

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

NOTICE OF PROPOSED REGULATORY ACTION CONCERNING:

Veterinary Drug Compounding

NOTICE IS HEREBY GIVEN that the California Veterinary Medical Board (Board) is proposing to take the action described in the Informative Digest below, after considering all comments, objections, and recommendations regarding the proposed action.

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 relevant to the action proposed, 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 November 3, 2025** or must be received by the Board at the hearing, should one be scheduled.

AUTHORITY AND REFERENCE

Pursuant to the authority vested by sections 4808, 4826.5, and 4836 of the Business and Professions Code (BPC), and to implement, interpret, or make specific BPC sections 4826.5, 4836, and 4840, the Board is considering amending 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 (CCR).

INFORMATIVE DIGEST / POLICY STATEMENT OVERVIEW

BPC section 4800.1 mandates that the protection of the public shall be the highest priority of the Board in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount. BPC section 4808 authorizes the Board, in accordance with the Administrative Procedure Act (Government Code section 11400 et seq.), to adopt, amend, or repeal such rules and regulations as may be reasonably necessary to enable it to carry into effect the provisions of the Veterinary Medicine Practice Act (Practice Act) (BPC section 4800, et seq.).

BPC section 4826.5 authorizes veterinarians and registered veterinary technicians (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.

This regulatory proposal will: 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 statute; 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 intravenous (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 of Proposal

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.

Evaluation of Consistency and Compatibility with Existing State Regulations

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

DISCLOSURES REGARDING THIS PROPOSED ACTION

FISCAL IMPACT ESTIMATES

The Board will continue to ensure compliance with veterinary drug compounding requirements through routine inspections of veterinary premises, and does not anticipate additional workload or costs.

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State:

The proposed regulations do not result in a fiscal impact to the state. This regulatory proposal will further update and clarify veterinary drug compounding requirements. The Board does not anticipate additional workload or costs.

The regulations do not result in costs or savings in federal funding to the state.

Nondiscretionary Costs/Savings to Local Agencies: None.

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

Mandate Imposed on Local Agencies or School Districts: None.

Significant Effect on Housing Costs: None.

BUSINESS IMPACT ESTIMATES

The Board has made the initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting business, including the ability 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.

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.

Any workload and costs to comply with the regulations are anticipated to be completed and incurred within normal business operations.

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 following: 1) the creation or elimination of jobs within the state; 2) the creation of new businesses or the elimination of existing businesses within the state; or, 3) the expansion of businesses currently doing business within the state.

This proposal would not have any of the above-referenced impacts, as explained in the "Business Impact Estimates" section of this notice.

Benefits of Regulation:

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. The regulatory proposal does not affect the State's environment.

Business Reporting Requirements

The regulatory action does not require businesses to file a report with the Board.

Effect on Small Business

The Board has determined that the proposed regulations will not affect small businesses. Any workload and costs to comply with the regulations are anticipated to be completed and incurred within normal business operations.

The proposed regulations would update and clarify minimum standards for veterinary premises to adhere to if they wish to provide drug compounding services.

CONSIDERATION OF ALTERNATIVES

In accordance with Government Code section 11346.5, subdivision (a)(13), 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 during the written comment period, or at the hearing if one is scheduled or requested.

AVAILABILITY OF STATEMENT OF REASONS AND RULEMAKING FILE

The Board has compiled a record for this regulatory action, which includes the Initial Statement of Reasons (ISOR), proposed regulatory text, and all the information on which this proposal is based. This material is contained in the rulemaking file and is available for public inspection upon request to the contact persons named in this notice.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations, and any document incorporated by reference, and of the ISOR, 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 OF CHANGED OR MODIFIED TEXT

After considering all timely and relevant comments, 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, with the modifications clearly indicated, will be available for review and written comment for 15 days prior to its adoption from the persons designated in this Notice as the Contact Persons and will be mailed to those persons who submit written comments or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

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 Persons named below or by accessing the website listed below.

CONTACT PERSONS

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

Name:	Justin Sotelo
Address:	California Veterinary Medical Board 1747 North Market Blvd., Suite 230 Sacramento, CA 95834
Telephone No.:	(916) 905-5511
Fax No.:	(916) 928-6849
E-Mail Address:	justin.sotelo@dca.ca.gov

The backup contact person is:

Name: Matt McKinney
Address: California Veterinary Medical Board
1747 North Market Blvd., Suite 230
Sacramento, CA 95834
Telephone No.: (916) 282-3529
Fax No.: (916) 928-6849
E-Mail Address: matthew.mckinney@dca.ca.gov

AVAILABILITY OF DOCUMENTS ON THE INTERNET

Copies of the Notice of Proposed Regulatory Action, ISOR, Proposed Regulatory Language of the regulations with modifications noted, as well as the Final Statement of Reasons when completed, and modified text, if any, can be accessed through the Board's website at:

https://www.vmb.ca.gov/laws_regs/proposed_regs.shtml