735-1735.8 and 1751), but no specific grant of authority existed in the Veterinary Medicine Practice Act authorizing licensed veterinarians to compound drugs for animal patients. The MDC identified that there was a lack of statutory authority for veterinarians to provide limited compounding services in their practices.

To provide statutory veterinary drug compounding authority, BPC section 4826.5 went into effect on January 1, 2017, and required the Board to promulgate regulations to address specified issues regarding the safe compounding of drugs. The Board's proposed drug compounding regulations have been in process since that time.

While better guidance may be provided by USP in the future, the Board does not choose to delay any longer the promulgation of drug compounding regulations. The proposed regulations address the issues the Board is obligated by statute to address in a rulemaking. If better standards become available in the future, the Board is not averse to amending these regulations. However, the hope of clear standards at some point in the future does not satisfy the Board's present statutory obligation to promulgate drug compounding regulations for veterinarians now.

The veterinary drug compounding statute, BPC section 4826.5, authorizes a licensed veterinarian or supervised registered veterinary technician (RVT) to compound drugs for animal use pursuant to Code of Federal Regulations, title 21, section 530 and in accordance with regulations promulgated by the Board. Veterinarians are required to perform all aspects of veterinary medicine in a manner consistent with current veterinary medical practice in this state. (CCR, tit. 16, § 2032.) The Second Modified Text amended proposed CCR, title 16, section 2091, subsection (a) to establish minimum drug compounding standards in the same way all veterinary medical practice is required to be performed. Given the continued evolution of drug compounding noted by MVH, the Board believes requiring veterinarians to adhere to minimum drug compounding standards in the profession is sufficient and accommodates future developments in drug compounding standards. As such, the Board declines to revise the proposed regulation to accommodate the recommendation.

Notably, the veterinary drug compounding statute and proposed regulations do not require a veterinarian to perform drug compounding. If a veterinarian is unsure of the minimum drug compounding standards in California, the veterinarian should not perform drug compounding and, instead, may issue a prescription to a pharmacy for drug compounding.

2. **CCR, title 16, section 2092, subsection (b)**. MVH states that consistency, uniformity, and quality standards are important in preparing compounded medication. MVH recommends, prior to enacting CCR, title 16, section 2092, subsection (b), the Board should seek to establish additional monographs for

common compounded animal drugs, in partnership with USP, the American Veterinary Medical Association (AVMA), and the FDA. MVH asserts that helping develop monographs would ensure consistency among California veterinarians in drug compounding and make it much easier for veterinarians to comply with the requirements in proposed CCR, title 16, sections 2092, subsection (b), and 2091, subsection (b).

Proposed Response: In the Second Modified Text, no changes were made to proposed CCR, title 16, section 2092, subsection (b), which would establish what information must be included in formula documents. As such, MVH's recommendation is irrelevant because it falls outside the scope of the specific adoption, amendment, or repeal being proposed in the Second Modified Text. Accordingly, the Board declines to revise the proposed regulation to accommodate the recommendation.

3. **CCR, title 16, section 2093**. In reference to proposed CCR, title 16, section 2093, MVH states that beyond-use dates are more common and more useful for compounded drugs. MVH recommends using beyond-use dates because it aligns with USP standards and would be beneficial to clients and their pets.

   Proposed Response: As discussed in greater detail in the ISR at pages 14-16, the Board chose to use the term "expiration date," instead of the term "beyond use date," to reflect the common usage of "expiration date" at veterinary premises and in veterinary software. Additionally, the only change in the Second Modified Text to proposed CCR, title 16, section 2093 was the elimination of subsection (c), which would have allowed expiration dates for compounded preparations to be extended under specific circumstances. The MVH recommendation does not address the extension of either expiration dates or beyond use dates and, thus, is irrelevant because it falls outside the scope of the specific adoption, amendment, or repeal being proposed in the Second Modified Text. Accordingly, the Board declines to revise the proposed regulation to accommodate the recommendation.

4. **CCR, Title 16, Section 2095**. In reference to proposed CCR, title 16, section 2095, MVH states that it does not believe it will be in the best interest of the profession, veterinarians, clients, or their pets to have veterinarians create their own monographs, and improperly compounding drugs can lead to dire consequences and negatively impact pet health. MVH recommends the Board work with USP, AVMA, and FDA to develop monographs for compounded veterinary drugs and refers back to the recommendation MVH makes concerning CCR, title 16, section 2092.

   Proposed Response: In the Second Modified Text, changes were made to proposed CCR, title 16, section 2095, subsections (c) and (d). The change to subsection (c) required that when a medication error is determined to have occurred, the client must be notified "immediately," which is sooner than the

previous language allowing notification “as soon as possible.” The change to subsection (d) eliminated language by which the Board sought to make peer review documents exempt from discovery, an action beyond the Board’s regulatory power.

However, the MVH recommendation that the Board should assist in developing monographs for compounding veterinary drugs does not address either of the changes made in proposed CCR, title 16, section 2095, subsections (c) and (d). As such, the MVH recommendation is irrelevant because it falls outside the scope of the specific adoption, amendment, or repeal being proposed in the Second Modified Text. Accordingly, the Board declines to revise the proposed regulation to accommodate the recommendation.

Action Requested:

The Board is asked to consider a motion to approve the proposed responses to the written comments received during the 15-day public comment period on the Second Modified Text and direct staff to incorporate the responses into the FSR when proceeding with the final rulemaking package.

The Board also is asked to consider a motion to direct staff to take all steps necessary to complete the Drug Compounding rulemaking process, and delegate to the Executive Officer the authority to make any technical or non-substantive changes to the rulemaking package and adopt the Second Modified Text to add sections 2090, 2091, 2092, 2093, 2094, and 2095 of article 11 to division 20 of title 16 of the California Code of Regulations.

Attachments:

1. Philip C. Tillman, DVM Letter
2. MARS Veterinary Health Letter

July 29, 2021

Justin Sotelo, Lead Administrative & Policy Analyst
Veterinary Medical Board
1747 N. Market Blvd., Ste. 230
Sacramento, CA 95834

Dear Mr. Sotelo,

Please consider my comments below regarding your proposed revisions to sections 2091, 2093, and 2095 of article 11, division 20, title 16 of the California Code of Regulations, related to Drug Compounding.

I am a California licensed veterinarian, presently retired, formerly engaged in small animal practice, and formerly Campus Veterinarian for the University of California, Davis. In both those prior careers I frequently compounded for specific, necessary purposes.

I think the proposed changes are clear, allow reasonable flexibility for practitioners, and I approve of their content. I do have an issue with some of the specific language employed, as it might be difficult to interpret and enforce. Specifically, I object to the use of the word “shall”. Regulators often like to use the word “shall”, because it does not occur in ordinary conversation, so to some people, it sounds “legal” or “official”. In fact it’s neither.

Shall, must, will, should, may

Your document uses the word "shall" repeatedly. "Shall" is currently frowned on in legal documents. The following is from the Federal Aviation Administration at:

https://www.faa.gov/about/initiatives/plain_language/articles/mandatory/

> Nearly every jurisdiction has held that the word "shall" is confusing because it can also mean "may, will or must." Legal reference books like the *Federal Rules of Civil Procedure* no longer use the word "shall." Even the Supreme Court ruled that when the word "shall" appears in statutes, it means "may."
>
> Bryan Garner, the legal writing scholar and editor of *Black's Law Dictionary* wrote that "In most legal instruments, shall violates the presumption of consistency...which is why shall is among the most heavily litigated words in the English language."

You should edit your proposed regulation and eliminate every use of the word “shall”. Where the action described is mandatory, the words "must" or "will" should be used. Where the action described is not mandatory, but is best practice or recommended, use the word "should". In cases where the action is optional or discretionary use the words "may" or "might".

Best regards,

Philip C. Tillman, DVM
Arroyo Grande, California

MARS
Veterinary Health
A Division of Mars Petcare

California Veterinary Medical Board
1747 N. Market Blvd., Ste. 230
Sacramento, CA 95834

Re: Mars Veterinary Health comments on proposed California Compounding Regulations

California Veterinary Medical Board:

Mars Veterinary Health, which represents 65,000 dedicated veterinary professionals worldwide, including more than 9,600 in the state of California, appreciates the opportunity to provide comments on proposed California regulation Article 11 of Division 20 of title 16 of the CCR.

We understand the spirit of the proposed regulation, which is to aide consumers, veterinarians, registered veterinary technicians, Deputy Attorneys General, and the Board to easily find the regulations applicable to drug compounding in a veterinary clinic. We wholeheartedly believe we should encourage this kind of structured quality in compounded medication for our veterinary patients.

However, there are components of the proposed regulation that may cause confusion and place undue burden on local practitioners should it be approved as-is.

Section 2091 (a)
Adequate standards for compounding veterinary drugs do not currently exist and it is unclear if the intention is to comply with state standards, U.S. Food and Drug Administration (FDA) guidance, and/or United States Pharmacopeia (USP) standards, which are expected to be released soon. Without adequate standards, veterinarians are going to be put in a precarious position of being responsible for ensuring the safety and efficacy of compounded medications without any guidance. It may be in the best interest of the profession to wait until such standards are finalized or clarify that veterinarians are responsible for meeting USP standards once they are developed.

Section 2092 (b)
As stated, the Board anticipates consumers and their animals will benefit from written formula documents, or monographs, for each compounded drug preparation made by veterinarians and RVTs, as the documents should provide consistency and uniformity in the drug preparations.

Consistency and uniformity are important, as are the quality standards that govern the preparation of compounded medication. Prior to enacting this aspect of the regulation, the

board should seek to establish additional monographs for common compounded animal drugs, in partnership with USP, American Veterinary Medical Association (AVMA), and the FDA. This would ensure that, in addition to the standards required by the VMB, there is consistency among California veterinarians in:

1. Formulas (ingredients and quantities)
2. Directions to correctly compound the preparation
3. Beyond-use dates based on stability studies
4. Packaging and storage information
5. Acceptable pH ranges
6. Stability-indicating assays

Helping develop monographs would make it much easier for veterinarians to comply with the requirements of Section 2092 (b) and 2091 (b) *A veterinarian shall not perform either sterile or non-sterile drug compounding when the complexity of the drug compounding exceeds the veterinarian's knowledge, skill, facilities, or available equipment.*

In the absence of this guidance, individual organizations will create their own monographs, which raises several concerns:

1. This is beyond the expertise of most veterinary practitioners (Section 2091 subsection (b));
2. It would require significant investment from small general practices seeking to hire the expertise; and
3. There will be dissemination amongst practitioners of formulas that have not been validated against independent, recognized standard methodologies.

This will be problematic for both licensee and client. It offers a false sense of protection for the practitioner and consumer and may expose the clinician to VMB discipline or other liability, if they are found negligent (failure to use reasonable care to prevent harm to oneself or to others, especially if the methodologies are found to be "insufficient" by USP or the VMB). It ultimately does not protect our pets by providing a consistent and uniform compounded drug preparation across the state of California.

Section 2093

Beyond-use dates are more common for compounded drugs, as they tend to be more useful than expiration dates. We also recommend using beyond-use dates because it aligns with USP standards and would be beneficial to clients and their pets.

Section 2095

Related to 2092, again, we recommend that the board work with the USP, AVMA, and FDA to develop additional monographs for compounded veterinary drugs. We do not believe it will be in the best interest of the profession, veterinarians, clients, or their pets to have veterinarians create their own monographs. Improperly compounding drugs can lead to dire consequences and negatively impact pet health.

Thank you for the opportunity to review the proposed regulation. Please don't hesitate to reach out if Mars Veterinary Health can answer any questions or contribute to the evolution of these important rules.

Best,

Kelly O'Brien
Director of Public Affairs
503-929-6817