

VETERINARY MEDICAL BOARD
FINAL STATEMENT OF REASONS

Subject Matter of Proposed Regulations: RVT Job Tasks

Section(s) Affected: Title 16, Division 20, Article 4, of the California Code of Regulations (CCR)¹ section 2036.

Updated Information:

The Initial Statement of Reasons is included in the file. The information contained therein is updated as follows:

The 45-day public comment period began on June 5, 2020 and ended on July 20, 2020. The Veterinary Medical Board (Board) did not hold a hearing. The Board received two letters of support.

The Board issued a 15-day Notice of Modified Text on August 12, 2020 to add subdivision (b) paragraph (5) Drug compounding from bulk substances and clarified in subdivision (c) paragraph (3) that drug compounding could only be performed from non-bulk substances. These two modifications were made to bring the compounding provisions in line with the federal changes made by the Food and Drug Administration's (FDA) "Draft Guidance on Compounding Animal Drugs from Bulk Drug Substances" (CVM GFI # 256²) released in November 2019. The FDA Draft Guidance specifically requires compounding of bulk substances to be done by or under the direct supervision of a veterinarian. The FDA expressed concerns about the safety, effectiveness, and quality of animal drugs compounded from bulk substances, which have not gone through agency pre-market review. These concerns are lessened when compounding involves non-bulk substances, which is why the Draft Guidance allows compounding of non-bulk substances to be done under indirect supervision of a veterinarian. The modifications also align the Modified Text with proposed revised language in the Board's Drug Compounding regulatory rulemaking³ adding a new Article 11, Compounding in a Veterinary Premises, adopting sections 16 CCR 2090, 2091, 2092, 2093, 2094, and 2095. The Board received one letter of support during the 15-day comment period.

¹ All CCR references are to title 16 unless otherwise noted.

² Available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-256-compounding-animal-drugs-bulk-drug-substances>.

³ OAL Notice file number Z2020-0701-01.

Local Mandate:

A local mandate is not imposed on local agencies or school districts.

Small Business Impact:

While the Board estimates that 80 to 90 percent (2,800 to 3,150) of the approximately 3,500 veterinary premises are small businesses, the Board has determined that this rulemaking proposal would have no significant adverse economic impact on business. The regulatory proposal will only impact Registered Veterinary Technicians (RVTs) and authorizes them to provide additional services under the indirect supervision of a licensed veterinarian.

Economic Impact:

The Board has determined that this regulatory proposal will not have any significant statewide adverse economic impact directly effecting businesses.

This regulatory proposal provides additional services to California consumers and their animals by allowing RVTs to provide already authorized animal health care tasks under the indirect supervision of a licensed veterinarian and aligning the regulations with current practice.

Anticipated Benefits of this Proposal:

This regulatory proposal focuses on identifying additional animal health care tasks an RVT can provide under the indirect supervision of a veterinarian, which will provide additional access to veterinary medical care for California consumers and their animals. For this reason, the Board anticipates that the proposal will benefit California consumers and their animals. This regulatory proposal does not affect worker safety or the state's environment.

Consideration of Alternatives:

No reasonable alternative to the regulatory proposal that was considered or that has otherwise been identified and brought to the attention of the Board would be more effective in carrying out the purpose for which the regulation is proposed, would be as effective or less burdensome to affected private persons than the proposed regulation, or would be more cost-effective 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.

Summary of Comments and Responses

No objections or recommendations for alternative approaches were received.

Comments received during the 45-day comment period:

Two letters of general support were received from the California Registered Veterinary Technicians Association and (jointly) from the California Association of Animal Physical Therapists (CAAPT) and the Animal Physical Therapy Coalition (APTC).

Comments received during the 15-day comment period:

One letter of general support was received from the California Registered Veterinary Technicians Association.

Response:

The Board thanks the commenters for their review and support; no text changes are needed in response.

Fiscal Impact:

The proposed regulations do not result in a fiscal impact to the state. The Board will ensure compliance through its current inspection programs and regimen. As a result, the Board does not anticipate additional workload or costs from the proposed regulations.