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MEMORANDUM

DATE	October 10, 2019
TO	Veterinary Medical Board
FROM	Amanda Drummond, Administrative Programs Coordinator
SUBJECT	**Agenda Item 15.B Sections 2090-2096, Article 11, Division 20, Title 16 of the CCR Regarding Drug Compounding**

Senate Bill (SB) 1193 (Hill, Chapter 484, Statutes of 2016) authorized veterinarians and registered veterinary technicians to provide limited compounding by animal patients (Business and Professions Code (BPC), § 4826.5). In July of 2016, the Veterinary Medical Board (Board) Multidisciplinary Advisory Committee (MDC) discussed developing a regulatory proposal to further define the restrictions and parameters for veterinarian drug compounding. The MDC reviewed the Code of Federal Regulations Title 21, Part 530.13, a summary of Federal Drug Administration (FDA) guidance document #230, titled "Compounding Animal Drugs from Bulk Drug Substances," and proposed Pharmacy Board regulations regarding drug compounding for consideration when developing drug compounding regulations for veterinary medicine.

In April of 2017, an MDC subcommittee met with the California Board of Pharmacy to determine the parameters of veterinary in-office compounding. The MDC explained its goals in obtaining limited compounding provisions and received the support of the Board of Pharmacy for the Board to regulate its own veterinary compounding. The Veterinary Medical Board (Board) approved the Drug Compounding regulatory language at the October 2017 Board meeting, which provided authority for the California Board of Pharmacy to inspect veterinary premises under CCR section 2096, subsection (a).

As discussed in the Board meeting in May of 2018 and July of 2019, the United States Pharmacopeia (USP), a non-profit organization that establishes standards for medication and guidelines for compounding products, is currently revising their guidelines to eliminate simple, moderate, and complex compounding which will therefore restrict clinicians from performing certain compounding. These updated guidelines, which were used in part to develop the standards for veterinary compounding regulations, will make it difficult for veterinarians to provide compounding services at veterinary premises due to the limited compounding services provided.

However, the passing of Assembly Bill (AB) 973 (Irwin, Chapter 184, Statutes of 2019) makes clear under California law that the California State Board of Pharmacy licenses and regulates the practice of pharmacy by pharmacists and pharmacy corporations, and the compounding of drug preparations by a pharmacy shall be consistent with the USP-National Formulary (See AB 973, Legislative Counsel's Digest; BPC, § 4126.8). With respect to veterinarians, RVTs, and

veterinary assistance controlled substance permit holders, BPC section 4170, subdivision (b), provides that the Veterinary Medical Board is charged with the enforcement of the Pharmacy Law as to the Board's respective licensees. Separately, per BPC section 4826.5, veterinarians may 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. As such, it is recommended that the Board review the previously approved language and consider removing Board of Pharmacy inspection authority over veterinary premises and deleting proposed CCR section 2096.

Attachments:

1. Proposed Language for Sections 2090-2096, Article 11, Division 20, Title 16 of the CCR Regarding Drug Compounding

California Code of Regulations
Title 16. Professional and Vocational Regulations
Division 20. Veterinary Medical Board

PROPOSED LANGUAGE

Proposed amendments to the regulatory language are shown in single underline for new text and ~~single strikethrough~~ for deleted text.

Add Article 11 (commencing with Section 2090) to Division 20 of Title 16 of the California Code of Regulations to read as follows:

Article 11. Compounding in a Veterinary Premises.

2090. Definitions.

(a) "Compounding" means any of the following activities performed in a registered veterinary premises by a licensed veterinarian that has established the veterinarian-client-patient relationship for the patient(s) or a registered veterinary technician under the direct or indirect supervision of that veterinarian:

(1) Altering the dosage form or delivery system of a drug.

(2) Altering the strength of a drug.

(3) Combining components or active ingredients.

(4) Preparing a compounded drug preparation from chemicals or bulk substances.

(b) "Compounding" does not include reconstitution of a drug pursuant to a manufacturer's direction(s) for oral, rectal, topical, or injectable administration, nor does it include the sole act of tablet splitting or crushing, capsule opening, or the addition of flavoring agent(s) to enhance palatability.

(c) "Expiration date" means the date, or date and time, determined from the date the preparation is compounded, after which administration of a compounded drug preparation shall not begin, the preparation shall not be dispensed, and the preparation shall not be stored other than for quarantine purposes.

Note: Authority cited: Section 4826.5, Business and Professions Code. Reference: Section 4826.5, Business and Professions Code.

2091. Veterinary Drug Compounding.

(a) A veterinarian shall ensure the safety and efficacy of a compounded drug preparation, including, but not limited to, avoiding known drug incompatibilities and inappropriate complications.

(b) A veterinarian shall not perform drug compounding when the complexity of the drug compounding exceeds the veterinarian's knowledge, skill, facilities, or available equipment.

(c) Sterile compounding shall be for immediate use except in the following conditions:

(1) A dilution of the ingredients is essential for the safe administration of the preparation.

(2) There are no other human or animal drugs that satisfy the need of this preparation.

(3) There is a historical documentation of the need, safety, and efficacy of the preparation.

(d) Only drugs approved by the United States Food and Drug Administration shall be used as the ingredients in a sterile compounded drug preparation.

Note: Authority cited: Section 4826.5, Business and Professions Code. Reference: Section 4826.5, Business and Professions Code.

2092. Policies and Procedures.

(a) A veterinary premises that engages in compounding drug preparations shall develop and maintain a written policies and procedures manual, which shall include:

(1) A list of each of the requirements of subsections (b) and (e) and sections 2093 and 2094.

(2) Policies and procedures for the training of a registered veterinary technician who may perform compounded drug preparations.

(3) Policies and procedures for a quality assurance program established pursuant to section 2095.

(b) For each compounded drug preparation, a formula document shall be maintained and include all of the following:

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) Expiration date of the preparation.

(4) Inactive ingredients to be used.

(5) Specific compounding steps to be used to prepare the drug.

(6) Instructions for storage, handling, and administration of the compounded preparation.

(c) The formula document may be included in the policies and procedures manual maintained pursuant to subsection (a).

(d) If the compounded drug preparation is not routinely compounded, a formula record for the preparation may be kept in the medical record of the patient.

(e) For each compounded drug preparation prepared for a patient, the following information shall be recorded in the patient's medical record:

(1) Name or initials of the veterinarian that made or supervised the making of a compounded drug preparation and the name or initials of the registered veterinary technician, if any, who made the compounded drug preparation.

(2) Expiration date of the compounded drug preparation.

(3) Directions for its storage and administration.

(4) Name, amount, and strength of the compounded drug preparation.

(5) Date the drug preparation was compounded.

(6) Proper storage of the compounded drug preparation.

(f) The veterinarian performing or supervising the compounding of drug preparations is responsible for the following:

(1) Training and supervision of the registered veterinary technician who is compounding the drug preparation.

(2) Proper storage of the drugs used in compounding and the compounded drug preparations.

Note: Authority cited: Section 4826.5, Business and Professions Code. Reference: Section 4826.5, Business and Professions Code.

2093. Expiration Dates.

(a) For non-sterile compounding, the expiration date shall not exceed either of the following:

(1) 180 days from the date the preparation is compounded.

(2) The shortest expiration date of any ingredient in the non-sterile compounded drug preparation.

(b) For sterile compounding, the expiration date shall not exceed either of the following:

(1) 30 days from the date the preparation is compounded.

(2) The shortest expiration date or beyond use date of any ingredient in the sterile compounded drug preparation.

(c) The expiration date may be extended if the product's integrity, potency, and quality are measurable and demonstrable.

Note: Authority cited: Section 4826.5, Business and Professions Code. Reference: Section 4826.5, Business and Professions Code.

2094. Labeling of Compounded Preparations.

All labeling of any compounded drug preparation shall comply with subsection (b) of section 2032.2.

Note: Authority cited: Section 4826.5, Business and Professions Code. Reference: Section 4826.5, Business and Professions Code.

2095. Quality Assurance.

(a) A veterinary premises that engages in compounding drug preparations shall establish a quality assurance program that documents and assesses medication errors to determine cause and an appropriate response.

(b) The purpose of the quality assurance program shall be to assess errors that occur in the compounding of drug preparations, as well as to evaluate and document adverse reactions of animal patients to compounded drug preparations.

(c) When a veterinarian determines that a medication error has occurred, the veterinarian shall as soon as possible communicate to the client or the client's representative the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.

(d) Records generated for and maintained as a component of the ongoing quality assurance program shall be considered peer review documents and not subject to discovery in any arbitration, civil, or other proceeding, except as provided hereafter. That privilege shall not prevent review of a veterinary premises's quality assurance program and records maintained as part of that system by the board or the California State Board of Pharmacy as necessary to protect the public health and safety or if fraud is alleged by a government agency with jurisdiction over the veterinary premises. Nothing in this section shall be construed to prohibit a client or client's representative from accessing records of the animal patient pursuant to subsection (b) of section 2032.3.

(e) Reports of drug contraindications and adverse reactions may be included in the quality assurance documentation.

Note: Authority cited: Section 4826.5, Business and Professions Code. Reference: Section 4826.5, Business and Professions Code.