

February 10, 2025

The Honorable Marc Berman, Chair
Assembly Business and Professions Committee
Co-Chair, Joint Legislative Sunset Review Committee
1021 O Street , Room 8130
Sacramento, CA. 98514

**RE: 2025 SUNSET REVIEW: BOARD OF PHARMACY
UNRESOLVED ISSUE: VETERINARY DRUG AVAILABILITY, LACK OF BOP ACTION**

Dear Chairperson Berman,

The California Veterinary Medical Association (CVMA), representing approximately 7,000 veterinarians, registered veterinary technicians, and students, appreciates the opportunity to comment on the California Board of Pharmacy (BOP) during its 2025 Sunset Review. In that regard, we are hopeful that the Legislature would give consideration to directing the BOP to meaningfully and effectively address the ongoing concerns of the veterinary profession, relative to compounded drug availability, which is seriously affecting patient care.

I. Veterinary Drug Availability Is Being Unduly Restricted Due to Excessive BOP Regulations

California is the only state in the country in which veterinarians cannot obtain, on an ongoing basis, medications that they need to treat patients. The lack of availability of these drugs is a result of excessively stringent and prohibitive BOP compounding regulations that disincentivize pharmacies from offering them in California. Such a proscriptive approach is absolutely unnecessary and places an untenable strain both on (a) consumers seeking basic care for their animals, and (b) veterinarians who have taken an oath to provide competent and humane care to their patients.

A prime example of this phenomenon is found in regard to ophthalmic ointments used in equine medicine. Prior to the BOP's below-described tightening of compounding regulations, these compounded ointments were available in California and were safe and effective in treating patients. Now, due to those same revisions, several of these drugs (see [Attachment 1](#)) are effectively no longer available, despite the fact that the BOP has never produced any evidence to show that previous compounding standards for these drugs resulted in any harm to

patients. Yet the Board continues to layer inhibitive rule upon rule on compounding pharmacies to the point that the pharmacies cannot justify the effort and expense in meeting the requirements to produce a medication that veterinarians need to treat patients. Without that essential compounding, veterinarians are left with few (sub-optimal) substitutes, and in many instances, no alternatives.

In one example of the lack of compounded drug availability, we have seen cases of rapidly progressing fungal eye infections in horses, causing significant pain to the animal and potential blindness. Previously, drugs such as miconazole, itraconazole, natamycin, or voriconazole were available options for veterinarians when treating these types of cases. Now, due to the severe BOP restrictions on compounding pharmacies, only itraconazole is available and may be challenging to obtain. In the meantime, horses are suffering and literally losing their eyes to blindness due to the BOP's regulatory overreach. (see [Attachment 12.](#))

II. The BOP Has Failed to Take Needed Steps to Ensure Veterinary Access to Critical Drugs

a. 2017-2022: The BOP's Precipitous Compounding Restrictions and Failure to Account for Veterinary Need

Prior to 2017, the regulatory landscape in California was such that veterinarians were able to acquire compounded medicines for use in patient care and treatment. In January of 2017, a BOP-commissioned regulatory package took effect that resulted in numerous compounding pharmacies discontinuing their veterinary product lines in California while others substantially reduced their product catalogs. In 2015 there were over a dozen veterinary compounding pharmacies in California, while only six remain today. Of those, all offer only a limited catalogue of medications due to the excessive regulatory burden and associated cost increases. The choices made by these pharmacies to reduce their product lines were multifactorial, but primarily due to the new BOP mandate for prohibitively short "beyond-use-dates" on sterile compounds.

As a consequence of this downsizing, veterinarians had to spend significant amounts of time calling different pharmacies to piece together enough medications to treat patients. This was disruptive to veterinary practice and frequently resulted in patients experiencing delays in receiving medication, or in veterinarians having to resort to prescribing a medication other than the one preferred. This problem persists today.

Via a March 2017 comment letter ([Attachment 2](#)), the CVMA reported this issue to the BOP, listed a number of important drugs in short supply at that time, and warned that while no drugs were reported to be altogether unavailable at that time, such availability would imminently result if changes were not instituted. In response, the BOP's Enforcement and Compounding Committee directed BOP staff to research the new regulations to determine if changes could be made to ensure that compounders could provide medications for veterinary use based on the previous regulations' safety and efficacy standards. Unfortunately, despite the fact that those prior regulations served the state well in allowing pharmacists to produce compounded

medications that were safe and efficacious for animal patients, BOP staff did not revive *any* of them.

In October of 2019, the CVMA again wrote a letter ([Attachment 3](#)) to the BOP expressing concern over veterinary compounded drug availability in California, and specifically addressing another restrictive BOP proposal, this time to (a) prevent veterinarians from dispensing compounded medication to clients for at-home administration to their pets, and (b) require veterinarians to report to the pharmacist each individual dose of a compounded medication being given to a patient. It was evident from this proposed action that the BOP was unfamiliar with the demands already placed on practicing veterinarians, and was creating excessively stringent regulations to police a non-existent issue. The CVMA implored the BOP to engage the CVMA and the California Veterinary Medical Board (CVMB) in dialogue regarding the gaps that veterinarians were experiencing when trying to provide treatment to their patients in the wake of BOP regulatory changes. Unfortunately, the CVMA's comments once again went unanswered.

The following year, 2020, the CVMA made multiple attempts (see [Attachment 4](#) as an example) to communicate with the BOP concerning the BOP's myopic legal interpretation of the Federal Food and Drug Administration's Animal Medicinal Drug Use Clarification Act (AMDUCA). Specifically, 21 CFR 530.13(a) makes a general statement that "nothing in this part shall be construed as permitting compounding from bulk drugs." The BOP used this statement as justification to draft numerous overly restrictive regulations that would result in compounding pharmacies no longer being able to compound drugs using active pharmaceutical ingredients, also known as "bulk drugs."

In its communications to the BOP, the CVMA pointed out that the FDA also published a draft Guidance for Industry #256 (GFI 256) which functions as a living inclusive list of active pharmaceutical ingredients from which compounding pharmacies may prepare medications pursuant to veterinarian prescription. In that regard, the FDA published GFI 256 because it is aware that several vital veterinary drugs are not available from pharmaceutical manufacturers.¹ The CVMA provided the BOP with an extensive list of important veterinary drugs that could only be obtained through the use of active pharmaceutical ingredients and implored the BOP to consider GFI 256 and incorporate its reference into draft regulations in order to ensure that pharmacists maintain the ability to provide crucial medications to veterinarians for their use on animal patients (see [Attachment 5](#) and [Attachment 11](#)). The BOP last week published a draft regulation referencing GFI 256, which will likely take months to years to take effect.

b. 2022-Present: The BOP's Failure to Respond to Shortages of Essential Compounded Medications for Veterinary Use

In January of 2022, after CVMA's multiple attempts to warn the BOP of likely drug availability issues that would result from their regulations and enforcement activity, reports began coming

¹ This is likely because those companies do not find enough profit incentive to endure the FDA approval process to bring those drugs to market.

in of veterinary drugs being altogether unavailable in California. ***Please note that California is the only state in the country in which veterinarians cannot obtain medications on an ongoing basis to treat their patients.*** Immediately upon receipt of these reports, the CVMA informed the BOP (see [Attachment 6](#)), asked that the situation be shared with BOP members, and solicited a meeting to discuss the problem. The BOP provided no response.

At the February 2023 meeting of the BOP's Enforcement and Compounding Committee, the CVMA appeared before this group to yet again highlight acute drug availability issues being experienced by the veterinary profession due to an industry shift in California veterinary compounding pharmacies. The CVMA relayed veterinarian-provided reports that clients could not find a pharmacy to fill their prescriptions for compounded medications, and thus pets were experiencing delays in prescribed treatment, or a failure of treatment altogether.

Accordingly, the CVMA asked the BOP to consider changing its regulations to allow compounding pharmacies to dispense a larger supply of compounded medications for veterinarians to use in-house and to secondarily dispense to clients. In that regard, the existing regulation permitted a compounding pharmacist to provide a veterinarian with a 120-hour on-hand, per-patient supply of medication (known as "office stock"). To help assuage the problem described above, the CVMA requested that this permission be extended to a seven-day supply of office stock (see [Attachment 7](#)). The BOP's Enforcement and Compounding Committee was lukewarm to the request, and it was apparent that they did not find the CVMA's reporting to be credible. No action was taken by the committee based on the request, but the CVMA was told to provide specific information to the BOP for further consideration.

The CVMA did as directed. Specifically, the CVMA surveyed member veterinarians and asked them two simple questions: 1) Had they been experiencing issues in obtaining medications (either FDA-approved or compounded) in the past year, and 2) When they ordered a compounded drug from a compounding pharmacy pursuant to a patient-specific prescription, was the wait to receive it greater than five days?

The purpose of these questions was to determine (a) whether—as had been reported—the veterinary profession was truly experiencing gaps in drug availability such as to necessitate the need for compounders to provide a larger supply of office stock, and (b) the effect of the BOP's regulations relative to resulting gaps in patient treatment. The results of the survey were overwhelming: 90% of respondents indicated that they were unable to obtain medications, and 88% reported that they had to wait longer than five days to receive a patient-specific medication from a compounder. (See [Attachment 8](#).)

As the BOP had requested, the CVMA again came back to the BOP (see [Attachment 9](#)) and reported the survey findings. The BOP staff response was, frankly, both frustrating and offensive. In their memo to the Enforcement and Compounding Committee members, BOP staff stated: *"It appears based on some of the information provided, that some pharmacies and veterinarian practices may be using compounded drug products in lieu of commercially available products as a cost saving measure. This is a violation of Federal law"* (see [Attachment 10](#).) Beyond the fact that there was no such information in the CVMA survey that could justify this

conclusion, the BOP's statement manifested a willful and intentional disregard of the actual information reported concerning medication shortages and its detrimental effect on patient care.

Since the above-described events and communications, the BOP just last week proposed regulatory changes seeking to increase the amounts of compounded medications that pharmacies may prepare for veterinarians to use and dispense during the course of practice (proposed 14-day allowance.) Unfortunately, these amendments are a small part of a lengthy and highly-contested regulatory package (most of which nothing to do with the subject matter of this letter) that is likely be stuck in the rulemaking process for a long period of time.

In addition to all of the above-described input, the CVMA has also brought specific examples to the BOP of how its obstructive regulatory framework is affirmatively harming California's animal population, such as that presented at the BOP's June 18, 2024 meeting (see [Attachment 12](#)). Those examples, like the comments described above, have produced no meaningful movement by or response from the BOP. In the meantime, the regulatory changes currently under review simply do not work towards solving drug availability issues that exist solely in California.

III. Request for Legislative Intervention

Based on its serial lack of meaningful responses to the CVMA's concerns, it is apparent that the BOP is disregarding their role in preventing veterinarians from being able to treat patients through their excessively prohibitive regulations. Their overly-burdensome and confusing rules have disincentivized veterinary compounding pharmacies from doing business in California, which has led to animal suffering in our state and stress on the veterinary profession and pet owners. Accordingly, the CVMA requests that the Sunset Review Committee give consideration to requiring the BOP staff to convene a stakeholder meeting, which would include representatives from the Assembly Business and Professions Committee and the Senate Business, Professions, and Economic Development Committee, to engage the CVMA, CVMB, and veterinary compounding pharmacies to find solutions to the acute drug availability issues plaguing the California veterinary profession; issues that exist specifically because of the BOP actions.

Thank you for your consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "Jennifer Hawkins, DVM". The signature is fluid and cursive, with the first name "Jennifer" being the most prominent.

Jennifer Hawkins, DVM; President
California Veterinary Medical Association

cc: Sunset Review Committee Co-Chair Senator Angelique Ashby

Robby Sumner, Chief Consultant, Assembly Business and Professions Committee

Edward Franco, Consultant, Assembly Business and Professions Committee

Sarah Mason, Chief Consultant, Senate Business, Professions, and Economic
Development Committee

Elissa Silva, Consultant, Senate Business, Professions, and Economic Development
Committee

Jessica Sieferman, Executive Officer, Veterinary Medical Board

Dr. Maria Solacito, President, Veterinary Medical Board

Christina DiCaro, CVMA Lobbyist, KP Public Affairs