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MEMORANDUM

SUBJECT	Agenda Item 8. Update and Discussion on Pending Regulations								
FROM	Justin Sotelo, Policy Specialist								
то	Veterinary Medical Board (Board)								
DATE	July 12, 2024								

The Board currently has four previously approved rulemaking packages pending in the rulemaking process, as described below. These four packages are in various stages of the initial phase of the rulemaking process. Additionally, there is one updated regulatory proposal (discussed below) that is being reconsidered for approval by the Multidisciplinary Advisory Committee (MDC) and Board at the respective July 2024 meetings.

Updates or changes in the status of rulemaking packages since April 2024 are provided below:

<u>Drug Compounding—California Code of Regulations (CCR), Title 16, Sections 2036.5, 2090, 2091, 2092, 2093, & 2094: IN PROCESS</u>

Update: At its October 2023 meeting, the Board directed the MDC to review the regulatory proposal to address discussion and issues raised at that meeting. After review, the MDC, Drug Compounding Subcommittee recommended additional changes, which were presented to, and subsequently approved by, the MDC at its January 2024 meeting. At its April 2024 meeting, the Board rescinded its prior motion approving proposed amendments to the regulatory text and approved updated regulatory text, along with some minor changes recommended at that meeting. The regulatory package is being prepared by staff for the initial phase of the rulemaking process.

Summary of Proposed Changes: The proposal would: (1) make technical revisions regarding animal health care tasks performed by permit holders and veterinary assistants (CCR, tit. 16, § 2036.5); (2) make technical revisions regarding Registered Veterinary Technician (RVT) drug compounding under the supervision of a veterinarian in a registered veterinary premises (CCR, tit. 16, §§ 2090, subs. (a), (b), 2091, subs. (b), (c)); (3) add a definition for "immediate use" (CCR, tit. 16, § 2090, subs. (e)); (4) clarify the definition of "office stock" regarding administration and dispensing of the office stock (CCR, tit. 16, § 2090, subs. (f)); (5) clarify the policy and procedure and master formula document requirements and documentation requirements for animal patient specific compounded drug preparations (CCR, tit. 16, § 2092, subs. (a)-(d)); (6) establish documentation

requirements for immediate use compounded drug preparations (CCR, tit. 16, § 2092, subs. (e)); (7) clarify compounded drug preparation documentation requirements in animal patient medical records (CCR, tit. 16, § 2092, subs. (f)); (8) make technical corrections regarding drug compounding training requirements (CCR, tit. 16, § 2092, subs. (g)); (9) establish expiration of non-immediate use intravenous (IV) or subcutaneous (SQ) compounded drug preparations (CCR, tit. 16, § 2093, subs. (c)); and (10) clarify drug compounding labeling requirements for office stock, establish labeling requirements for IV, intramuscular, and SQ drug preparations, and establishing labeling requirements for compounded drugs requiring refrigeration (CCR, tit. 16, § 2094).

<u>VCPR, Definitions, and RVT Tasks Updates (RVT Vaccine Administration)—CCR, Title 16, Sections 2032.1, 2034, and 2036: IN PROCESS</u>

Update: At its October 2023 meeting, the Board was informed that the MDC would be reviewing the proposed text to determine if any part of the proposal could be retained after the enactment of Senate Bill (SB) 669 (Cortese, Chapter 882, Statutes of 2023), which covers the same subject matter as the Board's proposal. As a result, this package was pulled from Agency review in October 2023. Staff is scheduled to meet with Regulations Counsel on August 16, 2024, to evaluate this proposal. An update will be provided at a future meeting.

Summary of Proposed Changes: As currently written, this proposal would have authorized RVTs to act as an agent of the supervising veterinarian to establish the veterinarian-client-patient relationship (VCPR) for purposes of administering preventative or prophylactic vaccinations or medications for the control or eradication of apparent or anticipated internal or external parasites to animal patients. To establish the VCPR, the proposal would have required RVTs, under direct veterinarian supervision, to examine the animal patient and administer the vaccines/medications according to written protocols and procedures, as specified. The proposal would have also required the supervising veterinarian and RVT to sign and date a statement whereby the supervising veterinarian would remain responsible for the acts of the RVT, and authorizing the RVT to act as the veterinarian's agent only for administering the vaccines/medications. Finally, the proposal would have required RVT disclosure to the client and required the supervising veterinarian to review the required documentation prior to prescribing or dispensing vaccines/medications.

Minimum Standards for Alternate Veterinary Premises—CCR, Title 16, Sections 2030, 2030.05, 2030.1, 2030.2, and 2030.3: IN PROCESS

Update: The Board's prior Regulations Counsel recommended amendments to this proposal, along with a proposal to initiate a rulemaking to amend CCR, title 24, section 1251 (Veterinary Facilities) in order to comply with the California Building Standards Law (Health & Saf. Code, § 18901 and following), which requires all regulations that are a "building standard" (as defined in Health & Saf. Code, § 18909) to be incorporated into title 24 of the CCR and not in other divisions of the CCR (see Health & Saf. Code, § 18940). The Board's Executive Officer has received confirmation from attorneys at the Office of Administrative Law (OAL) and the staff of

the California Building Standards Commission (CBSC) that amendments to both title 16 and title 24 are required to implement the proposed regulatory changes discussed by the Board over many meetings. The MDC, Alternate Veterinary Premises Subcommittee (Subcommittee) worked on potential revisions to this existing proposal, as well as proposed revisions to CCR, title 24, section 1251 (the Board's regulations involving Veterinary Facilities in the California Building Standards Code). The Subcommittee, Executive Officer, and Regulations Counsel met with stakeholders on December 8, 2023, to discuss the proposed changes. At its April 2024 meeting, the MDC recommended that the Board rescind prior motions approving proposed amendments to the regulatory text and approve updated regulatory text, along with some additional changes recommended at that meeting. Subsequently, at its April 2024 meeting, the Board also rescinded its prior motions approving proposed amendments to the regulatory text and approved updated regulatory text, along with the additional changes approved by the MDC. Board staff prepared the regulatory package for the initial phase of the rulemaking process, and it is currently being reviewed by the Department of Consumer Affairs (DCA) Budget Office and Regulations Counsel.

Summary of Proposed Changes: The amendments will standardize language utilized in modern veterinary practice and update the requirements for fixed veterinary premises, mobile veterinary premises, vaccination veterinary premises, and shelter premises. Additionally, the amendments will remove all apparent building standards, including any exemptions to those standards, from title 16. The proposed language: (1) takes into consideration the needs of large animal practitioners and limitations they have for equipment or movement of large animals; (2) the various mobile veterinary premises types, including house calls and services for equines or food animals/livestock; (3) helps clarify personnel authorized to provide vaccinations at a veterinary premises and the veterinarian's responsibilities; and (4) sets specified requirements for animal shelters.

Veterinary Facilities—CCR, Title 24, Section 1251: IN PROCESS

Update: As part of the Board's efforts to pursue regulatory amendments to improve the minimum standards for alternate veterinary premises, concerns were raised related to building standards regulations within CCR, title 24 that were identical to those in the Board's current regulations under title 16. It was noted that OAL likely would not approve exempting fixed premises from any standards mirroring the standards established under the California Building Standards Code (CCR, tit. 24). Multiple meetings with CBSC and OAL were held to discuss an appropriate solution. As a result, the MDC, Alternate Veterinary Premises Subcommittee recommended revising the previously approved Alternate Veterinary Premises rulemaking to remove all apparent building standards, including any exemptions to those standards, and renumber all remaining requirements accordingly. In addition, the Subcommittee recommended a separate proposal moving the building standards and related exemptions from the previous Alternate Veterinary Premises proposal to CCR, title 24, section 1251 and move any veterinary practice management standards to title 16. The MDC and Board reviewed and approved this proposal at their April 2024 meetings. Board staff prepared the regulatory package for the initial

phase of the rulemaking process, and it is currently being reviewed by the DCA Budget Office and Regulations Counsel.

Summary of Proposed Changes: As noted, the building standards proposal would move existing building standards and related exemptions from the Alternate Veterinary Premises proposal to CCR, title 24, section 1251 and move from that section any practice management standards to title 16.

Records—CCR, Title 16, Section 2032.3: IN PROCESS

Update: During the October 2023 MDC and Board meetings, it was determined that legislation would be necessary prior to amending the regulation, per the recommendations of the MDC, Medical Records Subcommittee (Subcommittee). Of those proposed amendments, the Subcommittee addressed concerns regarding when a copy or a summary of medical records must be provided to a client. Additionally, "authorized agent" was added throughout the proposal to allow for the client or their authorized agent to receive a copy or summary of the animal patient records when requested. At its January 2024 meeting, the MDC approved proposed regulatory text, along with additional clarifying changes made at that meeting. At the Board's April 2024 meeting, substantive concerns were raised during public comment related to the legislative and regulatory proposals. As a result, the Board referred the proposals back to the MDC. In May, the Subcommittee met with the California Veterinary Medical Association and the California Horse Racing Board on two occasions to work through the concerns related to the proposals. With regard to the regulatory proposal, the proposed provision adding client payment records to the record keeping requirement was removed from the proposed language (after considering the totality of concerns raised by stakeholders). At the July 2024 meetings, the MDC and Board will be asked to review and approve the updated regulatory proposal, so that the rulemaking process can be initiated once the corresponding legislative proposal is successful.

Summary of Proposed Changes: This proposal addresses the following: (1) changes the logical order of the required information that makes up an animal patient record to follow a SOAP (Subjective, Objective, Assessment, and Plan) format for recording patient medical encounters and medical record documentation, which is taught in the majority of veterinary schools; (2) addresses animal patient record keeping requirements for single patient records and group records; (3) makes animal patient record keeping requirements less prescriptive; and (4) addresses when a copy or a summary of records must be provided to the client, or the client's authorized agent.

<u>Attachment</u>

1. Attachment No. 1: Status of Pending VMB Regulations – Updated July 12, 2024

Status of Pending VMB Regulations

		INITIAL PHASE								FINAL PHASE							
Rulemaking Title	Current Status	Concept Date(s)	Board Approval	Submitted to DCA for PRE-Review	Submitted to DCA for INITIAL Review	DCA Director Approval	Submitted to Agency/Agency Approval	Notice Submitted to OAL & Notice Published by OAL	45-Day Comment Period	Public Hearing (Optional)	15-Day Comment Period (Modified Text), if applicable	Submitted to DCA for FINAL Review	DCA Director FINAL Approval	Submitted to Agency/ FINAL Agency Approval	Submitted to DOF/ DOF Approval	Submitted to OAL/ OAL Approval	Effective Date
Drug Compounding	Staff preparing regulatory package for initial phase	4/19/2022 10/18/2023 01/16/2024	01/25/2023 Re-Approved on 04/17/2024														
VCPR, Definitions, and RVT Tasks Updates (RVT Vaccine Administration)	Board's Request	10/16/2022	01/25/2023	04/13/2023	10/05/2023	10/11/2023	10/13/2023 Submitted 10/24/2023 Pulled from Review										
Minimum Standards for Alternate Veterinary Premises	Regulatory package submitted to DCA for pre- review	2017-2024	11/14/2018 04/19/2023 10/18/2023 Combined with the Minimum Standards for Shelter Premises Package Re-Approved on 04/17/2024	07/11/2024							Red Text	= Updates sind last meeting = Completed = Current Stat Pending					
Veterinary Facilities	Regulatory package submitted to DCA for pre-review	12/08/2023	04/17/2024	07/08/2024													
Veterinary Graduate Student Exemption / RVT Examination Eligibility	Pending Staff Review/ Development	04/23/2014	07/17/2019	04/06/2023													
Records	Pending Approval by MDC & Board on 07/23&24/2024		Pending Approval on 07/24/2024														