

**TITLE 16
VETERINARY MEDICAL BOARD**

NOTICE OF PROPOSED REGULATORY ACTION CONCERNING

Article 11. Compounding in a Veterinary Premises

Definitions, § 2090

Veterinary Drug Compounding, § 2091

Policies and Procedures, § 2092

Expiration Dates, § 2093

Labeling of Compounded Preparations, § 2094

Quality Assurance, § 2095

NOTICE IS HEREBY GIVEN that the Veterinary Medical Board (“Board”) is proposing to take the action described in the Informative Digest.

PUBLIC HEARING

The Board has not scheduled a public hearing on this proposed action. However, the Board will hold a hearing if it receives a written request for a public hearing from any interested person, or his or her authorized representative, no later than 15 days prior to the close of the written comment period. A hearing may be requested by making such request in writing addressed to the individuals listed under “Contact Person” in this notice.

WRITTEN COMMENT PERIOD

Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under “Contact Person” in this Notice, must be **received by the Board at its office no later than August 31, 2020**, or must be received by the Board at the hearing, should one be scheduled.

AVAILABILITY OF MODIFICATIONS

The Board, upon its own motion or at the request of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as the Contact Person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

AUTHORITY AND REFERENCE

Pursuant to the authority vested by section 4826.5 of the Business and Professions Code (BPC), and to implement, interpret, or make specific that section, the Board is considering adopting article 11 of division 20 of title 16 of the California Code of Regulations (CCR)¹, and adopting sections 2090, 2091, 2092, 2093, 2094, and 2095 of article 11 of division 20 of title 16 of the CCR.

INFORMATIVE DIGEST

BPC section 4826.5 authorizes veterinarians and registered veterinary technicians (RVTs) to provide limited drug compounding services for animal patients and requires the Board to adopt regulations defining the parameters of drug compounding services in veterinary premises. As such, the Board has promulgated regulations that provide minimum standards for drug compounding services performed by veterinarians and RVTs in veterinary premises.

This regulatory proposal will adopt CCR sections 2090, 2091, 2092, 2093, 2094, and 2095 to define drug compounding in veterinary premises and the parameters of a veterinarian or RVT providing drug compounding services, mandate that veterinary premises develop policies regarding drug compounding services, identify expiration dates for sterile and non-sterile drugs, enforce labeling requirements for compounded drugs, and require quality assurance protocols for drug compounding.

POLICY STATEMENT OVERVIEW/ANTICIPATED BENEFITS OF PROPOSAL

The primary mission of the Board is to protect consumers and animals through the development and maintenance of professional standards. This regulatory proposal promotes the health, safety, and welfare of consumers and their animals by clarifying the requirements as mandated in BPC section 4826.5 regarding drug compounding in veterinary medicine. By adopting the proposed regulations, the Board seeks to ensure that all veterinarians and RVTs providing drug compounding services have completed the necessary training requirements and 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.

Consistency and Compatibility with Existing State Regulations

During the process of developing these regulations and amendments, the Board has conducted a search of any similar regulations of these topics and has concluded that these regulations are neither inconsistent nor incompatible with existing state regulations.

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

FISCAL IMPACT ESTIMATES

The Board will be required to ensure compliance with the proposed regulations through routine inspections of veterinary premises. Any workload and costs are anticipated to be minor and absorbable within existing resources.

Fiscal Impact on Public Agencies Including Costs or Savings to State: The Board anticipates minor and absorbable enforcement-related workload and costs to implement the proposed regulations. Additional costs may be incurred in future Fiscal Years, and the Board may be required to request additional resources through the annual budget process for additional staff to accommodate the review and inspections of the veterinary premises providing drug compounding services.

Cost or Savings in Federal Funding to the State: None

Nondiscretionary Costs/Savings to Local Agencies: None

Local Mandate: None

Cost to Any Local Agency or School District for Which Government Code Sections 17500 - 17630 Require Reimbursement: None

Business Impact:

The Board has made an initial determination that the proposed regulations will not have a significant adverse economic impact directly affecting businesses, including the ability of California businesses to compete in other states. 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 Board is informed that drug compounding already occurs in veterinary premises. The regulatory proposal would provide minimum standards for drug compounding in the limited setting of a veterinary premises.

Cost Impact on Representative Private Person or Business:

The Board is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action. The Board is informed that drug compounding already occurs in veterinary premises. The regulatory proposal would provide minimum standards for drug compounding at veterinary premises, and for veterinarians and RVTs wishing to provide drug compounding services.

Effect on Housing Costs: None

EFFECT ON SMALL BUSINESS

The Board has determined that the proposed regulations will not affect small businesses. The proposed regulations would set minimum standards for veterinary premises to adhere to, if they wish to provide drug compounding services, but the Board is informed that drug compounding already occurs in veterinary premises.

RESULTS OF ECONOMIC IMPACT ASSESSMENT/ANALYSIS:

Impact on Jobs/Businesses:

The Board has determined that this regulatory proposal will not have any impact on the creation of jobs or new businesses or the elimination of jobs or existing businesses or the expansion of businesses in the State of California.

Benefits of Regulation:

This regulatory proposal focuses on developing 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. The regulatory proposal does not affect the state's environment.

CONSIDERATION OF ALTERNATIVES

The Board must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to its attention would be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposal described in this Notice, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Any interested person may submit comments to the Board in writing relevant to the above determinations at 1747 North Market Blvd., Suite 230, Sacramento, California 95834.

INITIAL STATEMENT OF REASONS AND INFORMATION

The Board has prepared an initial statement of the reasons for the proposed action and has available all the information upon which the proposal is based.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations, and any document incorporated by reference, and of the initial statement of reasons, and all of the information upon which the proposal is based, may be obtained upon request from the Board at 1747 North Market Blvd., Suite 230, Sacramento, California 95834.

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file, which is available for public inspection by contacting the person named below.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below or by accessing the website listed below.

CONTACT PERSON

Inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name:	Justin Sotelo
Address:	Veterinary Medical Board 1747 North Market Blvd., Suite 230 Sacramento, CA 95834
Telephone No.:	916-515-5238
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E-Mail Address:	Justin.Sotelo@dca.ca.gov

The backup contact person is:

Name:	Timothy Rodda
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Website Access: Materials regarding this proposal can be found at https://vmb.ca.gov/laws_regs/proposed_regs.shtml.